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| Country Name | The Project for Prevention and Control of Leptospirosis in the Philippines |
| Republic of the Philippines | |

I. Project Outline

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|---|---|--------------|---|---------------|-----------------|------------------------|--------------------------------|----------------------------------|--|---|---|
| Background | <p>Leptospirosis is one of the bacterial (spirochetal) zoonoses widely distributed in tropical and sub-tropical regions, and develops hepatic damage (causing jaundice), renal failure, hemorrhagic diathesis in human cases. Leptospira also infects animals such as rodents, canines, bovines and swine, and cause lethal disturbance as well as miscarriage and stillbirths. In the Philippines, an outbreak of leptospirosis was recorded after hygienic deterioration by flood incidents in Metro Manila in 2009 sending 1,670 people to hospitals and causing 104 deaths. On the other hand, there have been difficulties of cytological and clinical diagnosis on Leptospirosis. Therefore, researches were necessary to figure out the infection process and to establish rapid diagnosis method as well as to develop effective vaccines against various endemic serovars.</p> | | | | | | | | | | |
| Objectives of the Project | <p>Through establishing the Leptospirosis Prevention and Control Center (LepCon), conducting epidemiological studies, developing rapid methods/tools for the detection of anti-Leptospira antibodies and leptospiral antigens, developing vaccines to prevent leptospirosis in animals as well as enhancing advocacy activities for leptospirosis control, the project aimed at enhancement of the research and development (R&D) capacity of the College of Public Health, the University of the Philippines, Manila (CPH-UPM) for prevention and control of leptospirosis, thereby contributing to leptospirosis control in the Philippines in future.</p> <ol style="list-style-type: none"> Overall Goal: N/A Project Purpose: Research and development (R&D) capacity of CPH-UPM is enhanced for prevention and control of leptospirosis through the collaborative research. | | | | | | | | | | |
| Activities of the Project | <ol style="list-style-type: none"> Project Site: Manila Main Activities: 1) Renovation of the necessary parts at the laboratory in CPH-UPM, 2) Laboratory based surveillance to isolate Leptospira and to characterize isolates, field survey, serological test and bacteriological test, and epidemiology examination and analysis of environmental factors, 3) Development of a microcapsule agglutination test (MCAT), Enzyme-Linked Immunosorbent Assay (ELISA) system, and an immunochromatography test, 4) Development of inactivated vaccines, component vaccines, DNA vaccines and evaluation of efficacy and safety of them, 5) Dissemination of knowledge on leptospirosis for future leptospirosis control Inputs (to carry out above activities) <table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">Japanese Side</td> <td style="width: 50%;">Philippine Side</td> </tr> <tr> <td>1) Experts: 82 persons</td> <td>1. Staff Allocated: 26 persons</td> </tr> <tr> <td>2) Trainees Received: 12 persons</td> <td>2. Land and facilities: Office space and furniture</td> </tr> <tr> <td>3) Local cost: Cost for renovation of existing laboratories</td> <td>3. Local cost: Utility charges for research activities, cost for maintenance and repair of research equipment</td> </tr> </table> | | | Japanese Side | Philippine Side | 1) Experts: 82 persons | 1. Staff Allocated: 26 persons | 2) Trainees Received: 12 persons | 2. Land and facilities: Office space and furniture | 3) Local cost: Cost for renovation of existing laboratories | 3. Local cost: Utility charges for research activities, cost for maintenance and repair of research equipment |
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| Project Period | April, 2010 – March, 2015 | Project Cost | (ex-ante) 350 million yen, (actual) 266 million yen | | | | | | | | |
| Implementing Agency | College of Public Health-University of the Philippines Manila (CPH-UPM) | | | | | | | | | | |
| Cooperation Agency in Japan | Kyushu University, Chiba Institute of Science | | | | | | | | | | |

II. Result of the Evaluation

< Special Perspectives Considered in the Ex-Post Evaluation >

[Verification of the Overall Goal]

The Super Goal was stated as, “Leptospirosis is controlled in the Philippines” in the project design at the time of project preparation in 2009 and it was sustained after the revision of project design in November 2012. However, it is a long-term goal and is not achievable within 3 years after project completion. Since it is not realistic to verify the achievement level of this Super Goal at the time of ex-post evaluation, the ex-post evaluation assesses the status of the following two envisaged Overall Goals proposed by the terminal evaluation, which can be considered as “efforts for utilization of the research outcomes”:

- Vaccine candidate are further advanced, and novel diagnostics are registered and/or commercialized as diagnostic test kits in the Philippines.
- The research techniques provided by the Project are utilized for other researches by the Philippine side.

1 Relevance

<Consistency with the Development Policy of Philippines at the Time of Ex-Ante Evaluation and Project Completion>

The project was consistent with the Philippines’ development policies to focusing prevention and control of infectious diseases, such as “FOURmula ONE for Health (F1)” and “the National Objectives for Health 2011”.

<Consistency with the Development Needs of Philippines at the Time of Ex-Ante Evaluation and Project Completion >

The project was consistent with the Philippines’ development needs to establish rapid diagnosis methods as well as to develop effective vaccines against various endemic serovars due to critical outbreaks of leptospirosis after massive floods damaged Metro Manila in 2009. The Philippines continues to experience flooding particularly during the monsoon season increasing its risk against outbreaks of Leptospirosis. Hence, the project remains relevant even after project completion.

<Consistency with Japan’s ODA Policy at the Time of Ex-Ante Evaluation>

¹ SATREPS: Science and Technology Research Partnership for Sustainable Development

The project was consistent with “the Country Assistance Program for the Philippines” (2000), which was revised in 2008, prioritizing a support for promotion of self-reliance and improvement of living environment for the poor.

<Evaluation Result>

In light of the above, the relevance of the project is high.

2 Effectiveness/Impact

< Status of Achievement of the Project Purpose at the time of Project Completion>

The Project Purpose was achieved by the time of project completion. The standard diagnostic methods of leptospirosis in the Philippines, including direct and indirect methods, were established and the relevant documents were prepared (Indicator 1). The number of samples examined by different methods at the LepCon Center, which was established in CPH-UPM under the support of the project, increased from 128 in 2010 to 613 in 2012, but decreased to 308 in 2013 and 68 in 2014 (Indicator 2). The reason for the decrease in the number of samples examined at the LepCon Center after 2012 was the decrease in the number of patients in Metro Manila perceived to have been caused by better hygiene conditions brought about by less flood occurrences. It may have also been brought about by the occurrence of El Niño phenomenon causing mostly dry months instead of rainy season. As results of the project, 18 articles in total were published in international journals (Indicator 3). CPH-UPM collaborated with various institutions, including national government authorities, regional and local health related institutions, and international organization (Indicator 4).

<Continuation Status of Project Effects at the time of Ex-post Evaluation>

The project effects have been continued after project completion. The examinations and diagnosis by the standard methods established by the project have been continued: the number of samples examined at the LepCon Center sustained at around 140 in annual average for the period from 2015 to 2017. The results of seroprevalence studies by the project have been utilized by researchers of CPH-UPM. Academic articles based on the seroprevalence studies have been continuously produced and published in international peer-reviewed journals. The results of the researches under the project were disseminated in a 2-day symposium workshops conducted in December 2017 with attendance of WHO personnel, researchers from Thailand and Malaysia and various Philippine organizations. Furthermore, CPH-UPM has continued collaborative researches with various research institutes and continuously collaborate with Local Government Units (LGUs) for advocacy on leptospirosis control. For utilization of the project’s research outputs, the vaccine candidate developed from the project, LeptoVax, has already been registered as a Utility Model² and research activities related to development of the vaccine have been continued. In addition, CPH-UPM has regularly conducted surveillance on leptospirosis in collaboration with the College of Medicine-UPM, UP Visayas and UP Mindanao by 2019. The Department of Science and Technology (DOST) used the results of surveillance and economic impact assessment to justify the granting of related research proposals to researchers and faculty members of CPH-UPM and other collaborating universities.

The laboratory facilities, including the BSL (Biosafety Level)-2 laboratory, installed or renovated by the project have been maintained by CPH-UPM and utilized not only for the research activities but also for educational purpose by CPH-UPM and other collaborating universities. In particular, the BSL-2 laboratory has been continuously used for the testing of specimen samples of leptospirosis patients, mostly indigents who are referred from the DOH-managed hospitals in Metro Manila. On the other hand, the Leptospirosis Early Notification System (LENS) equipment procured by the project has not been in use because funding proposal by CPH-UPM for researches using LENS were not approved by DOST and the Newton Fund of UK though CPH-UPM is planning to submit another proposal to the Philippine Council for Health Research and Development (PCHRD).

<Status of Achievement for Envisaged Overall Goal at the time of Ex-post Evaluation>

The envisaged overall goal as the process to attain the Leptospirosis control in the country have been partially achieved at the time of ex-post evaluation. The vaccine candidates identified by the project were further advanced through the continuing research activities by CPH-UPM and other collaborative research institutes using the diagnostic kits developed by the project. While the diagnostic kits have not been registered or commercialized, it is being used by CPH-UPM in evaluating its archived serum samples. The vaccine for humans though has not yet been fully developed and commercialized (Envisaged Overall Goal 1). CPH-UPM has been continuously conducting dialogues with the College of Veterinary Medicine of UP-Los Baños to implement vaccine experiment on dogs for mass production and commercialization in future. So far, no timeline has not been set and a research proposal has not been submitted for funding though CPH-UPM has continued and advanced the related research activities by using research techniques transferred by the project in collaboration with other research institutes as mentioned above (Envisaged Overall Goal 2).

In terms of scientific literacy of government authorities, DOH used the information generated by the project in producing their own awareness campaign and educational materials about leptospirosis. Also, DOH utilized the results of seroprevalence surveys in advising DOH-managed hospitals in Metro Manila to refer their leptospirosis patients for laboratory testing in CPH-UPM (LepCon Center) thus augmenting the capacity of the Research Institute for Tropical Medicine (RITM) of DOH.

<Other Impacts at the time of Ex-post Evaluation>

Some positive impacts have been observed at the time of ex-post evaluation. The researchers of CPH-UPM improved their technical capacity for MAT. Their improvement has been endorsed by the results of proficiency tests conducted by the International Leptospirosis Society since they always get perfect scores. According to the interviews conducted by CPH-UPM to relatives of patients submitting specimens for laboratory diagnosis in the LepCon Center, the project also contributed to improvement of awareness of mothers about leptospirosis prevention and control through the advocacy activities under the project. Also, there is a growing media interest in leptospirosis prevention and control activities as evidenced by the increasing number of visits by media personnel to the LepCon Center. In addition, ex-counterpart staff of CPH-UPM were interviewed by local television and radio station for their science educational programs, thus contributing to awareness raising of the local communities about leptospirosis prevention and control.

<Evaluation Result>

Therefore, the effectiveness/impact of the project is high.

² A Utility Model (UM) is a system to protect intellectual property under the Intellectual Property Office of the Philippines. UM allows the right holder to prevent others from commercially using the registered UM without his authorization, provided that the UM is new based on the Registrability Report. Compared with invention patents, it is relatively inexpensive, faster to obtain, and with less stringent patentability requirements.

Achievement of Project Purpose and Overall Goal

| Aim | Indicators | Results | | | | | | | | | | | | | | | | | |
|---|--|---|------|------|------|------|------|------|------|------|-----|-----|-----|-----|----|-----|-----|-----|---|
| <p>(Project Purpose) Research and development (R&D) capacity of CPH-UPM is enhanced for prevention and control of leptospirosis through the collaborative research.</p> | <p>Indicator 1 The standard diagnostic method of leptospirosis in the Philippines is established and the relevant documents are prepared.</p> | <p>Status of the Achievement: achieved (continued) (Project Completion) The following diagnostic methods were established by the project and the related research documents were published;</p> <ul style="list-style-type: none"> ● Direct methods: Culture and polymerase chain reaction (PCR) methods ● Indirect methods: i) Microscopic Agglutination Test (MAT), ii) Specific immunoglobulinM (IgM) Rapid Diagnostic Tests like Lepto Dipstick, iii) Leptospira IgM Enzyme-Linked Immune Sorbent Assay (ELISA) (PanBio), iv) Microcapsule agglutination test (MCAT) <p>(Ex-post Evaluation) The methods of MAT, culture, and PCR have been used for analyzing samples from leptospirosis patients at the LepCon Center since the project completion.</p> | | | | | | | | | | | | | | | | | |
| | <p>Indicator 2 The number of samples examined by the different methods is increased at the Center.</p> | <p>Status of the Achievement: achieved (continued) (Project Completion/Ex-post Evaluation) The LepCon Center has continuously examined the samples of patients by the methods of MAT and culture.</p> <p>[Number of samples examined by the LepCon Center]</p> <table border="1" style="width: 100%; text-align: center;"> <tr> <td>2010</td> <td>2011</td> <td>2012</td> <td>2013</td> <td>2014</td> <td>2015</td> <td>2016</td> <td>2017</td> </tr> <tr> <td>128</td> <td>335</td> <td>613</td> <td>308</td> <td>68</td> <td>125</td> <td>157</td> <td>139</td> </tr> </table> <p>The number of samples varied by the weather conditions. In the years when floods were heavy, the number of samples examined was larger and the incidence of leptospirosis increased.</p> | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 128 | 335 | 613 | 308 | 68 | 125 | 157 | 139 | |
| | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | | | | | | | | | | | |
| | 128 | 335 | 613 | 308 | 68 | 125 | 157 | 139 | | | | | | | | | | | |
| <p>Indicator 3 The number of publications in peer-reviewed journals.</p> | <p>Status of the Achievement: achieved (continued) (Project Completion) In total, 18 articles were published in international journals with peer review by the end of the project.</p> <p>(Ex-post Evaluation) After project completion, 20 articles were published in peer-reviewed journals by 2018.</p> <p>[Number of publications in the peer-reviewed journals by the researchers participating in the project]</p> <table border="1" style="width: 100%; text-align: center;"> <tr> <td>2010</td> <td>2011</td> <td>2012</td> <td>2013</td> <td>2014</td> <td>2015</td> <td>2016</td> <td>2017</td> <td>2018</td> </tr> <tr> <td>4</td> <td>1</td> <td>0</td> <td>5</td> <td>8</td> <td>5</td> <td>6</td> <td>4</td> <td>5</td> </tr> </table> | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 4 | 1 | 0 | 5 | 8 | 5 | 6 | 4 | 5 |
| 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | | | | | | | | | | | |
| 4 | 1 | 0 | 5 | 8 | 5 | 6 | 4 | 5 | | | | | | | | | | | |
| <p>Indicator 4 The number of institutions in collaboration on research and advocacy.</p> | <p>Status of Achievement: achieved (continued) (Project Completion) CPH-UPM collaborated with the following institutions:</p> <ul style="list-style-type: none"> ➢ DOH and PCHRD-DOST for financial and technical supports ➢ Regional Epidemiology Surveillance Unit (RESU)-DOH and the Philippine Carabao Center for the field survey ➢ WHO/WPRO for the training on laboratory diagnosis of leptospirosis ➢ Manila Municipal Health Offices in Metro Manila, Health Department of 6 district health officers of Manila, 57 Barangay³ Health Station (BHS) for the advocacy activities <p>(Ex-post Evaluation)</p> <ul style="list-style-type: none"> ● The number of collaborative researches increased to 16 at the time of ex-post evaluation. The collaborative institutions with CHP-UPM are as follows: <ul style="list-style-type: none"> ➢ Philippine General Hospital, Tondo Medical Center, San Lazaro Hospital, Ospital ng Maynila Medical Center, Gat Andres Bonifacio Medical Center, Quezon City General Hospital, Rizal Medical Center, Quirino Medical Center, V. Luna General Hospital, Ospital ng Tondo, AFP Medical Center, Western Visayas Medical Center, Bicol Medical Center, Philippine Carabao Center, International Rice Research Institute, University of the Philippines-Visayas and University of the Philippines-Mindanao. ● Local Government Units (LGUs) in the National Capital Region (NCR) are also continuously collaborating with CPH-UPM on research and advocacy by disseminating information through posters and other information materials on leptospirosis made available by the project in health centers. | | | | | | | | | | | | | | | | | | |

³ Barangay is the smallest administrative division in the Philippines.

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| <p>(Envisaged Overall Goal 1) Vaccine candidate are further advanced, and novel diagnostics are registered and/or commercialized as diagnostic test kits in the Philippines.</p> | <p>N.A</p> | <p>(Ex-post Evaluation) partially achieved</p> <ul style="list-style-type: none"> ● Although vaccine candidates were further advanced through continuing research activities, these vaccines are not registered and commercialized yet. Also, vaccines for humans are not yet available. ● The LeptoVax vaccine, which development was started by the project, is still considered a “proof of concept” for the registration of patent and therefore not yet registered and commercialized though it has been registered as the Utility Model. ● The diagnostic kits developed by the project are not yet registered nor commercialized as well |
| <p>(Envisaged Overall Goal 2) The research techniques provided by the Project are utilized for other researches by the Philippine side.</p> | | <p>(Ex-post Evaluation) achieved</p> <ul style="list-style-type: none"> ● Research techniques provided by the project are continuously utilized by researchers of CPH-UPM and other collaborating universities and organizations ● As to the utilization of research techniques for pharmaceutical development, CPH-UPM has continuously been conducting dialogues with faculty members of the College of Veterinary Medicine of UP-Los Baños to do vaccine experiment on dogs ● CPH-UPM is confident that the experiment will be realized soon with positive results, after which mass production and vaccine commercialization will be undertaken. No timeline set yet on this endeavor. Research proposal is not yet submitted for funding; the vaccine development would require importation of dogs for experimental purposes so this research might take some time. |

Source : Terminal Evaluation Report, JST Completion Report, LepCon Database, Information provided by CPH-UPM, interview with ex-counterparts (4 persons)

3 Efficiency

The project cost and the project period were within the plan (ratios against the plan: 76% and 100%, respectively). The outputs were produced as planned. Therefore, the efficiency of the project is high.

4 Sustainability

<Policy Aspect>

Since leptospirosis is a health hazard associated with weather disturbances such as floods that causes economic losses, prevention and control of leptospirosis has been covered by the existing government policies and programs. In fact, leptospirosis is listed as a disease of rapid urbanization and industrialization by “the Philippine Health Agenda 2016-2022”. The National Unified Health Research Agenda 2017-2022 of the Philippine National Health Research System (PNHRS) that sets directions and identifies health research priorities listed health hazards associated with environment that includes leptospirosis as one of the priorities. The Philippines Development Plan (PDP) (2017-2022) aims at reducing the vulnerability of individuals and families from health-related shocks including leptospirosis hazard and identifies health as one of the priority sectors in formulating policy for advancing science, technology and innovation.

<Institutional Aspect>

For research and development (R&D) on leptospirosis prevention and control, CPH-UPM remains to be the main R&D body though the working groups created for the project had already been dismantled. As mentioned above, CPH-UPM has continued the research activities related to leptospirosis prevention and control in collaboration with other universities. Also, CPH-UPM has continued coordination institutionally with other universities, research institutes and government organizations as mentioned above. At the time of ex-post evaluation, 8 permanent staff of CPH-UPM, including newly employed, have been involved in the research and development for leptospirosis prevention and control but most of the former research counterparts (22 out of 26) had left CPH-UPM after the project. Although the number of staff of CPH-UPM engaged in the current research activities has been seen as sufficient so far, CPH-UPM thinks that it may become insufficient in the future as the R&D activities for leptospirosis prevention and control are expected to increase based on forecasts for flood events. Hiring job-order employees from time to time is considered a temporary measure. Organizational arrangement for O&M of the LepCon laboratory was concluded within UPM. The Department of Medical Microbiology (DMM) of CPH-UPM assumed the responsibility for the operation and maintenance of the project vehicles (2 units) and laboratory facility and equipment procured and renovated by the project.

<Technical Aspect>

The 8 permanent staff of CPH-UPM has sufficient skills and capacity to operate and maintain the LepCon Center and to promote research activities related to leptospirosis prevention and control. As mentioned above, they have continuously utilized the facilities and equipment provided by the project and continued research activities for leptospirosis prevention and control. The laboratory facilities, including the renovated BSL (Biosafety level)-2 laboratory in the LepCon Center installed by the project have been continuously utilized and maintained by CPH-UPM since CPH-UPM has sufficient capacity to properly operate and maintain those facilities. However, some equipment such as the air-conditioning unit and the LENS are unutilized.

<Financial Aspect>

CPH-UPM has continuously secured funds for continuing the research activities related to leptospirosis prevention and control from the central government through the annual budget of the University of the Philippines (UP) System, being one of the state universities and colleges (SUCs) in the country. In addition, CPH-UPM obtained funds from DOST-PCHRD (PhP 19 Million up to 2017 and PhP 0.5 Million up to 2018) and from the Philippine Institute of Traditional and Alternative Health Care (PITAHC) (PhP 1 Million up to 2019) all for individual (staff) research activities on leptospirosis. O&M requirements for the laboratory facilities and equipment procured and renovated by the project have been included in the annual budget of DMM of CPH-UPM under Maintenance and Other Operating Expenses (MOOE) though there is no specific budget allocated only for the LepCon Center. Therefore, the required operation and

maintenance cost have been secured.

<Evaluation Result>

There have been some concerns observed in the institutional aspect. Therefore, the sustainability of the effects through the project is fair.

5 Summary of the Evaluation

The project achieved the Project Purpose and partially achieved the envisaged Overall Goals through capacity development of research for diagnosis and vaccines to control leptospirosis as well as the advocacy activities to prevent it. CPH-UPM has continued the research activities for leptospirosis prevention and control in collaboration with other universities, research institutes and government authorities. As for sustainability, although there have been some concerns about the number of research staff for future expansion of the researches related to leptospirosis, CPH-UPM has sustained a capable research staff and secured the funds for research activities as well as maintenance of the research equipment and facility.

Considering all of the above points, this project is evaluated to be highly satisfactory.

III. Recommendations & Lessons Learned

Recommendations for Implementing Agency:

- 1) As discussed above, the LENS equipment procured by the project has not been utilized because the LENS project separately proposed by CPH-UPM to other funding institutions was not approved and therefore no related activities have been undertaken yet. In order to enhance project effects and their sustainability, it is recommended that CPH-UPM assess the operability of the equipment and revive the LENS project proposal by conducting dialogues with funding organizations
- 2) The utilization of research outcomes of the project has not led yet to policy making and program implementation. In light of this, it is recommended that CPH-UPM initiate dialogues with DOH and continue participating in related conferences which can lead to utilization of research outcomes for policy formulation and implementation

Lessons Learned for JICA:

- 1) It is important to conduct a stakeholders' project sustainability planning on or towards the middle of project implementation in order to give ample time to prepare and to capacitate the counterpart organization for ensuring continuity of project effects. This is considering that research outputs generated in SATREPS type of project are highly technical that requires more efforts from stakeholders to develop a realistic sustainability plan. Such plan should consider not only the technical and manpower requirements needed but also the financial implications of implementing said plan to ensure continuity. JICA Overseas offices e.g., Philippine Office, could design a sustainability planning workshop based on project monitoring information and conduct such workshop with maximum participation of key stakeholders of the project for promotion of related research activities.
- 2) It is also important to carefully examine the usability and maintenance requirements of any equipment during the project period before procuring such equipment. In this project, some equipment such as the RT-PCR (Reverse Transcription Polymerase Chain Reaction) machine has not been utilized because its utilization largely depends on the approval of a CPH-UPM project proposal by other funding institutions which did not happen. Other equipment such as air-conditioning units in the laboratory facility are found too costly to repair. The project team and JICA (overseas office) may review the project design and intended contributions of equipment in achieving project objectives. The review may include advantages of local procurement considering maintenance, efficacy and cost effectiveness.



Researcher processing samples in laboratory



National Symposium on Outcome of Program for Control & Prevention of Leptospirosis