Impact evaluation of doctor-to-doctor telehealth deployment in Lao Cai Province (former Yen Bai Province area), Vietnam

○Implementing Agencies

Names：

- Japan International Cooperation Agency (JICA) Vietnam Telehealth Project (Project for Strengthening Capacity Development System for Health Professionals through Tele-Health)
- Medical Services Administration (MSA), Ministry of Health (MoH), Vietnam
- Japan Institute for Heath Security (JIHS)

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Table of contents

1. Study outline 5
1.1 Outline 5
1.2 Flow chart and evaluation schedule 11
2. Background 13
2.1 Background 13
2.2 Significance of this evaluation 14
3. Objectives and items to measure/evaluate 15
4. Research (evaluation) design 16
4.1 Research (evaluation) design 16
4.2 Basis of scientific rationality 17
5. Target health facilities, patients, and interviewees 18
5.1 Target health facilities 18
5.2 Target patients for clinical effectiveness evaluation 19
5.2.1 Inclusion criteria 20
5.2.2 Exclusion criteria 20
5.2.3 Reasons for setting the criteria 20
5.3 Target interviewees for cost, impact on clinical care implementation, and sustainability evaluation 20
5.3.1 Inclusion criteria 20
5.3.2 Exclusion criteria 21
5.3.3 Reasons for setting the criteria 21
5.4 Sample size 21
5.4.1 Estimated numbers of subjects 21
5.4.2 Basis of estimating the numbers of subjects 22
6. Intervention 22
6.1 Overview of the intervention 22
6.1.1 Overview of the intervention 22
6.1.2 Anticipated adverse events 23
6.2 Protocol treatment 24
6.3 Combination therapy 24
7. Research methods and procedure 24
7.1 Subject recruitment 24
7.2 Subject registration 24
7.3 Collection of specimens 25
7.4 Information to be collected and collection procedures 25

7.4.1 Information to be collected for evaluation of clinical effectiveness 25
7.4.2 Information to be collected for evaluation of cost, impact on clinical care implementation, and sustainability 26
7.4.3 Information to be collected for evaluation of health facility utilization and safety 27
7.5 Information flows 28
7.5.1 Evaluation of clinical effectiveness 28
7.5.2 Evaluation of cost, impact on clinical care implementation, and sustainability 29
7.5.3 Evaluation of health facility utilization and safety 29
7.6 Study and observation periods 29
8. Consent acquisition 30
8.1 Informed consent 30
8.2 Informed ascent 31
8.2 Consent withdrawal 31
9. Evaluation and reporting of adverse events 31
9.1 Definition of adverse events 31
9.2 Definition of severe adverse events 31
9.3 Causal relationship with the intervention 31
9.4 Predictability of adverse events 32
9.5 Period and contents of data collection 32
9.6 Reporting of adverse events 32
9.7 Reporting of serious adverse events 32
10. Discontinuation and termination 33
10.1 Discontinuation of study participation 33
10.2 Discontinuation of the entire evaluation 33
10.3 Termination of the evaluation 33
11. Anticipated benefits and risks, and means to minimize risks 33
11.1 Anticipated benefits 33
11.2 Anticipated risks 34
11.3 Means to minimize risks 34
12. Ethical matters and considerations 34
12.1 Compliance with laws and guidelines 34
12.2 Handling of personal information 35
12.3 Compensation for adverse events 35
12.4 Assurance of treatment for non-participants 35
12.5 Provision of healthcare after the study 36
12.6 Handling of results obtained by the evaluation 36

12.7 Subjects' financial burden and reward 36
12.8 Source of funding 36
12.9 Conflict of interest 36
12.10 Disclosure of information 36
12.11 Publications of results 37
13. Statistical analyses 37
13.1 Subjects of statistical analyses 37
13.2 Statistical analyses 37
13.2.1 Statistical analyses for major evaluation items 37
13.2.2 Statistical analyses for minor evaluation items 39
13.2.3 Statistical analyses for safety evaluation item 39
13.2.4 Analyses of sub-populations 39
13.2.5 Intermediate analysis plan 39
14. Qualitative analysis in-depth interview records 39
15. Storage and disposal of specimens and information 40
15.1 Storage methods and period 40
15.1.1 Storage methods and period for specimens 40
15.1.2 Storage methods and period for information 40
15.2 Disposal methods 41
15.2.1 Disposal methods for specimens 41
15.2.2 Disposal methods for information 41
15.3 Utilization of data for different future studies 41
15.4 Security management procedure 41
16. Quality management and assurance 42
16.1 Data management 42
16.2 Monitoring 42
16.3 Audit 42
16.4 Data and Safety Monitoring Board 42
16.5 Report to the heads of the study institutions 42
17. Research organization 43
17.1 Research organization 43
17.2 Inquiry 44
17.3 Subcontracting 44
18. Others 44
18.1 List of abbreviations 44
18.2 Revision history 45

19. Reference 45

1. Study outline

1.1 Outline

Title	Impact evaluation of doctor-to-doctor telehealth deployment in Lao Cai Province (former Yen Bai Province area), Vietnam
Study purpose	This evaluation intends to generate scientific and implementational evidence of the impacts of telehealth solutions introduced to Lao Cai Province by the JICA Vietnam Telehealth Project.
Objectives	Major objective: To generate an impact evaluation report to be submitted to MoH at the end of the Project, so that the findings can be utilized in telehealth extension to other provinces.
	Minor objective: To ensure proper Project implementation to attain the project purpose with feed-back of the monitoring data.
Evaluation items	Major evaluation items: 1. **Clinical effectiveness:** Change in inpatient mortality rate, referral rate, length of stay (bed days), rate of conducting specified clinical interventions, etc. 2. **Cost:** Unit cost of telehealth session reflecting both direct and indirect costs incurred by the telehealth solution. 3. **Impact on clinical care implementation:** How telehealth changed human resources, work processes, workload, and other aspects of clinical care in target health facilities. 4. **Sustainability**: Prospect of long-term continuation of telehealth services after the JICA project terminates. 5. **Health facility utilization**: Change in the number of consultations and admissions at target health facilities. 6. **Safety**: Confirmation of any adverse events among patients due to telehealth.
	Minor evaluation items: 1. List of diagnostic and treatment items enabled by the telehealth deployment 2. Telehealth implementation frequency

	3. Number of health staff engaged in telehealth 4. Number of health facility staff trained on telehealth
Research design	This study employs baseline and endline surveys as well as annual reporting as data collection methods: 1. **Baseline survey**: Conducted between November 2025 and March 2026. Collect baseline information on the **clinical effectiveness** prior to the introduction of telehealth (2023 and 2024) from the Hospital Information System (HIS) and monthly non-communicable diseases (NCDs) reports at the target health facilities. 2. **Endline survey**: Conducted between April and June 2029. Collect post-intervention (2028) information on **clinical effectiveness, cost, impact on clinical care implementation**, and **sustainability**. 3. **Annual reporting**: Annual reporting form covering **health facility utilization** and **safety** will be submitted by target health facilities to the Project Office.
Research targets	***Target health facilities:*** At the provincial level: Lao Cai Provincial General Hospital (PGH) No. 1 (former Yen Bai Provincial General Hospital) (1 PGH) At the regional level: Yen Binh Regional Medical Center (RMC) and Luc Yen RMC (2 RMCs) At the commune level: Thac Ba Commune Health Center* (CHC), Cam An CHC*, Khanh Hoa CHC*, Bach Ha CHC, Dai Minh CHC, Muong Lao CHC, Minh Tien CHC, and Dong Quan CHC (8 CHCs including 3 former regional polyclinics*) ***Target patients for the evaluation of clinical effectiveness:*** In PGH HIS: ● All inpatients at PGH in 2023, 2024, and 2028. ● Inpatients referred from two target RMCs and two non-target RMCs (Tran Yen and Van Yen RMCs) to PGH with diagnosis of cardiopulmonary arrest (CPA), acute myocardial infarction (AMI), stroke (cerebral infarction), and moderate-to-severe injury* in 2023, 2024, and 2028 In RMCs HIS: ● All inpatients at target RMCs in 2023, 2024, and 2028

	● Inpatients referred from target CHCs with a diagnosis of CPA, AMI, stroke (cerebral infarction), and moderate-to-severe injury* in 2023, 2024, and 2028 In CHCs HIS and NCD reporting forms, ● Outpatients who visited target CHCs for hypertension, diabetes, and chronic obstructive pulmonary disease (COPD) in 2023, 2024, and 2028 ***Target interviewees for the evaluation of cost, impact on clinical care implementation, and sustainability:*** ● All Project staff (both Japanese and Vietnamese). ● Relevant managers of the target health facilities. ● Clinical staff mainly engaging in telehealth ● IT staff
Intervention	The intervention, which is the implementation of the JICA Vietnam Telehealth Project in Lao Cai Province, comprises the following three components: 1. **Installation of IT platform** to enable DtoD telehealth between PGH and RMCs, as well as between RMCs and CHCs through Virtual Private Network (VPN) connections, the introduction of a Picture Archiving and Communication System (PACS), and installation of additional personal computers (PCs). 2. **Installation of electrocardiogram (ECG) and ultrasound diagnostic imaging equipment** to five CHCs. 3. **Training** of medical staff at the target health facilities on telehealth utilization. Training of ECG and ultrasound utilization and diagnosis for the CHCs staff. Training of IT staff on system maintenance and troubleshooting. Through these, the Project aims to achieve: 1) Video consultations during both outpatient and inpatient care, enabling higher-level hospitals to provide support to lower-level health facilities; and 2) Medical image sharing across different levels of the health system.
Methods	**1. Evaluation of clinical effectiveness:** Pre- and post-intervention comparison of the following will be done; ● All-cause inpatient cure rate ● All-cause average length of stay

	● Inpatient cure rate and average length of stay of cardiopulmonary arrest (CPA) patients ● Inpatient cure rate and average length of stay of acute myocardial infarction (AMI) patients, and the rate of reperfusion therapy (fibrinolytics and percutaneous coronary intervention (PCI)) ● Inpatient cure rate and average length of stay of stroke patients, and the rate of tPA and cerebral catheter therapy among cerebral infarction patients ● Inpatient cure rate and average length of stay of moderate-to-severe injuries, and the rate of operations under general anesthesia ● Rate of patients with regular outpatient visits for hypertension, diabetes, and COPD patients at CHCs. ● Referral rate from CHCs to upper-level hospitals for hypertension, diabetes, and COPD patients due to either poor control or complications. The evaluation of the RMCs will be done by a pre-post and intervention-non-intervention comparison. **2. Evaluation of cost:** The unit cost of outpatient and inpatient telehealth sessions will be calculated and compare with the disbursement from the health insurance scheme. **3. Evaluation of impact on clinical care implementation and sustainability:** In the endline survey, in-depth interviews using a preset interview guide will elaborate on these aspects. **4. Evaluation of health facility utilization and safety:** Annual reporting form covering these aspects, submitted to the Project office, covering 2024-2028, will be analyzed.
Number of subjects	The following are the estimated numbers of patients (per year) targeted for the evaluation of clinical effectiveness: ● All inpatients at PGH in 2023, 2024, and 2028: **38,000** ● Inpatients referred from two target RMCs and two non-target RMCs to PGH with diagnosis of CPA, AMI, stroke (cerebral infarction), and moderate-to-severe injury in 2023, 2024, and 2028: **500** ● All inpatients at target RMCs in 2023, 2024, and 2028: **18,000**

	● Inpatients referred from target CHCs with a diagnosis of CPA, AMI, stroke (cerebral infarction), and moderate-to-severe injury in 2023, 2024, and 2028: **140** ● Outpatients who visited target CHCs for hypertension, diabetes, and COPD in 2023, 2024, and 2028: **15,000** The following are the estimated numbers of interviewees for the in-depth interviews: ● All Project staff (both Japanese and Vietnamese): **5 persons** ● Relevant managers of the target health facilities: **12 persons** ● Clinical staff mainly engaging in telehealth: **15 persons** ● IT staff: **5 persons**
Study period	From the date of Ethic Review Committee approval (in both Japan and Vietnam) to 30 December 2029
Research organizations	***JICA Vietnam Telehealth Project*** Principal investigator: Taketo Tanaka, Chief Advisor, JICA Vietnam Telehealth Project Co-investigators: Tran Lan Anh, Director, Lao Cai Provincial General Hospital Diem Son, Deputy Director, Lao Cai Provincial General Hospital Pham Dac Ninh, Director, Planning Department, Lao Cai Provincial General Hospital Maiko Hashimoto, Project Coordinator, JICA Vietnam Telehealth Project Do Huyen Trang, Project Officer, JICA Vietnam Telehealth Project Vu Danh Truong, Technical Officer, JICA Vietnam Telehealth Project Nguyen Thi Tuyen, Project Assistant, JICA Vietnam Telehealth Project ***Medical Services Administration (MSA), Ministry of Health, Vietnam*** Principal investigator: Le Sinh Quan, Division of Quality Management & DOHA, MSA, MoH, Vietnam ***Japan Institute for Health Security (JIHS)*** Principal investigator: Hitoshi Murakami, Deputy Director-General, Bureau of Global Health Cooperation, JIHS
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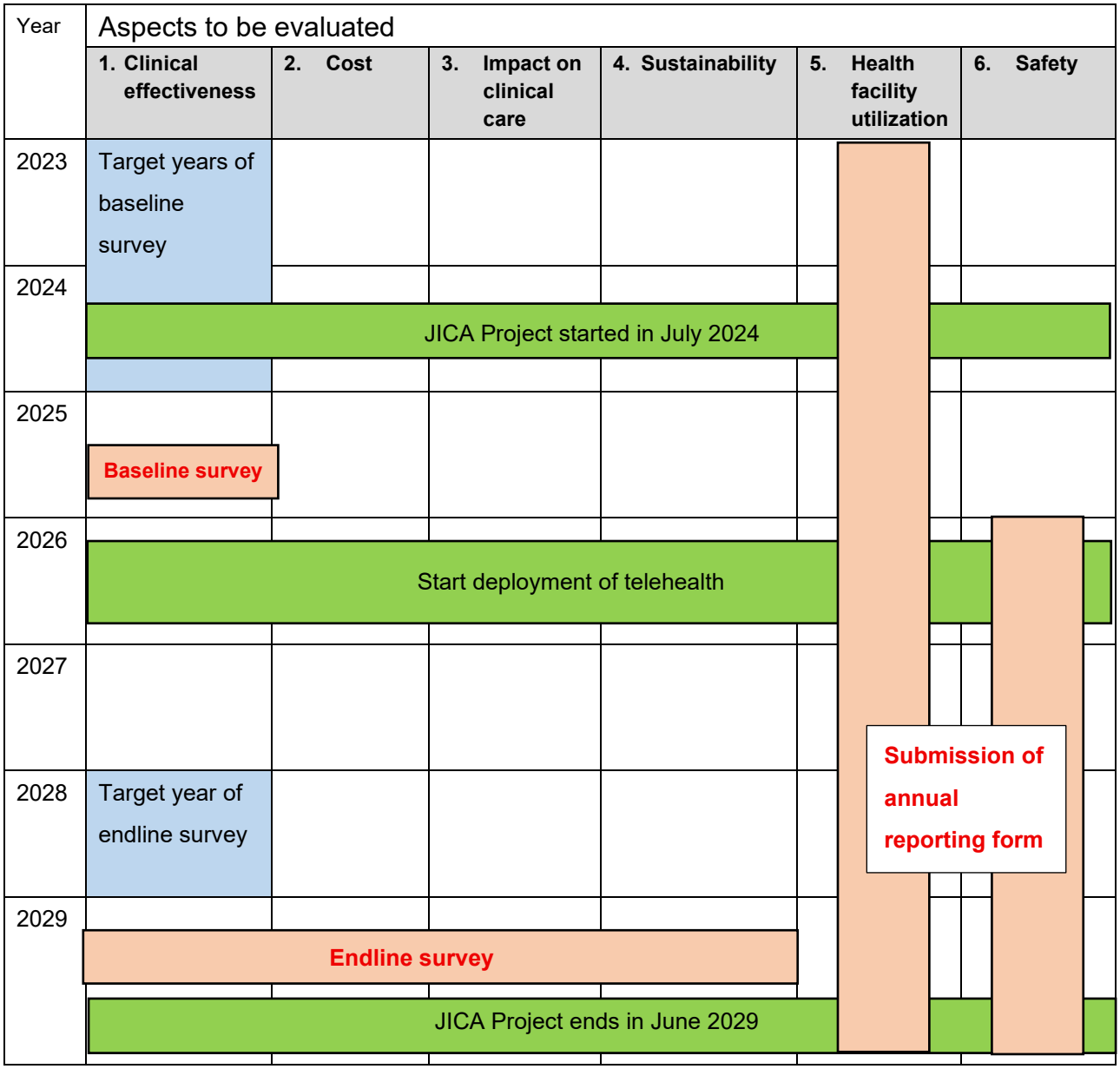
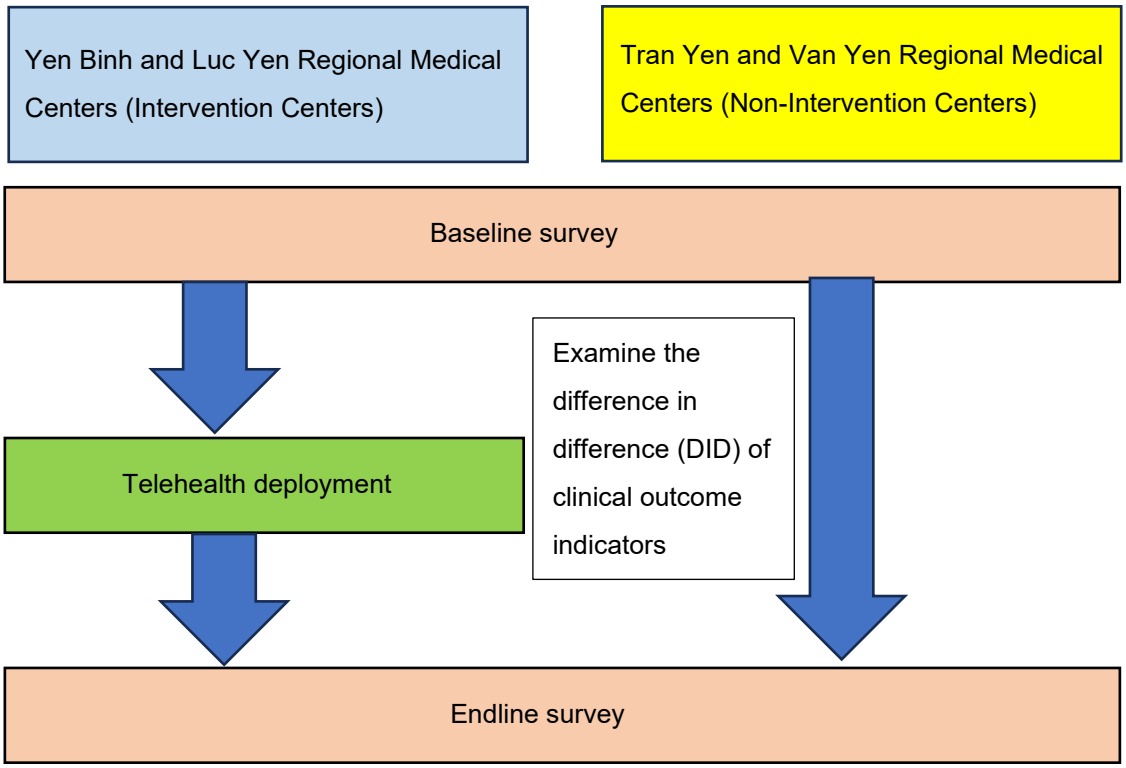
1.2 Flow chart and evaluation schedule



- The baseline survey will be conducted over a three-week period between November 2025 and March 2026.
- The endline survey will be conducted over a four-week period between April and June 2029.

For the evaluation of the clinical effectiveness of telehealth deployment at Regional Medical Centers:



2. Background

2.1 Background

Telehealth emerged as a new model of healthcare delivery in Vietnam during the COVID-19 pandemic. In 2020, the Ministry of Health (MoH) launched a project to connect hospitals online for diagnostic consultations and training. In 2023, the revised Law No. 15 on Medical Examination and Treatment was enacted, explicitly referencing telehealth. In the broader policy context, Resolution No. 57 was adopted in 2024 to promote science and technology innovation, including digital transformation (Dx). Against this backdrop, the Government of Vietnam requested support from the Government of Japan to implement a telehealth project in 2022. Following several preparatory missions and discussions, the Japan International Cooperation Agency (JICA) launched the Vietnam Telehealth Project, formally titled Project for Strengthening Capacity Development System for Health Professionals through Telehealth (hereinafter referred to as “the Project”), in July 2024.

The Project aims to implement telehealth in Lao Cai Province (formerly the Yen Bai Province area) and to enhance the capacity of health professionals. On July 1, 2025, Yen Bai Province was merged with Lao Cai Province, forming the new Lao Cai Province. The main counterparts of the Project are the Medical Services Administration (MSA), MoH, and the Department of Health of Lao Cai Province. The project period is five years, from 2024 to 2029. During the Project’s planning phase, it was agreed that the focus would be exclusively on doctor-to-doctor (DtoD) telehealth, rather than doctor-to-patient (DtoP) telehealth, due to limited smartphone connectivity in remote mountainous areas such as Lao Cai, where diagnostic accuracy could be significantly compromised.

The scope of telehealth evaluation in the existing literature includes clinical effectiveness, cost, impact on clinical care implementation, sustainability, health facility utilization, safety, access to care, and stakeholder experience or perception (1–5). Among these, this evaluation focuses on the first six aspects, which are considered more relevant to the assessment of DtoD telehealth. Also, it will focus on the following seven priority conditions/diseases primarily targeted by the Project: Emergencies (particularly cardiopulmonary arrest (CPA), acute myocardial infarction (AMI), stroke, and moderate-to-severe injury), hypertension and its complications, diabetes and its complications, and chronic obstructive pulmonary disease (COPD).

2.2 Significance of this evaluation

One of the major challenges facing Vietnam's health system is the disparity between urban and rural areas. As of 2022, life expectancy at birth was 76.8 years in urban areas, compared to 73.2 years in rural areas, including Lao Cai. The infant mortality rate and the under-five mortality rate were 7.0 and 10.5 per 1,000 live births in urban areas, respectively, while in rural areas, they were 12.8 and 19.7, respectively. DtoD telehealth is expected to help bridge this gap by enhancing the diagnostic and treatment capacity of frontline health facilities through support from higher-level hospitals.

The clinical efficacy of DtoD telehealth has been demonstrated primarily in high-income countries. In cases of CPA, telematics support provided by expert physicians to nurses during cardiopulmonary resuscitation (CPR) has been shown to increase the rate of successful defibrillation and shorten the time required to complete CPR (6). For AMI, pre-arrival electrocardiogram (ECG) transmission has reduced inpatient mortality, percutaneous coronary intervention (PCI)-related mortality, door-to-needle time, and door-to-balloon time, while increasing the proportion of patients who received reperfusion therapy (7–10). In the case of stroke, expert-assisted administration of tissue-type plasminogen activator (tPA) therapy at frontline health facilities has led to reductions in inpatient mortality, complication rates, and the risk of long-term disability (11, 12). Among the seven studies cited above, only two—those focusing on AMI outcomes in Brazil and Chile—specifically addressed low- and middle-income countries (LMICs).

For DtoP telehealth, remote patient monitoring and teleconsultation for individuals with hypertension (13–15), diabetes (16–18), and COPD (19–22) have been shown to reduce blood pressure, HbA1c levels, and rates of hospital admissions and emergency department visits, respectively. Among the ten studies cited above, only one—focusing on hypertension in Iran—specifically addressed LMICs.

Existing literature on evaluation aspects other than clinical effectiveness, namely cost (23–25), impact on clinical care implementation (26, 27), sustainability (28–30), health facility utilization (31, 32), and safety (33, 34) has again mostly focused on DtoP telehealth in high-income countries (HICs). Evidence in LMICs remains scarce. Therefore, this evaluation aims to help address that gap in the context of a mountainous province in Vietnam.

3. Objectives and items to measure/evaluate

Objectives	Items to measure/evaluate	Reasons for selecting items
Major		
To generate an impact evaluation report to be submitted to MoH at the end of the Project, so that the findings can be utilized in telehealth extension to other provinces.	Major evaluation items are: 1. **Clinical effectiveness:** Change in inpatient cure rate*, referral rate, length of stay (bed days), rate of conducting specified clinical interventions, etc. 2. **Cost:** Unit cost of telehealth session reflecting both direct and indirect costs incurred by the telehealth solution. 3. **Impact on clinical care implementation:** How telehealth changed human resources, work processes, workload, and other aspects of clinical care in target health facilities. 4. **Sustainability**: Prospect of long-term continuation of telehealth services after the JICA project terminates. 5. **Health facility utilization**: Change in the number of consultations and admissions at target health facilities. 6. **Safety**: Confirmation of any adverse events among patients due to telehealth.	Existing literature identified these and other items as important aspects of telehealth evaluation. We selected those that are relevant for evaluating DtoD telehealth.
Minor		
To ensure proper Project implementation to attain the project purpose with feed-back of the monitoring data.	Minor evaluation (monitoring) items are: 1. List of diagnostic and treatment items enabled by the telehealth deployment 2. Telehealth implementation frequency 3. Number of health staff engaged in telehealth	These items enable the Project to monitor whether the activities are progressing as planned.

	4. Number of health facility staff trained on telehealth	

*The inpatient cure rate, rather than the inpatient mortality rate, will be measured because in Vietnamese hospitals, terminally ill patients are often taken home by their families, and therefore their deaths are not recorded as inpatient deaths.

4. Research (evaluation) design

4.1 Research (evaluation) design

Research type and hypotheses:

For the evaluation of clinical effectiveness, a pre- and post-intervention comparison will be conducted by both baseline and endline surveys. Additionally, to assess the clinical effectiveness of Regional Medical Centers, a comparison between the intervention group and a non-intervention group will be employed. The main hypotheses for this aspect of the evaluation are as follows:

1) The deployment of telehealth through the JICA Telehealth Project will improve the inpatient cure rate and increase the rate of specific clinical interventions (e.g., PCI and tPA therapy), while reducing referral rates and the average length of stay (bed days), particularly at Regional Medical Centers and Commune Health Centers (CHCs).
2) The intervention will enhance the regularity of outpatient visits for patients with hypertension, diabetes, and COPD at CHCs.

For the evaluation of cost, impact on clinical care implementation, and sustainability, a post-intervention assessment will be conducted by the endline survey. Cost will be analyzed using unit cost analysis, while the latter two aspects will be assessed through qualitative data collection based on an interview guide and thematic analysis.

For the evaluation of health facility utilization and safety, annual reporting forms submitted by the target health facilities will be used from 2024 to 2028. Regarding facility utilization, we hypothesize that the intervention will increase utilization rates by enhancing clinical capacity.

Number of trial arms and intervention duration:

Only the evaluation of the clinical effectiveness of Regional Medical Centers will include two arms: an intervention group and a non-intervention group. All other aspects of the evaluation will involve a single arm (intervention group only). The intervention, namely the provision of

telehealth services, will begin in March 2026 with the installation of the IT platform and the provision of diagnostic equipment to CHCs, and will continue at least until June 2029, when the JICA Project is scheduled to conclude. However, the project aims to ensure the sustainability of the telehealth system beyond the project period.

Single or multiple institutions:
This is a multi-institutional study conducted jointly by the JICA Vietnam Telehealth Project, the Medical Services Administration (MSA) of MoH, Vietnam, and the Bureau of Global Health Cooperation of the Japan Institute for Health Security (JIHS). The study covers one Provincial General Hospital, two Regional Medical Centers, and eight commune health centers (CHCs), including three former regional polyclinics.

Stratification:
For the evaluation of clinical effectiveness, patient data extracted from the Hospital Information System (HIS) at the target health facilities, along with monthly reporting forms on non-communicable diseases (NCDs) submitted to MoH, will not be stratified. Instead, we will adjust for covariates such as sex, age, and disease severity (if available) in a multivariate analysis examining the association between the intervention and clinical effectiveness indicators.

4.2 Basis of scientific rationality

The Project’s intervention does not involve the introduction of a single pharmaceutical or therapeutic technology. Instead, it entails the deployment of DtoD telehealth, which may have multiple implications for clinical practice at the 11 target health facilities. Consequently, randomizing the facilities and allocating them to intervention and non-intervention groups was not feasible. Instead, the selection of target facilities was determined through discussions and negotiations between Japanese stakeholders (JICA and the Project) and Vietnamese counterparts (the provincial authorities of Lao Cai and MoH), based on social relevance and operational feasibility. Therefore, it is necessary to strike a balance between scientific rigor, contextual relevance, and feasibility.

A pre- and post-intervention comparison is considered the most feasible method for evaluating clinical effectiveness. Only for the Regional Medical Centers a comparison between intervention and non-intervention groups will be conducted, as these groups can be readily constructed using data from the Provincial General Hospital's HIS. Regarding the clinical effectiveness of the Provincial General Hospital, since it is the only provincial-level

facility and is expected to provide support to lower-level health facilities, rather than receive support through DtoD telehealth, establishing a non-intervention control group is neither feasible nor necessary. For the CHCs, comparing the eight intervention CHCs with the other eight non-intervention CHCs is operationally, financially, and administratively infeasible. To minimize bias due to confounding, we will adjust for covariates such as sex, age, and disease severity (if available) using multivariate analysis to assess the association between the intervention and clinical effectiveness indicators.

The evaluation of cost, impact on clinical care implementation, and sustainability will be conducted as a one-time assessment during the endline survey, using unit cost analysis and qualitative data collection, followed by thematic analysis. The evaluation of health facility utilization and safety will be carried out through the analysis of annual reporting forms submitted by the target health facilities. For both evaluations, we will, as much as possible, calculate population-based indicators such as the outpatient consultation rate, inpatient admission rate, and the incidence rate of adverse events associated with telehealth, based on the total number of outpatient telehealth consultations and inpatient cases supported via tele-support. These indicators will be used to compare across facilities and to test the statistical significance of any observed changes. However, due to the abolition of districts as of 1 July 2025 and the merger of provinces and communes, the catchment areas of all target health facilities have changed. As a result, calculating population-based rates may be challenging. In such cases, we will instead compare absolute numbers.

5. Target health facilities, patients, and interviewees

5.1 Target health facilities

Target health facilities are:

At the provincial level: Lao Cai Provincial General Hospital (PGH) No. 1 (former Yen Bai Provincial General Hospital)

At the regional level: Yen Binh Regional Medical Center (RMC) and Luc Yen RMC

At the commune level: Thac Ba CHC*, Cam An CHC*, Khanh Hoa CHC*, Bach Ha CHC, Dai Minh CHC, Muong Lao CHC, Minh Tien CHC, and Dong Quan CHC.

*These CHCs are former regional polyclinics and possess significantly greater clinical capacity than other CHCs. They are equipped with ultrasound and ECG machines, which are not available in other CHCs.

5.2 Target patients for clinical effectiveness evaluation

Evaluation purpose	Evaluation indicators	Patients whose records are to be extracted	Data source
Evaluation of the clinical effectiveness of **PGH**	● All-cause inpatient cure rate at PGH ● All-cause average length of stay at PGH	All inpatients at PGH in 2023, 2024, and 2028	PGH HIS
Evaluation of the clinical effectiveness of **RMCs**	● Inpatient cure rate and average length of stay of CPA, AMI, stroke (cerebral infarction), and moderate-to-severe injury* patients at PGH ● Rate of reperfusion therapy (fibrinolytics and PCI) among AMI patients at PGH ● Rate of tPA and cerebral catheter therapy among cerebral infarction patients at PGH ● Rate of operations under general anesthesia among moderate-to-severe injury* patients at PGH	Inpatients referred from two target RMCs and two non-target RMCs (Tran Yen and Van Yen RMCs) to PGH with diagnosis of CPA, AMI, stroke (cerebral infarction) and severe injury* in 2023, 2024, and 2028	PGH HIS
	● All-cause inpatient cure rate at two target RMCs ● All-cause average length of stay at two target RMCs	All inpatients at target RMCs in 2023, 2024, and 2028	Target RMCs HIS
Evaluation of the clinical effectiveness of **CHCs**	● Inpatient cure rate and average length of stay of CPA, AMI, stroke (cerebral infarction), and moderate-to-severe injury* patients at two target RMCs ● Rate of tPA among cerebral infarction patients at two target RMCs	Inpatients referred from target CHCs with diagnosis of CPA, AMI, stroke (cerebral infarction), and moderate-to-severe injury* in 2023, 2024, and 2028	Target RMCs HIS
	● Referral rates from CHCs to upper-level hospitals (national, provincial, and regional) among hypertension, diabetes,	Patients referred from CHCs to upper-level hospitals due to poor	CHCs HIS/ Monthly

	and COPD patients due to poor control or complications.	control or complications of hypertension, diabetes, and COPD	NCD reports
	● Rate of patients with regular outpatient visits** for hypertension, diabetes, and COPD patients at CHCs.	Outpatients who visited target CHCs for hypertension, diabetes, and COPD in 2023, 2024, and 2028	Monthly NCD reports

PGH: Provincial General Hospital; CPA: cardiopulmonary arrest; AMI: acute myocardial infarction; PCI: percutaneous coronary intervention; tPA: tissue-type plasminogen activator; RMCs: Regional Medical Centers; CHCs: Commune Health Centers; NCD: non-communicable diseases.

*Moderate-to-severe injury is defined as trauma requiring hospitalization at PGH or RMCs, based on the classification of the National Research Institute for Earth Science and Disaster Resilience (NIED), Japan.

** Patients with regular outpatient visits are defined as those who attend outpatient appointments monthly, every two months, or every three months, without any missed visits throughout the year. Patients who visit less frequently or who miss any appointments during the year are classified as having irregular visits. Regularity will be assessed for each of the three target years: 2023, 2024, and 2028.

5.2.1 Inclusion criteria

1) All those patients who match the descriptions of “Patients whose records to be extracted” columns in the above table.

5.2.2 Exclusion criteria

2) Patients whose records are missing necessary data required to calculate above evaluation indicators.

5.2.3 Reasons for setting the criteria

To ensure relevance of data to conduct analyses of change in clinical efficacy after the telehealth deployment.

5.3 Target interviewees for cost, impact on clinical care implementation, and sustainability evaluation

5.3.1 Inclusion criteria

1) All Project staff (both Japanese and Vietnamese).

2) Relevant managers of the target health facilities.
3) Clinical staff who are mainly engaging in telehealth services in the target health facilities.
4) IT staff in the Provincial General Hospital and Regional Medical Centers.

5.3.2 Exclusion criteria

1) Above target personnel who do not agree to participate in the interview.

5.3.3 Reasons for setting the criteria

To ensure informed consent among the interviewees.

5.4 Sample size

This evaluation does not apply sampling, but rather study all relevant patient data and interviewees after applying the inclusion and exclusion criteria mentioned above.

5.4.1 Estimated numbers of subjects

The following numbers of patients for which HIS and NCD report data will be extracted for the evaluation of clinical effectiveness are estimates based on health facility statistics:

Patient categories	Anticipated number (persons)/ year
All inpatients at PGH in 2023, 2024, and 2028	38,000
Inpatients referred from two target RMCs and two non-target RMCs (Tran Yen and Van Yen RMCs) to PGH with a diagnosis of CPA, AMI, stroke (cerebral infarction), and moderate-to-severe injury in 2023, 2024, and 2028	500
All inpatients at target RMCs in 2023, 2024, and 2028	18,000
Inpatients referred from target CHCs with a diagnosis of CPA, AMI, stroke (cerebral infarction), and moderate-to-severe injury in 2023, 2024, and 2028	140
Outpatients who visited target CHCs for hypertension, diabetes, and COPD in 2023, 2024, and 2028	15,000

PGH: Provincial General Hospital; RMCs: Regional Medical Centers; CPA: cardiopulmonary arrest; AMI: acute myocardial infarction; CHCs: Commune Health Centers; COPD: chronic obstructive pulmonary disease.

Furthermore, the following number of interviewees will be interviewed for the evaluation of cost, impact on clinical care implementation, and sustainability of telehealth:

Interviewees categories	Anticipated number (persons)
All staff of the Project Office (both Japanese and Vietnamese)	5
Relevant managers of the target health facilities	12
Clinical staff who are mainly engaging in telehealth services in the target health facilities	15
IT staff in the Provincial General Hospital and Regional Medical Centers	5

5.4.2 Basis of estimating the numbers of subjects

The number of patients for whom HIS and NCD report data will be extracted for the evaluation of clinical effectiveness is estimated based on 2023 health facility statistics. The number of interviewees is estimated based on the existing staffing levels and the sufficiency needed to obtain relevant qualitative information regarding cost, impact on clinical care delivery, and sustainability.

6. Intervention

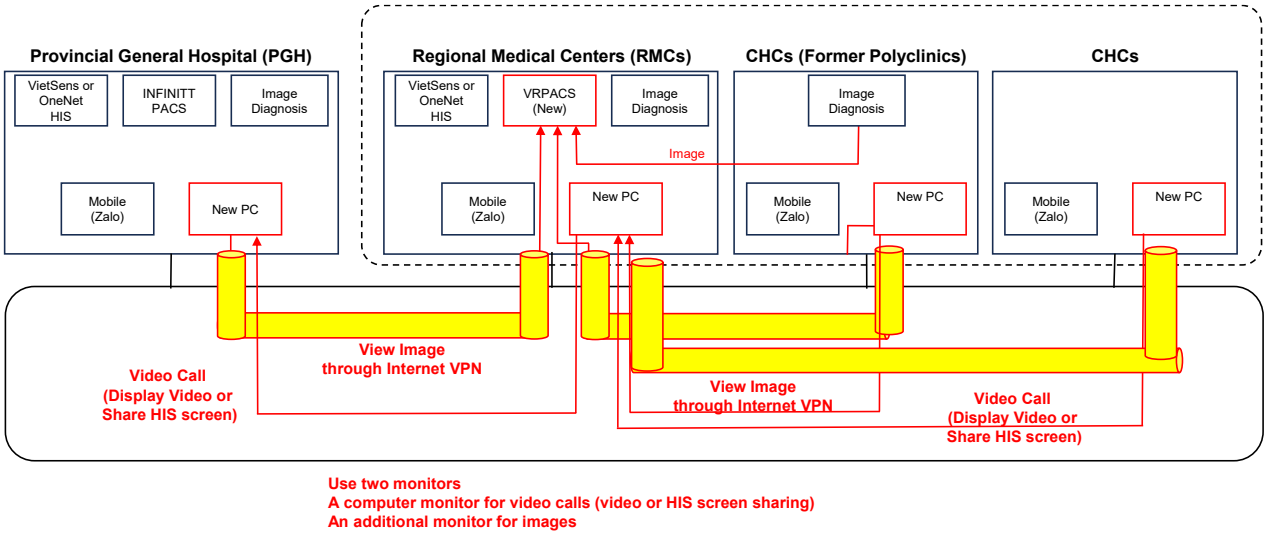
6.1 Overview of the intervention

6.1.1 Overview of the intervention

The intervention, which is the implementation of the JICA Vietnam Telehealth Project in Lao Cai Province, comprises the following three components:

1) Installation of IT platform to enable DtoD telehealth between Provincial General Hospital (PGH) and Regional Medical Centers (RMCs), as well as between RMCs and Commune Health Centers (CHCs) through Virtual Private Network (VPN) connections, the introduction of a Picture Archiving and Communication System (PACS), and installation of additional personal computers (PCs).
2) Installation of electrocardiogram (ECG) and ultrasound diagnostic imaging equipment to five CHCs that were not classified as regional polyclinics prior to the administrative reform on 1 July 2025.
3) Training of medical staff at the target health facilities on telehealth utilization. Training of ECG and ultrasound utilization and diagnosis for the CHCs staff. Training of IT staff on system maintenance and troubleshooting.

The following diagram shows the outline of the IT platform to be installed:



Through these, the Project aims to achieve: 1) Video consultations during both outpatient and inpatient care, enabling higher-level hospitals to provide support to lower-level health facilities; and 2) Medical image sharing across different levels of the health system to facilitate accurate diagnoses and treatment decisions. The intervention is scheduled to begin in March 2026.

The PACS will be purchased outright rather than rented. In the former Yen Binh District area, it will be procured from the local vendor, VietSen. In the former Luc Yen District area, it will be procured from the local vendor, OneNet. Philips PageWriter TC10 ECG and Mindray TE Air i3P ultrasound diagnostic imaging equipment will be installed at the five CHCs.

6.1.2 Anticipated adverse events

The deployment of DtoD telehealth generally ensures that higher-level hospitals provide support to lower-level health facilities, thereby improving, rather than diminishing, the quality of care at those facilities. However, such deployment and the provision of equipment to CHCs may potentially lead to overdiagnosis and overtreatment beyond the capacity of health facilities at various levels, possibly resulting in adverse events for patients.

To mitigate such risks, a Technical Working Group—comprising the MSA, the Administration of Science, Technology, and Training (ASTT), the National Health Information Center (NHIC), MoH of Vietnam, and the Project—will develop DtoD telehealth guidelines and standard operating procedures (SOPs) prior to the deployment of the telehealth solution and equipment, to ensure safety. In addition, before the installation of ECG and ultrasound machines at the five CHCs, CHC staff will receive training on the use of these devices at the

Provincial General Hospital and will obtain the necessary certification that authorizes them to perform diagnostic procedures using this equipment, in accordance with MoH regulations.

6.2 Protocol treatment

Not applicable since our intervention is the deployment of DtoD telehealth, rather than the introduction of a single pharmaceutical or therapeutic intervention.

6.3 Combination therapy

Not applicable.

7. Research methods and procedure

7.1 Subject recruitment

Source Population: For the evaluation of the clinical effectiveness of telehealth, the source population consists of all patients recorded in the HIS at PGH, RMCs, and CHCs, as well as the NCD reports at CHCs in 2023, 2024, and 2028. For the evaluation of the cost, impact on clinical care implementation, and sustainability of telehealth, the source population includes the Project staff and all personnel of the 11 target health facilities.

Target of recruitment: For the evaluation of the clinical effectiveness, specific patient categories listed in the “Patients whose records are to be extracted” column of the table in Section 5.2 will be selected from the above source population, and their data will be extracted from the HIS and the monthly NCD reports. For the evaluation of the cost, impact on clinical care implementation, and sustainability, relevant informants will be selected from the source population based on the degree of their engagement with the DtoD telehealth services.

7.2 Subject registration

The patients and interviewees selected through the process described in Section 7.1 above will be considered registered. For patients whose data are to be extracted from the HIS and NCD reports, the unique patient ID assigned by each of the 11 target health facilities will, in principle, be used as the research ID. Interviewees will be assigned a unique research ID by the research team.

7.3 Collection of specimens

Not applicable. This evaluation does not collect any human specimens.

7.4 Information to be collected and collection procedures

7.4.1 Information to be collected for evaluation of clinical effectiveness

For the evaluation of the clinical effectiveness of telehealth, the following information will be extracted from the HIS at PGH, RMCs, and CHCs, as well as the monthly NCD reports at CHCs covering 2023, 2024, and 2028.

Data source	**Indicators of clinical effectiveness**	**Information to be collected**
PGH HIS	All-cause inpatient cure rate at PGH	● Total number of admissions at PGH ● Total number of inpatients at PGH who were cured and discharged
	All-cause average length of stay at PGH	● Bed days of all inpatients at PGH
	Inpatient cure rate and average length of stay of CPA, AMI, stroke (cerebral infarction), and moderate-to-severe injury patients at PGH among inpatients referred from 2 target and 2 non-target RMCs	●Total numbers of CPA, AMI, stroke (cerebral infarction), and moderate-to-severe injury inpatients at PGH referred from 2 target and 2 non-target RCMS, **AND** those who were cured and discharged among them ●Bed days at RMCs of CPA, AMI, stroke (cerebral infarction), and moderate-to-severe injury inpatients referred from 2 target and 2 non-target RMCs
	Rate of reperfusion therapy (fibrinolytics and PCI) at PGH among AMI patients referred from 2 target and 2 non-target RMCs	● Total number of AMI inpatients referred from 2 target and 2 non-target RMCs who received reperfusion therapy at PGH
	Rate of tPA and cerebral catheter therapy among cerebral infarction patients at PGH	●Total number of cerebral infarction inpatients referred from 2 target and 2 non-target RMCs who received tPA and cerebral catheter therapy at PGH
	Rate of operations under general anesthesia among moderate-to-severe injury patients at PGH	●Total number of moderate-to-severe injury inpatients referred from 2 target and 2 non-target RMCs who underwent operation under general anesthesia at PGH

RMCs HIS	All-cause inpatient cure rate at two target RMCs	● Total number of admissions at RMCs ● Total number of inpatients at RMCs who were cured and discharged
	All-cause average length of stay at two target RMCs	●Bed days of all inpatients at RMCs
	Inpatient cure rate and average length of stay of CPA, AMI, stroke (cerebral infarction), and moderate-to-severe injury patients at two target RMCs	●Total numbers of CPA, AMI, stroke (cerebral infarction), and moderate-to-severe injury inpatients at target RMCs referred from target CHCs, **AND** those who were cured and discharged among them ●Bed days at RMCs of CPA, AMI, stroke (cerebral infarction), and moderate-to-severe injury inpatients referred from target CHCs
	Rate of tPA among cerebral infarction patients at two target RMCs	●Total number of cerebral infarction inpatients at RMCs who received tPA therapy
CHCs HIS & NCD reports	Referral rates from CHCs to upper-level hospitals (national, provincial, and regional) among hypertension, diabetes, and COPD patients due to poor control or complications.	●Total numbers of patients referred to upper-level hospitals among hypertension, diabetes, and COPD patients due to poor control or complications at CHCs ●Total numbers of patients with hypertension, diabetes, and COPD who are treated at CHCs
	Regularity of outpatient visits for hypertension, diabetes, and COPD patients at CHCs.	●Dates of outpatient visit of patients with hypertension, diabetes, and COPD who are treated at CHCs

7.4.2 Information to be collected for evaluation of cost, impact on clinical care implementation, and sustainability

For the evaluation of cost, impact on clinical care implementation, and sustainability, the following information will be collected primarily through in-depth interviews guided by an interview guide reflecting these categories. For cost, the information obtained from the interviews will be cross-validated against accounting records from the Project Office and the target health facilities.

Evaluation items	Categories of information to be collected
Cost	● Direct capital costs (e.g. servers, PCs, ECG, ultrasound, etc.) ● Indirect capital costs (e.g. shared building cost) ● Direct recurrent costs (e.g. equipment maintenance fees) ● Indirect recurrent costs (e.g. shared staff salaries) ● Annual numbers of outpatient and inpatient telehealth sessions (obtained through the annual reporting forms)
Impact on clinical care implementation	● Impacts on staffing ● Impacts on workload ● Impacts on workflow ● Impacts on consultation time per patient ● Impacts on quality of care ● Diagnostic and therapeutic procedures newly enabled by the DtoD telehealth
Sustainability	● Staff perception of financial sustainability of telehealth ● Staff perception of operational sustainability of telehealth ● Suggestions to ensure sustainability (budgeting, law and regulation, staffing, IT solutions, clinical capacity, etc.)

7.4.3 Information to be collected for evaluation of health facility utilization and safety

These evaluation items will be monitored annually through the submission of annual reporting forms by the target health facilities. For the former, the number of outpatient visits and hospital admissions will be monitored. For the latter, any incidence of adverse events should be reported by the target health facilities to the Project Office.

7.5 Information flows

7.5.1 Evaluation of clinical effectiveness

Within target health facilities:

HIS and monthly NCD report data will be extracted by the researchers.

In principle, information that allows individual identification will not be extracted. Instead, patient IDs and dates of admission (DOA) will be used to check for duplicate cases.

For the sole purpose of calculating referral rates from CHCs to upper-level hospitals, patient names and dates of birth (DOB) will be used to match all patients with NCDs to those referred due to poor control or complications. This matching will be conducted within the target health facilities. After matching, patient names will be deleted and DOBs will be replaced with age (in years). Therefore, no personally identifiable information will remain in the datasets once they leave the health facilities.

*Patient names and DOB will be used because different IDs are employed across databases, including national ID, health insurance ID, patient ID, and treatment ID.

Within the Project Office and JIHS:

The extracted data (in Excel format) will be aggregated and converted into formats compatible with statistical software.

Statistical analysis will be conducted jointly by the Project Office and the Bureau of Global Health Cooperation, JIHS.

Within the research organizations including MSA:

Analyses results will be reviewed and commented by MSA, MoH, Vietnam

7.5.2 Evaluation of cost, impact on clinical care implementation, and sustainability

Within target health facilities:

In-depth interviews using a pre-set interview guide, along with a review of accounting reports, will be conducted. Interviews will be audio-recorded. Interviewees' names, positions, and affiliated facilities will be anonymized, and a linkage file will be created. During and after data collection, the linkage file will be stored by the Principal Investigator in a secure, password-protected SharePoint folder at the Bureau of Global Health Cooperation, JIHS.

Within the Project Office and JIHS

Audio-recorded interviews will be transcribed verbatim in Vietnamese and then translated into English. Thematic analysis will be conducted. Unit cost analysis, based on cost data and the quantity of telehealth services, will also be performed. The above analyses will be conducted jointly by the Project Office and the Bureau of Global Health Cooperation, JIHS.

Within the research organizations including MSA

Analyses results will be reviewed and commented by MSA, MoH, Vietnam

7.5.3 Evaluation of health facility utilization and safety

The annual reporting form, which includes the number of outpatient visits and admissions, as well as any adverse events related to either outpatient or inpatient telehealth, will be submitted once a year by all target health facilities. Data analysis will be conducted jointly by the Project Office and the Bureau of Global Health Cooperation, JIHS.

7.6 Study and observation periods

Study period: From the date of Ethic Review Committee approval (both at JIHS and at MoH, Vietnam) to 31 December 2029

Registration period: This evaluation is a retrospective study, therefore does not apply a prospective subject registration.

Observation period:

Evaluation of clinical effectiveness: The baseline survey covers the entire 2023 and 2024, while the endline survey covers the entire 2028.

Evaluation of cost, impact on clinical care implementation, and sustainability: The endline survey covers the entire 2028.

***Evaluation of health facility utilization and safety*:** The annual monitoring through the annual reporting form covers 2024-2028.

8. Consent acquisition

8.1 Informed consent

For the evaluation of clinical effectiveness, this evaluation will retrospectively review data from the HIS and NCD reports. Obtaining individual consent from the target patients is difficult due to challenges in subsequent follow-up. Therefore, information about the study will be disclosed through an information disclosure form, which will be posted in the outpatient departments of the target health facilities prior to data collection. Patients will be given the opportunity to opt out and refuse the use of their data for the research.

For the interviews conducted to evaluate cost, the impact on clinical care implementation, and sustainability, written informed consent will be obtained from all participants prior to their involvement in the study. The contents of the explanation document will be communicated verbally. Interviewees will be given sufficient time to consider participation before signing the consent form. The explanation will include the purpose, methodology, potential risks and benefits of the study. It will also clarify that participation is entirely voluntary, that refusal will not result in any disadvantage, and that consent may be withdrawn at any time without penalty.

For the evaluation of health facility utilization and safety, the annual reporting form does not contain any personally identifiable information. Reports of adverse events will include only the occurrence and details of the events, without identifying any patients. In the event of an adverse event—whether reported in the annual form or in between reporting periods—the Project Office will visit the target health facility and conduct a thorough investigation, independent of this evaluation.

8.2 Informed ascent

Not applicable because all interviewees are adults.

8.2 Consent withdrawal

For the evaluation of clinical effectiveness, target patients may contact the research team—whose contact information (email addresses and telephone numbers) will be provided in the information disclosure form posted in the outpatient departments of the target health facilities prior to data collection—to express their intention to opt out of the evaluation. For interviewees participating in the evaluation of cost, the impact on clinical care implementation, and sustainability, consent may be withdrawn at any time by submitting a consent withdrawal form to the Project Office, in which case their data will be deleted.

9. Evaluation and reporting of adverse events

9.1 Definition of adverse events

Although this evaluation does not directly apply invasive procedures, the deployment of DtoD telehealth may have a wide range of impacts on clinical practices at the target health facilities. Therefore, the Project will monitor the adverse events associated with the telehealth at least annually by the annual reporting form, but at any time they occur by the notification of the target facilities. In this evaluation, we define adverse events as any unfavorable symptoms, signs, illnesses, or abnormal clinical laboratory values observed in a patient that are determined by medical doctors at the target health facilities to be related to telehealth. It should be noted that the adverse events may also occur among patients who are not the target of the clinical effective evaluation.

9.2 Definition of severe adverse events

Among the adverse events defined above, those resulting in deaths, are life-threatening, requiring hospitalization or prolongation of existing hospitalization for treatment, and resulting in permanent or significant disability or dysfunction are defined as severe adverse events.

9.3 Causal relationship with the intervention

As mentioned above, the deployment of DtoD telehealth may have a broad range of impacts on clinical practice, rather than representing the introduction of a single pharmaceutical or

therapeutic intervention. Therefore, assessing causality is inherently challenging due to the multifaceted nature of the intervention. Since adverse events are defined as those associated with telehealth, the determination that an event meets this definition involves a judgment by medical doctors at the target health facilities that it is related to telehealth. This judgment will be made as part of routine clinical care at the target facilities.

9.4 Predictability of adverse events

Since our intervention (telehealth deployment) does not involve the introduction of a single pharmaceutical or therapeutic product, information on any specific product or service does not allow for the prediction of adverse events.

9.5 Period and contents of data collection

Information on adverse events will be collected for the duration of the Project (2024-2029) and even beyond, with the initiative of Lao Cai Provincial Health Department and MoH, Vietnam. The annual reporting form will monitor the occurrence and details of the events. In the event of an adverse event—whether reported in the annual form or in between reporting periods—the Project Office will visit the target health facility and conduct a thorough investigation, independent of this evaluation.

9.6 Reporting of adverse events

For all adverse events, the following information shall be recorded: the name of the event, date of onset, course of the event, measures taken in response, outcome, and date of outcome. In addition, the severity, seriousness (if assessed), and the causal relationship with the telehealth shall also be documented. If the collected adverse event is determined to be a serious adverse event, the principal investigators shall report it in accordance with Section 9.7. For non-serious adverse events related to the telehealth deployment, the principal investigators and the Project Office shall report them to the Ethics Review Committee and the President of JIHS, as well as MSA, MoH, Vietnam, and both the Vietnam Office and the Headquarters of JICA.

9.7 Reporting of serious adverse events

For serious adverse events, as for the non-serious cases, the principal investigators and the Project Office shall report them to the Ethics Review Committee and the President of JIHS, as well as MSA, MoH, Vietnam, and both the Vietnam Office and the Headquarters of JICA.

10. Discontinuation and termination

10.1 Discontinuation of study participation

Participation of patients whose data from the HIS and NCD reports will be analyzed, as well as interviewees, will discontinue under the following circumstances:

- If they choose to opt out or withdraw their consent
- If the principal investigators deem it necessary

Participants who discontinued participation will not be replaced by new participants.

10.2 Discontinuation of the entire evaluation

If the following situation occurs and the principal investigators decide that the evaluation should be discontinued, the entire evaluation may be discontinued.

- When a serious violation/non-compliance with the ethical guidelines or study protocol is found
- When a fact that impair or may impair ethical validity or scientific rationality is found
- In case the request or recommendation for discontinuation was made by the head of the study institution or the relevant authority
- When the principal investigators decide to discontinue

The principal investigators will make the final decision to discontinue the entire evaluation in consultation with JICA. In case of discontinuation, the principal investigators will report to the Ethics Review Committee and the President of JIHS, as well as MSA, MoH, Vietnam, and both the Vietnam Office and the Headquarters of JICA. They will also notify the interviewees.

10.3 Termination of the evaluation

The evaluation ends on 31 December 2029.

11. Anticipated benefits and risks, and means to minimize risks

11.1 Anticipated benefits

The patients targeted for the evaluation and interviewees are not anticipated to benefit in explicit ways. However, since the evaluation provides both the MoH and the provincial authority with the necessary evidence for the expansion of the telehealth model, patients in general in Vietnam may benefit from the future improvement of healthcare.

11.2 Anticipated risks

The deployment of DtoD telehealth generally ensures that higher-level hospitals provide support to lower-level health facilities, thereby improving, rather than diminishing, the quality of care at those facilities. However, such deployment and the provision of equipment to CHCs may potentially lead to overdiagnosis and overtreatment beyond the capacity of health facilities at various levels, possibly resulting in adverse events for patients. The in-depth interviews may cause a minor distraction from the interviewees' occupational duties.

11.3 Means to minimize risks

To minimize the risk of adverse events associated with DtoD telehealth, a Technical Working Group—comprising the MSA, the Administration of Science, Technology, and Training (ASTT), the National Health Information Center (NHIC), MoH of Vietnam, and the Project—will develop DtoD telehealth guidelines and standard operating procedures (SOPs) prior to the deployment of the telehealth solution and equipment, to ensure safety. In addition, before the installation of ECG and ultrasound machines at the five CHCs, CHC staff will receive training on the use of these devices at the Provincial General Hospital and will obtain the necessary certification that authorizes them to perform diagnostic procedures using this equipment, in accordance with MoH regulations.

12. Ethical matters and considerations

12.1 Compliance with laws and guidelines

All researchers involved in this study abide by the Declaration of Helsinki (revised 2013, Fortaleza) and conduct the study in accordance with the "Ethical Guidelines for Medical and Biological Research Involving Human Subjects" issued by the Ministry of Health, Labour and Welfare, Japan. The research protocol, participant information sheet, informed consent form, consent withdrawal form, and interview guide will be reviewed and approved by the Ethics Review Committees of both JIHS and the MoH, Vietnam. The study will commence only after obtaining permission from the President of the research organization (JIHS). If any of the above documents require modification, such changes will be subject to renewed review and approval by the Ethics Review Committees and the President of JIHS. The principal researchers will ensure that all participating researchers complete research ethics training prior to involvement and continue to receive training throughout the study period.

12.2 Handling of personal information

As mentioned in the Section 7.5.1 above, for the patient data extracted from the HIS and NCD reports, in principle, information that allows individual identification will not be extracted. Instead, patient IDs and dates of admission (DOA) will be used to check for duplicate cases. Only for calculating referral rates from CHCs to upper-level hospitals, patient names and dates of birth (DOB) will be used to match all patients with NCDs to those referred due to poor control or complications. This matching will be conducted within the target health facilities. After matching, patient names will be deleted and DOBs will be replaced with age (in years). Therefore, no personally identifiable information will remain in the datasets once they leave the health facilities.

Also, as mentioned in the Section 7.5.2 above, interviewees' names, positions, and affiliated facilities will be anonymized, and a linkage file will be created. During and after data collection, the principal researchers will create a linkage file that will be stored by the principal investigator of JIHS in a secure, password-protected SharePoint folder at the Bureau of Global Health Cooperation, JIHS. Qualitative data analysis will be conducted with the transcribed and translated narrative data without personal information.

12.3 Compensation for adverse events

The intervention in the context of this evaluation refers to the implementation of the JICA Vietnam Telehealth Project itself. Compensation for adverse events, as defined in Sections 9.1 and 9.2 above, will be determined through an agreement among the directors of the target health facilities, the Provincial Health Office, the Project Office (in consultation with JICA), and MSA, MoH, Vietnam—rather than by the principal researchers. Such decisions fall under local medical administration and the framework of Japan–Vietnam bilateral technical cooperation, rather than being part of this evaluation exercise alone.

12.4 Assurance of treatment for non-participants

Not applicable since our intervention is the deployment of DtoD telehealth, rather than the introduction of a single pharmaceutical or therapeutic intervention.

12.5 Provision of healthcare after the study

Not applicable since our intervention is the deployment of DtoD telehealth, rather than the introduction of a single pharmaceutical or therapeutic intervention. Telehealth services are expected to be continued even after the termination of the Project in June 2029.

12.6 Handling of results obtained by the evaluation

As stated in Section 3 as one of its main objectives, this evaluation aims to produce an impact evaluation report to be submitted to the Ministry of Health (MoH) at the end of the Project, so that the findings can be used to support the expansion of telehealth to other provinces. Patients will not be informed of the evaluation results. However, interviewees—most of whom are staff members of the target health facilities—will be provided with the evaluation report through the provincial authorities and facility managers.

12.7 Subjects' financial burden and reward

Neither patients nor interviewees will bear any financial burden for participating in this evaluation. They will also not receive any monetary or in-kind compensation for their participation.

12.8 Source of funding

This evaluation is funded by Japan International Cooperation Agency (JICA) as part of the budget for the JICA Vietnam Telehealth Project.

12.9 Conflict of interest

Conflicts of interest that may occur throughout this evaluation will be reported to the JIHS Conflict of Interest Management Committee in advance and will be managed appropriately according to the examination results. There is no conflict of interest to declare regarding this evaluation.

12.10 Disclosure of information

Information on the outline and results of this evaluation will be posted—and updated as appropriate—on the Project's website, after obtaining permission from JICA. In accordance with the ethics guidelines, since this evaluation is an intervention study, it was registered at

jRCT (Japan Registry of Clinical Trials) on 5 August 2025 with clinical research implementation plan number of jRCT1032250282.

12.11 Publications of results

On top of the evaluation report to be submitted to the MoH, Vietnam, the results of this evaluation will be published in academic journals and presented at academic conferences. The publication time is scheduled from 2026 to 2029. The authors at the time of submission to academic journals will be decided through discussions among the principal investigators and other Vietnamese stakeholders, taking into consideration the degree of contribution to the evaluation.

13. Statistical analyses

13.1 Subjects of statistical analyses

Only the evaluations of clinical effectiveness and health facility utilization will involve statistical analyses. For the former, data extracted from either the HIS or the NCD reports of target patients, as specified in Section 5.2, will be analyzed statistically. For the latter, data submitted through the annual reporting forms by all target health facilities from 2024 to 2028 will be subject to statistical analysis.

13.2 Statistical analyses

13.2.1 Statistical analyses for major evaluation items

Evaluation of clinical effectiveness:

The hypothesis for the evaluation of clinical effectiveness is that the telehealth deployment through the Project improves clinical outcomes for patients at the target health facilities. Following table displays indicators for evaluating clinical effectiveness of the telehealth deployment and the analytic methods applied to test the significance of difference between the baseline (pre-intervention) and endline (post-intervention) figures.

Evaluation purpose	Evaluation indicators	Data source	Methods of statistical analyses
Evaluation of the clinical effectiveness of **PGH**	● All-cause inpatient cure rate at PGH ● All-cause average length of stay at PGH	PGH HIS	● Multiple logistic regression ● Unpaired t-test ● Analysis of covariance

Evaluation of the clinical effectiveness of **RMCs**	● Inpatient cure rate and average length of stay of CPA, AMI, stroke (cerebral infarction), and moderate-to-severe injury* patients at PGH ● Rate of reperfusion therapy (fibrinolytics and PCI) among AMI patients at PGH ● Rate of tPA and cerebral catheter therapy among cerebral infarction patients at PGH ● Rate of operations under general anesthesia among moderate-to-severe injury* patients at PGH	PGH HIS	● General linear model (GLM) for testing difference in difference (DID)
	● All-cause inpatient cure rate at two target RMCs ● All-cause average length of stay at two target RMCs	Target RMCs HIS	● Multiple logistic regression ● Unpaired t-test ● Analysis of covariance
Evaluation of the clinical effectiveness of **CHCs**	● Inpatient cure rate and average length of stay of CPA, AMI, stroke (cerebral infarction), and moderate-to-severe injury* patients at two target RMCs ● Rate of tPA among cerebral infarction patients at two target RMCs	Target RMCs HIS	● Multiple logistic regression ● Unpaired t-test ● Analysis of covariance
	● Referral rates from CHCs to upper-level hospitals (national, provincial, and regional) among hypertension, diabetes, and COPD patients due to poor control or complications.	CHCs HIS/ Monthly NCD reports	● Multiple logistic regression
	● Rate of patients with regular outpatient visits** for hypertension, diabetes, and COPD patients at CHCs.	Monthly NCD reports	● Multiple logistic regression

PGH: Provincial General Hospital; CPA: cardiopulmonary arrest; AMI: acute myocardial infarction; PCI: percutaneous coronary intervention; tPA: tissue-type plasminogen activator; RMCs: Regional Medical Centers; CHCs: Commune Health Centers; NCD: non-communicable diseases.

*, **See table in Section 5.2 for the definition of moderate-to-severe injury and patients with regular outpatient visits.

Evaluation of health facility utilization:

The hypothesis for the evaluation of health facility utilization is that the telehealth deployment through the Project increases utilization by enhancing the clinical capacities of the target health facilities. A chi-square (χ^2) test will be applied to assess the significance of differences in population-based outpatient consultation rates and admission rates, provided that catchment population data are consistently available for both the pre- and post-intervention periods, despite the administrative reform implemented on 1 July 2025.

13.2.2 Statistical analyses for minor evaluation items

Among the minor evaluation items specified in Section 3, the diagnostic and treatment services enabled by the telehealth deployment will be descriptively tabulated. The frequency of telehealth implementation, the number of health personnel involved in telehealth, and the number of health facility staff trained in telehealth will be monitored annually and presented in a summary table. No statistical comparison between the pre- and post-intervention periods will be conducted.

13.2.3 Statistical analyses for safety evaluation item

Adverse events will be monitored annually through the annual reporting forms. No statistical analysis will be applied to the reported numbers of adverse events. Instead, qualitative details of the events will be closely examined to ensure an appropriate response.

13.2.4 Analyses of sub-populations

We do not conduct the analyses of sub-populations.

13.2.5 Intermediate analysis plan

We do not conduct the intermediate analysis.

14. Qualitative analysis in-depth interview records

The records of the in-depth interviews will be transcribed verbatim to Vietnamese, then translated to English. Thematic analysis will be conducted by inductively coding the narrative texts and identify themes and sub-themes. The structure of the themes will eventually be identified.

15. Storage and disposal of specimens and information

15.1 Storage methods and period

15.1.1 Storage methods and period for specimens

Not applicable, as no human specimens will be collected in this evaluation.

15.1.2 Storage methods and period for information

The master digital dataset files extracted from the HIS and NCD reports, which contain no personally identifiable information, will be password-protected and stored in a secure, password-protected SharePoint folder at the Bureau of Global Health Cooperation, JIHS. These files will be shared with the principal investigators at the Project and MSA upon request. At those offices, the datasets will be stored on password-protected removable hard drives and kept in lockable cabinets.

The audio recordings of the interviews will be password-protected and stored in a secure, password-protected SharePoint folder at the Bureau of Global Health Cooperation, JIHS. In principle, these data will not be shared with other principal investigators. The master transcript files of the interviews will also be password-protected and stored in a secure, password-protected SharePoint folder at the Bureau of Global Health Cooperation, JIHS. These files will be shared with the principal investigators at the Project and MSA upon request. At those offices, the datasets will be stored on password-protected removable hard drives and kept in lockable cabinets. The consent forms and consent withdrawal forms signed by the interviewees will be stored in a lockable cabinet at the Project Office.

Also, as mentioned in the Section 7.5.2 above, interviewees' names, positions, and affiliated facilities will be anonymized, and a linkage file will be created. During and after data collection, the principal researchers will create a linkage file that will be stored by the principal investigator of JIHS in a secure, password-protected SharePoint folder at the Bureau of Global Health Cooperation, JIHS.

The annual reporting forms, which will be submitted digitally from the target health facilities to the Project Office, will be password-protected and stored in a secure, password-protected SharePoint folder at the Bureau of Global Health Cooperation, JIHS and password-protected removable hard drives that will be kept in lockable cabinets at the Project and MSA.

The digital dataset files, audio recordings, and transcript files will be stored for 10 years after the completion of the evaluation or 8 years after the final publication of the research results, whichever is later. The consent forms and consent withdrawal forms will be stored for three years after the completion of the evaluation.

15.2 Disposal methods

15.2.1 Disposal methods for specimens

Not applicable, as no human specimens will be collected in this evaluation.

15.2.2 Disposal methods for information

Paper documents will be shredded to render them unrecoverable and then disposed of in accordance with waste management regulations. In the case of non-rewritable electronic media, they will be physically destroyed to make data retrieval impossible and then properly disposed of according to the same regulations. For rewritable electronic media, the data will either be physically destroyed or overwritten with dummy data multiple times to make the original data unrecoverable, and then similarly discarded. If any participant withdraws consent, the principal investigators will delete the corresponding digital record or transcript file from the dataset.

15.3 Utilization of data for different future studies

If the stored data are to be used for future studies with different objectives, a research proposal must be submitted to the Ethics Review Committees at JIHS and MoH, Vietnam and approved prior to use. In such cases, an information disclosure document will be prepared for an opt-out procedure to ensure that participants have the opportunity to decline participation in the new study. Existing data will not be shared with researchers at other institutions.

15.4 Security management procedure

Information in paper form is strictly managed in a lockable cabinet at the Project Office, which has controlled access. Information in electronic form will be password-protected and stored either in a secure, password-protected SharePoint folder at the Bureau of Global Health Cooperation, JIHS, or on password-protected removable hard drives kept in lockable cabinets at the Project Office or MSA. All data analyses will be conducted using files that contain no personally identifiable information. Access to the evaluation data is limited to

principal investigators and co-investigators who have been approved by the Ethics Review Committees. All researchers are required to complete ethics training.

16. Quality management and assurance

16.1 Data management

Patient data will be directly extracted from the HIS and NCD reports. The audio recordings of the in-depth interviews will be transcribed and translated at JIHS. The annual reporting forms will be stored as submitted by the target health facilities. Data analyses will be primarily conducted by the principal investigator at JIHS, in collaboration with those at the Project and MSA. The principal investigators will manage all of the above data.

16.2 Monitoring

Monitoring of adverse events associated with telehealth will be conducted through the submission of annual reporting forms by the target health facilities.

16.3 Audit

An audit will not be conducted because, although this study evaluates a health system intervention (telehealth deployment), it is not a clinical trial.

16.4 Data and Safety Monitoring Board

A Data and Safety Monitoring Board (DSMB) will not be established for this evaluation.

16.5 Report to the heads of the study institutions

The principal investigators report the progress of the study to the head of the research organization, namely the President of JIHS, Director of Human Development Department, JICA and the Director of MSA, MoH, Vietnam through the procedure set by the Ethics Review Committees. In case the study is discontinued or terminated, it will be reported promptly.

The principal investigators will promptly report to above heads of institutions in the following cases:

- When facts or information are obtained that undermine the ethical validity or scientific rationale of the evaluation

- When information is obtained that may compromise the ethical validity or scientific rationale of the evaluation and could affect the continuation of the evaluation
- When facts or information are obtained that undermine the appropriateness of the evaluation's conduct or the credibility of the evaluation results
- When information is obtained that may compromise the appropriateness of the evaluation's conduct or the credibility of the evaluation results
- When a serious adverse event is identified
- When there is a serious concern from the perspective of respecting the rights of research participants or the conduct of the evaluation, such as a leakage of evaluation-related information
- The status of evaluation progress and occurrence of adverse events during the evaluation (in principle, once a year)
- When the evaluation is completed

17. Research organization

17.1 Research organization

JICA Vietnam Telehealth Project

Principal investigator: Taketo Tanaka, Chief Advisor, JICA Vietnam Telehealth Project

Co-investigators:

Tran Lan Anh, Director, Lao Cai Provincial General Hospital

Diem Son, Deputy Director, Lao Cai Provincial General Hospital

Pham Dac Ninh, Director, Planning Department, Lao Cai Provincial General Hospital

Maiko Hashimoto, Project Coordinator, JICA Vietnam Telehealth Project

Do Huyen Trang, Project Officer, JICA Vietnam Telehealth Project

Vu Danh Truong, Technical Officer, JICA Vietnam Telehealth Project

Nguyen Thi Tuyen, Project Assistant, JICA Vietnam Telehealth Project

Medical Services Administration (MSA), Ministry of Health, Vietnam

Principal investigator: Le Sinh Quan, Division of Quality Management & DOHA, MSA, MoH, Vietnam

Japan Institute for Health Security (JIHS)

Principal investigator: Hitoshi Murakami, Deputy Director-General, Bureau of Global Health Cooperation, JIHS

17.2 Inquiry

Name of institution: JICA Vietnam Telehealth Project

Person in charge: Ms. Nguyen Thi Tuyen, Project Assistant

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17.3 Subcontracting

Not applicable, as no part of the research procedures will be subcontracted.

18. Others

18.1 List of abbreviations

Abbreviations	Non-abbreviated terms
AMI	acute myocardial infarction
CHC	commune health center
COPD	chronic obstructive pulmonary disease
CPA	cardiopulmonary arrest
CPR	cardiopulmonary resuscitation
DID	difference in difference
DOHA	Direction of Healthcare Activities
DtoD	doctor-to-doctor
DtoP	doctor-to-patient
ECG	electrocardiogram
HIS	hospital information system
JICA	Japan International Cooperation Agency
JIHS	Japan Institute for Health Security
MoH	Ministry of Health, Vietnam
MSA	Medical Services Administration, Ministry of Health, Vietnam
NCDs	non-communicable diseases
PACS	Picture Archiving and Communication System
PCI	percutaneous coronary intervention

tPA	tissue-type plasminogen activator
VPN	Virtual Private Network

18.2 Revision history

Version name	Date of development	Revisions made	Reason for the revisions
Version 1.0	31 July 2025	—	Initial development of study protocol

19. Reference

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