

2.2.2 Achievement of activities under 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 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

Procedure manuals of emergency case are available. But at present, staff members seem inexperienced to quickly and adequately response to such situation. But there is a concern to take emergency response more seriously, which is not just for equipment at BSL-3 laboratories but also for people inside. Unless the emergency management is set up, safety operation and maintenance of the BSL-3 laboratories will not be accomplished. Hence, emergency training including evacuation can be considered.

Regular Inspection

As for regular inspection, the system is currently being developed, thus NIHE staff is learning to undertake regular inspection. But with up-coming major inspections such as annual inspection, it is necessary to provide technical support during such a large inspection.

Operation and Maintenance Data record and analysis

One area to improve is better supervision of maintenance record of BSL-3 laboratory equipment. Usually equipment check is done and maintenance records are written by staff of BS and MME Departments. However, such data is not further analyzed by BS Department at this moment. In order to ensure operation and maintenance in a safety manner, it is important to keep records and analyze the situation especially when some problems occur, which was also acknowledged during interviews. To response to the situation, it is necessary to train staff on data utilization and analysis. With evidence-based operation, it can be aimed for staff to develop a plan of operation and maintenance in the future.

Collaboration work and Additional personnel

The mobile and new HTC BSL-3 laboratories are now in operation for 24 hours a day. All equipments are supposedly monitored and maintained by engineers of BS Department day and night. Due to staff shortage of BS Department, MME Department engineers are also assigned to support operation and maintenance of the laboratories on the night and weekend shift. Those support engineers are conversant with their specific

expertise such as mechanical equipment and electricity, however in order to be involved in the operation and maintenance work on behalf of BS Department, they need to be trained to acquire broader knowledge and skills of the work, and also to handle emergency case. It is indeed that such collaboration work with different departments is ideal to response to the current situation for now, however recruiting and training more full-time engineers at BS Department to exclusively operate and maintain BSL-3 laboratories should be considered in the future.

| Activities | Achievement |
|---|---|
| 2-1. Establish Operation and Maintenance Division within BS Department. | <p>Operation and Maintenance Division was newly established in BS Department. Two engineers were assigned in November 2006, and one engineer was assigned in May 2008 to the Operation and Maintenance Division at BS Department.</p> <p>(ANNEX) 2. Project Activity List</p> |
| 2-2. Conduct training of operation and maintenance of BSL-3 laboratories for maintenance/laboratory staff | <p>One head from the MME Department, and three engineer staff members from the Operation and Maintenance Division of BS Department participated in the counterpart training on Biosafety (BSL-3 laboratory maintenance) in Japan.</p> <p>Two engineer staff from the MME Department took the counterpart training on Laboratory Maintenance. Those trainings included specifically topics of how to operate and maintain new equipments at HTC such as boiler, chiller, automatic control unit, and air-handling unit.</p> <p>The local training for operation of the BSL-3 laboratories was conducted by the Japanese experts in a total of 11 times as of October 2008. The breakdowns are the following-</p> <ul style="list-style-type: none"> • In 2006, 3 trainings for 2 engineers from BS Department • In 2007, 7 trainings for 2 engineers from BS Department • In 2008, 3 trainings for 9 engineers from BS Department and the MME Department <p>(ANNEX) 7. List of Counterpart Training in Japan 8. List of Local Training</p> |

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|---|--|
| <p>2-3. Establish regular maintenance system for BSL-3 laboratories</p> | <p>Daily checkup of necessary equipment is done, and maintenance records are being written by staff of BS and MME Departments. The records are usually entered to computer by engineers from BS Department; however further analysis using the record data has not been done yet.</p> <p>Plan of periodical inspection was developed by the MME Department in collaboration with BS Department. Based on the inspection plan, equipments including boiler, chiller, air-conditioning and filter will be inspected and cleaned.</p> <p>Basic procedure for emergency response to operation and maintenance of equipment is written in SOP although engineers do not have enough experience yet in such situation.</p> <p>Register book for management of equipment was developed, which describes picture of each equipment, model number, specs, year, manufacturer and also records of failure/breakdown.</p> <p>Three store rooms were cleaned and classified according to store condition of commodity, whether specific condition to store need to be considered or not. Inventory management list including item, number, and place for each spare part was developed.</p> <p>Local reliable companies, which provide spare parts and offer repair and maintenance service, are identified to establish logistic system for the BSL-3 laboratories.</p> <p>24 hour- operation, the mobile and HTC BSL-3 laboratories are operated and maintained by BS Department for 24 hours a day. For out-of-hours (nights and weekends), its operation and management is done in collaboration with the MME Department.</p> <p>Staff allocation, two additional engineers joined the MME Department to strengthen the Department in October 2008, thus a total of eight technical staff including engineers is assigned to the Technical Division. The new members received the basic and practical training by the Japanese experts.</p> <p>Collaboration work to strengthen collaboration work with BS Department and MME Department, weekly joint meetings are held. Agenda includes progress of the week, plan of the coming week, problems arising, and solutions to take. The meeting is usually chaired by engineer staff from the MME Department. The Japanese experts join each meeting as observers. Both heads of departments also join once a month. From June to October 2008, 15 meetings were held.</p> <p>Maintenance equipment for BSL-3 laboratory was provided by the Project in 2007, and it is currently planned to do the same in 2008. A total amount cost of the maintenance equipment provided is US\$ 65,900 worth. Moreover, additional fund from the Project Management Cost was allocated for the BSL-3 laboratory equipment for training materials. These equipments were necessary mainly for on-the-job training purpose as the Japanese experts needed to practically demonstrate how to maintain the BSL-3 laboratories in their technical assistance. Most maintenance equipment other than on-the-job training purpose was provided by the Vietnamese side.</p> |
| | <p>(ANNEX) 5. List of Equipment provided by JICA 10. Local Agent List 15. Content of the meeting between MME Dept and Biosafety Dept</p> |

| | |
|--|---|
| <p>2-4. Establish logistics system for spare parts and repair works for BSL-3 laboratories</p> | <p>A list of all spare parts and consumable supplies and materials for the BSL-3 laboratories was developed by BS and MME Departments.</p> <p>Three store rooms were cleaned and classified according to store condition of commodity, if require specific condition to store or not. Inventory management list including item, number, and place for each spare part was developed.</p> <p>Local reliable companies, which provide spare parts and offer repair and maintenance service, are identified to establish logistic system for BSL-3 laboratory.</p> <p>When problems are identified, NIHE staff, usually BS and MME Departments contact companies for spare and/or repair.</p> <p>(ANNEX) 10. Local Agent List</p> |
|--|---|

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

| Verifiable Indicators | Achievement |
|--|--|
| <p>Establishment of operation and maintenance division, function of the division and job description of the staff are authorized by NIHE</p> | <p>Operation and Maintenance Division was established in BS Department. Three engineers were assigned to the Division at BS Department and trained to operate and maintain the BSL-3 laboratories by the Japanese experts. Their job descriptions were officially authorized by NIHE.</p> <p>The Division works in close collaboration with MME Department.</p> |

2.2.3 Achievement of activities under Output 3

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

As for activities under Output 3, the training manual was developed and training on Basic Biosafety and Use of BSL-3 Laboratory was conducted. In addition, Standard Operational Procedure 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.

Ways forward to achieve Output 3 would be as follows-

Activity 3-1

- A section of sharing a laboratory with different pathogens will be added to existing SOPs and training manuals.
- SOPs and training manual with focus on each pathogenic agent to test at the BSL-3 laboratories will be developed. Those include Good Microbiological Techniques (GMT) based on risk assessment.

Activity 3-2

- Based on the manual above, training will be conducted for researchers.

Activity 3-3

- Quality of the training including teaching methods and materials to will be reviewed and improved.

Activity 3-4

- Quality of laboratory practice will be upgraded through implementing SOP on Laboratory Techniques for Influenza

Activity 3-6

- Management system for registering highly pathogenic agents will be established.

| Activities | Achievement |
|---|--|
| 3-1. Develop training manual of testing high pathogenic viruses in BSL-3 laboratories | <u>Training Manual for Basic Biosafety and Use of BSL-3 Laboratory</u> was developed in two language (English, Vietnamese) (ANNEX) 9. List of Publication (2006-2008) |
| 3-2. Conduct training on Biosafety for technical staff based on the training manual | Based on the training manual, 2-day training on Basic Biosafety and Use of BSL-3 Laboratory was carried out by BS Department. <u>Training Contents</u> Day 1: Biosafety concept and regulation Day 2: Operation and Maintenance of BSL-3 Laboratory and its practice From March to October 2008, the training was held four times with a total of 100 participants including 68 NIHE researchers and other Institutions. Participants who completed the training were registered as researchers who are eligible to use pathogens at BSL-3 laboratory. As of October 2008, 18 trained NIHE researchers used BSL-3 laboratory after the training. (ANNEX) 8. List of Local Training 21. Numbers of registered researchers and actual users working with BSL-3 pathogens |
| 3-3 Review training manual regularly after training courses | <u>Training Manual for Basic Biosafety and Use of BSL-3 Laboratory</u> is being reviewed and revised periodically. |

| | |
|--|--|
| <p>3-4. Improve laboratory practice under supervision for laboratory testing for diagnosis</p> | <p>Short-term experts reviewed the laboratory testing procedure and made technical inputs to improve it.</p> <p>At the new HTC BSL-3 laboratory, laboratory testing for diagnosis of avian influenza virus were carried out for 800 specimens in total from July to mid-October 2008.</p> <p>At the Mobile BSL-3 laboratory, laboratory testing for diagnosis of avian influenza virus were carried out for 633 specimens in total from May 2007 till early October 2008.</p> <p>Out of 68 trained researchers, currently 18 researchers are actually using BSL-3 laboratory in their research work. Out of 18 users, 11 are from the Virology Department working on avian influenza.</p> <p>The BSL-3 animal laboratory (BSL-3 Lab 4) is currently making test run with mice since November 2008.</p> <p>Four researchers from user departments took the counterpart trainings on Laboratory Training in their own research area including Virology, Bacteriology, and HIV/AIDS.</p> <p>(ANNEX) 7. List of Counterpart training in Japan 19. HTC BSL-3 Laboratories Practice Report 20. Mobile BSL-3 Laboratory Practice Report</p> |
| <p>3-5. Develop and implement SOP for testing highly transmissible pathogens in BSL-3 laboratories</p> | <p>Procedure manuals for testing highly transmissible pathogens in BSL-3 laboratories were developed for researchers.</p> <p><u>Standard Operational Procedure on Laboratory Techniques for Influenza</u> (English) in September 2008.</p> <p><u>Instruction for Diagnosis of Rickettia</u> (Japanese, Vietnamese) in August 2008.</p> <p>(ANNEX) 9. List of Publication (2006-2008)</p> |
| <p>3-6. Strengthen management system for registration of highly pathogenic agents</p> | <p>Low Temperature Freezer was purchased to store pathogens.</p> <p>(**It is planned to develop and strengthen further maintenance and management system for registration of pathogens at BSL-3 laboratory given the proper equipment installed.)</p> <p>(ANNEX) 5. List of Equipment provided by JICA</p> |

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

| Verifiable Indicators | Achievement |
|--|---|
| All necessary documents are developed and implemented. | <p><u>Training Manual for Basic Biosafety and Use of BSL-3 Laboratory</u> is developed. BS Department conducted trainings, which cover Biosafety concept and the BSL-3 Standard Operational Procedure (SOP). Researchers who use the BSL-3 laboratory follow the SOP.</p> <p><u>Standard Operational Procedure (SOP) on Laboratory Technique for Influenza</u> is developed. Researchers follow the SOP when they test and diagnose avian influenza at the BSL-3 laboratories.</p> <p>Training manuals and SOPs with focus on each highly hazardous transmissible pathogenic agent to test at the BSL-3 laboratories are not developed yet.</p> |

2.3. Project Purpose and Overall Goal

2.3.1 Achievement of 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.

Nevertheless, the Project has successfully produced visible outcomes. These outcomes include establishment of BS 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.

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.

| Verifiable Indicators | Achievement |
|---|---|
| The system of biosafety management is established and properly implemented and all necessary records are being produced according to the regulations. | <p>Biosafety Department is established.</p> <p>NIHE Biosafety Regulation and some SOPs were developed and currently implemented.</p> <p>Training on Biosafety was conducted for researchers and technical staff.</p> <p>All necessary records and documents such as application form for utilization of lab and operation and maintenance records are developed. The operational and maintenance records are collected, however not fully analyzed.</p> |

2.3.2 Achievement of Overall Goal

“BSL-3 laboratories are fully functioned and maintained in NIHE.”

With regard to the Overall Goal, as already stated above BSL-3 laboratories are now in full operation, the number of diagnosis and research activities by registered researchers has been increasing. However, it is still a challenge to maintain the BSL-3 laboratories in NIHE.

| Verifiable Indicators | Achievement |
|--|---|
| Numbers of registered researchers and actual users working with BSL-3 pathogens as well as number of diagnosis/investigation/ research performances increase | <p>68 researchers who participated in the training on Biosafety and Use of BSL-3 Laboratory became registered researchers. Currently 18 registered users use BS Department in their research activities.</p> <p>At the new HTC BSL-3 laboratory, laboratory testing for diagnosis of avian influenza virus were carried out for 800 specimens in total from July to mid-October 2008.</p> <p>At the Mobile BSL-3 laboratory, laboratory testing for diagnosis of avian influenza virus were carried out for 633 specimens in total from May 2007 till early October 2008.</p> |

2.4 Implementation Process

There are some promoting factors throughout implementation process as follows.

Vietnamese Commitment

NIHE shows a strong commitment to the Project from the fact that NIHE provided not only human resource to establish a new BS Department within a short period of time, but also financial support to install the Mobile BSL-3 laboratory. Such strong commitment and ownership is there mainly because it is the first time to install the BSL-3 lab in Vietnam, thus it feels responsible for the success as a national representative. In fact, the Ministry of Health and the government recognize the progress and achievement of the Project as

noteworthy.

Partnership between NIHE and Japanese experts

The Project was designed for capacity development of NIHE through transferring advance technique to use and maintain BSL-3 laboratory properly.

At first, it took some time to develop trust with NIHE staff. Yet they attained trust and respect for the Japanese technical inputs over time as they recognized highly skilled and dedicated work by the Japanese experts. Even though most of the Japan's technical inputs were provided through dispatching short-term experts, the same experts were assigned at frequent intervals. During their duty, their highly skilled expertise was fully utilized in Vietnam to support NIHE staff. Moreover, they even continue providing technical support to the counterpart from Japan.

Contribution of the mobile BSL-3 laboratory

Introduction of the mobile BSL-3 laboratory which was unprecedented input by the Japanese side enabled establishment of the Biosafety basis before launching the HTC BSL-3 laboratories. It also allowed NIHE to diagnose avian influenza pathogen from May 2007.

Project Management and Monitoring

Gained such trust and respect from NIHE, Japanese experts and the NIHE counterpart developed close monitoring system of the activities. Annual and semi-annual activity reports have been prepared by the counterpart to submit to the Project. For instance, when different short term experts came to provide technical assistance in their areas of expertise (e.g. Biosafety, Laboratory Maintenance, Laboratory Operation & Facility Management), the head of BS Department made sure to accompany them throughout the process. It helped BS Department not only to learn new skills and knowledge but also to monitor each activity more closely. Furthermore, from day-to-day interaction with the Project, the counterpart especially BS Department staff has acquired a good level of understanding JICA's standard method for project management (Project Cycle Management Methodology). Their increased capacity of the project management seems significant as most Vietnamese counterpart members are originally trained as researchers and/or scientists, thus do not usually have enough management experience.

For the Japanese experts, they ensured to monitor activities by being present at various meetings including the Biosafety management meeting and the BS & MME departments joint meeting as technical advisors.

In addition, two Joint Coordinating Committee (JCC) meetings have been held by the time of the Terminal evaluation (March 2007 and April 2008). NIHE director, the counterpart (Biosafety and Virology departments), the Japanese experts and JICA representatives participated in those meetings for annual review of activity progress and plan of the following year.

Coordination skill

Strong coordination and leadership skills were expected from the newly established BS Department 1) to introduce a new concept “Biosafety” to other user departments, 2) to develop and put the NIHE’s Biosafety Regulation into practice, 3) to strengthen the Biosafety Committee, 4) to operate and maintain BSL-3 laboratory and so on. These acts would not be achieved effectively without involving other user departments. At the time of the mid-term evaluation, it was pointed out needs of strengthening coordination system and leadership at BS Department.

By the terminal evaluation, it is observed that BS Department increased coordination capacity and leadership. For instance, BS Department can organize and chair various coordination meetings, conduct the certified Biosafety Training and monitor activities. However, there is still more to be done where supervising laboratory activities for other user departments should be strengthened, management system for registration of pathogens at the BSL-3 laboratories should be established, and more. To achieve so, BS Department may require more human resource. But before anything else, the department needs more time and experience as it goes.

On other hand, hindering factor which set back activities in implementation process is stated below.

Delayed full operation of BSL-3 laboratories

Both the mobile and the HTC BSL-3 laboratories delayed full operation as originally planned with the following reasons:

As for the mobile BSL-3 laboratory, transfer from NIID to NIHE was delayed in almost five months due to full upgrading of the facility as well as complicated administrative procedure both in Japan and Vietnam. After installing the mobile laboratory in November 2006, more technical input and working time were necessary for installation and adjustment in order to respond to unpredictable problems. It took six months from the installation to its full operation using pathogens.

With regard to the HTC BSL-3 laboratories, they began full operation with testing practice around late June 2008. Firstly, completing a part of HTC construction by the Vietnamese side was delayed while facility of the BSL-3 laboratories was ready by the grant aid in January 2008. Once the operation began, some problems and failure reports of facilities and equipment were informed by the Vietnamese side. This could be common at the initial stage of installing highly sophisticated facility like BSL-3 laboratory. Most of the problems have been solved. A few remaining problems are in the process of responding, and must be solved by the end of 2008.

3. Evaluation by Five Criteria

3.1 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 most recent Master Plan developed by the government of Vietnam, “Comprehensive Development Design for the Health System in Vietnam to 2010 and Vision by 2020” states that responding to emerging and re-emerging infectious diseases is an urgent task. Other development policy and planning papers such as “Strategy for socio-economic development 2001-2010” and “Five-year socio-economic development plan 2006-2010” come into the same line.

According to the Japanese Government’s 2004 Country Assistance Plan for Vietnam and Aid Implementation Policy for Vietnam (1st version, 2008 May) state that 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 and sustainability plan.

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. In 2008, it continues to report outbreaks of H5N1 in poultry from several provinces throughout the country and to confirm some human cases. All five newly reported cases this year were reported as death as a result. Thus, this current situation remains to be a threat in the whole region.

Table 3-1. Cumulative Number of Confirmed Human Cases of Avian Influenza A/ H5N1 Reported to WHO As of 8th November 2008

(Source: WHO website. <http://www.who.int>)

| Country | 2003 | | 2004 | | 2005 | | 2006 | | 2007 | | 2008 | | Total | |
|------------|-------|--------|-------|--------|-------|--------|-------|--------|-------|--------|-------|--------|-------|--------|
| | cases | deaths | cases | deaths | cases | deaths | cases | deaths | cases | deaths | cases | deaths | cases | deaths |
| Azerbaijan | 0 | 0 | 0 | 0 | 0 | 0 | 8 | 5 | 0 | 0 | 0 | 0 | 8 | 5 |
| Bangladesh | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 |
| Cambodia | 0 | 0 | 0 | 0 | 4 | 4 | 2 | 2 | 1 | 1 | 0 | 0 | 7 | 7 |
| China | 1 | 1 | 0 | 0 | 8 | 5 | 13 | 8 | 5 | 3 | 3 | 3 | 30 | 20 |
| Djibouti | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| Egypt | 0 | 0 | 0 | 0 | 0 | 0 | 18 | 10 | 25 | 9 | 7 | 3 | 50 | 22 |
| Indonesia | 0 | 0 | 0 | 0 | 20 | 13 | 55 | 45 | 42 | 37 | 20 | 17 | 137 | 112 |
| Iraq | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 2 | 0 | 0 | 0 | 0 | 3 | 2 |
| Lao | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 2 | 0 | 0 | 2 | 2 |
| Myanmar | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 |
| Nigeria | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 1 | 1 |
| Pakistan | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 1 | 0 | 0 | 3 | 1 |
| Thailand | 0 | 0 | 17 | 12 | 5 | 2 | 3 | 3 | 0 | 0 | 0 | 0 | 25 | 17 |
| Turkey | 0 | 0 | 0 | 0 | 0 | 0 | 12 | 4 | 0 | 0 | 0 | 0 | 12 | 4 |
| Viet Nam | 3 | 3 | 29 | 20 | 61 | 19 | 0 | 0 | 8 | 5 | 5 | 5 | 106 | 52 |
| Total | 4 | 4 | 46 | 32 | 98 | 43 | 115 | 79 | 88 | 59 | 36 | 28 | 387 | 245 |

Total number of cases includes number of deaths.

WHO reports only laboratory-confirmed cases.

All dates refer to onset of illness.

Close collaboration with National Institute of Infectious Diseases (NIID) in Japan is found very appropriate as NIID acquires high level of knowledge and experience to transfer to NIHE.

3.2 Effectiveness

As stated in the section of Activities and Output, 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 staff to operate and maintain the BSL-3 laboratories as well as training researchers to use the laboratories.

In spite of smooth progress above, due to unpredictable circumstances, practical part of the activities using

the BSL-3 laboratories was pushed back as the full operation of the BSL-3 laboratories was delayed.

As described more in the summary section of Activities and Output, some activities were identified and suggested to carry out 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.

For the above reasons, delays in BSL-3 operation and more activities, it seems the Project need more time to implement all activities. At the end of carrying out them, it is a high possibility of the Project being very effective.

3.3 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.

All equipment have been procured and utilized fully by the Counterparts. The counterpart training opportunities in Japan have been cited in interviews as extremely useful and practical for the Counterparts to obtain new technical capabilities. Dispatch of the Japanese experts has also been viewed favorably by the NIHE staff. Many experts were posted to the Project as short-term experts, but ensured to come several occasions for the same post. The expertise of the Japanese experts is considered to be excellent as they obtain advanced and specialized skills to transfer, which were irreplaceable.

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. Additionally, in order to operate and maintain both the mobile and HTC BSL-3 laboratories, BS Department needed to collaborate with MME Department, which required more time to establish working relationship than anticipated.

Secondly, as mentioned earlier in the section of 3.2 Effectiveness, to ensure safety operation of the BSL-3 laboratories, it was found out in the implementation process that additional activities (but within the PDM framework) were necessary. They were originally not foreseen, but crucial ones to achieve the Outputs. Due to unpredictable factors, a few planned activities were not yet completed.

3.4 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 Project stakeholders and the Evaluation Team observed the following positive impacts relating to Project’s interventions.

First of all, internal positive impact is that researchers can now conduct testing and research on BSL-3 pathogens. It was mentioned in the interviews that users feel safer to work on testing and investigating pathogens in their research at the BSL-3 laboratories, and also they try on an advanced technique such as microneutralization test, which was not possible before at BSL-2 laboratories. In other words, operating BSL-3 laboratories can offer researchers more access to advanced researches which would benefit the country as a whole.

Secondly, as WHO and other institutions also recognize, one of the biggest external impacts is that NIHE established the BS Department and developed the Biosafety system to operate the first BSL-3 laboratories for the first time in Vietnam, which became a role model for others. It is indeed establishment of the Biosafety system contributed a great deal to the national policy making.

Thirdly, NIHE’s diagnostic results of RT-PCR 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.

Another external impact is that 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.

Furthermore, 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. Also a number of visitors

including many VIPs came domestically and internationally to observe the Project activities. All in all, they resulted in a big effect of publicity.

NIHE staff now has capacities to conduct training course on Biosafety for laboratory staff outside NIHE.

With regard to regional impact, under supervision of MOH, NIHE conducted seminar on emerging and re-emerging infectious disease control at NIHE for participants from the neighboring countries such as Cambodia and Laos in JICA-Asean Regional Cooperation Meeting (JARCOM) scheme.

3.5 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. It is because political, financial and technical supports are highly expected from not just the institution but also the national government as NIHE is recognized as the first role model of the Biosafety in Vietnam.

3.5.1 Organizational/Institutional Aspect

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.

3.5.2 Financial Aspect

Financial aspect of sustainability is also promising as NIHE regards Biosafety activity as a high priority in line with the government. 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.

3.5.3 Technical Aspect

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. Even so, they still need more time and experience till they are confident in ensuring 1) safety operation of the BSL-3 laboratories including proper response to emergency case, 2) quality and safety test performance, and 3) management of registration of highly hazardous transmissible pathogens. In order to achieve the satisfactory level of activities, nevertheless, recruiting and training more staff on Biosafety is essential. 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.

4. Conclusions

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.

5. Recommendations

Based on the review on the achievement of the activities and the outputs of the Project, both sides confirmed the recommendations as follows:

5-1 Biosafety management

- 5-1-1 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.
- 5-1-2 To make Biosafety activities more practically applied among all users, Information, Education and Communication (IEC) materials should be developed and utilized.

5-2 Operation and Maintenance

- 5-2-1 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.

- 5-2-2 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.

5-3 Laboratory activities

- 5-3-1 Training manuals and SOPs with focus on specific pathogens including rabies, anthrax, tuberculosis, rickettsial diseases and others, needs to be developed (Activity 3-1).
- 5-3-2 Laboratory practice under supervision for testing and diagnosis by internal and external experts should be improved (Activity 3-4).
- 5-3-3 Management system including SOPs for registration of highly pathogenic agents should be strengthened (Activity 3-6).

5-4 Extension of the Project period

5-4-1 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.

5-4-2 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.

5-4-3 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

5-4-4 Recommended inputs during the extended period

Japanese side

Long and short-term experts

Training in Japan

Provision of equipment

Local cost

Vietnamese side

Counterpart officers

Equipment and materials

Local cost

5-5 For the future

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

6. 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.