



ANNUAL
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REPORT

2014-2015

TDF



Our Vision

Equitable universal access to health for economic prosperity

Our Mission

National and local community development through research, training, service, and healthcare delivery in the prevention and control of infectious diseases of public health importance.

Our Thrusts

To conduct research, training and service in infectious diseases of public health importance

To enter into partnership with public and private agencies in the implementation of programs in the control of infectious diseases

To enter into partnership with national and international institutions involved in research to ensure technology transfer

To ensure technology transfer that cured patients in developing human resources for health nationally and internationally through collaboration with national and international institutions

To serve as a national and international training center for infectious diseases

Introduction

For the year 2014 -2015, the Tropical Disease Foundation continues its involvement to pursue excellence in research. A new clinical trial to assess the efficacy, safety and tolerability of a combination of moxifloxacin, PA-824, and pyrazinamide treatments with varying doses and treatment lengths in subjects with drug-sensitive (DS) pulmonary TB compared to standard HRZE treatment was undertaken by TDF. TDF Laboratory was chosen to serve as its central laboratory among four (4) sites. Clinic also served as one of the clinical sites to support the study.

TDF continues to thrive in conducting quality trainings on tuberculosis as one of its thrusts. One of the highpoints in training service was the participation of Ms. Claudette Guray, member of the TB Infection Control Core Group, a sub-working group of the Stop TB Partnership as resource speaker in the panel group discussion on “Ways to scale-up TB Infection Control activities nationally and build country capacity.” The activity was conducted in Barcelona, Spain as part of the 45th Union World Conference on Lung Health sponsored by the International Union Against Tuberculosis and Lung Disease.

The findings of operational research conducted by TDF in the first and second quarter of 2014 regarding reasons for patients’ loss to follow-up during MDR-TB treatment in the Philippines was presented by Dr. Thelma Tupasi presented to stakeholders last September 25, 2014. The findings of this study will be helpful to the National TB Program of the government in finding a better approach in addressing issues on why patients failed to continue TB treatment.

SERVICES



DOTS Clinic

In line with TDF's mission statement of equitable universal access to health, TDF's DOTS clinic continue to provide services and support to the needs of patients suffering from Tuberculosis.

Target patients are residents of Makati area located within the 2 kilometer radius. Patients who belong to the working sector are also attended to in the clinic. Clinic is open until 7:00PM to accommodate this working group.

The table below represents the clinic census as of July 2015:

No. of Screened Patients	228 patients
No. of Patient's Enrolled	49 patients
Outcome Breakdown:	
Screen Failure	32 (66%)
Cured	11 (22%)
Loss to Follow-up	2 (4%)
Died	1 (2%)
Failed	1 (2%)
Not Evaluated	2 (4%)

TDFI – Satellite Treatment Center for MDR-TB

The performance of the Satellite Treatment Center in the past year is as follows:

No. of Presumptive DRTB Screened	54 patients
No. of Confirmed RR-TB	39 patients
All DRTB cases registered	58 patients

Aside from being a source of potential study subjects, the STC also allows the Foundation to provide continuing care for screening of failed subjects, as well as those who discontinued.

External Quality Assurance (EQA) for Laboratory Tests

The TDF laboratory regularly participates in EQA provided by the National TB Program- CHD Makati, and Bangkok National TB Reference Laboratory for microscopy test using ZN and Auramine O respectively. In addition, the TDF laboratory has participated in the EQA provided by Integrated Quality Laboratory Services (IQLS), based in Lyon, France since December 2011. The IQLS provides quality assurance for AFB smear microscopy using Auramine O, TB culture identification, and DST on MGIT both for 1st and 2nd line drugs.

As seen in the table below, TDF's laboratory has performed successfully in the standard diagnostic testing for TB, confirming TDF's adherence to international standards.

TEST	Round 7 (October 2014- December 2014)	Round 8 (May 2015- July 2015)
Microscopy (Fluorescent)	95.00%	91.75%
TB culture identification	100%	100%
DST- 1st Line Drugs (MGIT)	94.25%	97.25%
DST- 2nd Line Drugs	97.50%	97.50%
Average	96.69%	96.63%



Study 213

Protocol Title: “A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group Trial to Evaluate the Safety and Efficacy of Delamanid (OPC-67683) Administered Orally as 200 mg Total Daily Dose for Six Months in Patients With Pulmonary Sputum Culture-positive, Multidrug-resistant Tuberculosis”.

The current enrolment and treatment status are below:

Randomized	21 patients
Completed Period 1 (with IMP/Placebo)	16 patients
Discontinued Period 1 (with IMP/Placebo)	5 patients
Completed Period 1 (with IMP/Placebo)	16 patients
With Treatment Outcome	17 patients
Ongoing Treatment.....	4 patients
Completed Study Visits at Month 30	6 patients

MSD Trial (OnceMRK)

“A Phase III Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Reformulated Raltegravir 1200mg Once Daily Versus Raltegravir 400mg Twice Daily, Each in Combination with TRUVADATM, in Treatment-Naive HIV-1 Infected Subjects”

Sponsored by Merck Sharp & Dohme, TDF was designated as a site for a clinical trial that aimed to expand the options for the treatment of HIV-1 infected subjects. The study is headed by Dr. Carmenchu Echiverri as Principal Investigator.

Site Enrolment Status

Subjects Screened	13 patients
Subjects Randomized	10 patients
Screen Failures.....	3 patients
Discontinuations	16 patients

TB in Jail

Philippine jails are overcrowded and poorly ventilated. These conditions, added to the limited of access to treatment, allow the TB bacilli to thrive making the inhabitants vulnerable to the disease. In 2012, a prevalence study conducted in Philippine jails by Borja et al showed that

CRX positive TB, smear positive TB, and culture positive TB registered at 35%, 12.5% and 21.2% respectively. The same study also revealed that the incidence of bacteriologically confirmed pulmonary TB in prisons was 4 – 5 times higher compared to the general population.

Considering this, the Innovations and Multisectoral Partnerships to Achieve Control of Tuberculosis (IMPACT) and the International Committee of the Red Cross (ICRC) carried out a study to determine the actual number of tuberculosis (TB) cases in the Quezon City Jail and to manage them according to the National TB Control Program in order to lead to a decrease in inmate mortality and morbidity due to TB. The study also examined the patterns of resistance and susceptibility using first and second line anti-TB drugs, performed comparative analysis if culture and DST results between the conventional culture method and the molecular method using the GeneXpert machine.

As an integral part of the study, the Tropical Disease Foundation was commissioned to conduct the laboratory examination of the samples collected from the study participants. Sputum samples were transported from the Quezon City jail and the tests performed by TDF medical technologists. The results were then transmitted to the study team.



The research revealed that out of 810 inmates and staff enrolled 29.9% (242 people) were TB positive. Of these, 39.3% (95) were found to be

susceptible to first line drugs. Various levels of drug resistance were discovered in 47.46% of the study population, broken down as follows: 23.6% (57) were found to have mono-resistant TB (resistant to only one first line anti-TB drug), 9.1% (22) were poly-resistant (resistant to more than one first-line anti-TB drug, other than both Isoniazid and Rifampicin), and 14.46% (35) had multi-drug resistant TB (resistance to at least both isoniazid and rifampicin).

RESULT:

Number of inmates enrolled	804
Number of jail staff enrolled	6
TOTAL Number of subjects enrolled	810
TB PREVALENCE	242
TB PREVALENCE RATIO	29.9%

DRUG SUSCEPTIBILITY PATTERN	
PATTERN	
Pan-Susceptible	95.....39.3%
Mono-Resistant	57.....23.6%
Poly-Resistant.....	22.....9.1%
Multi-Drug Resistant.....	35.....14.46%

The TB in Jail research started on June 19, 2014 and ended in October 23, 2014.

LAM Phase III

LAM Phase III is “Evaluation of LAM-ELISA test for the detection of Mycobacterium tuberculosis in sputum specimens of adult pulmonary TB suspects: comparison with AFB smear microscopy, Lowenstein-Jensen medium, the BACTEC MGIT 960 culture, and Xpert MTB/Rif.”

The main objective for LAM Phase III is to determine the sensitivity and specificity of the LAM-ELISA test as compared to the currently available TB diagnostics in the market. Stage 1 of the study officially started in 04 November 2013 while Phase III ended in January 8, 2015.

NC-006 (M-Pa-Z)

The TDF Clinic was designated as one of the sites for the study entitled “A Phase 3 Open-Label Partially Randomized Trial to Evaluate the Efficacy, Safety, and Tolerability of the Combination of Moxifloxacin plus PA-824 plus Pyrazinamide after 4 and 6 Months of Treatment in Adult Subjects with Drug Sensitive Smear-Positive Pulmonary Tuberculosis and After 6 Months of Treatment in Adult Subjects with Multi-Drug Resistant, Smear-Positive Pulmonary Tuberculosis” sponsored by the TB Alliance. Patient enrollment commenced on May 2015.

As part of the study, the TDF Laboratory was designated as the central laboratory for four sites in the Philippines. TDF lab personnel were charged with doing the screening evaluation of sputum smears for AFB as well as rapid molecular tests to determine susceptibility to rifampicin and/or flouroquinolones. DNA was also extracted from the samples and sent to the Stellenbosch University in South Africa to test for susceptibility to pyrazinamide. In addition, the designated central labs for the study also conducted subculture of isolates on LJ slopes. These along with DNA extracted from the slope were sent to the central laboratory at the University College London.



NC006 with
Gabriel Roxas
and Robert Hunt
of TB Alliance





Tuberculosis Infection Control Consultation:

What Are High Burden Countries Doing and How Can These Efforts be Strengthened?

TB infection control (TBIC) is a vital factor in the prevention, diagnosis, and treatment of tuberculosis. However, it is frequently neglected in comparison to other aspects of disease control. The absence, or minimal adherence, to TBIC has led to increased incidents in drug-susceptible and drug resistant TB in in patient and outpatient settings and causing unnecessary and preventable morbidity and mortality among patients and health care workers.

In October 31, 2014, a TBIC consultation facilitated by the CDC and the WHO engaged a panel composing of country representative and TBIC experts to discuss the following:

- the best TBIC practices being implemented in high HIV settings
- the TBIC tools currently being used and available for adaptation
- the best practices in scaling-up TBIC activities which includes healthcare worker surveillance.

Ms. Claudette Guray, TDF Laboratory Manager, who was designated as a member of the TB Infection Control Core Group, was invited as a Resource Speaker in the discussion.

The activity was conducted in Barcelona, Spain as part of the 45th Union World Conference on Lung Health sponsored by the International Union Against Tuberculosis and Lung Disease.

Introduction to Mycobacterium Tuberculosis Diagnostics Program

Members of the TDF Laboratory conducted a one-week intensive training for the staff of Beckton-Dickenson associates, on March 9 – 13, 2015. The training aimed to provide capacity building among BD personnel. Activities included; training, coaching, and bench-work. This partnership established collaboration between the two organizations.

Participants included BD associates from five Asian countries included:

- | | |
|---------------------------------|---------------------------------|
| 1. Charlie Lin- Taiwan | 4. Xueming Qi- China |
| 2. Dijana Davbidovic- Australia | 5. Hong Bao Quyen Tran- Vietnam |
| 3. Annn Cheng- China | 6. Amelito Esquejo- Philippine |

They were trained by TDF Laboratory staff including - Claudette Guray, Laboratory Manager, Mark Bernardino, Anthony Geronimo, Maita Deblois, Ros Joachim Marcelino, Elizabeth Kaye Corpuz, Redentor Puno, Jr., Gina Javier, Christian Lepiten



TDF Laboratory and Management team
with Beckton-Dickton participants



TDF Laboratory team
with Beckton-Dickton participants

“Evaluation of reasons for patients’ loss to follow-up during multi-drug resistant tuberculosis treatment in the Philippines”

A stakeholder’s meeting was organized by Tropical Disease Foundation last September 25, 2014 at H2O Hotel, Manila to present the results, conclusions and recommendations of “Evaluation of reasons for patients’ loss to follow-up during multi-drug resistant tuberculosis treatment in the Philippines.

In her study, Dr Tupasi showed that despite advances in MDR-TB diagnostic and treatment, there has been an increase in the patients lost to follow-up (from 21% – 39%) and a decrease in treatment success rates in 2007 (63%) – 2011 (44%). A third of the patients who were lost to follow-up (LTFU) started treatment with extensively drug resistant TB (XDR-TB) or pre-XDR-TB. For these reasons, the National TB Program, Department of Health requested that a study be done to identify factors associated with LTFU and to document patients’ perspectives on the types and delivery of interventions that could positively impact the prevention or reduction of LTFU among MDR-TB patients.

The study covered 273 patients who were randomly selected from 15 MDR-TB treatment centers. In-depth interviews were done as well as data extracted from their medical records. Once data collection was completed, a thematic analysis generated descriptive statistics of the behavioral data and factors associated with LTFU were identified.

Some of the significant findings include:

1. Independent factors for LTFU from MDR-TB treatment in the Philippines
 - Alcohol abuse
 - Patient's higher self-confidence to adhere to treatment at the time of treatment initiation
 - Self-rated severity of vomiting (Adverse drug reaction)
2. Independent factors protective against LTFU
 - Receiving assistance from the TB Program (e.g. transportation allowance)
 - Patients armed with better general knowledge about TB
 - Higher level of trust and rapport with the Health Care Worker
3. Medication side effects or the fear of side effects was most commonly cited by LTFU patients as their primary reason for non-adherence to treatment.
4. The most effective types of support the National TB Program could provide to help patients adhere to treatment according to patients is the covering of transportation costs for travel to the treatment centers. In view of these, the following recommendations were made:
 - Close and strict monitoring for, and free treatment of Adverse Drug Reaction's (ADR) such as nausea, vomiting, dizziness and extreme fatigue.
 - Assistance with cost of transportation, food, and housing are essential for patients living below or slightly above the poverty line as the lack of these might be an obstacle to treatment adherence. Delays or interruption in the provision of these assistance could cause patients to self-terminate treatment.
 - Address adverse drug reactions by developing a comprehensive list based on the most reported side effects and making ancillary medicines available.

- Provide additional trainings to all PMDT facilities, to aggressively monitor and treat ADRs for free.
- Educate patients on expected side effects prior to the start of treatment.

Philippine Advance Biorisk Officer Training (Batch 3) Personal Protective Equipment

As part of a leading public health foundation specializing in treating infectious diseases of public health importance, TDF staff are given opportunities to share their expertise with others in the field. So in 2015, Ms Claudette Guray, TDF Laboratory Manager, was once again invited to be a Resource Speaker at the Philippine Advanced Biorisk Officer Training (Batch 3) Personal Protective Equipment.

The training was held on June 8, 2015 at the Hotel Centro in Puerto Princesa, Palawan.





CAPABILITY
.....
**& TECHNICAL
ASSISTANCE**

In line with its commitment to excellence, the Tropical Disease Foundation strongly believes in capacity building of its staff. Thus, in 2014 and 2015, the following trainings attended by TDF employees:

VETO, RHOLINE GEM MARTIN S.
UBALDE, JOHN PHILLIP C.

PHILCAT'S 21ST ANNUAL CONVENTION

Aug. 14-15, 2014 / Crown Plaza Hotel
Ortigas Center

GURAY, CLAUDETTE V.

**45TH UNION WORLD CONFERENCE
ON LUNG HEALTH**

Oct. 24-Nov. 3, 2014 / Barcelona, Spain

VETO, RHOLINE GEM MARTIN S.
UBALDE, JOHN PHILLIP C.
BALIWAGAN, MARIA BEGONIA R.

**TRAINING FOR THE NEW MANUAL OF
PROCEDURES FOR THE NATIONAL
TUBERCULOSIS PROGRAM 5TH EDITION**

Nov. 25-27, 2014
Ciudad Christia San Mateo Rizal

VETO, RHOLINE GEM MARTIN S.
BALIWAGAN, MARIA BEGONIA R.
JOSON, EVELYN S.
NAVAL, LEILANI C.
PUNO, REDENTOR JR M.
GERONIMO, ANTHONY A.

**HEALTHCARE INNOVATION SOLUTIONS
SERIES** / November 13, 2014

Intercontinental Manila, Makati City

BERNARDINO, MARK LESTER M.
MARCELINO, ROS JOACHIM S.
CORPUZ, ELIZABETH KAYE A.
GUDA, GLAIZA ERIKA B.

**MICROBIAL GENES & PRODUCTS FOR
DIAGNOSTICS AND THERAPEUTICS**
Nov. 27, 2014 / Trinity University of Asia
Quezon City

DEBLOIS, MAITA B.

**TRAINING FOR THE NEW MANUAL OF
PROCEDURES FOR THE NATIONAL
TUBERCULOSIS PROGRAM 5TH EDITION**
Dec. 2-4, 2014 / Ciudad Christia
San Mateo, Rizal

VETO, RHOLINE GEM MARTIN S.

**MDR TB IN CHILDHOOD AND CLINICAL
TRIAL PREPAREDNESS**
Feb. 17, 2015 / Brentwood Suites,
Quezon City

NAVAL, LEILANI C.
NUCUM, MARITA I.

**THE ESSENTIALS OF HR AND LABOR
LAW COMPANY POLICY**
Feb. 27, 2015 / AIM Conference Center
Makati City

BELEN, JOVITA P.
SEBASTIAN, ANDREA
CABANATAN, MA. LOURDES O.

EVERYTHING ABOUT VAT
Apr. 16, 2015 / AIM Conference Center
Makati City

BELEN, JOVITA P.
NUCUM, MARITA I.

**FRINGE BENEFITS TAX & EMPLOYEES
WITHHOLDING TAX**
Apr. 16, 2015 / AIM Conference Center
Makati City

GURAY, CLAUDETTE V.
GERONIMO, ANTHONY A.
BERNARDINO, MARK LESTER M.

**W.A.V.E. - WORK ATTITUDES AND
VALUES ENHANCEMENT: CREATING
AND NURTURING A VALUE DRIVEN
ORGANIZATION**
Apr. 29, 2015 / AIM Conference Center
Makati City

GURAY, CLAUDETTE V.

**3RD TRAINING PROGRAM FOR
ADVANCED BIOSAFETY
OFFICERS TRAINING COURSE**

Jun. 8-9, 2015 / Puerto Prinsesa, Palawan

NUCUM, MARITA I.
ORTIZ, MARILOU B.
BALIWAGAN, MARIA BEGONIA R.
GURAY, CLAUDETTE V.
GERONIMO, ANTHONY A.
BERNARDINO, MARK LESTER M.

**PRO-ACTIVE SUPERVISION AND
LEADERSHIP SKILLS**

Jun. 25, 2015 / AIM Conference Center
Makati City

NUCUM, MARITA I.
ORTIZ, MARILOU B.
BALIWAGAN, MARIA BEGONIA R.
JOSON, EVELYN S.

**PRACTICAL PROBLEM SOLVING AND
DECISION MAKING SKILLS**

Jun. 25, 2015 / AIM Conference Center
Makati City

CARIDAD, MA. TERESA A.

**HANDLING COMPLAINTS AND DEALING
WITH UNHAPPY CUSTOMERS**

Jul. 9, 2015 / AIM Conference Center
Makati City

NAVAL, LEILANI C.

**STRATEGIC PLANNING AND
INNOVATION**

Jul. 20-24, 2015 / Kuala Lumpur, Malaysia

UBALDE, JOHN PHILLIP C.
DALUZ, ABIGAIL S.

**PROVIDER INIATIATED HIV &
COUNSELING & TESTING**

Jul. 28-30, 2015 / Ciudad Christia, Ampid,
San Mateo, Rizal

DEBLOIS, MAITA B.

**PMDT TB PROGRAM IMPLEMENTATION
REVIEW AND DATA QUALITY CHECK**

Jul. 27-29, 2015

MARCELINO, ROS JOACHIM S.

TRAINING ON HIV PROFICIENCY TESTING

Jul. 27-31, 2015 / RITM, Muntinlupa City

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Publications

August 2014 to July 2015

1. Yuen CM, Kurbatova EV, Tupasi T, Caoili JC, Van Der Walt M, Kvasnovsky C, Yagui M, Bayona J, Contreras C, Leimane V, Ershova J, Via LE, Kim H, Akksilp S, Kazenny BY, Volchenkov GV, Jou R, Kliiman K, Demikhova OV, Vasilyeva IA, Dalton T, Cegielski JP. "Association between Regimen Composition and Treatment Response in Patients with Multidrug-Resistant Tuberculosis: A Prospective Cohort Study." *PLoS Med.* 2015 Dec 29;12(12):e1001932. doi: 10.1371/journal.pmed.1001932. eCollection 2015 Dec. PMID:26714320
2. Cegielski JP, Kurbatova E, van der Walt M, Brand J, Ershova J, Tupasi T, Caoili JC, Dalton T, Contreras C, Yagui M, Bayona J, Kvasnovsky C, Leimane V, Kuksa L, Chen MP, Via LE, Hwang SH, Wolfgang M, Volchenkov GV, Somova T, Smith SE, Akksilp S, Wattanaamornkiet W, Kim HJ, Kim CK, Kazenny BY, Khorosheva T, Kliiman K, Viiklepp P, Jou R, Huang AS, Vasilyeva IA, Demikhova OV; Global PETTS Investigators. "Multidrug-Resistant Tuberculosis Treatment Outcomes in Relation to Treatment and Initial Versus Acquired Second-Line Drug Resistance." *Clin Infect Dis.* 2016 Feb 15;62(4):418-30. doi: 10.1093/cid/civ910. Epub 2015 Oct 27. PMID:26508515
3. Kurbatova EV, Dalton T, Ershova J, Tupasi T, Caoili JC, Van Der Walt M, Kvasnovsky C, Yagui M, Bayona J, Contreras C, Leimane V, Via LE, Kim H, Akksilp S, Kazenny BY, Volchenkov GV, Jou R, Kliiman K, Demikhova OV, Cegielski JP. "Additional drug resistance of multidrug-resistant tuberculosis in patients in 9 countries." *Emerg Infect*
4. Kurbatova EV, Cegielski JP, Lienhardt C, Akksilp R, Bayona J, Becerra MC, Caoili J, Contreras C, Dalton T, Danilovits M, Demikhova OV, Ershova J, Gammino VM, Gelmanova I, Heilig CM, Jou R, Kazenny

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5. Cegielski JP, Chen MP, Tupasi TE, Leimane V, Volchenkov GV; "Reply to Soman et al, Alffenaar et al, Metcalfe et al, and Raoult." Global Preserving Effective TB Treatment Study Investigators. " *Clin Infect Dis*. 2015 Mar 15;60(6):971-3. doi: 10.1093/cid/ciu1150. Epub 2014 Dec 19. No abstract available. PMID:25527654
6. Bastos ML, Hussain H, Weyer K, Garcia-Garcia L, Leimane V, Leung CC, Narita M, Penã JM, Ponce-de-Leon A, Seung KJ, Shean K, Sifuentes-Osornio J, Van der Walt M, Van der Werf TS, Yew WW, Menzies D "Treatment outcomes of patients with multidrug-resistant and extensively drug-resistant tuberculosis according to drug susceptibility testing to first- and second-line drugs: an individual patient data meta-analysis."; Collaborative Group for Meta-analysis of Individual Patient Data in MDR-TB. *Clin Infect Dis*. 2014 Nov 15;59(10):1364-74. doi: 10.1093/cid/ciu619. Epub 2014 Aug 5.
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