

Evaluation Summary

I. Outline of the Project		
Country : Vietnam	Project title : The project for capacity development for National Institute of Hygiene and Epidemiology to control emerging and re-emerging infectious diseases	
Issue/Sector : Health	Cooperation scheme : Technical Cooperation Project	
Division in charge : Infectious Disease Control Division, Human Development Department	Total cost : 283,000 (thousand) yen	
Period of Cooperation	(R/D): 20/03/06~19/03/09	Partner Country's Implementing Organization : National Institute of Hygiene and Epidemiology (NIHE)
	(Extension): (F/U) :	Supporting Organization in Japan : National Institute of Infectious Diseases, Japan (NIID)
Related Cooperation Project :	Grant Aid "The project for improvement of safety laboratory for National Institute of Hygiene and Epidemiology" (E/N signed in September, 2006)	
<p>1. Background of the Project</p> <p>In Vietnam, emerging diseases has occurred such as Severe Acute Respiratory Syndrome (SARS) in 2003 and Avian Influenza since 2004. Especially regarding Avian Influenza, there have been more than 50 deaths and concern for spread of infections is growing. In order to maintain health and safety of people in Vietnam and in neighboring countries, measures to control the disease were urgently needed to be taken.</p> <p>Under these circumstances Japan International Cooperation Agency (JICA) conducted a project formulation survey for the purpose of analyzing the capability of testing and diagnosis of National Institute of Hygiene and Epidemiology (NIHE) and of elaborating a future possible cooperation. As a result of the survey, an official request was submitted by the Vietnamese government in 2005 for the grant aid for Biosafety Level (BSL) 3 laboratories in the NIHE High-tech Center (HTC), which was approved in 2006. The construction of the laboratories was completed in January 2008.</p> <p>Together with the request for the grant aid, a request was submitted for the Technical Cooperation Project on capacity development of NIHE to safely manage and operate those BSL-3 laboratories and to examine highly hazardous transmissible pathogens. Based on the request, the Project has started on March 20, 2006 for three years.</p>		
<p>2. Project Overview</p> <p>The project aims at strengthening capacity to examine highly hazardous transmissible pathogens for controlling emerging and re-emerging diseases. Especially it focuses on establishment of biosafety regulation and system in NIHE, and on capacity development of NIHE to operate and maintain the BSL-3 laboratories, which are the first to be introduced in Vietnam, and to conduct laboratory testing.</p>		

(1) Overall Goal: BSL-3 Laboratories are fully functioned and maintained in NIHE.

(2) Project Purpose: NIHE has capacity to examine highly hazardous transmissible pathogens properly in the BSL-3 laboratories that meets international standard.

(3) Outputs

Output 1: Biosafety regulation/system in NIHE which includes management and operation of BSL-3 laboratories is established.

Output 2: The capacity of NIHE to operate and maintain BSL-3 laboratories is established.

Output 3: The capacity of NIHE to conduct laboratory testing of highly hazardous transmissible pathogens in BSL-3 laboratories is established.

(4) Inputs

Japanese side : (Total 283,000 (thousand) Yen)

Long-term Expert	<u>4</u>	Equipment	55,030 (thousand)Yen
Short-term Expert	<u>34</u>	Local cost	20,500 (thousand) Yen
Trainees received	<u>12</u>		

Vietnamese Side :

Counterpart Allocation

Land and Facilities: Provision of two office rooms and equipment to the Project

Local Cost: 1,285,900,000VND (USD78,542)

II. Evaluation Team

Members of Evaluation Team

Name	Job Title	Organization and Position
Ms. Naoko UEDA	Team Leader	Director, Infectious Disease Control Division, Human Development Department, JICA
Dr. Masato TASHIRO	Laboratory Testing	Director, Department of Virology III (Viral Diseases & Vaccine Control), National Institute of Infectious Diseases (NIID)
Dr. Kazuyoshi SUGIYAMA	Biosafety	Director, Division of Biosafety Control and Research, NIID
Ms. Tomomi IBI	Cooperation Planning	Staff, Infectious Disease Control Division, Human Development Department, JICA
Ms. Makiko KINOSHITA	Evaluation Analysis	Global Link Management Inc.
Period of Evaluation	9/ 11/ 2008~ 26/ 11/ 2008	
Type of Evaluation : Terminal		

III. Results of Evaluation

1. Project Performance

1-1 Activities and Outputs

(1) Output 1”*Biosafety regulation/system in NIHE which includes management and operation of BSL-3 laboratories is established.*”

The Biosafety (BS) department was newly established in NIHE and the 1st and 2nd versions of the NIHE’s Biosafety Regulation were developed. Biosafety Committee was established and its meeting has been held regularly in order to promote activities.

In addition, training manual was developed and training on Basic Biosafety and Use of BSL-3 Laboratory has been implemented by BS Department in collaboration with other user departments. The training was held four times and a total of 100 staff members attended. Laboratory Operation Manual and Standard Operational Procedure (SOP) were also developed, the basis of the Biosafety system is firmly established for safety operation and maintenance of the BSL-3 laboratories.

(2) Output 2 “*The capacity of NIHE to operate and maintain BSL-3 laboratories is established.*”

With regard to activities under Output 2, it is confirmed that some planned activities have been done towards achievement of Output 2. Capacity of both BS and Materials and Medical Equipment (MME) Departments was reinforced by recruiting new engineers and training them. It is observed that the training in Japan and local trainings are useful to directly apply to their day-to-day work. Moreover, collaboration and cooperation with two departments in the area of operation and maintenance work were facilitated and strengthened. With such effort, capacity of NIHE to carry out routine work in operation and maintenance for the BSL-3 laboratories has been steadily improved. At the same time, ability to ensure safety operation of the BSL-3 laboratories is currently being developed.

To intend to ensure safety operation and achieve Output 2 confidently, the following can be considered: Emergency response and evacuation training, Regular Inspection, Operation and Maintenance Data record and analysis, Collaboration work and Additional personnel to BS Department.

(3) Output 3 “*The capacity of NIHE to conduct laboratory testing of highly hazardous transmissible pathogens in BSL-3 laboratories is established.*”

The training manual was developed and training on Basic Biosafety and Use of BSL-3 Laboratory was conducted. In addition, SOP on Laboratory Techniques for Influenza was also developed. As of October 2008, 100 staff participated in the training including 68 NIHE researchers. They are now eligible to use the BSL-3 laboratories. Currently 18 researchers use the BSL-3 laboratories in their research activities.

However, some activities remain in progress at the time of the terminal evaluation. Especially laboratory practice under supervision for laboratory testing for diagnosis is still being carried out at the moment (Activity 3-4), and management system for registration of highly pathogenic agents is not established (Activity 3-6). As for Activity 3-1, training

manual was developed for highly transmissible pathogens in general, but it is not focused on other specific pathogens including rabies, anthrax, tuberculosis, rickettsial diseases and others. For that reason, implementing activities under Output 3 is still on the way.

1-2 Project Purpose

“NIHE has capacity to examine highly hazardous transmissible pathogens properly in the BSL-3 laboratory that meets international standard.”

Achievement of the Project Purpose is not optimal at the time of the terminal evaluation. It is because some activities remain uncompleted to achieve the Project Purpose.

In other words, it can be concluded that the basis of the Biosafety system is firmly established through the project’s activities having been done. At the same time, in order to meet the international standard, uncompleted activities should be carried out and strengthened, which can lead to ensure 1) safety operation and maintenance of the BSL-3 laboratories, 2) quality and safety test performance, and 3) management of registration of highly hazardous transmissible pathogens.

1-3 Implementation Process

Some promoting factors throughout implementation process are 1) a strong commitment by the Vietnamese side, 2) partnership between NIHE and Japanese experts, 3) contribution of the mobile BSL-3 laboratory, 4) effective project management and monitoring and 5) enhanced coordination capacity and leadership of the BS Department. On the other hand, hindering factors which set back activities are that 1)it took more time than anticipated to transfer, installation, adjustment and operation of the mobile BSL-3 laboratory, and that 2) more time was needed to begin full operation of the High-tech Center (HTC) BSL-3 laboratories due to some factors such as the delay in completing a part of HTC construction by the Vietnamese side.

2. Summary of Evaluation Results

(1) Relevance

The Project is highly relevant to the emerging needs and the national policies in Vietnam. It is also highly relevant to the Official Development Assistance (ODA) policies of Japan.

In the policies and plans developed by the government of Vietnam such as “Comprehensive Development Design for the Health System in Vietnam to 2010 and Vision by 2020” ,“Strategy for socio-economic development 2001-2010” and “Five-year socio-economic development plan 2006-2010”states that responding to emerging and re-emerging infectious diseases is an urgent task.

According to the Japanese Government’s 2004 Country Assistance Plan for Vietnam actions towards emerging and re-emerging infectious diseases is an urgent matter in the health sector. Furthermore, strengthening relationship with NIHE is a key to control of the epidemic. JICA’s recent Country Assistance Strategy also has the same approach, stating importance of close collaboration with NIHE as well as their capacity building.

Vietnam is the second most affected country by highly pathogenic avian influenza in the

world after Indonesia. As of November 2008, its cumulative number of confirmed human cases of Avian Influenza A/H5N1 reached to 106 including 52 deaths. Thus, this current situation remains to be a threat in the whole region.

Close collaboration with NIID in Japan is found very appropriate as NIID acquires high level of knowledge and experience to transfer to NIHE.

(2) Effectiveness

The Project is expected to be very effective when all activities are implemented.

First of all, the Project has successfully built the foundation of Biosafety activities, including establishment of BS Department, development of the NIHE Biosafety Regulation and SOPs, and training of staff to operate and maintain the BSL-3 laboratories as well as training of researchers to use the laboratories.

On the other hand, some activities were identified and suggested to carry out in the implementation process. These specific activities are a) more advanced training to operate and maintain the HTC BSL-3 laboratories, b) training on emergency response, c) data analysis for operation and maintenance, d) development of training manuals with focus on each pathogen, and so on. They are in fact within the existing PDM framework and are indispensable to meet the international standard and to achieve the Project Purpose.

(3) Efficiency

Overall, efficiency of the Project was good with quality, quantity and timing of the provision of most inputs being adequate and thus utilized for the current achievement level of the Outputs.

The input by the Japanese side such as equipment, experts and counterpart training in Japan has been appropriate in quality, quantity and timing.

As for the input from the Vietnamese side, NIHE is responsible for installation fee for the Mobile BSL-3 laboratory and running cost at HTC including equipment for regular inspection. NIHE also established BS Department and allocated staff to new posts. Although two trained counterparts are currently on leave, NIHE made sure to replace their absence by recruiting additional staff promptly.

There are a few factors that limited efficiency in achieving outputs includes the following. Firstly, the Project originally expected staff, who was trained at the mobile BSL-3 laboratory, to operate the HTC BSL-3 laboratories without major technical difficulties. However, it required more time than anticipated to train staff further on operation and maintenance specifically for the HTC BSL-3 laboratories, because operating methods and facility size were found quite different from the mobile BSL-3 laboratory which staff was trained on first. Secondly, to ensure safety operation of the BSL-3 laboratories, it was found out that additional activities (but within the PDM framework) were necessary. They were originally not foreseen, but crucial ones to achieve the Outputs.

(4) Impact

The evaluation team observes that increased capacity to examine highly hazardous

transmissible pathogens properly at the BSL-3 laboratories will be contributed to the attainment of the Overall Goal “BSL-3 laboratories are fully functioned and maintained in NIHE” if all activities including unfinished ones are also implemented. The Vietnamese side is committed to provide financial and personnel support in order to maintain the BSL-3 laboratories, which means Important Assumption to achieve the Overall Goal is met.

Furthermore, the following positive impacts relating to Project’s interventions are observed.

- 1) Operating BSL-3 laboratories can offer researchers more access to advanced researches dealing with the BSL-3 pathogens which would benefit the country as a whole.
- 2) NIHE developed the Biosafety system to operate the first BSL-3 laboratories for the first time in Vietnam, which became a role model for others. The establishment of the Biosafety system contributed a great deal to the national policy making.
- 3) NIHE’s diagnostic results of H5N1 HPAI cases were reviewed by WHO, and NIHE was accredited that diagnostic results can be accepted by WHO without double checking by a WHO H5 Reference Laboratory. This means NIHE is established as a national Reference Laboratory, and also is expected to play a role of a Regional Reference Laboratory in the future.
- 4) The National Infectious Disease Control Law, which was approved in November 2007, includes a new chapter on Biosafety. Followed by enforcement of the Law, NIHE is asked to be a resource for developing the first national Biosafety Regulation.
- 5) As the Biosafety system with BSL-3 laboratory was newly introduced to Vietnam, media and newspapers in Vietnam and Japan highlighted activities at NIHE with JICA. It resulted in a big effect of publicity.
- 6) NIHE staff now has capacities to conduct training course on Biosafety for laboratory staff outside NIHE. A seminar on emerging and re-emerging infectious disease control was conducted at NIHE for participants from the neighboring countries such as Cambodia and Laos.

(5) Sustainability

In view of the current national policies, organizational aspects, financial aspects, and technical aspects, it is observed that the sustainability of the effects of the Project after its completion would be high.

As policy papers state, the government of Vietnam sees responding to emerging and re-emerging infectious diseases as an urgent task. Thus, the government will be supportive to NIHE’s duty and expecting its successful outcomes. NIHE itself shows a strong responsibility and commitment to operate and maintain the BSL-3 laboratories by establishing BS Department and ensuring to allocate motivated and qualified personnel to the Department in a prompt manner. NIHE also has a willingness to attain a position to train other institutions both domestically and regionally on Biosafety in the near future.

Financial aspect of sustainability is also promising as NIHE is already committed to assure budget allocation for regular inspection, operation and maintenance fee, and human resource. Equally, NIHE recognizes an urgent need to formulate energy-saving measures as financial burden to maintain the laboratories can be predicted in the future.

With regard to technical capacity, trained NIHE staff members have increased their capacities in carrying out routine work in operation and maintenance of the BSL-3 laboratories.

With commitment from NIHE, it is hopeful that trained staff will continue to play important roles to operate and maintain the BSL-3 laboratories in the long run.

3. Conclusion

The Project has successfully produced visible outcomes. These outcomes include establishment of the Biosafety Department, and the Biosafety Regulation and the BSL-3 SOP, and SOPs for laboratory technique on Influenza, which are aligned with the WHO Biosafety Manual. The training on Biosafety and BSL-3 laboratory has been conducted. As a result, engineer staff members carry out routine work in operation and maintenance for the BSL-3 laboratories according to SOPs. And also, trained researchers began conducting laboratory test at the BSL-3 laboratories. These activities built the basic system of Biosafety management.

However, achievement of the Project Purpose is not optimal at the time of the terminal evaluation. It is because some activities remain to be completed to achieve the Project Purpose. In order to meet the international standard, those uncompleted activities should be carried out and strengthened, which can lead to ensure 1) safety operation and maintenance of the BSL-3 laboratories, 2) quality and safety test performance, and 3) management of registration of highly hazardous transmissible pathogens.

There are some unpredictable factors that delayed the progress of the activities. Even though the Project continues to make every effort to pursue attainment of the Project Purpose, it reveals to be inevitable to complete all necessary activities within the current project period.

Therefore, it is highly recommended to extend the project's cooperation term for one and a half year so as to achieve the Project Purpose by implementing the remaining activities.

4. Recommendations

Biosafety management

- (1) The level of the capacity and leadership of the Biosafety Department needs to be enhanced further to have a better collaboration with other user departments.
- (2) To make Biosafety activities more practically applied among all users, Information, Education and Communication (IEC) materials should be developed and utilized.

Operation and Maintenance

- (3) NIHE's ability to ensure safety operation and maintenance of the BSL-3 laboratories should be further improved especially in terms of emergency response and evacuation training, regular inspections, and operation and maintenance data analysis.
- (4) It should be considered to recruit and train more full-time engineers at the Biosafety Department to exclusively operate and maintain BSL-3 laboratories for 24-hour-operation.

Laboratory activities

- (5) Training manuals and SOPs with focus on specific pathogens including rabies, anthrax, tuberculosis, rickettsial diseases and others, needs to be developed (Activity 3-1).

(6) Laboratory practice under supervision for testing and diagnosis by internal and external experts should be improved (Activity 3-4).

(7) Management system including SOPs for registration of highly pathogenic agents should be strengthened (Activity 3-6).

Extension of the Project period

(8) Based on the result of the evaluation, both sides confirmed that it is strongly recommended to extend the project's cooperation term for one and a half year. The necessities of the extension are as follows:

a) In order to make the NIHE's capacity meet the international standard, uncompleted activities should be carried out and strengthened, which can lead to ensure safety management of the BSL-3 laboratories.

b) Some activities to carry out were identified and suggested in the implementation process. These specific activities are the following: a) more advanced training to operate and maintain the HTC BSL-3 laboratories, b) training on emergency response, c) data analysis for operation and maintenance, d) development of training manuals with focus on each pathogen, and so on. They are in fact within the existing PDM framework and are indispensable to meet the international standard and to achieve the Project Purpose.

(9) Some unpredictable factors that delayed the progress of the activities are as follows:

a) It took more time to transfer, install, adjust and operate the mobile BSL-3 laboratory than anticipated due to unpredictable reasons both in Japan and Vietnam.

b) The HTC BSL-3 laboratories took also several months from completion of the facility to its full operation using pathogens. Once the operation begun, there were some problems and failure reports of facilities and equipment, a few of which are in the process of solving.

c) The engineer staff, who was trained at the mobile BSL-3 laboratory, required more time than anticipated to be trained further on operation and maintenance specifically for the HTC BSL-3 laboratories.

d) Due to the factors mentioned in 1) to 3) above, technical assistance and on-the-job-training using the BSL-3 laboratories had been limited during the delayed period.

e) NIHE staff would not experience annual inspection during the current project's period, because the full operation of the HTC BSL-3 laboratories was delayed to June 2008, even though the technical assistance is indispensable to conduct such a large scale inspection. Therefore practical experience of annual inspections with technical assistance is vital for NIHE staff.

(10) Activities to be completed during the extended period

During the extended project period more emphasis should be put on accomplishment of the activities under Output 2 and 3 within the framework of the current PDM as follows:

a) Output 2

Activity 2-2

- More advanced training to operate and maintain the HTC BSL-3 laboratories
- Training on emergency response

Activity 2-3

- Regular inspections
- Data analysis for operation and maintenance

b) Output 3

Activity 3-1

- Adding a section of sharing a laboratory with different pathogens to existing SOPs and training manuals
- Development of SOPs and training manual with focus on each pathogenic agent to test at the BSL-3 laboratories

Activity 3-2

- Training for researchers based on the manual above

Activity 3-4

- Upgrading quality of laboratory practice under supervision for testing and diagnosis by internal and external experts for avian influenza

Activity 3-6

- Strengthening management system for registering highly pathogenic agents

(11) Recommended inputs during the extended period

- Japanese side

Long and short-term experts, training in Japan, provision of equipment and local cost

- Vietnamese side

Counterpart officers, equipment and materials and local cost

For the future

Collaboration between NIHE and Japan is strongly encouraged in the future as well through optimizing best practices of the Project.

5. Lessons Learned

In the field of advanced technique such as BSL-3 laboratory, combination of technical cooperation projects with the grant aid was found to be effective. It is highly recommended for future programs.

It needs to ensure sufficient time and experience for counterparts to be able to feel confident in operating highly sophisticated facilities like BSL-3 laboratory in the context of Biosafety especially when they are inexperienced.

Cooperation in the field of laboratory requires measures of biosafety and biosecurity management which meet international standard.