Taiwan Epidemiology Bulletin

April 9, 2013/ Vol.29 / No.7

Original Article

Implementation of Authorized Laboratory Testing Institutions for Communicable Diseases in Taiwan, 2011

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Abstract

In order to improve accuracy of test reports, shorten the testing time, reduce the waste of medical resources by duplicate laboratory tests, and conduct effective disease control, Department of Health, Executive Yuan, Republic of China has implemented the laboratory designation, commissioning, and authorization systems according to Article 46 of the Communicable Disease Control Act. It provides a rapid, accurate, and convenient laboratory network for all citizens. Furthermore, Centers for Disease Control, Taiwan (Taiwan CDC) designated one laboratory testing institution to assist testing the risk group 4 pathogens in 2004. On August 12, 2008, it started to authorize laboratory testing institutions for testing categories 2-4 communicable diseases. Moreover, Taiwan CDC has adjusted its policy implementation by developing yearly tailored strategies based on the analyzing the reasons of failure applications each year. From August 12, 2008 to December 31, 2011, a total of 20 diseases, 245 laboratory testing institutions, and 955 testing items have been authorized. The largest number (210 institutions) of authorized laboratory testing institutions was testing acute hepatitis C, and followed by syphilis (153 institutions), acute hepatitis A (133 institutions), gonorrhea (76 institutions); acute hepatitis B (65 institutions), typhoid fever (62 institutions), shigellosis (58 institutions), paratyphoid fever (52 institutions), tuberculosis (except multidrug-resistant tuberculosis) (32 institutions), melioidosis (27 institutions), invasive *Haemophilus influenzae* type b infection (19 institutions), toxoplasmosis (14 institutions), varicella (10 institutions), *Legionella* ssp. in aquatic environments (9 institutions), mumps (5 institutions), legionellosis (2 institutions), diphtheria (1 institution), dengue fever (1 institution), enterohaemorrhagic *E. coli* infection (1 institution) and cholera (1 institution). In the future, the laboratory system will collaborate with the national health insurance system and the laboratory accreditation system to provide a convenient and quality-assured laboratory network to promote disease control specialty as well as the quality of medical service so as to ensure the health of all citizens.

Keywords: Communicable Disease Control Act, laboratory testing institution for communicable diseases, laboratory network for communicable diseases

Introduction

The national health is rooted in good disease control, in which the quality of laboratory diagnosis will directly influence the detection accuracy of outbreak or clusters. In order to improve accuracy of test reports, shorten the testing time, reduce the waste of medical resources by duplicate laboratory tests, and conduct effective disease control, Department of Health, Executive Yuan, Republic of China, according to Article 46 of the Communicable Disease Control Act [1], revised the Regulations Governing the Management of Laboratory Diagnoses for Communicable Diseases and Testing Institutions and Laboratories [2] and the Review Guideline for Authorized Laboratory Testing Institutions (hereafter simply referred to as Guideline) [3] in 2008. Therefore, a laboratory network for testing of communicable diseases was set up to include designated, commissioning, and authorized laboratory testing institutions. Furthermore, Centers for Disease Control, Taiwan (Taiwan CDC) have designated one laboratory institution to assist laboratory diagnosis of the risk group 4 pathogens in 2004. On August 12, 2008, it started to authorize laboratory testing institutions for testing category 2-4 communicable diseases [4].

Based on the Guideline, the laboratory diagnosis for 40 notifiable communicable diseases in categories 2-4 were open to clinical laboratories. They are 16 diseases in category 2 (diphtheria, typhoid fever, dengue fever, paratyphoid fever, shigellosis, amoebiasis, malaria, measles, acute hepatitis A, enterohaemorrhagic *E. coli* infection (EHEC infection), hantavirus syndrome, cholera, rubella, chikungunya fever, West Nile fever, and epidemic typhus fever), 11 diseases in category 3 (pertussis, Japanese encephalitis, tuberculosis (except multidrug-resistant tuberculosis), congenital rubella syndrome, acute hepatitis B and C, mumps, legionellosis (including *Legionella* ssp. in aquatic environments), invasive *Haemophilus influenzae* type b infection, syphilis, and gonorrhea), and 13 diseases in category 4 (leptospirosis, melioidosis, botulism, invasive pneumococcal disease, Q fever, endemic typhus fever, Lyme disease, tularemia, scrub typhus, varicella, cat-scratch disease, toxoplasmosis, and Creutzfeldt-Jakob disease). All kinds of laboratories, including local health bureaus, medical centers, regional hospitals, local hospitals, and private laboratory institutions, could submit applications to become the authorized laboratory testing institutions for the above-mentioned diseases. The required documents include an accreditation certificate issued by laboratory accreditation organizations/a proficiency test proof by the proficiency testing organizations, the standard operating procedures and others. Once the laboratory is authorized to conduct the confirmation test of certain diseases, which mean no specimens need to be sent to laboratories of Taiwan CDC for further confirmation. These laboratories only need to upload the test results onto the Notifiable Communicable Disease Surveillance System, and provides timely feedbacks to the physician, and health authorities in local and central governments.

Analysis of current status

From August 12, 2008 to December 31, 2011, of the 40 diseases that the confirmation testing are open for authorized laboratory testing institutions, only 29 diseases have received the applications. Among them, 20 diseases were approved for being tested by the authorized laboratories. These diseases are diphtheria, typhoid fever, dengue fever, paratyphoid fever, shigellosis, acute hepatitis A, EHEC infection, cholera, tuberculosis (except multidrug-resistant tuberculosis), acute hepatitis B and C, mumps, legionellosis (including *Legionella* ssp. in aquatic environments), invasive *Haemophilus influenzae* type b infection, syphilis, gonorrhea, melioidosis, varicella, toxoplasmosis, and scrub typhus (a terminated disease later) (Table 1). Among 245 laboratory testing institutions, the largest institution number was 210 in which conducted the tests in acute hepatitis C, and followed by syphilis (153 institutions), acute hepatitis A (133 institutions), gonorrhea (76 institutions); acute hepatitis B (65 institutions), typhoid fever (62 institutions), shigellosis (58 institutions), paratyphoid fever (52 institutions), tuberculosis (except multidrug-resistant tuberculosis) (32 institutions), melioidosis (27 institutions), invasive *Haemophilus influenzae* type b infection (19 institutions), toxoplasmosis (14 institutions), varicella (10 institutions), *Legionella* ssp. in aquatic environments (9 institutions), mumps (5 institutions), legionellosis (2 institutions), diphtheria (1 institution), dengue fever (1 institution), EHEC infection (1 institution) and cholera (1 institution). During the period of 2009 and 2011, the number of specimens testing in diseases (acute hepatitis A, acute hepatitis B, acute hepatitis C, syphilis, and gonorrhea) that were notified after the positive laboratory test of the patients ranged from 744 to

Table 1. Review and application status of the 40 communicable diseases opened for clinical laboratories to conduct the confirmation tests, 2008-2011

Status	Diseases with Authorized laboratory testing institutions	Diseases without authorized laboratory testing institutions	Diseases without application	Diseases with authorized laboratory testing institution terminated
Communicable diseases	Diphtheria, typhoid fever, dengue fever, paratyphoid fever, shigellosis, acute hepatitis A, enterohaemorrhagic *E. coli* infection, cholera, tuberculosis (except multidrug-resistant tuberculosis), acute hepatitis B and C, mumps, legionellosis (including *Legionella* ssp. in aquatic environments), invasive *Haemophilus influenzae* type b infection, syphilis, gonorrhea, melioidosis, varicella, and toxoplasmosis	Amoebiasis, malaria, measles, rubella, congenital rubella syndrome, botulism, invasive pneumococcal disease, cat-scratch disease	Hantavirus syndrome, chikungunya fever, West Nile fever, epidemic typhus fever, pertussis, Japanese encephalitis, leptospirosis, Q fever, endemic typhus fever, Lyme disease, tularemia, Creutzfeldt-Jakob disease	Scrub typhus
Total	19	8	12	1

21,218 (Table 2). The number of specimens in the period of 2009 and 2010 for tuberculosis tests conducted by contract laboratories was 512,824. A small number of specimens (ranging from 2-198) were tested for dengue fever, shigellosis, typhoid fever, toxoplasmosis, invasive *Haemophilus influenzae* type b infection, and paratyphoid fever. No specimen was received in the other 7 diseases.

Implementation process

The reasons that laboratories fail the application to become authorized laboratory testing institutions from 2008 to 2011 included incomplete or no confirmation tests, no laboratory accreditation qualification or incomplete proficiency test document, no standard operation procedures (SOP) or SOP incomplete and unqualified technicians (Figure 1). In 2008, 182 applications were failed because of incomplete proficiency test documents (106 applications for typhoid, paratyphoid, Gonorrhea, cholera, melioidosis and others; 58%), and testing methods incomplete or no confirmation methods (76 applications for measles, amoebiasis, malaria, rubella, legionellosis, congenital rubella syndrome, invasive pneumococcal disease and others; 42%). Reasons behind these failures to complete authorization include (1) insufficient policy marketing channels to disseminate information to those target clinical laboratories; (2) no proficiency tests available for some bacterial diseases; and (3) confusion of confirmation and screening tests.

Table 2. Number of specimens tested for various communicable diseases by authorized laboratory testing institutions during the period of 2009-2011

Name of communicable disease	Number of specimens tested by authorized laboratory testing institutions				Number of specimens tested by Taiwan CDC
	2009	2010	2011	Total	
Acute hepatitis A	242	252	250	744	153
Acute hepatitis B	271	254	231	756	26
Acute hepatitis C	462	377	402	1,241	17
Syphilis	7,120	6,980	7,118	21,218	42
Gonorrhea	2,163	2,336	2,072	6,571	50
Tuberculosis (except multidrug-resistant tuberculosis) (contract lab.)	136,934	188,207	187,683	512,824	2,984
Dengue fever	0	0	198	198	60,068
Shigellosis	0	0	43	43	8,916
Typhoid fever	0	0	21	21	2,079
Toxoplasmosis	0	0	4	4	438
Invasive *Haemophilus influenzae* type b infection	0	0	4	4	428
Paratyphoid fever	0	0	2	2	518
Diphtheria	0	0	0	0	157
EHEC infection	0	0	0	0	1,468
Cholera	0	0	0	0	3,548
Mumps	0	0	0	0	730
Legionellosis (including aquatic specimens)	0	0	0	0	10,186
Melioidosis	0	0	0	0	195
Varicella	0	0	0	0	62

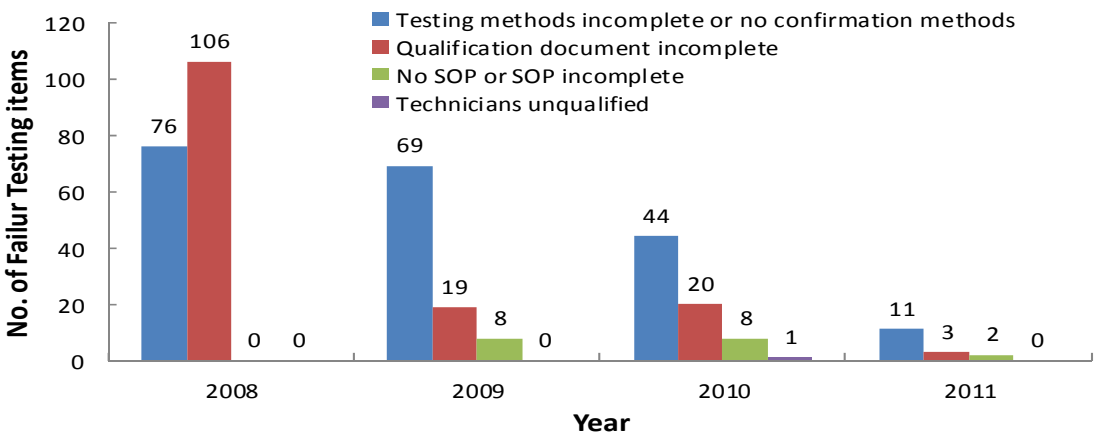

Figure 1. Analysis of factors in applications failure to become authorized laboratory test institutes in the period of 2008 and 2011

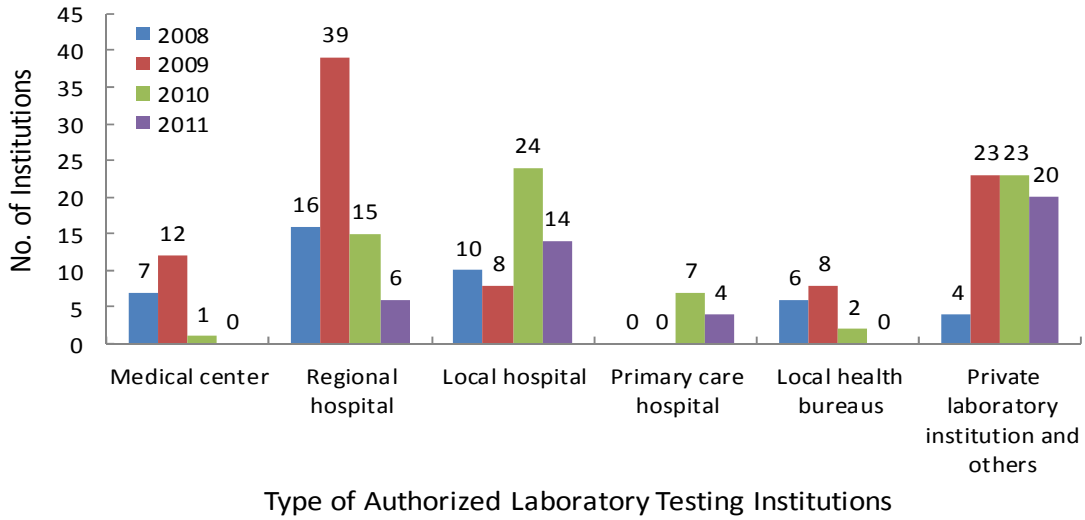

Figure 2. The type of authorized laboratory testing institutions for testing communicable diseases in the period of 2008 and 2011

Based on the above analysis of factors in applications failure to become authorized laboratory test institutes, Taiwan CDC has adjusted its policy implementation by developing yearly tailored strategies and indicators. The strategy for 2009 were (1) collaboration with accreditation or proficiency testing providers, including Taiwan Accreditation Foundation (TAF) and Taiwan Society of Laboratory Medicine (TSLM) to find the potential candidates of authorized laboratory testing institutes for policy marketing; (2) adoption the proficiency tests for universal bacterial groups; and (3) disease promotion by steps according to the characteristics of diseases. Six diseases with large quantities of specimens, high levels of automatic procedures, and easily standardized testing methods were selected as priority items. They were tuberculosis (except multidrug-resistant tuberculosis), syphilis, gonorrhea, acute hepatitis A, acute hepatitis B, and acute hepatitis C. After the implementation of the adjustment strategies, the number of newly authorized laboratory testing institutes in 2009 increased to 90 and the number of applications reached 456. The majority of the laboratories submitting applications were medical centers or regional hospitals (Figure 2). This indicated that the

adjusted strategies and approaches were correct to produce the expected outcomes. In addition, the number of applications failed to become authorized laboratory testing institutes reduced to 96 in 2009. Between 2008 and 2011, the percentage of testing items passed had obviously increased from 42% to 91% while the percentage of institutes being authorized ranged from 92% to 100% (Figure 3). During the period of 2009 and 2011, the main reason that a laboratory was not authorized was incomplete testing methods or no confirmation tests (accounting for 72%, 60%, and 69% in 2009, 2010, and 2011, respectively). This indicated that testing methods constituted the major problem preventing laboratories from receiving authorization. Therefore, to disseminate the qualification of authorized laboratory testing institutes should be strengthened so that all clinical laboratories could establish the required confirmation testing methods. Furthermore, incentives or breakdown of confirmation methods should also be available.

Since 2010, except for continuing collaboration with TSLM and TAF, implementation of this policy was also extend to local health bureaus by incorporating it into the communicable diseases control project. Furthermore, Taiwan CDC combined the on-site assessments of authorization laboratory testing institutes and TAF accredited bodies. Additionally, TAF has also assisted Taiwan CDC based on the standards of ISO15189 to train 25 on-site assessors. In the same year, on-site visits to authorized laboratory testing institutes that were not TAF accredited bodies were conducted. Since 2011, a project for promoting the quality of laboratory diagnosis for communicable diseases was commissioned to a professional group, the Taiwan Association of Medical Technologists (TAMT). Through this project, TAMT members voluntarily reached consensus to initiate a series of campaigns to promote quality of laboratory diagnosis.

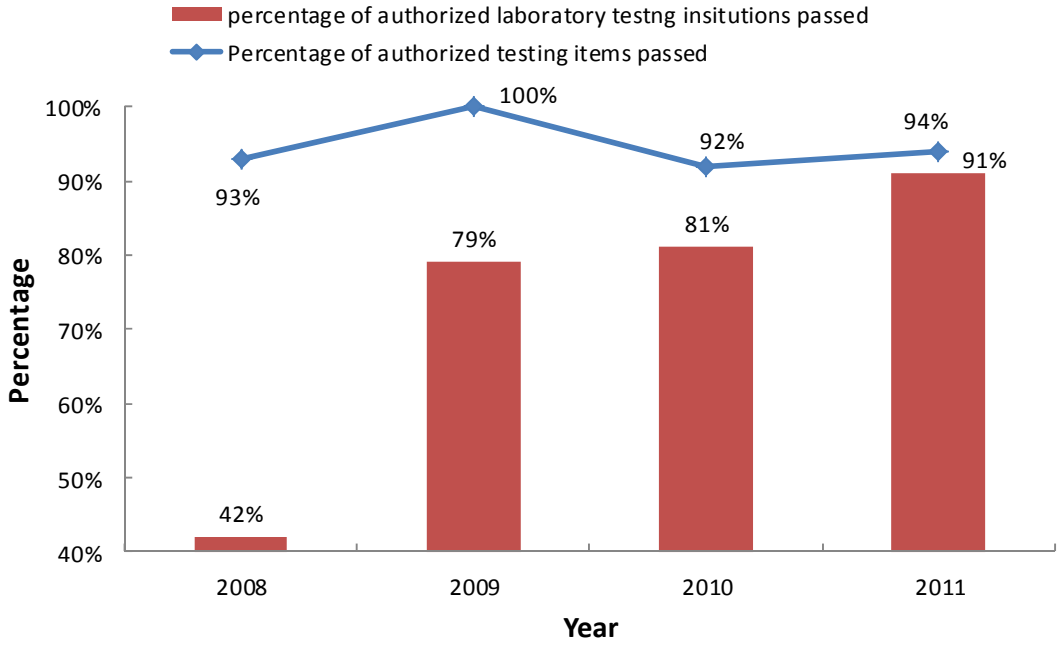

Figure 3. Percentage of authorized laboratory testing institutions and testing items passed by year in the period of 2008 and 2011

Discussion

The confirmation testing of communicable disease could only be performed by national laboratories in the central government before 2008 in Taiwan. However, the decentralization of this task to other clinical laboratories has advantages on time-saving for specimen handling, minimizing the risks of specimen transportation, shortening the distance between physicians and laboratories to provide timely feedback for patient therapy [5], and avoiding duplicate tests. In addition, the accuracy of the laboratory results could be ensured through regulations and guidelines. Other countries have formulated regulations to promote the quality of the laboratory diagnosis and assisted through associations or foundations by developing relevant standards and accreditation. For example, the United States has passed the Clinical Laboratory Improvement Amendments (CLIA), which the funding is supported by the Centers for Medicare & Medicaid Services (CMMS). The Office of Clinical Standards and Quality, Division of Laboratory System of the CMMS is responsible for implementation of these amendments [6]. Furthermore, the Division of Laboratory System, Centers for Disease Control and Prevention, USA is responsible for laboratory techniques and qualities [7], while the Food and Drug Administration, USA review and approve in vitro diagnostic (IVD) reagents [8]. The Clinical and Laboratory Standards Institute (CLSI) provides various standard test methods [9, 10] and the College of American Pathologists (CAP) provides proficiency test and accreditation services for clinical laboratory to ensure the consistency of testing results and laboratory quality [11].

Although the implementation of laboratory authorization system in Taiwan has good preliminary results, there are still rooms to improve in establishing a self-managed nationwide laboratory network to perform confirmation testing for communicable diseases. On technical aspect, it is difficult to standardize all technical regulations because of test and disease diversity. On the management level, the scale of the laboratory facilities vary widely from one another, with some being affiliated with a medical center size while others being run by only one person. The large scale laboratories can join TAF accredited bodies and ensure quality control by accreditation, while small scale laboratories could hardly meet the same requirements. In implementing the regulation, the Articles 67, 69 and 70 of the Communicable Disease Control Act have specified penalties for laboratories failing to diagnosis, reporting, and confirmation testing of communicable diseases. However, due to lack of incentives and incomplete policy implementation, only promotion and education can be made, which affected the implementation outcomes. In terms of the testing cost, the testing fees performed by these authorized laboratories are paid by the National Health Insurance Bureau (NHIB) of Taiwan, which patients have the right to choose any hospital for medical service. Therefore, under the limited NHIB's resources, how to establish a laboratory network that can perform high quality testing and provide timely test results to physicians for patient therapy is really a challenge for the laboratory authorization system.

At present, under limited human and budget resources in Taiwan governments, a full policy implementation is almost impossible to complete. Under a system of democratic governance right, a modern government should develop website governance concept, build up a good cooperative

relationship between government and private sectors to elevate administrative efficiency in government and to effectively use available resources. Therefore, policymakers should open the testing for all Notifiable Communicable Diseases in Categories 2-4 to private sector to link the clinical diagnosis and patient treatments, which are supported by NHIB. Furthermore, becoming one check item in hospital evaluation or hospital accreditation will increase incentives and improve laboratory management. Public health authorities should play a supportive role on those disease diagnoses, which can performed by clinical laboratories. National laboratories should focus on diseases, which require a higher level of biosafety laboratory, have rare cases with high cost testing, or need high complexity tests. Their tasks also include public health service and developing new rapid assays and testing techniques [12]. Furthermore, Taiwan CDC will cooperate with Taiwan FDA for supplying good-quality IVD reagents, TAF for performing laboratory accreditation for self-management, and local health agencies for enforcing relevant regulations to provide a convenient and quality-assured laboratory network for testing of communicable diseases. This enhances techniques in disease control and promotes high quality of medical service so as to ensure the health of all citizens.

In order to make laboratory authorization system more exhaustive, Taiwan CDC has completed revision of the Guidelines on 17 July, 2012. It opened the testing for almost all notifiable communicable diseases in categories 2-4 to clinical laboratories, including meningococcal meningitis, acute hepatitis D, acute hepatitis E, enteroviruses infection with severe complications, complicated influenza, human immunodeficiency virus infection, NDM-1 infection of enterobacteriaceae, and brucellosis. The screening tests for confirmation of amoebiasis, syphilis, and HIV infection were also included in this revision as well as the biosafety level of laboratories. Each testing methods (such as culture, molecular genotyping, and antibody detection) pose different level of risk to laboratory technician. Moreover, in 2013, local health bureaus will include authorization permit-audition into routine hospital supervision or evaluation activities to ensure commissioned-market mechanism. Hopefully, this will assist to reach the goals of linking laboratory authorization system with the national health insurance system.

Conclusion

The laboratory authorization system effectively integrates the laboratory resources for medical service and public health. Testing results conducted by clinical laboratories were reported to public health authorities to perform disease control. Additionally, through payment of the national health insurance system, laboratory accreditation system, and regulatory management, high quality testing can be ensured, therefore, to enhance the quality of patient care and the health of the general public.

Acknowledgements

We would like to deeply thank Taiwan Accreditation Foundation, Taiwan Society of Laboratory Medicine, Taiwan Association of Medical Technologists, local health bureaus, and colleagues in the Center for Research and Diagnostics, Centers for Disease Control, for their

contributions in promoting the laboratory authorization system for communicable diseases.

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Initial Impact Assessment of the New Taitung Office of Sixth Branch, Centers for Disease Control

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Abstract

Situated away from the main centers of Taiwan, the Taitung region lacks the necessary resources for healthcare and disease prevention. Because of its remote location and transportation inconvenience, travelling between Taitung and Hualien takes up to six or seven hours, incurring high travel and time costs for public health officers and making it uneconomical. To spread the workload and disease prevention resources more evenly (as at the time, there were concerns over the effectiveness of Taitung's tuberculosis control programs), and to save on expenses, the Sixth Branch, Centers for Disease Control (CDC) established the "Taitung County Tuberculosis Control Taskforce" in July 2011 to oversee the local health bureau's tuberculosis control programs. In October of the same year, the Taitung Office was established, with tuberculosis control as its priority. Since then, the Taskforce and the Taitung Office have worked closely with the Taitung County Health Bureau to improve its efficiency in preventing and controlling communicable diseases including tuberculosis. In just over a year, progress has been made in Taitung's disease prevention and control programs, particularly with regards to tuberculosis control. Initial conservative estimates suggested that the establishment of the Taitung Office saved NT$433,000 on expenses. Having an office locally also allowed for close monitoring and supervision of the communicable diseases prevention programs run by the local public health bureau. The time saved from long distance travel can be used on improving the quality of auditing, as well as increasing the efficiency and capacity of local health bureau's disease prevention and control programs, ensuring better public health.

Keywords: DOTS (Directly Observed Treatment, Short-Course), Tuberculosis, Cost-effectiveness analysis, Cost-benefit Analysis

Introduction

Taitung County is geographically long and narrow. An area of 3,515 square kilometers is divided into 16 city and townships, including five mountainous townships. Taitung's population density has been estimated at 65 persons per km², only one tenth of the national figure.

The majority of Taitung's medical and disease prevention resources are concentrated in Taitung city. Many young people leave the county to study and work in the cities because of public transport inconveniences. These people are often of lower socioeconomic strata. At the end of 2011, Taitung County had a population of 228,290 persons, 27% of whom were dependents [1].

The CDC's National Communicable Disease Surveillance Systems showed that the most common infectious diseases in Taitung over the last five years in descending order were tuberculosis (TB), syphilis, scrub typhus, Human Immunodeficiency Virus Infection/ Acquired Immunodeficiency Syndrome (HIV/AIDS), and invasive pneumococcal diseases, and influenza with complications [2]. The number of incident tuberculosis cases in Taitung rose in

2008 and 2009. During 2009 to 2010, both Taitung's TB incidence and mortality rates were the highest in Taiwan. Most of Taitung's TB indicators worsened.

CDC's Sixth Branch covers both Hualien and Taitung counties. Originally the branch had Xinxing Office and Port Quarantine Office in Hualien City. As Hualien City is 180 km away from Taitung City, it was difficult to manage the needs of both counties. A more even distribution of staff and resources became necessary.

Taking into consideration of Taitung's transportation system, medical resources and the capacity of its front line disease prevention programs, as well as the huge human, time and economic costs incurred by long distance trips, the Sixth Branch set up its Taitung office in October 2011. With its own disease prevention specialists, the office would be able to work closely with the Taitung County Health Bureau to improve its tuberculosis control.

This report aims to analyze the initial impact of the new Taitung Office on the region's disease control programs and the cost benefits of setting up the office. It is hoped that the experience shared here will be useful to other agencies in promoting similar programs.

Initial Impact on Taitung's Tuberculosis Control Program

In recent years, the World Health Organization has been actively promoting the use of DOTS (directly observed treatment, short-course) to manage tuberculosis patients, in order to effectively control and prevent the spread of tuberculosis [3].

Since adopting DOTS in 2006, tuberculosis incidence in Taiwan has decreased from 67.4 per 100,000 persons to 57.2 in 2010, a reduction of 15.1%. Although the rate in Taitung also decreased by 5% from 104.9 per 100,000 to 99.7 in 2010 (Table 1), it was still 1.74 times higher than the national average.

The mortality rate of tuberculosis in Taiwan dropped from 3.7 per 100,000 persons to 3.2 in 2009, a decline of 13.5%. However, the mortality rate in Taitung jumped by 11.3% from 9.7 per 100,000 persons in 2006 to 10.8 in 2009 (Table 2), more than 1.5 times the national figure [4].

Despite some progress made in tuberculosis control over the years, according to Taiwan's annual tuberculosis report, Taitung still had Taiwan's highest incidence and mortality rate for tuberculosis in 2009. Tuberculosis have been dropped from the list of the county's top ten killer diseases, but in Taitung's mountainous townships and isolated areas, TB was still one of the top ten causes of death. So tuberculosis control and prevention must remain as the focus of Taitung's public health programs.

Table 1. Number of new TB cases and incidence rates in Taitung during 2006 to 2011

Region/Year	Number of New TB Cases						Incidence Rate (per 100,000 persons)					
	2006	2007	2008	2009	2010	2011	2006	2007	2008	2009	2010	2011
Taiwan	15,378	14,480	14,265	13,336	13,237	12,634	67.4	63.2	62.0	57.8	57.2	54.5
Taitung County	249	215	233	263	231	223	104.9	91.6	100.1	113.3	99.7	97.2

Table 2. Number of TB deaths and TB mortality rates in Taitung between 2006 and 2011

Region/Year	Number of Deaths						Mortality Rate (per 100,000 persons)					
	2006	2007	2008	2009	2010	2011	2006	2007	2008	2009	2010	2011
The Whole of Taiwan	832	783	762	748	654	638	3.7	3.4	3.3	3.2	2.8	2.8
Taitung County	23	19	12	25	20	17	9.7	8.1	5.2	10.8	8.6	7.4

During January to July 2011, the number of new TB cases in Taitung increased more sharply, raising concerns over the quality of its DOTS program. In response, on July 14, 2011, the Sixth Branch established the "Taitung County Tuberculosis Control Taskforce" to step up the supervision of Taitung County's TB prevention programs. Later in October, the Taitung Office was set up to execute disease prevention and control, quarantine, and the taskforce responsibilities. Seven main indicators, as explained in the following sections, were used by the taskforce to monitor and assess the results, and to adjust their methods accordingly.

TB control in Taitung was originally managed by the Taitung Chronic Disease Control Center (TCDCC). After introducing DOTS in May 2006, because DOTS program was overseen by CDC and TCDCC had achieved limited results in promoting the program, DOTS program was transferred to Taitung County Health Bureau during the second half of 2006. As the bureau made tuberculosis control its priority and had support from the bureau chief, the bureau achieved very good results. However, in August 2010, following internal restructuring of the health bureau, DOTS program was transferred back to TCDCC.

As TCDCC's main task lay in treating patients, it did not have enough staff to manage the prevention and control side of the work. The center also lacked the level of authority to effectively manage and order local public health centers. Therefore, DOTS program results deteriorated.

In August 2011, at the recommendation of CDC and its Sixth Branch, the chief of the Taitung Health Bureau made immediate decision to take over the TB control programs and staff. Once again TB prevention and control was made as the main priority. Because of the active involvement of the bureau chief and the manager of the Bureau's Disease Control section, much progress has been made since then, and TB statistics have improved.

On January 18, 2012, the taskforce called its 17th meeting. As the Taitung Health Bureau has been actively putting staff and resources into the TB control and has reached the annual target set for 2011, the taskforce has completed their job. TB prevention and control by the Taitung office is now back to the usual management.

1. Percentage Increase of new Tuberculosis Cases

The "Mobilization Plan to Half Tuberculosis in Ten Years", launched by the Department of Health, Executive Yuan, estimated that Taitung's TB incidence rate should decrease from 115.2 per 100,000 persons in 2005 to 57.6 in 2015. However, from 2005 to 2010, Taitung's TB incidence rate had only decreased by 13.4%, nowhere near the targeted reduction of 29.3%, and

at this rate, would be 28.8% higher than the targeted reduction by 2015.

Data collected by the CDC's Central Communicable Disease Surveillance Systems showed that during January to July of 2011, Taitung's new TB cases increased by 30.6% compared with the same period in 2010. This increase indicated a possible deterioration of the TB control programs. To remedy the situation, the taskforce appointed a person to go through each TB patient's record, to find suspected cases early, and to inform local health authorities in time. The taskforce also sent staff at least three times a month to review the DOTS programs of local health centers to ensure that these programs were properly managed.

Data collected from the surveillance system also showed that the number of new cases in 2011 decreased by 3.5% compared with the same period in 2010. Of those 223 new cases, 180 were diagnosed when they presented with symptoms at the doctor's office, while 43 were identified through active case-finding, a rate of 19.3%. Methods used in active case-finding included contact tracing, mobile chest X ray screening of high risk groups, and community disease prevention programs.

During January to July 2012, there were 109 new TB cases, which was 24.8% less than the 145 cases reported during the same period in 2011, and 8.4% less than the 119 cases in 2010. This clearly showed an improvement in the TB prevention programs.

2. Quality Control of Patient Support and Case Management

The quality of DOTS programs depend on DOTS rate and the quality of in-person care offered to TB patients. Literatures showed that DOTS rate could affect a patient's recovery. Using patients who received 60% DOTS patient care as a baseline, those patients whose percentage went below this line were ten times more likely to have poor prognosis. Patients who did not participate in DOTS were 73 times more likely to have poor prognosis [5]. Therefore, patients must be encouraged to participate in DOTS programs. Delivering medicine in-person to a patient and not leaving until the patient has swallowed the medicine ensures the quality of DOTS programs, and increases treatment quality and success rate.

The DOTS Implementation rate in Taitung has always been above 90%, but the percentage of A-level Observation (A-level:≥70% of treatment in the first two months was observed, and 60% of the entire treatment course was observed in-person; B-level: ≥60% of the entire treatment course was observed; C-level: all others.) had been low. During January to July 2011, its A-level Observation rate was only 66.9%, much lower than the national average of 84.2%. Although its rate of C-level Observation, compared with the same period in 2010, declined by 5.5%, Taitung was still one of the worst performing areas in Taiwan.

The taskforce and the Taitung Office persisted with their supervision and monitoring on Taitung's DOTs program, offering immediate assistance to patients who refused DOTS and those cases whose observation rates were low.

In 2012, the DOTS implementation rate rose to 98.2%, higher than the national average of 95.3%. The A-level observation rate climbed to 88.5% while the rate of C-level went down from 8.1% to 5.7%. Although both figures still fall short of the national average of 89.2% and

5.3% respectively, they are nonetheless a huge improvement over 2011's figures of 32.3% and 29.6% respectively (Table 3).

3. Contact-Tracing

Contact-tracing can effectively identify new TB cases or patients with latent TB infections, and is an important task and policy in TB prevention. Contacts traced include those who lived with index case, or who are in contact with index case for more than 8 hours a day or more than 40 hours cumulatively [6]. A chest X-ray and tuberculin skin test can identify cases to be referred for further treatment and education.

From 2005 to July 2011, there were 4,299 contacts in Taitung who were not traced within 12 months. The completion rate was only 10%. To increase the rate of contact-tracing within 12 months, Taitung health authorities were required to step up their contact tracing speed through inter-city and inter-bureau cooperation, and to report their results weekly – measures which were effective in stimulating progress.

By the end of 2011, another 973 contacts in Taitung had been traced. In total, 5,272 persons have completed contact-tracing. After eliminating 499 cases that had data errors or had lost contact, 4,051 persons were examined. The completion rate reached 84.9%, far better than the figure prior to the establishment of the taskforce.

Data collected in February 2012 showed that Taitung's contact-tracing rate in 2010 reached 90%, which was clearly better than the national average of 75% and resulted in Taitung ranking second in the country for contact-tracing. Compared with the figure in 2009 (33%), the rate has increased by 57% (Table 4).

With continued effort from the Taitung Office, during January to August 2011, Taitung Health Bureau examined 87.1% of contacts within 12 months. After deducting 61 cases which did not require any action, the completion rate increased to 89.9%.

4. Latent Tuberculosis Infection Treatment

Patients infected with tuberculosis usually do not develop active tuberculosis disease straight away. Patients have latent tuberculosis infection (LTBI) during this period. At this

Table 3. DOTS implementation rates of confirmed TB cases and quality monitoring of direct observation between 2011 and 2012

Period	Region	DOTS Implementation Rate (%)	Total (person)	A-level (person)	Percentage (%)	B-level (person)	Percentage (%)	Level A & B (person)	Percentage (%)	C-level (person)	Percentage (%)
Jan – July 2010	Taitung County	94.4	81	51	63	19	23.5	70	86.4	11	13.6
	The Whole Country	88.5	4,448	2,461	55.3	1,135	25.5	3,596	80.8	852	19.2
Jan – July 2011	Taitung County	97.2	136	91	66.9	34	25	125	91.9	11	8.1
	The Whole Country	95.4	5,414	4,559	84.2	486	9	5,045	93.2	369	6.8
Jan – July 2012	Taitung County	98.2	87	77	88.5	5	5.8	82	94.3	5	5.7
	The Whole Country	95.3	5,226	4,660	89.2	291	5.5	4,951	94.7	275	5.3

Note: A-level: ≥70% of treatment in the first two months was observed, and 60% of the entire treatment course was observed in-person; B-level: ≥60% of the entire treatment course was observed; C-level: all others.

Table 4. Confirmed TB cases and their contacts who completed X-ray at the 12th month

Period	Region	Confirmed TB Cases	TB Contacts				
			Total Number (Person)	Completed Number (Person)	Completion Rate	Unfinished (Person)	Incomplete Rate
2009	Taitung County	285	2,397	789	33%	1,608	67%
	Taiwan	11,970	68,039	44,595	66%	23,444	34%
2010	Taitung County	199	1,263	1,138	90%	125	10%
	Taiwan	10,301	70,574	53,048	75%	17,526	25%

stage, the number of bacteria in the body is much less, and treatment can effectively reduce the risk of developing active in the future.

Taiwan is a medium-high burden country for tuberculosis. After both the case-finding rate and treatment success rate improve through effective DOTS program and TB contact-tracing, targeted LTBI treatment can then be used as a complementary strategy.

Taitung's Directly Observed Preventive Therapy (DOPT) program has had 100% completion rate for three years in a row, from 2009 to 2011. By the end of 2011, the 34 LTBI cases under treatment had all been enrolled in DOPT.

5. Mobile X-ray Screening

Geographically, Taitung covers a large area that is long and narrow. Compared with cities on western Taiwan, Taitung have few medical facilities which are unevenly distributed. As a result, in areas with high TB rates, or isolated areas with few medical facilities, active case-finding, such as mobile X-ray screening, is necessary to fill the gaps left by passive case-finding. Since 2011, Taitung County has stepped up its TB prevention program, offering more mobile X-ray screenings in mountainous villages and low socioeconomic communities.

During January to June 2011, Taitung's mobile X-ray unit screened 1,216 persons from mountainous villages, 33.8% of the targeted 3,593 persons. During the same period, 128 persons from low socioeconomic communities were screened, a mere 6.4% of the targeted 2,000 - clearly lagging behind.

To improve the effectiveness of mobile X-ray screening, the taskforce and the Taitung Office asked Taitung Health Bureau and local health clinics to increase the frequency of screenings, and to encourage people from low socioeconomic groups to attend them. Thanks to the cooperation between contracted hospitals, local health clinics, and staff from the Sixth Branch, by the end of 2011, Taitung's mobile X-ray unit had screened 5,331 persons in mountainous villages, an increase of 4,115 persons since the establishment of the taskforce. Not only has the target now been met, but the completion rate has also reached 148.4%. As to the low socioeconomic group, mobile X-ray unit reached its target at the end of October, after screening 2,750 persons, a completion rate of 137.5%.

Statistics from CDC showed that in 2011, Taitung's mobile X-ray screenings in mountainous villages had a participation rate of 80.5%. This was not only higher than the

national average of 59.8%, but was also the highest in the country. In total, the mobile X-ray unit screened 17,119 persons in Taitung in 2011. Of those screened, 10,085 persons (59%) were screened after the Taitung Office was set up. In 2011, there were 18 cases identified through mobile X-ray screenings, with 9 identified after the establishment of the Taitung Office (Table 5).

By August 2012, Taitung's mobile X-ray units had screened 12,405 persons and completed 72.5% of the target. The active case-finding rate was 120.9 per 100,000 persons, higher than the 2011 rate of 105.1 (Table 6).

6. Quality of TB Case Management

Local health authorities must categorize and close each TB case according to patient outcome, i.e. treatment completion, diagnosis excluded, died, or transferred out. Closure of cases must go through internal auditing, and are subject to external audits from CDC and its branch office. Each case is verified through system review and randomly selected hard-copy records are checked. Cases that do not meet the standard of internal audits would be corrected and the number of randomly selected records increased when mistakes are found, in order to improve the quality of case management.

The results of system review showed that during January to July 2011, Taitung had 16 cases that failed auditing. This equated to 2.3 errors per month. Mistakes made include

Table 5.Results of Taitung's Mobile X-ray Screening in 2011

Category	Screened (persons)		Cases Found (cases)		Incidence Rate (per 100,000 persons)
	Full Year	After*	Full Year	After*	
Mountainous Villages	5,331	4,115	9	5	168.8
Correctional facilities	6,296	3,383	3	2	47.7
Low Socioeconomic Groups	2,321	2,193	4	2	172.3
General population	3,120	394	2	0	64.1
Long Term Care Facilities	51	0	0	0	0
Total in Taitung	17,119	10,085	18	9	105.15
Total in Taiwan	54,243		113		208.32

Note: *after the Taitung Office was set up.

Table 6. Results of Taitung's Mobile X-ray Screening in 2011

Category	Screened (persons)		Cases Found (cases)		Incidence Rate (per 100,000 persons)	
	2011	Jan – Aug 2012	2011	Jan – Aug 2012	2011	Jan – Aug 2012
Mountainous Villages	5,331	4,251	9	7	168.8	164.7
Correctional facilities	6,296	4364	3	3	47.7	68.7
Low Socioeconomic Groups	2,321	3,128	4	3	172.3	95.9
TB-Contacts	767	662	2	2	260.8	302.1
General population	3,120	0	2	0	64.1	0.00
Long Term Care Facilities	51	0	0	0	0	0.00
Total in Taitung	17,119	12,405	20	15	105.2	120.9
Total in Taiwan	54,243	--	113	--	208.32	--

incomplete recording of treatment, delayed updating of information, smear-positive patients not included in DOTS, and delays in closing a case.

The establishment of the taskforce and the Taitung Office allowed for strengthened supervision and reviewing of TB case management at the local Health Bureau. During the 5 months prior to the end of 2011, there was only one error made in Taitung, an average of 0.2 cases per month. Two cases did not pass auditing during January to July 2012, an equivalent of 0.28 errors per month. Both errors were caused by delays in case closure. This shows that being able to supervise and audit locally has greatly improved the quality and efficiency of TB case management in Taitung.

7. Success Rate of TB Treatment

DOTS treatment means that health professionals, or other trained health care workers, provide and observe patients taking their medication. This patient-centered method, in conjunction with the provision of daily health supplements, can effectively improve patients' immunity, treatment success rate, and minimize the development of drug resistance.

During January to July 2011, before the taskforce was established, treatment success rate for new TB patients was 73.1%. Following the establishment of the taskforce, the success rate for January to December 2010 had increased to 73.3%, which was a 0.5% improvement from 72.8% in 2009. Although the taskforce had completed its first stage of tasks on the January 18, 2012, Taitung's TB program continued under the supervision of the Taitung Office and has achieved a success rate of 76.5% in 2011, a 3.4% increase compared with the same period in the preceding year.

Tuberculosis is a disease transmitted through droplet and air; it can affect anyone. Because tuberculosis has a long latency period and does not have obvious symptoms during its early stages, patients often are unable to obtain early diagnosis, causing them to infect those around them without knowing it.

Thanks to the joint effort of CDC's Taitung Office and the Taitung County Health Bureau, programs such as TB contact investigation and mobile X-ray screening, have all improved their completion rates. Hidden cases within the communities were able to be found early and referred for treatment in order to reduce TB sources.

Early identification and treatment avoid further waste of medical resources caused by the delay in treating TB patients, and is hugely beneficial to society.

Analysis of Economic Benefit

The main responsibility of Taiwan CDC is to formulate policies and plans for the prevention and control of communicable diseases. This includes plans for immunization, infectious disease prevention, disease surveillance, reporting, investigating, testing, quarantine, health emergency drills and response plans, training, and the stockpiling of medicines, equipment and personal protective equipments.

The CDC's branch offices are responsible for the supervision, advising, assistance, and assessment of infectious disease prevention program execution by local health authorities; in addition, they are in charge of quarantine at international and designated ports, identifying and reporting visitors who maybe carrying infectious diseases.

To ensure the quality of disease prevention programs offered by the local health authorities, each CDC branch needs to visit its local health clinic regularly to assess and review their progress.

1. Quarantine and Disease Prevention Tasks

Although Taitung's Fong Nien Airport was designated a domestic airport, in an effort to boost tourism, , it has received 42 chartered international flights from Tokyo, Xiamen, Hongkong, Guiyang, and Nanjing since 2009. Since November 2011, a weekly international flight between Nanjing and Taitung has also been in operation.

Before the establishment of the Taitung Office, quarantine was carried out staff based in Hualien City. Infrared temperature monitors used for quarantine at Taitung's Fong Nien Airport had to be transported by staff from Hualien, who usually drove because of the lack of direct public transport between Hualien and Taitung airports.

As for the DOTS program of TB control, the Sixth Branch had to send staff from Hualien to Taitung five times a month to attend meetings for DOTS review and auditing. Although trains were available between Taitung and Hualien, staff often had to drive instead because some DOTS cases required personal visits to the villages.

Routine tasks in acute infectious disease control required the supervisors to meet with staff from the local health bureau for weekly inspection of local educational institutions, childcare centers, public areas, and healthcare facilities; as well as twice monthly spot checks on mosquito density and dengue fever reports. Inspecting immunization work at local health clinics was also an important task of the Sixth Branch, but this was done at the same time as the DOTS program reviews in order to save time and labor.

2. Cost-benefit Analysis

a) Setup and operating costs

Initial setup of the Taitung Office cost about NT$1,210,000 which covered office equipment, machines and miscellaneous items. Ongoing operating costs equate to about NT$312,000 a year, which covers office rental, water, electricity and security contractors.

b) Save on travel expenses

Staff travel expenses include the costs of transportation, accommodation, meals and miscellaneous expenses. Prior to the establishment of the Taitung Office, CDC staff at the Hualien office had to travel to Taitung to deal with its quarantine and prevention programs for tuberculosis and other acute infectious diseases. In total, 157 trips were made and the agency's car was used 30 times, costing NT$230,000 on staff travel. On average, staff had to make 18 trips a month, costing NT$26,000 a month in travel expenses.

After setting up the Taitung Office, staff based in Taitung took 59 business trips, costing NT$13,000 in travels. On average, 20 business trips were made each month at

NT$4,000, which is only 15.4% of what was spent previously (Table 7). Setting up the Taitung Office has saved NT$22,000 every month on travel expenses - a saving of NT$264,000 every year.

Setting up the Taitung Office also allowed its staff to monitor programs and attend to meeting and quarantine needs more closely. Data from January to August 2012 showed that the number of regular call outs in Taitung had increased to 31 a month. Had the Taitung Office not been set up, it would have cost NT$83,000 a month for staff to travel from Taitung to Hualien. Now that these tasks can be handled by staff from the Taitung Office, travel costs have been reduced to under NT$15,000 a month - a saving of NT$816,000 a year.

c) Save on Time Costs

Prior to the establishment of the Taitung Office, quarantine work in the Taitung area was carried out by staff located in Hualien. The 180 km distance between Hualien and Taitung means a seven-hour round trip regardless of whether one is driving or taking the train. If the visit included Daren, Taitung's southernmost township, another four hours would be added to the trip. Hence, every business trip from Hualien to Taitung would require at least 1.5 days, (8 hours of travelling and 4 hours of work), to allow reasonable time for completion of tasks.

Based on the previous calculation of 18 trips per month, setting up the Taitung Office would have saved 126 hours, which is equivalent to 15.8 working days. Considering that Taitung office has been getting 31 callouts a month, setting up an office in Taitung would have saved 217 hours, or 27.1 working days – a huge amount of time.

Statistics obtained from the Ministry of Transport showed that in Taiwan, travel costs equated to around 60% to 80% of the average salary [7]. An average 80% time saving on average salary of NT$45,000 a month would equate to a saving of NT$39,000 every month on wages, or up to NT$465,000 every year.

Conclusion

In the first half of 2011, Taitung achieved less than satisfactory marks in the seven main areas of tuberculosis control. Other than latent TB infection treatment, all other indicators were deteriorating, raising concerns over the effectiveness of Taitung's TB management. However, after Sixth Branch set up the Taitung Office and a task force, CDC was able to increase its

Table 7. Travel Expenses Comparison Before and After Setting up the Taitung Office

Category	Rounds of Business Trip Before Setting up the Taitung Branch (Jan – Sep 2011)	Rounds of Business Trip Before Setting up the Taitung Branch (Oct – Dec 2011)
Quarantine Tasks	50	16
TB Control Tasks	61	29
Acute Infectious Disease Control	46	14
Total	157	59
Total Travel Expenses (NT dollar)	230,000	13,000
Average Travel Expenses per month (NT dollar)	26,000	4,000

supervision. Combined with the restructuring and re-organization of the Taitung County Health Bureau, problems in Taitung's disease prevention programs were able to be dealt with and its progress was evident. Those main indicators have also been showing similar trends.

Setting up the Taitung Office reduced costs related to long distance travel and accommodation, and saved staff time. After deducting the operational costs of the Taitung Office, it is estimated that NT$969,000 could be saved every year, or at least NT$433,000 by a more conservative calculation.

Having an office in Taitung also allows CDC to closely monitor and supervise local health authorities and to improve the quality of its auditing. It also increased the disease prevention capacity of local health authorities and health clinics. The Taitung Office allows for a faster response to outbreaks, ensuring the health of the general public.

The Sixth Branch set up a task force in July 2011 and established the Taitung Office in October 2011. Since then, through working closely with Taitung County Health Bureau, an improvement is evident in just over a year. Front line public health workers have also been able to increase the capacity of disease prevention programs. However, preventing and controlling chronic diseases such as TB require long term effort, and Taitung Office's full effect would not be completely evident in just one to two years. In the long term, Taitung Office would make a considerable contribution to disease prevention.

Acknowledgements

Many thanks to the Third Division of the Centers for Disease Control and the Taitung County Health Bureau for the information supplied. Special thanks also to Mr. Chin-Yuan Chang for coordinating the establishment of the Taitung Office and for supplying the information.

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The Taiwan Epidemiology Bulletin series of publications is published by Centers for Disease Control, Department of Health, Taiwan (R.O.C.) since Dec 15, 1984.
Publisher : Feng-Yee Chang
Editor-in-Chief : Yi-Chun Wu **Telephone No :** (02) 2395-9825
Executive Editor : Hsin-Yi Wang, Li-Gin Wu **Website :** http://teb.cdc.gov.tw/
Address : No.6, Linshen S. Road, Taipei, Taiwan 100 (R.O.C.)
Suggested Citation :
[Author].[Article title].Taiwan Epidemiol Bull 2013;29:[inclusive page numbers].