

Medical Examination Manual for Training Released Version



National Center for Global Health and Medicine
Bureau of International Health Cooperation
Disease Control and Prevention Center
Infection Control and Prevention

I. Purpose of Medical Examinations

National Center for Global Health and Medicine (NCGM) holds training programs in Japan for medical professionals from around the country and the world. As a training organizer, NCGM needs to check the health of participants and ensure safe and smooth training. In addition to monitoring the health of participants, NCGM must guarantee the safety of patients and pregnant women in the healthcare facilities where clinical training takes place. In particular, precautions must be taken to prevent international participants from spreading measles and active tuberculosis (TB) in Japanese hospitals. In Japan, those who want to participate in hospital tours and clinical training are usually requested to submit their measles, rubella, mumps, and varicella antibody test results, vaccination status, and chest X-rays in advance, but it is often difficult for participants from low- or middle-income countries to meet such requirements.

Therefore, this Manual has been developed by NCGM's Bureau of International Health Cooperation, Disease Control and Prevention Center (DCC), and Infection Prevention and Control (IPC) team to outline the procedures that are acceptable to both training participants and facilities and effective in ensuring safe and smooth training without unnecessary restrictions on participation.

These procedures are subject to change during COVID-19 outbreaks to meet the hospital's infection control requirements.

II. Applicable Training and Persons

Applicable training

This Manual applies to the following training courses that accept participants from inside and outside of Japan:

- All courses <u>involving clinical training</u> (See Figure 1. Definition of clinical training);
 and
- 2. Courses involving no clinical training and **lasting 30 days or more**.

This Manual does not apply to courses involving no clinical training and lasting less than 30 days.

Definition of clinical training

Clinical training is defined as training where participants may come in contact with patients at their bedside or in examination rooms at hospitals. This definition is illustrated in Figure 1 with examples of training settings. In light of the fact that while an indefinite number of exposures have taken place in outpatient areas, access to inpatient areas is limited to medical professionals and healthy family members and friends, clinical training is defined as training where participants enter inpatient areas or where participants may come into direct contact with patients (including outpatients). Any change to this definition under unavoidable circumstances must be discussed with the IPC team.

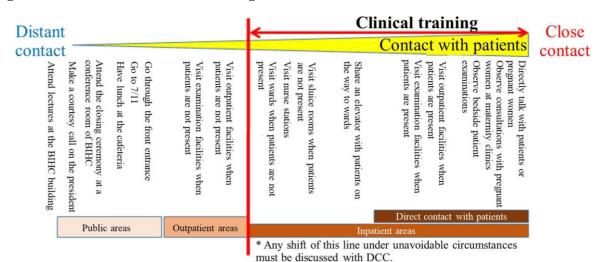


Figure 1. Definition of clinical training

Applicable persons

This Manual applies to all individuals who enter any of the areas specified in the definition of clinical training, including participants from inside and outside of Japan, training attendants and other accompanying persons, training coordinators, and interpreters.

III. Details of Medical Examinations

- 1. Symptom assessments (e.g., chronic cough and weight loss) and chest X-rays for active TB screening (Send X-ray films to Japan)
- 2. Measles, mumps, rubella, and varicella antibody test results or double vaccination certificates

IV. Precautions for Medical Examinations

The domestic training manager should take the following precautions in preparing training sessions.

- 1. Invitation to applications and consent acquisition
 - Clarify the requirement of medical examinations in the course information and application guidance and confirm that each applicant has consented to medical examinations (including antibody testing, vaccinations, and chest X-ray examinations) through the application process (Applications without the consent cannot be processed). In addition, confirm that each applicant has consented that they may lose their eligibility to participate in training due to their health conditions.
- 2. Collection of information on vaccines and antibody tests in participants' countries Collect information on the availability of antibody testing and vaccines in participants' countries. Support can be requested from local training managers to find vaccination sites (ranging from public hospitals to private clinics for foreigners). Also, refer to the lists of vaccination sites for individual countries and regions, including developing countries, on the website of the Ministry of Foreign Affairs: The World's Medical Information. http://www.mofa.go.jp/mofaj/toko/medi/vaccine/

In developing countries, vaccines are often available at clinics and pharmacies for foreigners. Therefore, useful information may be collected from clinics for Japanese and other foreign residents.

It is not allowed to use vaccines personally imported from neighboring countries or Japan because they may cause side reactions that cannot be locally addressed.

- 3. Payments for antibody tests and vaccinations
 - Discuss with participants who will bear the costs of vaccinations and antibody tests, which are usually highly expensive.
- Management of participants' personal information
 Participants' medical examination results and other personal information should be handled with care to prevent their disclosure to unauthorized persons.

5. Timeline

Refer to the medical examination flowcharts and be sure to complete the process before the training session. Ensure the X-ray films is received in Japan no later than six weeks before the training session and the measles, mumps, rubella, and varicella vaccination process starts at least six weeks before the training session (because these live vaccines should be administered in two doses at intervals of four weeks).

6. Communication with participants

The domestic training manager should keep close contact with participants to ensure they complete all the preparation before the training session. In particular, pay close attention to the vaccination schedule as the process is subject to errors, such as inappropriate simultaneous administration and intervals.

7. Health management during the training session

Check the body temperatures and health conditions of participants during the session. Any participant who develops a fever should be taken to a hospital and absent from training.

Confirm that each participant has consented to the above matters.

V.

Medical Examination Procedures

1. Active TB screening

1) Submission of chest X-ray films

* Applicants are requested to submit a digital copy in DICOM-PDI format or original X-ray film taken within the past year (via DHL or other courier services). A chest X-ray examination report (e.g., a health checkup report) issued within the past year by a Japanese medical institution can be submitted as an alternative. The examination results should be submitted to the domestic training manager.

Applicants are not eligible to participate in training unless their X-ray film is received in Japan at least six weeks before the training session.

In principle, applicants must submit an X-ray film with their application form. Although applicants with abnormal chest X-rays are generally screened out (because those suspected of active TB are not allowed to take flight), the decision should be made individually based on the X-ray analysis results. Moreover, in special cases where applicants have no access to X-ray scanning services in their countries, they should be supported (consulted on their behalf) to undergo X-ray examinations in Japan after they arrive. This support should not be offered to applicants who cannot undergo X-ray examinations due to personal reasons.

2) X-ray analysis procedures and handling of the analysis results

(i) Procedure for X-ray images to be taken outside of Japan and analyzed in Japan (Medical Examination Flowchart 1-A)

The training administrator brings applicants' X-ray films to a medical institution in Japan for consultation and X-ray analysis on their behalf. A doctor at the medical institution in Japan is asked to fill in Appendix 2 based on the analysis results. The training administrator obtains approval from the IPC Director.

(ii) Procedure for X-ray images to be taken outside of Japan and analyzed at NCGM (Medical Examination Flowchart 1-B)

The training administrator requests an outpatient receptionist to issue patient ID cards and capture applicants' X-ray images. After capturing the X-ray images, a radiologist (the chief of the diagnostic radiology division, a doctor-in-charge of the nuclear medicine division, or the director of the department) is requested to analyze the X-ray images, and the domestic training manager fills in Appendix 2 based on the analysis

results. The completed Appendix 2 is submitted by the training administrator to the IPC Director to obtain approval.

- (iii) Procedure for X-ray images to be taken at a medical institution in Japan (For applicants with no access to X-ray scanning services in their countries)
 - If X-ray images are taken at a **medical institution** in Japan, the results (e.g., analytical reports) should be submitted with Appendix 2 to the IPC Director to obtain approval.
- 3) Procedure to follow when abnormal shadow suspected of TB is observed in chest X-rays
 - (i) The domestic training manager informs the applicants (and sends a CC to the local training managers in their countries)

The applicants are informed of the following three points: 1. The applicants need to submit additional materials to participate in training; 2. Without the additional materials, the applicants cannot enter Japan; and 3. Based on the additional materials, the training institution will decide whether to accept the applicants.

In addition, the applicants are asked whether the same abnormality was detected over six months ago or within the last six months (or for the first time).

- (ii) The doctors in charge in their countries fill in the Medical Certification for TB

 Control (Appendix 4) based on the additional materials and examination results

 The applicants must submit the following materials with comments as well as an X-ray film.
 - If the same abnormality was detected over six months ago
 - A) A chest X-ray film taken before (over six months ago)* (Dated)
 - B) TB examinations (3 sputum smear tests + 3-week culture test or PCR test) (Dated)
 - C) Other examinations (and CT films, if available): Add diagnostic evidence for the diagnosis of diseases other than TB)
 - D) TB treatment history, if available (resume, time period, and treatment year)
 - * If the X-ray film attached to the application form was taken over six months ago, submit an X-ray film taken at the time of request (at present).
 - If the abnormality was detected for the first time
 - * In principle, it is advisable to give priority to detailed examinations and therefore postpone the visit to Japan.

- A) If more than one month has passed since the last X-ray was taken, take another X-ray and submit it
- B) TB examinations (3 smear tests + 3-week culture test or PCR test) (Dated)
- C) IGRA or PPD (tuberculin reaction)
- D) If possible, take a CT scan and submit it
- E) TB treatment history, if available (resume, time period, and treatment year)

(iii) The IPC Director consults a TB specialist (a respiratory medicine doctor or infectious disease medicine doctor, if available) on the following options and makes a final decision within two days from the receipt of the additional materials

- □ Confirm eligibility for training in Japan (For applicants diagnosed as obsolete TB or other diseases)
- □ Determine eligibility for training in Japan based on additional examination results (For applicants suspected of TB)
- □ Cancel eligibility for training in Japan (For applicants highly and undeniably suspected of TB)

A notice of this decision should be sent to the training management team and signed in the footer of the page by the person in charge.

2. Submission of measles, mumps, rubella, and varicella antibody test results or 2-dose immunization certificates

1) If the participant can submit vaccination certificates (administered in two doses at intervals of four weeks) (Medical Examination Flowchart 2-A)

The participant should submit one of the following documents as proof of vaccinations: Form A2; vaccination certificates issued by a medical institution in the participant's country; or vaccination records, such as a maternal and child health handbook. Neither the participant's recollection of vaccinations nor medical history can be considered as an alternative. Any obvious error (e.g., stating that the participant has been administered vaccines not available in their country) should be questioned with the participant.

2) If the participant can access measles, mumps, rubella, and varicella antibody tests in their country (Medical Examination Flowcharts 2-A and 2-B)

If the participant can access antibody tests in their country, the participant must undergo the tests in their country.

Table 1. Thresholds for antibody positivity

	POSITIVE	WEAK POSITIVE	
Measles	EIA method: 16 or higher (Japan); 0.72 IU/mL or higher (international threshold) PA method: 1:256 or higher NT method: 1:8 or higher	Between equivocal and "POSITIVE" threshold	
Mumps	EIA method: 4 or higher (Japan); Positive (overseas)	Between equivocal and "POSITIVE" threshold	
Rubella	EIA method: 8 or higher (Japan); 18.4 IU/mL or higher (international threshold) HI method: 32 times or higher	Between equivocal and "POSITIVE" threshold	
Varicella	EIA method: 4 or higher; IAHA method: 1:4 or higher (Japan); Positive (overseas)	Between equivocal and "POSITIVE" threshold	

(i) If the participant has tested **positive**

Participants who have tested positive above the thresholds using the methods specified in Table 1 are allowed to attend clinical training on the condition that they submit Appendix 2 with the test results.

(ii) If the participant has tested <u>weak positive</u> (If the participant requires **one dose** of vaccines as shown in the Medical Examination Flowchart 2-B)

The thresholds set out in this Manual are higher than the commonly used thresholds for antibody positivity (established by Japanese Society for Infection Prevention and Control). Therefore, some participants who have tested positive may have antibody levels below the thresholds set out in this Manual.

These participants should be considered weak positive and <u>allowed to attend clinical</u> <u>training on the condition that they receive one dose of vaccines</u>.

(iii) If the participant has tested <u>negative</u> (If the participant requires **two doses** of vaccines as shown in the Medical Examination Flowchart 2-B)

Participants with negative antibody results are allowed to attend clinical training on the condition that they receive two doses of vaccines. Participants who have tested negative using other methods than specified are also allowed to attend clinical training

on the condition that they receive two doses of vaccines.

Even though all the required vaccines can be co-administered, the second dose should be administered four weeks after the first dose (at an interval of 27 days) because they are live vaccines.

- (iv) If the participant has tested ± (equivocal) positive or positive without reference to antibody levels, using other test methods than specified (If the participant requires one dose of vaccines as shown in the Medical Examination Flowchart 2-B)

 Because it cannot be determined whether their antibody levels exceed the thresholds, the participant should be considered weak positive and allowed to attend clinical training on the condition that they receive one dose of vaccines.
- 3) If the participant cannot meet the requirements specified in 1) and 2) and needs to receive two doses of measles, mumps, rubella, and varicella vaccines (If the participant requires two doses of vaccines as shown in the Medical Examination Flowchart 2-B)
 - The participant needs to receive two doses at least four weeks apart (at a minimum interval of 27 days) and submit proof of these vaccinations no later than a week before the training session
 - The participant must submit one of the following as proof of vaccinations: Form A2; vaccination certificates issued by a medical institution in the participant's country; or a maternal and child health handbook (the participant's recollection of vaccinations cannot be considered as an alternative)
 - Vaccination cards without lot numbers are acceptable though it is desirable that lot numbers are stated
 - Because they are live vaccines, the schedule should be made taking into account that the first and second doses must be administered at intervals of at least four weeks (at a minimum interval of 27 days)
 - Participants who cannot receive live vaccines due to pregnancy, immunodeficiencies, or allergies should be consulted and supported individually
 - After the second dose, the vaccination certificate should be submitted to the domestic training manager.
- 4) If the participant can only receive one dose (cannot receive two doses) in their country (If the participant requires two doses of vaccines: (iv) If the participant can only receive one dose in their country as shown in the Medical Examination Flowchart 2-B)

- Participants who have received the first dose in their countries at least 28 days before the training session may receive the second dose at a medical institution in Japan after they arrive. However, they cannot attend clinical training for six days after the second dose.
- In this case, the domestic training manager should consult a medical institution in Japan (on behalf of the participant) in advance (before their arrival in Japan), discuss the past vaccination history and the vaccination schedule after arrival in Japan, and make an appointment for vaccination.
- After the second dose, the vaccination certificate should be submitted to the domestic training manager.
- 5) If the participant has no access to vaccines in their country (If the participant requires one dose of vaccines: (ii) If the participant cannot get vaccinated in their country as shown in the Medical Examination Flowchart 2-B)

The local training managers should make all possible efforts to help participants get vaccinated (e.g., finding vaccination sites including clinics for foreigners). Participants who cannot receive any doses in their countries are taken to a medical institution in Japan after they arrive to undergo antibody tests to determine whether they can attend clinical training. So far, it has been found that people in some countries can only access MMR vaccine and cannot access varicella vaccine. Although all participants should acquire immunity to varicella as well as measles, mumps, and rubella, some participants who cannot access varicella vaccine in their countries, no matter how much they try, may follow the following steps as exceptions. After the second dose, the vaccination certificate should be submitted to the domestic training manager.

If the participant can be vaccinated against measles, mumps, and rubella but not against varicella

The participant should be given a varicella antibody test and vaccination at the same time after they arrive in Japan. The participant should follow one of the following steps, depending on the test results:

- > Tested above the threshold......Allowed to attend clinical training after the test results are confirmed
- ➤ Tested weak positive ······ Allowed to attend clinical training seven days after the vaccination
- > Tested negative Allowed to attend clinical training seven days after the vaccination (Enhanced health monitoring)

The participant is **subject to close monitoring to check for fever and rashes during the training session**.

- International participants attending clinical training should, in principle, meet the requirements for varicella antibody testing and vaccination as set forth in the international training manual (This is strongly recommended if the participant is in their 20s or 30s).
- Participants with extremely limited access to vaccination and/or antibody testing may exceptionally be given varicella vaccine immediately after they arrive in Japan and allowed to attend clinical training seven days after the vaccination.

3. COVID-19 vaccination status and contact tracing information

Participants must fill in and submit Form A3 (COVID-19 risk assessment) to the domestic training manager.

- (i) Comply with the hospital's infection control and prevention requirements (wear a mask in the hospital)
- (ii) Participants who have marked any of the symptoms should consult an infectious disease physician and undergo an examination.

VI.

Documents to Be Submitted

Depending on whether the participant attends clinical training during their session, some of the following documents should be completed based on the above results and submitted to the IPC Director.

< Documents to be submitted >

Table 2. Medical certificates and test results to be submitted depending on the training content (O refers to documents to be submitted)

Document	Document prepared by	Deadline	* Course without clinical training			* Course including clinical training
			Less than 1 day	2-29 days	30 days or more	Irrelevant of the number of days
Medical History (Form A1) (or equivalent documents)	Participant	Before arrival in Japan	X	О	О	O
 (i) Chest X-ray certificate (in the form issued by Japanese medical institutions) or DICOM or Chest X-ray film (ii) Test Report / Clinical Training Attendance Permit (Appendix 2) 	(i) Physician (ii) Domestic training manager / Japanese medical institution	Before arrival in Japan	X	X	0	О
(iii) Test Certificate / Permit (Appendix 3)	IPC Director	After arrival in Japan	X	X	О	О
(iv) COVID-19 Risk Assessment (A3)	Participant	After arrival in Japan	О	О	О	О

1. Medical History (Form A1 or Appendix 1)

Participants should fill in the Medical History form, either in English (Form A1) or Japanese (Appendix 1), and submit it to the domestic training manager through the local training managers in their countries before arrival in Japan (Equivalent medical history forms can be used as an alternative).

2. Test Report / Clinical Training Attendance Permit (Appendix 2)

The Test Report form should be completed and accompanied by a chest X-ray analysis report and vaccination certificates or antibody test results. After confirming the results, the IPC Director determines whether the participant can attend the training session and signs the Clinical Training Attendance Permit.

3. Test Certificate / Permit (Appendix 3)

This form is used for participants who undergo medical examinations at NCGM. A travel clinic doctor should fill in Appendix 3 and hand it over to the domestic training manager or training administrator. It is noted that the certificate fees are charged on the date of issuance.

4. COVID-19 Risk Assessment (A3)

The COVID-19 Risk Assessment form should be completed by each participant and confirmed by the domestic training manger before the training session. If any of the symptoms are marked, immediately should consult an infectious disease physician and undergo an examination. If the participant has no symptoms or close contact with someone infected with COVID-19, the form does not need to be signed.