

## A Varicella Outbreak in a Primary School, Taiwan, 2010

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### Abstract

Varicella is a vaccine preventable disease and its vaccination was proceeded in some cities and areas in Taiwan since 1998. This report describes a cluster infection of varicella in a primary school.

From March 1 to June 30, 2010, school teachers and medical care staffs recorded varicella infection of the students. Varicella vaccination status was checked in National immunization information system (NIIS) and varicella infection status of this school prior to this outbreak was inquired in NIIS and Notifiable Disease Reporting System. Telephone interview with the patients and their parents were also conducted to understand the severity of the disease, clinical symptoms and duration time. The infected students were home isolated for at least one week until the vesicles healed. Disinfection was proceeded and varicella prevention education was provided to prevent further exposure.

There were 742 students in this school; 28 (3.8%) were infected with varicella and 401 (54%) had received varicella vaccine prior to this outbreak. Except 6 students, all other students received varicella vaccine at

least 5 years ago before outbreak. During this event, 23 students were infected and the attack rate was 3.2%; 10 of the 23 patients had received varicella vaccine. The efficacy of varicella vaccination calculated through this event was 40%. Compared to patients without immunization, patients previously vaccinated were less likely to develop moderate or severe disease (odds ratio: 0.110, confidence interval: 0.009-1.013,  $p=0.036$ ) and the duration time was shorter (odds ratio: 0.021, confidence interval: 0.000-0.352,  $p<0.001$ ).

This report revealed a varicella outbreak in a school where most students received vaccination for at least 5 years ago and single dose of varicella vaccine may be insufficient in long term protection from varicella infection. However, previous varicella vaccination may help in decreasing the severity of illness and duration time.

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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 :** Min-Ho Lai

**Executive Editor :** Li-Gin Wu, Hsiu-Lan Liu

**Telephone No :** (02) 2395-9825

**Address :** No.6, Linshen S. Road, Taipei, Taiwan 100 (R.O.C.)

**Website :** <http://teb.cdc.gov.tw/>

**Suggested Citation :**

[Author].[Article title].Taiwan Epidemiol Bull 2011;27:[inclusive page numbers].

**Keyword:** varicella cluster infection, National immunization information system, varicella vaccination efficacy

## Introduction

Herpesvirus is the pathogen for varicella and herpes zoster [1]. Children are the main targets in the irregularly - inoculated population [2]. Although varicella is a self-healed disease in most healthy children and adults, it can induce severe complications such as pneumonia, central nervous system (CNS) infection, secondary bacterial infection, or even death. These severe complications are particularly found in population with insufficient immune function [3]. The virus may be incubated in sensitive neurons in dorsal root ganglia in CNS after first infection, which may induce herpes zoster many years later.

Live varicella vaccine was developed in USA in March, 1995. A nation-wide regular inoculation for children was then conducted [4-5] and had decreased the morbidity and mortality of varicella [6]. However, cluster

infection of varicella was still sporadically recorded, even in schools which had high vaccination rate of varicella. One dose of varicella vaccine may not provide long term and sufficient efficacy [7]. Thus, 1-dose procedure was substituted by 2-dose procedure in USA in 2007 [8]. In developed countries, regular varicella vaccination may create higher benefit comparing to the medical and social cost [9-10]. Therefore, more and more countries proceed regular vaccination or priority immunization procedure (such as for medical staffs and patients with insufficient immune function) [11].

Before regular varicella vaccination, children under 10 years old are main targets of this pathogen and the highest incidence rate was recorded in children between 4-5 years old in Taiwan [12]. Since 1998, regular free varicella vaccination was conducted in Taipei City, and similar procedure was started in Taichung City and Taichung County since 1999 [12]. In 1999 after the "921 earthquake" occurred in middle Taiwan, the government subsidized the varicella vaccine for children in disaster area. From 2004, general varicella vaccination for children over 1 year old was started in the country. This report describes an outbreak of varicella infection in a primary school in 921 earthquake disaster area.

## Community situation

This outbreak occurred in a primary school in central Taiwan. The town was surrounded by mountains and geographically separated from other towns in the county. However, it was located in a tourism area and attracted tourists from other areas frequently. There were 6 grades in this primary school

and each grade had 4 to 5 classes (22-35 students per class). Classes were separated in 2 buildings but shared 1 sport field.

### **Patient definition and collection**

The targets of this report were students who had clinical symptoms of itching, cutaneous vesicles and/or exanthema, and were diagnosed as varicella by medical doctor from March 1 to June 30, 2010. Natural varicella infection was defined as patients who had no record of varicella vaccination in NIIS and by telephone interview. Breakthrough infection was defined as patients with at least 1 dose of varicella vaccination recorded in NIIS or Notifiable Disease Reporting System and immunization date was at least 42 days before disease occurred. In disease duration time, patients with less than 50 cutaneous vesicles were considered mild in clinical severity and those with more than 50 cutaneous vesicles were considered to be moderate or higher in clinical severity. Body temperature over 37.5C was defined as fever. Disease duration time was defined as the time frame from cutaneous vesicles, exanthema or fever to disappear of exanthema, fever or vesicles healing.

### **Investigation of varicella vaccination and varicella situation before outbreak**

ID numbers of all school students were collected by school staffs for checking varicella vaccination record in NIIS (including vaccination date, and varicella record before vaccination). Related information could be obtained from Communicable Disease Reporting System.

Varicella is a communicable disease and the list of previously infected students before this outbreak (March 3, 2010) were retrieved from these systems.

### **Case investigation**

We contacted parents through telephone interview to understand the disease condition (including potential diseases, form and number of cutaneous vesicles/exanthema, fever severity, and duration time), medical records (hospitalization or house care), disease complication (such as pneumonia), and varicella vaccination record. Varicella vaccination record was double checked through NIIS.

### **Cluster infection prevention and isolation procedure**

During the outbreak, infected children were recommended to stay home, avoid after-school activities (such as talent class) and keep off other children in the same house. Patients were not allowed to go to school before cutaneous vesicles healed (at least 1 week, including weekend). School environment (tables, chairs and floor) was disinfected by 500 ppm diluted bleach. Information about varicella prevention, transmission route and duration time was provided by Bureau of Public Health. Furthermore, students were encouraged to wash hands more frequently.

### **Statistical analysis**

Immunization coverage rate was calculated as follows: number of students with previous vaccination before outbreak (March 1, 2010) / number of students in this

primary school. Vaccine effectiveness (VE) was defined as follows: difference of attack rate among unvaccinated population (ARU) and attack rate among vaccinated population (ARV) / ARU. The infected patients prior to this outbreak were excluded. The equation was:

$$VE = \frac{ARU - ARV}{ARU} \times 100\%$$

The comparison of clinical symptoms between unvaccinated group and vaccinated group was analyzed by Fisher's exact test (Stata Software, 10<sup>th</sup> edition) and  $p < 0.05$  was considered statistically significant.

## Results

There were 742 students in this school and the varicella vaccination and disease situation prior to this outbreak was shown in Table 1. Twenty eight students (3.8%) had

varicella before this outbreak, 13 were found in Notifiable Disease Reporting System and 15 were from NIIS. All 28 students were not infected by varicella during this outbreak. 401 students had received varicella vaccine before and the vaccine covering rate was 54.0%.

All varicella vaccinated students (except 6 students) received their vaccination over 5 years ago before March 2010 (Table 2). All 6 students were first graders. four received the vaccination over four and half years ago, one was 3 years and 9 months ago, and the other one was only 2 months ago.

Most students were vaccinated after 1 year of age, whereas 6 students received vaccination before 1 year old (3 were 11 months old, 1 was 8 months old, 1 was 4 months old and 1 was 3 months old).

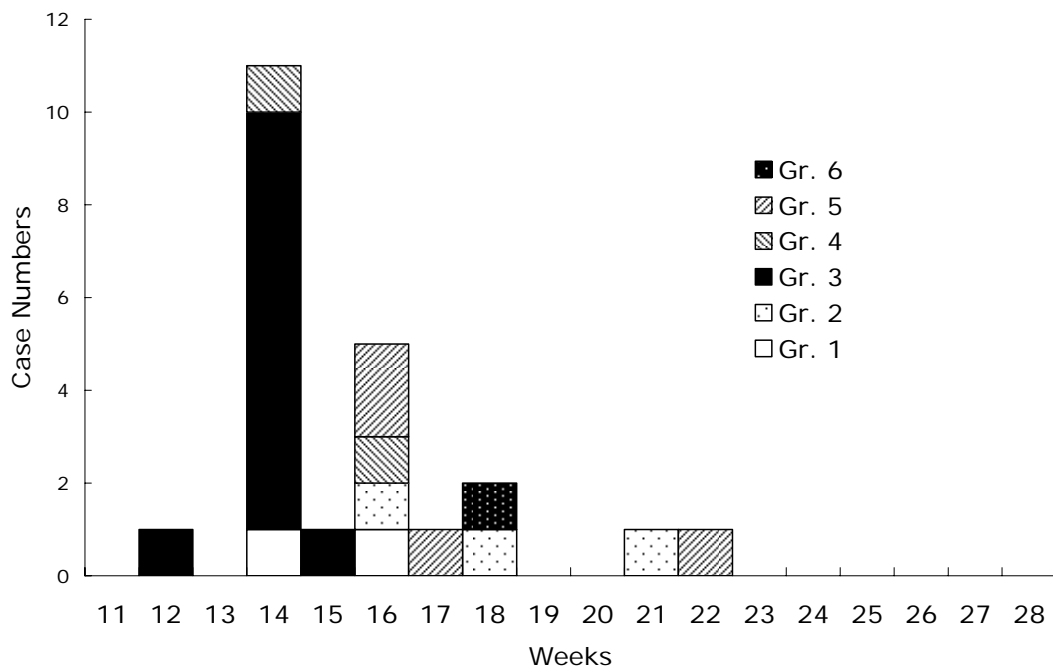
**Table 1. Varicella vaccination and disease situation prior to this outbreak**

Vaccination and disease situation prior to this outbreak	No. of patient in each grade (%)						Total (%)
	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	5 <sup>th</sup>	6 <sup>th</sup>	
Had been infected by varicella	1(1)	3(3)	7(6)	5(4)	8(5)	4(3)	28(4)
Had vaccination	85(85)	59(61)	67(54)	55(40)	69(47)	66(49)	401(54)
Unvaccinated	13(13)	35(36)	50(40)	78(57)	71(48)	66(49)	313(42)
Total	99(100)	97(100)	124(100)	138(100)	148(100)	136(100)	742(100)

**Table 2. The time duration and age distribution of varicella vaccination before this event**

Variable of varicella vaccination	Grade of student						Total
	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	5 <sup>th</sup>	6 <sup>th</sup>	
Duration from vaccination to this event (year)							
Medium	5.8	6.7	6.9	6.9	6.9	6.9	6.8
Shortest	0.2	5.9	5.0	5.9	5.1	6.1	0.2
Longest	6.5	6.9	9.1	9.3	10.4	12.0	12.0
Age of vaccination (years old)							
Medium	1.1	1.4	2.3	3.0	3.8	4.9	2.0
Youngest	1.0	1.0	0.3	1.0	0.7	0.3	0.3
Oldest	6.7	2.4	3.5	4.5	6.2	6.0	6.7

The first varicella patient of this event was found on March 19 and the last one was noted on May 24. A total of 23 patients were recorded in this outbreak (Figure). One of these 23 patients had asthma while other 22 patients had no substantial disease. All 23 students had no skin disease. Two patients who had no record of varicella vaccination were hospitalized due to fever and generalized cutaneous vesicle. No clinical complication was found in all 23 patients. Four in-home transmissions (8 patients) were noted during this outbreak. The duration time between the first and second patient in these 4 events was 14 days (2 events), 10 days (1 event) and 24 days (1 event). No in-home transmission was noted in other cases. From first grade to sixth grade in this school, the number of varicella patients was 2, 3, 11, 2, 4 and 1, respectively.



**Figure.** The epidemiologic curve of this varicella outbreak

**Table 3.** The attack rate of this varicella outbreak

Vaccination and disease situation prior to this event	Number	No. of patient in this event	Attack rate
Had varicella prior to this event	28	0	0%
Had vaccination	401	10	2.5%
No vaccination record	313	13	4.2%

Varicella disease situation of vaccinated and unvaccinated student was listed in Table 3. Ten of the 23 cases had received varicella vaccination. The dates of varicella vaccination of these patients were over 5 years ago (except 1 case). The shortest time duration was 4 years and 9 months, while the longest was 8 years and 4 months (medium time duration was 6 years and 10 months). The average attack rate of this varicella outbreak was 3.2%. The attack rate for unvaccinated and vaccinated student was 4.2% and 2.5%, respectively. The vaccine effectiveness was 40.0%.

Comparisons of clinical symptoms between unvaccinated and vaccinated patients were revealed in Table 4. Vaccinated patients were unlikely to develop moderate or higher in disease severity (odds ratio: 0.110, 95% confidence interval: 0.009-1.013,  $p=0.036$ ) and

**Table 4. The correlation of clinical symptoms and vaccination history**

	Total (n=23)	Vaccinated patient No. (n=10)	Odds ratio(95% confidence interval)	<i>p</i>
Moderate and severe	11	2	0.110(0.009-1.013)	0.036
Fever>37.5°C	9	4	1.067(0.142-7.721)	1.000
Disease duration >=5 days	14	2	0.021(0.000-0.352)	<0.001

with shorter disease duration time (odds ratio: 0.021, 95% confidence interval: 0.000-0.352,  $p < 0.001$ ) comparing to those with no vaccination. However, there was no difference in the rate of fever between these two groups.

### Discussion

This report describes a varicella outbreak in a school where most students had received varicella vaccination for over 5 years. We recognized the vaccine effectiveness and clinical symptoms of breakthrough infection through this investigation. Many studies in the past 10 years had evidenced that varicella vaccination was unable to provide long term protection from infection [13-14]. Chaves et al. found in a large-scale study with 350,000 people that the breakthrough infection rate after varicella vaccination was gradually increased from 1.6 / 1,000 people to 58.2 /1,000 people with 9-year duration [15]. In addition, another 10-year duration study recorded that the breakthrough rate in 1-dose vaccination group of people was 3.3 times higher than 2-dose vaccination group [16]. Two-dose varicella vaccination procedure was then recommended in 2007 in the USA due to frequently found breakthrough cases and cluster infection events [8]. General varicella vaccination for children was proceeded since 2004 and the reports of breakthrough infection cases were rare [13]. General 2-dose vaccination policy has not been adopted in

Taiwan yet, however, the occurrence of local breakthrough infection cases and cluster infection events are highly possible. This investigation may provide a reference for further vaccination policies.

In previous studies, the clinical symptoms (cutaneous vesicles<50, fever) and hospitalization duration of breakthrough infection patients were milder and shorter than naturally infected patients [17-18]. Patients with varicella vaccination within 5 years also had milder disease situation than those who had vaccination over 5 years [15]. In our report, disease severity and duration of breakthrough infection patients was milder than naturally infected cases, however, the severity of fever was not significantly different. This difference could be due to the attitude of parents and medical method. Taiwanese parents concern about fever very much and, thus, medical doctors usually use stronger antipyretic medicines for treatment. Active medical treatment may cause insignificant difference in fever severity between breakthrough and naturally-infected patients.

Emerging of patients in a frequency of 2 weeks was noted in epidemic curve. The emerging tendency of varicella patients was corresponded with the incubation time of varicella (13-17 days). Varicella infected students were asked to stay home for at least



1 week. However, the students who contacted with patient 1 to 2 days prior to disease occurring may develop clinical signs of varicella within 13-17 days. This situation could cause varicella patient emerging and may be the reason that was observed in the epidemic curve.

There were a few limitations in our study. First, the attack rate of varicella was only 3.2% and the analysis of vaccination effectiveness may be inaccurate based on this attack rate. Second, acquiring varicella disease prior to this event through NIIS or Notifiable Disease Reporting System may underestimate the real disease situation. Tan et al. analyzed disease data from Bureau of National Health Insurance and Notifiable Disease Reporting System from 2000 to 2002 and found that less than 9% of diagnosed varicella cases were reported to Centers for Disease Control [19], although varicella had been categorized as notifiable diseases since 1997. In this investigation, none of the 15 varicella-infected students recorded in NIIS had been reported to Notifiable Disease Reporting System. Thus, to recognize previously varicella-infected students by Notifiable Disease Reporting System may underestimate the real disease status.

This event revealed disease situation and prevention of varicella outbreak in a school with most student received vaccination for over 5 years. We noticed the vaccination effectiveness was 40% and disease severity and duration was milder in breakthrough infection patients than naturally infected patients. This may provide a reference for further varicella vaccination policy.

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### **The Effectiveness of Empowerment Training to DOTS Observer in Kaohsiung City**

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## Abstract

In order to effectively control and prevent tuberculosis (TB), many countries in the world have adopted DOTS (Directly Observed Treatment Short-Course) strategy to elevate treatment success rate of TB cases and to prevent the increasing of multidrug resistant TB cases through the practice of “sending medicines to patient’s hands, observing patient’s intake of medicine, and leaving after checking patient’s swallowing of medicine.” Since DOTS observers are the soul of DOTS strategy, their empowerment in DOTS implementation are worthy of exploration. This study includes 44 DOTS observers in Kaohsiung City and employs one-group pretest-posttest design and five-point Likert-type scale to evaluate TB knowledge and empowerment level of DOTS observers before and after one-day empowerment training. The results indicate that training activities can improve TB knowledge and empowerment level of DOTS observers. In conclusion, we proposed five recommendations for improving DOTS observers’ quality as follows: to improve DOTS observer’s health, caring traits, and safety; to control the number of patients reasonable for one DOTS observer; to strengthen ability in recognizing TB medicine and identifying its side effect; to ensure that updated policy has been understood and implemented by DOTS observers; and to increase the experience sharing and dialogue among DOTS observers. This report can be used as a reference in planning DOTS observer’s training program and in developing DOTS policy.

**Keywords:** empowerment education and training, tuberculosis (TB), DOTS observers,

## Introduction

It is estimated that a total of 2 billion people, accounted for one third of the world’s population, is currently infected with tubercles bacillus world wide, and around 5-10% of those infected develop tuberculosis (TB) [1]. In Taiwan, TB is the notifiable disease with the largest number of cases and deaths, with an incidence of 68 cases per hundred thousand populations and a mortality of 3.6 cases per hundred thousand populations in 2006 [2]. In order to control TB effectively, Taiwan government initiated the “Mobilization Plan to Reduce by Half the Occurrence of Tuberculosis in a Ten-Year Period” and set the goal to reduce half of the incidence of TB in each county in complying to the Global Plan to Stop TB 2006-2015 developed by the Stop TB Partnership, and the suggestions provided by experts and researchers. To reach the goal, the plan adopted the Directly Observed Treatment Short-Course (DOTS) strategy as recommended by the World Health Organization [3]. Based on studies conducted in Taiwan and other countries, the completed treatment rate was only 28-50%, default rate was 5-9.1%, and death rate was 37.7-45.5% among TB cases without DOTS management, compared with the completed treatment rate 75-89%, default rate 0-3.5%, and death rate 13.6-16.7% among those with DOTS management. This supports that DOTS management can improve the completed treatment rate and decrease the default rate

and death rate of TB cases [4-6]. Undoubtedly, the DOTS observers play a very important role in DOTS implementation. They not only need to assist patients to correctly complete medicine intake for TB treatment but also act as a significant bridge between the medical care system and the patients [7-8].

DOTS observers stand in the first line of TB control in terms of the public health intervention. They have the responsibilities of correctly sending anti-TB drugs to patients and observing the patients actually swallowing the drugs, monitoring the occurrence of side effect among patients, routinely participating the meeting and discussion on management of DOTS cases, and assisting the patients' contacts to complete TB screening test [7-8]. In order to successfully achieve the goals of this mission, DOTS observers should be trained and educated continually to maximize their capabilities. Therefore, Taiwan Centers for Disease Control (Taiwan CDC) clearly requires in the DOTS strategy implementation plan that DOTS observer should complete at least 16 hours of pre-job training and a minimum of 12 hours of on-the-job training [9]. Although this requirement has been enforced for several years in Taiwan, no studies on the effectiveness of the training course on the elevation of capability of DOTS observer have been published. In order to prevent the training activity from a mere formality and to definitely fulfill the spirit of DOTS strategy, the effectiveness of empowerment training to DOTS observers is worthy of further exploration. Therefore, we conducted an evaluation on the effectiveness of empowerment training course administered

by the Kaohsiung City government for the elevation of empowerment of DOTS observer, to provide health authorities with a reference in performing the program of elevating the working ability of DOTS observer.

### **Materials and Methods**

The one-group pretest-posttest design was employed and DOTS observers working for the Department of Health of Kaohsiung City Government were included as study subjects in this study. All of the subjects were provided with a one-day training course designed specifically for DOTS observers, with the course arrangement focused on the issues closely related to DOTS activity and highlighted in the TB Control Manual instituted by Taiwan CDC [9], including the provisions of the Communicable Disease Control Act and TB control policy, emotional management and communication skill, health management and health improvement of TB patients, sharing of experience in DOTS implementation, and dialogue among observers (Table 1).

To collect data, a structural questionnaire was given to observers who agreed to participate in this study before and after the training intervention and the questionnaire was filled out in anonymity. The structural questionnaire was created in referring to previous studies [7-9], including three major parts. The first part lists seven questions on basic information of participants, including sex, age, marital status, education, and occupation. The second part has twelve questions on knowledge about regulations and TB control. Questions 1-8 is "yes or no" questions and 9-12 is "fill in the blank"

**Table 1. Summary of DOTS observer training program**

Topics	Course goals	Course outlines	Time	Type
Notifiable Communicable Disease Control Act & TB Control Policy	<ol style="list-style-type: none"> <li>1. to know current TB control policy</li> <li>2. to know the process of lab test for TB case and conditions to take specimen from contacts, to improve lab test quality and number of tested contacts</li> <li>3. to understand isolation policy of TB case and to assist local government to enforce national law</li> </ol>	<ol style="list-style-type: none"> <li>1. notification and confirmation of TB case</li> <li>2. mobilization plan to reduce TB by half in ten years</li> <li>3. current TB control policy</li> <li>4. TB isolation policy</li> <li>5. DOTS policy</li> <li>6. laboratory test of TB</li> <li>7. contact screening policy</li> </ol>	50 min	lecture
Emotional management & Communication skill	<ol style="list-style-type: none"> <li>1. to know the emotional management tips and communication skill</li> <li>2. to perceive own daily emotional appearance and communication skill</li> <li>3. to learn interview skill and application</li> </ol>	<ol style="list-style-type: none"> <li>1. definition of emotion</li> <li>2. effective emotional management</li> <li>3. methods to relief emotion</li> <li>4. ways of communication</li> <li>5. obstacle occurred in communication</li> <li>6. successful communication skills</li> <li>7. skills for interview</li> </ol>	50 min	lecture discussion
Health management & Health improvement	<ol style="list-style-type: none"> <li>1. to know the tips for maintaining one's healthy life</li> <li>2. to learn the tips for emotional relaxation and to recharge life energy</li> </ol>	<ol style="list-style-type: none"> <li>1. explanation of exercise for energetic life</li> <li>2. exercise practice</li> </ol>	50 min	lecture demonstration
Sharing of experience in DOTS implementation	<ol style="list-style-type: none"> <li>1. to provide a role model through experience sharing of experienced DOTS observers</li> <li>2. to arouse resonance among DOTS observers and to inspire sense of missions in DOTS implementation</li> </ol>	<ol style="list-style-type: none"> <li>1. DOTS experience in homeless citizens</li> <li>2. experience in accompanying patient to visit hospital</li> <li>3. role of DOTS observers in the relationship between doctor and patient</li> <li>4. feedback and response from other DOTS observers</li> </ol>	50min	lecture discussion
Dialogue with, among DOTS observers	<ol style="list-style-type: none"> <li>1. to correctly identify medicine for TB treatment in Kaohsiung areas through creative method, picture card of drug to avoid giving wrong drug</li> <li>2. to answer questions on DOTS implementation</li> <li>3. to improve motivation and efficiency in DOTS activity</li> </ol>	<ol style="list-style-type: none"> <li>1. presentation of picture card of drug used in Kaohsiung areas</li> <li>2. discussion and exchange of experience</li> <li>3. award to individual and group with extraordinary achievement in DOTS</li> </ol>	30 min	discussion award

questions which participant was asked to write the name of medicine shown in the picture. The participant can get a maximum of 12 points, one point for one correct answer and zero point for wrong answer or without an answer. Therefore, the higher scores the participant gets, the better the knowledge about TB he has. Part three is an empowerment measurement sheet containing 23 questions to evaluate the level of confidence and capability of the observer in delivery of TB medicine, communication with patients, cooperation with other members in DOTS team, competency in DOTS implementation, and prevention of self

infection. The five-point Likert-type scale was used to measure the scores of questions in part three. One means “strongly disagree” and 5 was “strongly agree” for all of the questions except two reverse scoring questions that 1 means “strongly agree” and 5 was “strongly disagree.” The two questions are “I feel stressful to work as a DOTS observer, and I am afraid of dealing with uncooperative patients.” Therefore, a higher score obtained by the participant means a higher level of self-perceived empowerment. All three drafted questionnaires were reviewed by five experts and wording modification and

suggestions made by three DOTS observers in other counties and then revised as the final edition. Data collected from the completed questionnaires were encoded, input, and processed by applying the software of SPSS Window14.0 version, and then descriptive and inferential statistical analysis, such as number counting, percentage calculation, mean value and standard deviation estimation, and McNemar test and Paired t-test analysis, were conducted.

## Results

### A. Demographic characteristics of study subjects

Of the 50 DOTS observers in Kaohsiung

City, 44 participated in the study, with 42 valid questionnaires, and two incompletes. The majority (72.7%) of the 42 participants is female at the age of 23-62 years, with an average age of 51.18 years, and the age group with the most number of participants is 50-59 (59.1%). Most (77.3%) of the participants are married and more than half (56.8%) of them has a senior high school diploma. A large part (40.9%) of participants has worked for DOTS for 3-4 years, with an average of 2.84 years. The average time spent for one TB case is 10-20 minutes in a high percentage (75%) of the participants, with a maximum of an average of 10.52 cases for one day (Table 2).

**Table 2. Demographic characteristics of the study subjects (n=44)**

Items	No.	%
<b>Sex</b>		
Male	12	27.3
Female	32	72.7
<b>Age<sup>1</sup></b>		
	<b>(51.18±0.45)</b>	
20-29	1	2.3
30-39	1	2.3
40-49	13	29.5
50-59	26	59.1
60 and older	3	6.8
<b>Marital status</b>		
Single	3	6.8
Married	34	77.2
Divorced	5	11.4
Widowed or living together	2	4.6
<b>Education</b>		
Elementary School	1	2.3
Junior High School	4	9.1
Senior High School	25	56.7
College	9	20.5
University	5	11.4
<b>Years of being DOTS observer<sup>1</sup></b>		
	<b>(2.84±1.84)</b>	
<1	2	4.5
1-2	16	36.4
3-4	18	40.9
5 and more	8	18.2
<b>Average time for one DOTS patient visit<sup>1</sup></b>		
	<b>(19.77±6.48)</b>	
<10 minutes	3	6.8
10-20 minutes	33	75
>20 minutes	8	18.2
<b>Number of cases visited in a day<sup>1</sup></b>		
	<b>(10.52±3.66)</b>	
<5	3	6.8
5-10	15	34.1
11-15	23	52.3
>15	3	6.8

Note: <sup>1</sup> Values are expressed as means plus or minus SD.

**B. DOTS observers’ knowledge about TB before and after empowerment training intervention**

Before training, less than 80% of participants provided a correct answer on next four questions. These are “Only the contacts staying with the index case more than 8 hours in a day or those living together with the index case need to receive screening test.”, “Although TB case has been isolated for treatment, a written notice for mandatory

isolation should still be issued.”, “For cases treated with EMB, vision examination and color vision examination need to be conducted only once in a month.”, and “If a case is 45Kg, has received treatment for three months, and is susceptible to all medicine, the treatment regimen should be RFN 300mg 1# +RFN 150mg 1#+PZA 2#+EMB 2#.” Two of the four questions involved TB control policy and other two were related to TB treatment (Table 3).

**Table 3. DOTS observers’ knowledge about TB control before and after empowerment training intervention (n = 44)**

Questions	Number of participants with correct answer (%)		P- value
	Pre-test	Post-test	
<b>TB control policy</b>			
1. TB patients violate regulation of mandatory isolation will be fined 10-150 thousand NT dollars. (Yes)	40 (90.9)	44 (100.0)	0.125 <sup>1</sup>
2. Although TB case has been isolated for treatment, a written notice of mandatory isolation should still be issued. (No)	34 (77.3)	38 (86.4)	0.344 <sup>1</sup>
3. Based on Article 48, Communicable Disease Control Act, public health sector may conduct screening test for TB contacts. (Yes)	38 (86.4)	42 (95.5)	0.219 <sup>1</sup>
4. Only the contacts staying with the index case more than 8 hours in a day or those living together with the index case need to receive TB screening test. (No)	24 (54.5)	31 (70.5)	0.016* <sup>1</sup>
<b>Overall mean score (SD) for TB control policy</b>	<b>3.09 (0.91)</b>	<b>3.52 (0.73)</b>	<b>&lt;0.001*<sup>2</sup></b>
<b>TB treatment medicine</b>			
1. RFN means anti-TB medicine INH, RMP, and PZA. (No)	39 (88.6)	43 (97.7)	0.125 <sup>1</sup>
2. For TB cases treated with EMB, vision examination and color vision examination need to be conducted only once in a month. (No)	34 (77.3)	43 (97.7)	0.004* <sup>1</sup>
3. If a TB case is 45Kg, has received treatment for three months, and is susceptible to all medicine, the treatment regimen should be RFN 300mg 1# +RFN 150mg 1#+PZA 2#+EMB 2#. (No)	31 (70.5)	33 (75.0)	0.754 <sup>1</sup>
4. For TB cases receiving kidney dialysis, TB medicine should be taken before dialysis. (No)	42 (95.5)	44 (100.0)	0.500 <sup>1</sup>
5. To answer the name of anti-TB drug shown in the picture (RFN)	43 (97.7)	43 (97.7)	1.000 <sup>1</sup>
6. To answer the name of anti-TB drug shown in the picture (PZA)	40 (90.9)	43 (97.7)	0.250 <sup>1</sup>
7. To answer the name of anti-TB drug shown in the picture (RMP)	40 (90.9)	43 (97.7)	0.250 <sup>1</sup>
8. To answer the name of anti-TB drug shown in the picture (INH)	36 (81.8)	42 (95.5)	0.031* <sup>1</sup>
<b>Overall mean score (SD) for anti-TB regimen</b>	<b>6.93 (1.26)</b>	<b>7.59 (0.99)</b>	<b>&lt;0.001*<sup>2</sup></b>
<b>Overall mean score (SD) for knowledge of TB control</b>	<b>10.02 (1.84)</b>	<b>11.11 (1.29)</b>	<b>&lt;0.001*<sup>2</sup></b>

Note: <sup>1</sup>: The results were obtained by performing McNemar test. \*: P<0.05

<sup>2</sup>: The results were obtained by performing Paired t-test. \*: P<0.05

After training, the overall average score for all questions about knowledge of TB control increased from 10.02 to 11.11 points, with a statistically significant difference ( $p < 0.001$ ). The average score for questions involving TB control policy increased from 3.09 to 3.52 points, having a statistically significant difference ( $p < 0.001$ ). The average score for questions related to TB treatment regimen increased from 6.93 to 7.59 points, reaching a statistically significant difference ( $p < 0.001$ ) (Table 3).

#### C. DOTS observers' empowerment level about TB before and after training intervention

Based on the collected questionnaires, the participants' empowerment level in DOTS implementation reaches above the intermediate value before training. The question, "I am confident that I will not wrongly give the patient the medicine for other patients." has the highest score, with an average value of 4.76 points. However, there are five questions that the average score was less than four points. These are, in ascending order, "I feel stressful to be a DOTS observer.", "I am afraid of meeting uncooperative patient.", "I have the ability to identify the side effect that may happen in a patient.", "I have the confidence to persuade the uncooperative patient to take medicine.", and "I am confident that I will not contract TB from the DOTS patient." (Table 4).

After the training, the average score for all questions about participants' overall empowerment in TB increased from 99.93 to 103.29 points, reaching a statistically significant difference ( $p = 0.001$ ). When analyzed by separate issues in part three, the

average score for questions about TB treatment medicine increased from 35.07 to 36.78 points, with a significant difference ( $p < 0.001$ ). Similarly, the average empowerment score for questions involving communication with patient, cooperation with other DOTS team members, and competence in DOTS implementation and TB infection prevention increased from 21.81 to 22.88 ( $p < 0.001$ ), from 26.81 to 27.76 ( $p = 0.006$ ), and from 16.24 to 16.92 ( $p = 0.002$ ), respectively, showing a significant difference in each of them (Table 4).

### Conclusions and Suggestions

This study shows that the empowerment training can improve TB knowledge and enhance empowerment level of DOTS observers. Based on the results of the study, we proposed five recommendations to improve DOTS observers' quality as follows:

#### A. To improve DOTS observer's health, caring traits, and safety

This study shows that although the score for questions of both "I am confident that I will not contract TB from the DOTS patient." and "I feel stressful to be a DOTS observer." was at intermediate level, but it was lower than other questions. Therefore, it is necessary to strengthen the empowerment in infection prevention and stress relief so as to improve DOTS observer's health. In order to avoid the DOTS observers, the workers at the first line of TB control, being infected from DOTS cases and know how to manage stress, things can be done in three ways [8-10]: infections sources, transmission routes, and host immunity. For infections sources, the infectivity of DOTS case can be determined



**Table 4. Empowerment level of DOTS observers before and after empowerment training intervention (n = 42)**

Questions	Mean Pre-test	(SD) Post-test	P-value <sup>1</sup>
<b>Delivery of TB medicine</b>			
1. I have the ability to identify the side effect that may happen in my TB patient.	3.76(0.79)	4.21(0.65)	<0.001*
2. I have the confidence to persuade even the uncooperative patient to take medicine.	3.80(0.68)	4.26(0.70)	<0.001*
3. I have the confidence to complete the missions of correctly delivering anti-TB medicines to patient, observing the patients taking correct dosage of the medicine, and ensuring the patient swallowing the correct dosage.	4.74(0.50)	4.86(0.35)	0.058
A. I can correctly judge whether I have delivered the item and dosage of anti-TB medicine as it is described in treatment guideline.	4.33(0.68)	4.55(0.63)	0.048*
5. I am confident that I will not wrongly give the patient the medicine for other patients.	4.76(0.43)	4.83(0.38)	0.262
6. I am confident that my patient is satisfied to the time delivering the medicine.	4.60(0.50)	4.60(0.59)	1.000
7. I am confident that I can correctly input the daily record of my DOTS patient into the computer.	4.64(0.53)	4.79(0.42)	0.183
8. I am confident that my DOTS patient will complete full course of medicine treatment.	4.45(0.63)	4.69(0.47)	0.006*
Mean value of sub-total score (SD)	35.07(2.51)	36.78(3.03)	<0.001*
<b>Communication with patients</b>			
1. I am confident of maintaining a good relationship with DOTS patients.	4.60(0.57)	4.62(0.54)	0.534
2. I am afraid of meeting uncooperative patient. (reverse question)	3.30(1.15)	4.21(0.65)	<0.001*
3. I have confidence to build up a credible relationship with my DOTS patients.	4.57(0.59)	4.60(0.59)	0.800
4. I am confident that I have a good communication with my DOTS patients.	4.59(0.59)	4.71(0.55)	0.168
5. I am confident that I can enduringly listen to any voice from my DOTS patients.	4.67(0.53)	4.79(0.42)	0.168
Mean value of sub-total score (SD)	21.81(2.53)	22.88(2.04)	0.002*
<b>Cooperation with other members in DOTS team</b>			
1. I have confidence "to immediately forward any problems from DOTS patients" to my nurse supervisor.	4.69(0.56)	4.81(0.40)	0.133
2. I have confidence to maintain a good communication with my nurse supervisor.	4.74(0.50)	4.81(0.40)	0.372
3. I have confidence to find support resources for solving problems that I may encounter when visiting DOTS patients.	4.27(0.54)	4.50(0.55)	0.006*
4. I am confident that I can share any information about my DOTS patients with other team members in DOTS meeting.	4.40(0.54)	4.55(0.55)	0.083
5. I am confident that I can assist my nurse supervisor to facilitate TB screening test of contacts.	4.43(0.63)	4.55(0.59)	0.133
6. I will fully cooperate with other members in DOTS team to refer my patient to pertinent hospital.	4.29(0.60)	4.55(0.55)	0.010*
Mean value of sub-total score (SD)	26.81(2.47)	27.76(2.37)	0.006*
<b>Competency in DOTS implementation and prevention of TB infection</b>			
1. I am confident that I am a competent DOTS observer.	4.55(0.59)	4.62(0.54)	0.183
2. I am confident that I will not contract TB from the DOTS patient.	3.85(0.98)	4.14(0.95)	0.012*
3. I feel stressful to be a DOTS observer. (reverse question)	3.24(1.03)	3.38(1.10)	0.244
4. I think that it is sacrosanct to be a DOTS observer.	4.60(0.63)	4.79(0.47)	0.031*
Mean value of sub-total score (SD)	16.24(2.16)	16.92(2.02)	0.002*
<b>Mean value of overall total score (SD)</b>	<b>99.93±8.07</b>	<b>103.29±8.35</b>	<b>0.001*</b>

Note: <sup>1</sup>The results were obtained by performing Paired t-test, \*: P<0.05.

through sputum test. Based on the TB Control Manual, sputum positive TB cases should receive sputum test monthly until they are negative. Therefore, DOTS observer should update the result of sputum test of the DOTS cases so that he can not only know whether the DOTS cases should receive sputum test in the following month but also determine the infectivity of the DOTS cases so that he can take protective measures in good time to avoid being infected [9]. As to the transmission route, since TB is spread through airborne means, DOTS observer should either advise TB patient to wear surgical mask or wear N95 mask himself when visiting the patient in a closed space. Furthermore, we suggest that DOTS observer should open the windows of the room to maintain a fresh air supply and the observer himself should stay upwind to avoid infection [10]. Regarding host immunity, the course of “health management and health improvement” in the training program was just purposely arranged to let DOTS observers learn the tips for emotional relaxation and recharge their life energy. In addition, DOTS observer should receive yearly health examination to detect disease early and cure early [8-9].

Another issue is that most of the DOTS observers in Kaohsiung City are female. Although previous study shows that no significant difference was found between male and female in the commitment of DOTS implementation. This means sex is not a factor of probably affecting the commitment of DOTS observers [11]. However, the mannish trait in male traditionally existed contradiction with some of the caring behavior and this may affect the performance of male in caring of TB

patients. Therefore, for male observers, the value of caring for others should be emphasized and assistance in enhancing caring ability should be provided [12], and, for female observers, training about how to protect their own safety should be strengthened.

#### **B. To control the number of patients reasonable for one DOTS observer**

Based on Article 30 of the Labor Standards Act, a worker shall not have regular working time in excess of eight hours a day and forty-eight hours a week [13]. This study shows that the average time for caring a DOTS patient is about 10-20 minutes. Adding the time spent in transportation, it takes an average of 30 minutes for one patient. Occasionally, they may need to deal with incident in patient or accompany the patient to visit hospital. Therefore, the TB Control Manual proposes that a reasonable arrangement should be one DOTS observer for ten TB patients. The average number of TB patients for one DOTS observer in Kaohsiung City was 10.52 cases a day. Although the number of TB patients may be more or less during a period of time, it is being controlled in a number of not exceeding 16 cases. In addition, since patients are central to DOTS implementation, in order to assist the patient to complete the course of treatment, it is inevitable to send TB medicine to the patient on a holiday. Therefore, DOTS observer may need to work for at least five or more days a week or even on holidays [9]. In order to ensure good quality care for TB patients and follow the regulations of the Labor Standards Act, we suggest that the number of patients and the number of days off work for each DOTS observer should be checked regularly on a

monthly basis, and the number of DOTS observers should be adjusted appropriately.

### **C. To strengthen ability in recognizing TB medicine and identifying its side effect**

To ensure that TB patients have properly been given the right medicines, the medicines for DOTS patients in Kaohsiung City were prepared and checked by two professional workers followed the Standard Operating Procedures for "Sending TB Medicine". The patient's name, date, and medicine name and dosage were marked on medicine bag. This is probably the reason why the question "I am confident that I will not wrongly give the patient the medicine for other patients." has recorded the highest score. However, because a wide range of medicines have been used in clinical treatment, the medicine with the same name may have three different shapes; some DOTS observers may not recognize the name among them. Therefore, we arranged the activities of creative sharing among observers in the training program by sharing the creative method of using a card with drug picture to correctly recognize TB medicine administered in Kaohsiung areas. These activities have contributed to the improvement of knowledge in recognition of TB medicines. To ensure the accuracy of TB medicine given to patients, DOTS observers could not just be a transporter conveying the medicines prepared by professional personnel. They also need to clearly know what it looks like to enhance the safety of medication usage among TB patients. Therefore, we suggest that picture cards for each TB medicine could be created and be considered as a torch handed over to new DOTS

observers, and that a medicine recognition test should be conducted to DOTS observers.

In addition, the pretest score for question "I have the ability to identify the side effect that may happen in my TB patient" was lower than other questions, and the question "If a TB case is 45Kg, has received treatment for three months, and is susceptible to all medicine, the treatment regimen should be RFN 300mg 1# +RFN 150mg 1#+PZA 2#+EMB 2#." recorded the lowest pretest score. This indicates that the knowledge in identification of side effect caused by TB medicine and in the complicated treatment regimen for TB cases should be strengthened in DOTS observers. The commonly occurred side effects in TB medicine include neuropathy (side effect of INH), skin itching (INH, RIF, and PZA), blurred vision (EMB), renal failure (Streptomycin), and gastrointestinal upset (INH, RIF, and PZA) [14]. However, these are side effects anticipated based on pharmacological knowledge. In practice, the TB cases are often accompanied with other disease and, therefore, may simultaneously take medicine for treatment of other diseases. Thus, DOTS observers working in the first line of TB control have to know the handling procedures for uncomfortable complaints that they may face in caring TB patients, and must immediately report any complaints to nurse supervisor who will determine whether side effects have occurred and whether the TB patients need to be referred to specific physician or just sent to a clinic directly. We also suggest that the ability in identification of side effects should be emphasized in training program in the future through sharing of real example or picture. In addition, for TB cases

with complicated treatment regimen, public health nurses should take it as an example and give DOTS observers an opportunistic education so that they can understand the reason why such complicated regimen has been prescribed for the patients. Moreover, public health nurses should encourage DOTS observers to attend TB case confirmation review meeting held in Kaohsiung, Pingtung, and Penghu areas in order to improve their ability in dealing with TB cases with special conditions.

**D. To ensure that updated policy has been understood and implemented by DOTS observers**

As stated in the TB Control Manual, from January 1, 2010 on, the contacts of TB cases need to receive screening test were expanded from only those staying with the index case more than 8 hours in a day or those living together with the index case to those staying with the index case with an accumulation of 40 hours or more during infectious period. However, around 40-50 percent of participants did not know about the new screening policy before attending the program. Contact screening test has the function of helping to identify infection sources, to give prophylactic treatment to infected contacts timely, and to early send ill TB contact to hospital [9]. The number of contacts receiving TB screening test in Kaohsiung City is lower than others. DOTS observers visit TB patients at least five days a week. If they can keep updated with policy development, they will be able to report to DOTS team about the contacts meeting the definition of screening test but not yet receiving the test, and this will, therefore,

increase the number of tested contacts. Therefore, it is important for DOTS observers to keep updated with policy development.

In addition, the document issued by the Department of Health on April 16, 2010 required that, in order to monitor the occurrence of side effect, optic neuritis, among TB cases receiving EMB treatment, DOTS observers should conduct color vision examination for TB cases at least once in a week during the period of DOTS implementation. However, around 20-30 percent of DOTS observers still conducted this examination in a frequency of once in a month. Although the scores obtained by DOTS observers for the above two questions have significantly increased after training, we suggest that all DOTS observers should be timely informed of any newly developed policy, such as to inform all DOTS observers by using a written notice described the policy and by asking them to sign their name on it to make sure that they have read and understood the policy or to strengthen the dissemination of the policy on DOTS case management meeting. In addition, public health nurse should take the responsibilities to monitor the implementation of the policy and to make sure that DOTS observers have really followed the policy so as to protect the right of TB cases.

**E. To increase the activities of experience sharing and dialogue among DOTS observers**

This study shows that the pretest score for questions “I am afraid of meeting uncooperative patient.” and “I have the confidence to persuade even the uncooperative patient to take medicine.” were lower than other questions. This indicates that

it is a challenge for DOTS observers to deal with the uncooperative patients. Therefore, an activity about “DOTS experience in homeless citizens” was arranged in the empowerment training program. In this activity, experienced DOTS observers were invited to share their experience in handling the homeless TB patients to allow other DOTS observers to learn the skills for managing uncooperative patients and to have opportunities for sending feedback and exchanging experience, and, in the end, to enhance DOTS observers’ sense of job satisfaction and accomplishment. Another activity “dialogue with, among DOTS observers” was arranged to understand the DOTS observers’ difficulty in DOTS implementation, to let DOTS observers know the available resources, and to allow DOTS observers to perceive that DOTS patient management is the common responsibility of members in the DOTS team which each role in DOTS implementation is essential and closely associated. It is just like the Taiwan CDC’s slogan, “Disease Control Is Just Like A Battle, to Be Consolidated, Specialized, and Toiled for Winning.” The scores obtained by participating DOTS observers for the two questions after empowerment training were significantly improved. Therefore, we concluded that training program should not merely arrange lectures on medical knowledge and should include the courses of experience sharing and dialogue among DOTS observers to enforce the goals of empowerment training.

### Limitations

There are two limitations of this study. First, the study subjects include only the

DOTS observers in Kaohsiung City, which makes the conclusions unable to be inferred to DOTS observers in other geographical areas. Therefore, more DOTS observers in other areas could be included in future studies to enhance the ability of inference. Second, the pretest and posttest were conducted immediately before and after the training, the results reflect only the instant changes in their minds. However, we are not sure whether the training intervention to DOTS observers has produced influence on their practices. A study to evaluate the efficacy of training intervention in practical implementation of DOTS observers is, therefore, worthy to be conducted in the future.

### Acknowledgements

We would like to thank Health Station of Cianzhen District in Kaohsiung City for the generous provisions of picture in TB medicine used in Kaohsiung and Pingtung areas.

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