

## RESEARCH ARTICLE

# Pharmacy DOTS Initiative (PDI): A case study on integrating pharmacies in the tuberculosis directly observed treatment-short course (TB DOTS) network in the Philippines

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### ABSTRACT

**Background:** Tuberculosis (TB) is a disease that has continuously burdened Filipinos. Various programs have been launched by public and private sectors to decrease the incidence of TB and to scale up TB prevention and control in the country. In line with this, pharmacists have been contributing to the campaign against TB since 2004 through the implementation of the Pharmacy DOTS Initiative (PDI). Through the project Innovations and Multi-Sectorial Partnerships to Achieve Control of TB (IMPACT), PDI was relaunched in the country in 2014.

**Objectives:** This case study aims to evaluate the impact of PDI on TB prevention and control by assessing the effectiveness of the technical assistance package rolled out during program implementation.

**Methods:** A review of documents was done to evaluate the achievement of the specific targets of PDI.

**Results:** Among the targets, the percentage of actively referring pharmacies and the number of referrals made throughout the program failed to meet the target. The remaining program targets such as the establishment of a referral system, training of pharmacy personnel, adoption of a TB DOTS curriculum in pharmacy schools, and presence of national legislation, policies, and guidelines relevant to PDI were satisfactorily met.

**Conclusion:** PDI had a good response at the start of its implementation, but several issues resulted in the inability to sustain the interventions and achieve set targets.

**Keywords:** tuberculosis, program evaluation, case study, Philippines

## Introduction

The Philippines is one of 30 high-burden countries that contribute more than 85% to all tuberculosis (TB) cases worldwide. According to recent global reports, the incidence of TB in the Philippines in 2015 was estimated at 322 per 100,000 population (95% uncertainty interval [UI]: 277 - 370 per 100,000), and accounted for 3.47% of total disability-adjusted life years (DALY) in the country (95% UI: 3.19% - 3.75%) [1,2]. Furthermore, in 2013, the Philippine Department of Health (DOH) reported TB as the eighth leading cause of morbidity (71.5 per 100,000 population)

and mortality (23.7 per 100,000 population) among Filipinos [3]. The burden of disease is further complicated by the emergence of drug-resistant strains. According to the World Health Organization (WHO), the Philippines is one of 30 countries with high-burden for multi-drug resistant (MDR) TB with an estimated incidence of 17 per 100,000 population (95% UI: 14 - 20 per 100,000 population) [1,4]. These estimates were attributed to the discontinuity in the screening-diagnosis-treatment continuum and deviations from standards of care for TB in the country [5].

In the past two decades, programs were developed for TB prevention and control. Among these, the Directly Observed Treatment Short Course (DOTS) chemotherapy strategy has been implemented on a global scale. In addition, the Millennium Development Goals brought more attention and investment in TB prevention and control [1,5].

The pharmacy is often the first health facility that a patient can access. Therefore, pharmacists are in the best position to detect possible TB cases and conduct referrals to the proper facilities [6]. The involvement of pharmacists in TB prevention and control in the Philippines started in 2004. The Pharmacy DOTS Initiative (PDI) was conceptualized by the Philippine Tuberculosis Initiatives for the Private Sector (PhilTIPS) through the United States Agency for International Development (USAID) [7]. Through this initiative, pharmacy personnel participated in training programs that aimed to increase knowledge on TB, discourage dispensing of anti-TB drugs without a valid prescription, and refer patients to TB facilities.

PDI was re-implemented by the Linking Initiatives and Networking to Control Tuberculosis (TB LINC) in 2010 and Philippine Pharmacists Association (PPhA) in 2012. Through this initiative, pharmacies engaged in a pilot program that was expected to contribute to improving TB case detection and cure rates. However, the reduction in the proportion of patients who self-medicate remained low because of the relatively small number of pharmacies engaged [8].

Finally, in 2014, the project Innovations and Multi-Sectorial Partnerships to Achieve Control of TB (IMPACT) was launched by USAID Philippines through the Philippine Business for Social Progress (PBSP). Through this project, PPhA was awarded a sub-grant as the technical assistance provider to scale up the number of pharmacies engaged in PDI for the period of January 2014 to September 2016 [9].

The goal of IMPACT was to address high TB incidence and gaps in clinical practice for TB. A case study on the implementation of PDI is an essential component in evaluating its impact on TB prevention and control. This case study aims to assess the effectiveness of the technical assistance package delivered through the PDI. Specifically, this study outlines and summarizes the effectiveness of PDI based on specific targets, namely: (1) at least 60% of pharmacies actively implementing PDI in the identified implementation sites; (2) presence of a referral system and its reporting and recording elements (*e.g.*, referral slips, TB referral logbook); (3) 3,000 pharmacists, pharmacy

assistants, and owners trained on PDI; (4) 100% of member schools of the Philippine Association of Colleges of Pharmacy (PACOP) adopting the TB DOTS Curriculum; (5) 60,000 presumptive TB cases referred to DOTS facilities; and (6) presence of national legislation, policies, and guidelines relevant to PDI (*e.g.*, Philippine Pharmacy Act, National Dispensing Guidelines, etc.)

## Methodology

A review of documents submitted by the PDI Project Team to PBSP was conducted to assess the effectiveness of the technical assistance package. The documents submitted to PBSP include the technical assistance package, eight quarterly reports and one annual report, and the final technical report. Data on effectiveness indicators were iteratively abstracted by research assistants/associates from source documents, and encoded in data abstraction forms. Abstracted data were inspected by a separate set of research assistants/associates to check for accuracy and consistency of abstraction and encoding.

To monitor the demand for TB services, the number of pharmacies engaged in PDI and the number of presumptive TB cases referred to DOTS facilities were selected as indicators. An increase in the demand was indicative of improved health-seeking behaviors and practices. In assessing the improvement and expanded capacity of private providers to deliver DOTS services, the number of pharmacy personnel trained on PDI was considered. Lastly, the improvement in policy and financing environment for private sector involvement was evaluated through the presence of national legislation, policies, and guidelines relevant to PDI. The enforcement of national legislation and policies was recognized to be essential to ensure the sustainability of the pharmacy sector's contribution to TB control.

For the implementation of PDI, there were 33 sites chosen across the country. Community pharmacies, hospital pharmacies, and DOTS facilities were mapped in the 33 implementation sites. The engaged pharmacies from the mapped PDI implementation sites committed to strengthen the DOTS referral system. These pharmacies were provided with referral slips and TB referral logbooks. The local government units (LGU) and National TB Control Program (NTP) coordinators were oriented on the referral slips distributed to engaged pharmacies. They were instructed to accept these referral slips and record them as pharmacy sector contribution. The patient information

recorded in the filled-out referral slips were collated by the PDI area coordinator and summarized for submission to the Provincial or City Health Office. TB referral logbooks were developed and distributed to record the names of presumptive TB patients referred to DOTS facilities.

Trainings were conducted for proper orientation on PDI interventions to be executed under the PDI. Master Trainers on PDI were the first group trained on PDI interventions. PDI interventions were divided into three groups depending on the type of patient that enters the pharmacy, and these include patients who buy cough preparations without prescription, patients who buy anti-TB drugs without prescription, and patients who buy anti-TB drugs with prescription. Master Trainers on PDI conducted roll-out training and capacity building sessions on pharmacy personnel of the engaged pharmacies.

## Results

The review of documents yielded data on the accomplishments of the PDI (Table 1). A total of 7,138

pharmacies were mapped in 33 sites, of which 62% (4,426) were engaged in the PDI. By the 3rd quarter of 2016, only 54% (2,377) of engaged pharmacies were actively referring presumptive TB patients to the nearest TB DOTS facility. With only 33% of mapped pharmacies actively referring presumptive TB patients, the program was unable to reach the target of at least 60% of mapped pharmacies actively implementing PDI.

Referral slips were distributed to engaged pharmacies; thereby, allowing them to serve as referral points for self-medicating presumptive TB patients. Aside from referral slips, TB referral logbooks approved by the Philippine Food and Drug Administration (FDA) were distributed to engaged pharmacies in the first quarter of 2016. A total of 42,118 referrals were made by engaged pharmacies throughout PDI implementation – corresponding to 70% of the 60,000 presumptive TB cases targeted to be referred to TB DOTS facilities.

Through 124 capacity building sessions, 6,517 pharmacy personnel (4,129 pharmacists, 1,593 pharmacy assistants,

**Table 1.** Summary of project targets and corresponding accomplishments.

TARGET	ACCOMPLISHMENT
At least 60% of pharmacies actively implementing PDI in the identified implementation sites	A total of 7,138 pharmacies were mapped in the 33 PDI sites. 62% (4,426) of these mapped pharmacies were engaged in the project. By third quarter of 2016, only 54% (2,377) of the engaged pharmacies were found to be actively referring presumptive TB patients to their corresponding TB DOTS facility. The pharmacies actively referring presumptive TB patients correspond to only 33% of the total pharmacies mapped in the 33 PDI sites.
Presence of the referral system and its reporting and recording elements (e.g., referral slips, TB referral logbook)	Referral slips were distributed to engaged pharmacies. The TB Referral Logbook was distributed to the engaged pharmacy in the first quarter of 2016 after approval by the FDA.
3,000 pharmacists, PAs, and owners trained on PDI	A total of 6,517 pharmacy personnel (4,129 pharmacists, 1,593 pharmacy assistants, 795 drugstore owners) and 552 LGU representatives.
100% PACOP member schools adopting the TB DOTS Curriculum	100% of the target PACOP schools adopted the TB DOTS Curriculum.
60,000 presumptive TB cases referred to DOTS facilities	The engaged pharmacies generated 42,118 referrals.
Presence of national legislation, policies and guidelines relevant to PDI (e.g., Philippine Pharmacy Act, National Dispensing Guidelines, etc.)	The following national legislations, policies and/or guidelines relevant to PDI were enacted: <ul style="list-style-type: none"> <li>▪ RA 10918 (The Philippine Pharmacy Act)</li> <li>▪ TESDA Training Regulation for Pharmacy Assistants (NC III Certification)</li> <li>▪ Philippine Practice Standards for Pharmacist (PhilPSP)</li> </ul>

795 drugstore owners), and 552 LGU representatives were trained on PDI interventions. The number of personnel trained through the program surpassed the target of pharmacy personnel. In addition, participants of capacity building sessions were also asked to sign pledges of commitment to implement PDI in their pharmacies.

The adoption of the TB DOTS Curriculum was limited to member schools of the Philippine Association of Colleges of Pharmacy (PACOP) that are within or near PDI implementation sites. Faculty members of twenty-two (22) out of the 29 mapped pharmacy schools were trained on the Enhanced Curriculum on Tuberculosis Control for Philippine Pharmacy. The other seven (7) remaining schools were not yet provided with the enhanced curriculum because they were newly opened schools, and were not yet eligible for PACOP membership. Thus, 100% of eligible PACOP schools adopted the TB DOTS Curriculum achieving the target of the PDI Program.

Several national legislation, policies, and guidelines were enacted throughout the implementation of PDI. Instruments such as Republic Act No. 10918 (Philippine Pharmacy Act), Food and Drug Administration (FDA) Circular No. 2014-025 (Guideline on Implementation of New Rules and Regulation on the Licensing of Drugstore/Pharmacy/Botica and Similar Outlets following Administrative Order No. 2014-0034, dated 13 October 2014), and DOH Administrative Order 2014-0034 (Rules and Regulations on the Licensing of Establishments Engaged in the Manufacture, Conduct of Clinical Trial, Distribution, Importation, Exportation, and Retailing of Drug Products, and Issuance of Other Related Authorizations) contained provisions relating to TB prevention and control. In the Philippine Pharmacy Act, only pharmacies under the direct supervision of a pharmacist (Category A) are allowed to dispense prescription medicines, including anti-TB drugs, resulting in a focused effort in the control and regulation of anti-TB drug dispensing. Furthermore, the new law requires the maintenance of a referral registry for all retail pharmacies. The referral registry lists patients referred to different health facilities including TB DOTS facilities. This also prohibits the distribution of anti-TB drugs as physician's sample and the enforcement of the "No prescription, no dispensing" of TB drugs policy.

The inclusion of topics on TB and PDI interventions in the Training Regulation for Pharmacy Assistants – National Certificate III (under the Technical Education and Skills Development Authority [TESDA]), and in the Pharmacy Licensure Exam was enacted through PDI. Furthermore, the

PDI – Pharmacy DOTS Curriculum will be included as a reference in the upcoming Policies, Standards and Guidelines (PSG) for Pharmacy Education. This will later become part of the Commission on Higher Education (CHED) Memorandum Order (COM) for the new pharmacy curriculum to be implemented in 2018. Finally, the Philippine Practice Standards for Pharmacy (PhilPSP) has been approved for implementation and dissemination. The PPhA-PDI advocated for the inclusion of the pharmacist's role and competencies in the PhilPSP.

## Discussion

Even though the proportion of engaged pharmacies (*i.e.* 62%) exceeded the target, the proportion of actively referring pharmacies points to the inability to sustain the commitment of engaged pharmacies in patient referrals throughout program implementation. Several factors might have contributed to the relatively low proportion of actively referring pharmacies. A number of the engaged pharmacies closed their business during the PDI implementation period and were counted as non-referring pharmacies. Thus, there might have been some overestimation when attributing attrition of actively referring pharmacies to sustainability issues. Some of the implementation sites already had strong LGU-led TB advocacy programs even before program implementation; hence, there was decreased need, and – consequently – use of the referral system of engaged pharmacies. In addition, there were problems encountered in health facilities where presumptive TB patients are referred to. These problems include unavailability of anti-TB drugs and issues regarding the staff in TB DOTS facilities (such as unfriendly or unwelcoming staff). Barriers to an active patient referral practice of the pharmacies such as problems in the TB DOTS facility and existing TB advocacy programs in the community were also documented in similar programs linking community pharmacies and TB DOTS center implemented in neighboring Asian countries. There were difficulties in sustaining the participation of engaged pharmacies to the referral system primarily because of its impact on the sales of the pharmacy. The participating pharmacies were concerned that the referred patient will choose to get his/her medications in another pharmacy instead of going to the TB DOTS center for proper diagnosis [6]. The inability to sustain active referral activity contributes to the low detection rate of TB [10].

On the other hand, while the number of pharmacy personnel targeted for training under PDI was greatly exceeded, the knowledge gained through the capacity



building sessions was not effectively used in implementing the program in the individual pharmacies leading to difficulties in sustaining the implementation of PDI. A major implementation issue encountered was the fast turnover of pharmacy personnel, resulting in the discontinuity in the transfer of knowledge and skills to newly hired pharmacy personnel. In addition, some pharmacy personnel who trained for PDI did not actually report to their assigned pharmacies; thus, pharmacy personnel who were present in the pharmacies did not get to apply PDI interventions. Skills training for the pharmacy personnel employed and actively performing pharmacy duties can be conducted to supplement the initial training. This can assist the personnel in making referrals and increase their confidence in providing advice to the patient. Subsequent trainings can increase awareness on the program and improve referral rates [11].

In terms of the referral of presumptive TB cases, the number of recorded referrals might be lower than the actual number of referrals made by engaged pharmacies because of such issues as distance between sites, time constraints, and lack of human resources for retrieval of the referral slips generated per site. Most patients were not accustomed to receiving advice from pharmacists. There was low confidence in the provision of information by the pharmacist. Therefore, patients may not be receptive to the referrals made by pharmacists leading to a decline in the number of referred patients received by the TB DOTS center [6,11]. Referred patients were reluctant to visit TB DOTS center because of poor service quality and unavailability of the TB drugs. Other issues in the DOTS center include long waiting times, difficult process, and unfriendly staff in the center [6,11]. Communication between engaged pharmacies and the TB DOTS may contribute to the reinforcement of the program goals and improve the quality of service [11].

The inclusion of TB DOTS in the BS Pharmacy curriculum serves as the first step in ensuring that pharmacists are equipped with the appropriate knowledge and skills about TB control and prevention. Similarly, a National Tuberculosis Curriculum Consortium (NTCC) was established in the USA for the improvement of TB education in the undergraduate and graduate students of various healthcare disciplines. NTCC provides an established foundation and in-depth introduction on the knowledge, skills, and attitudes for TB management and control [12]. The Consortium proved to be instrumental in providing adequate TB knowledge and practice competency among the students [13].

The findings presented in this paper were based only on a review of documents submitted by the PPhA-PDI Project Team to PBSP-IMPACT. Thus, the evaluators were limited to perusing existing data collated by the project implementers and submitted to the funder as part of reportorial requirements. Feasibility considerations precluded conduct of primary data collection to validate information abstracted from the documents, a point of consideration for future work.

The PDI under IMPACT achieved the majority of its specific targets throughout the implementation period. Major issues encountered in achieving other targets (such as the number of actively referring pharmacies and referral slips generated) can be attributed to gaps in program management. Furthermore, there were internal issues with engaged pharmacies such as the closing down of the business, and fast turnover of pharmacy personnel. Monitoring and evaluation were limited to targets mentioned in this paper; thus, the achievement of the project's goal is difficult to assess.

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## Declaration of Interest

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