Outputs and Outcome of the Pharmacy Directly-Observed Treatment Short-Course (DOTS) Initiative in the Philippines

Kim L. Cochon[1]*, Amiel Nazer C. Bermudez[1], Diana Dalisay A. Orolfo[2], Jonathan P. Guevarra[3], Michelle D. Avelino[2], Azar G. Agbon[2], Jorel A. Manalo[4], Eden C. Mendoza[5], Ronald Allan M. Fabella[5], Carl Abelardo T. Antonio[4,6]

*Corresponding author's email address: klcochon@up.edu.ph

[1]Department of Epidemiology and Biostatistics, College of Public Health, University of the Philippines Manila, Manila, Philippines
[2]College of Public Health, University of the Philippines Manila, Manila, Philippines
[3]Department of Health Promotion and Education, College of Public Health, University of the Philippines Manila, Manila, Philippines
[4]Department of Health Policy and Administration, College of Public Health, University of the Philippines Manila, Manila, Philippines
[5]Philippine Business for Social Progress, Manila, Philippines
[6] Department of Applied Social Sciences, The Hong Kong Polytechnic University, Kowloon, Hong Kong

RESEARCH ARTICLE

Abstract

Objective: This is an evaluation of the effectiveness of the technical assistance package for the Pharmacy DOTS Initiative (PDI) in the Philippines.

Methodology: Five pre-identified implementation sites were included in the evaluation. A survey was conducted to ascertain pharmacies currently implementing PDI and the number of TB presumptive cases referred by these pharmacies. Data abstraction was performed to determine the change in the number of TB cases seen by local TB programs after its implementation.

Results: Findings revealed that the proportion of pharmacies actively referring presumptive TB patients is not significantly lower than 60% (p=0.1892). Furthermore, results showed that the average monthly referrals were not statistically lower than 20 clients per month (p=0.9159). Nevertheless, interrupted time series analysis found no statistically significant immediate effects (p=0.516) and long-term effects (p=0.3673) on the total number of new TB cases identified after the PDI was implemented in the year 2014.

Conclusion: The PDI was able to achieve outputs related to pharmacy engagement and referral of TB presumptive clients. However, the PDI was unsuccessful in increasing the actual number of TB presumptive cases seen by local TB programs in its implementation sites.

Keywords: *tuberculosis, Directly Observed Treatment Short Course (DOTS), Innovations and Multi-Sectoral Partnerships to Achieve Control of TB (IMPACT), evaluation, Philippines*

Introduction

Tuberculosis (TB) is a major contributor to the Philippines' disease burden. In fact, TB is one of the leading causes of morbidity (71.5 per 100,000 population) and mortality (23.7 per 100,000 population) among Filipinos [1]. The 2016 Global Tuberculosis Report estimated the incidence of TB in the country at 322 per 100,000 population (95% Uncertainty Interval [UI]: 277–370 per 100,000), which was the basis for ranking the Philippines as one of the 30 high-burden countries for TB [2].

While overall trends indicate a general decline in TB incidence both globally and locally, the health risks posed by

TB remains as emergence of drug-resistant strains contribute to more complicated treatments and increase in healthcare costs. With an estimated incidence of 17 per 100,000 population (95% UI: 14–20 per 100,000 population), the Philippines was also identified by the World Health Organization as among the 30 countries globally with high-burden for MDR-TB [2].

As a response to the persistent threat of TB in the country, the Innovations and Multi-Sectoral Partnerships to Achieve Control of TB (IMPACT) was launched by the United States Agency for International Development (USAID) Philippines through the Philippine Business for Social

Progress (PBSP). The overall goal of the project was to reduce the prevalence of, and increase the case detection and cure rates for, TB nationwide. The project actively engaged both the public and private sectors for a more holistic approach in its various TB prevention and control measures [3].

The Pharmacy DOTS Initiative (PDI) is an activity under IMPACT that involved pharmacists in the community in the prevention, detection, and management of TB. DOTS stands for Directly Observed Treatment Short Course (DOTS), which provides an effective, low-cost alternative to other TB treatment plans [4,5]. The PDI builds on the fact that a pharmacy has a strategic role in reaching and capturing self-medicating TB patients and is a possible avenue for providing patients with correct information through counselling, dispensing of appropriate drugs, and referring them to TB DOTS facilities for further diagnosis and treatment [6,7].

The pharmacists and drugstores who participated in the PDI were expected to contribute to the attainment of the following objectives: (1) Prevent self-medication among TB symptomatic individuals through education and referral by trained pharmacists and drugstore attendants; (2) Institute behaviour change among pharmacists, pharmacy assistants and drugstore owners towards participating in the NTP; (3) Strengthen and/or institutionalise compliance to national and local policies supporting TB DOTS; and (4) Sustain and institutionalise the participation of pharmacists in TB control in the country [5].

This evaluation aimed to assess the effectiveness of the PDI. Specifically, it evaluated whether the outputs and outcomes that were pre-determined by IMPACT and project implementers for PDI project were achieved in selected implementation sites. The success indicators assessed in this study were the following: (1) 60% of the pharmacies

engaged participated in the PDI (output); (2) at least 20 TB presumptive clients were referred monthly by each participating pharmacy to the local TB program (output); and (3) an increase in the number of new TB cases seen by local TB programs before and after the implementation of PDI (outcome).

Methodology

The research team utilized a non-experimental program evaluation design to compare the outputs and outcomes before and after implementation of the PDI. This design was selected for pragmatic reasons, i.e., the research team was commissioned to carry out a summative evaluation of the PDI towards the close-out phase, making it difficult to properly assign controls for purposes of comparison.

The evaluation of the project was carried out in five pre-identified PDI implementation sites in the Philippines. From each implementation site, the municipality with the highest number of participating pharmacies was chosen for inclusion in this evaluation. Pharmacies that participated in the PDI were surveyed from each of the identified municipalities (Table 1).

The research team conducted a survey of pharmacy representatives with a self-administered questionnaire (SAQ) and sourced data from TB referral logbooks of participating pharmacies to gather evidence concerning the attainment of the first two outputs of the PDI on pharmacy involvement and pharmacy referrals. Data abstraction was performed to determine the number of TB cases seen by local TB programs three years before and during the first six years of implementation of the project. This data was used to ascertain the contribution of the PDI on TB case detection in the community.

Table 1. *PDI Project Evaluation Sites*

PBSP-IMPACT Region	Province/City	Evaluation Site	No. of Referring Pharmacies	Actual Number of Respondent Pharmacies	Response Rate (%)
North Luzon	Pangasinan	San Carlos City	16	13	81.25
National Capital Region	Caloocan City	Barangay 176	20	13	65.00
South Luzon	Batangas	Batangas City	47	17	36.17
Visayas	Northern Leyte	Palo	5	3	60.00
Mindanao	Zamboanga del Norte	Dipolog City	16	12	75.00
		TOTAL	**104**	**58**	**55.77**

Data were encoded in Microsoft Office Excel (version 1701) and analysed using Stata IC (release 12.0). In addition, to descriptive statistics, a one-tailed Wald test for one population proportion was used to determine if at least 60% of identified pharmacy establishments participated in the project. A one-tailed t-test for one population mean was performed to determine if each participating pharmacy referred at least 20 TB presumptive clients to the local TB program every month. Lastly, an interrupted time series analysis was done to determine if there is a significant difference in the number of TB presumptive cases seen by local TB programs before and after the implementation of the PDI. A 10% level of significance was used for all the hypothesis testing performed.

Results

Pharmacy Engagement

The research team enumerated a total of 104 pharmacies, composed of 83 independent or small to medium-chain pharmacies (I/SMC) and 21 large chain (LC) pharmacies. Only 58 of the 104 pharmacies (42 I/SMC and 16 LC) in the 5 pre-identified implementation sites were found to be in operation and were willing to participate in the assessment (Table 1).

The 46 pharmacies that were excluded from the study were either (a) no longer operating (28), (b) cannot be located (10), (c) duplicate entries in the database of participating pharmacies maintained by the PDI project team (6), or (d) were not willing to participate (2). Further, 27 out of the 28 pharmacies that were no longer in operation were independent or small to medium-chain pharmacies.

Of the 58 pharmacies included in the evaluation, all reported that they were still implementing the PDI at the time the evaluation was conducted. This translates to at least 56% (58 out of 104) of the pharmacies actively referring presumptive TB patients to the local TB DOTS facility. Significance testing revealed that the proportion of pharmacies actively referring presumptive TB patients is not statistically lower than 60% (p=0.1892), which indicates that this output was met by the PDI.

Pharmacy Referrals

Pharmacy representatives from each of the pharmacies included in the evaluation were interviewed. Majority (53% or 31 out of 58) of these representatives were pharmacists, while the rest were either pharmacy assistants (38% or 22 out of 58), pharmacist-pharmacy owners (7% or 4 out of 58), or pharmacy owners (2% or 1 out 58). The average duration of employment of the interviewed pharmacy personnel (i.e. pharmacists and pharmacy assistants) was 5.4 years (with a standard deviation (SD) of 64.9 months). Less than half (41 or 24 out of 58) of the pharmacy representatives reported that they received training related to the engagement of pharmacies in DOTS for patients with TB in the last five years (Table 2). Meanwhile, all the respondents claimed that they ask for a prescription first when a client with cough comes to the pharmacy to purchase an antibiotic or an anti-TB drug.

The survey from the pharmacy representatives revealed that an average of 32 pharmacy clients (with SD of 60 clients) were referred to the local TB DOTS facility by the pharmacies evaluated since the start of their participation in the PDI. Significance testing showed that the average monthly referrals was not significantly lower than 20 clients per month (p=0.9159). This suggests that this output was met by the initiative. However, it must be noted that

Table 2. *Distribution of Interview Respondents According to Training Received*

Pharmacy Personnel	Received training related to the engagement of pharmacies in the DOTS chemotherapy			Total
	Yes	No	Cannot Recall	
Pharmacist	17	12	2	31
Pharmacy Assistants	4	17	1	22
Pharmacist – Pharmacy Owners	3	1	0	4
Pharmacy Owners	0	1	0	1
TOTAL	**24**	**31**	**3**	**58**

Table 3. *Number of New TB Cases Identified Between 2011-2016*

Location	Prior to PDI implementation			During PDI implementation		
	2011	**2012**	**2013**	**2014**	**2015**	**2016**
San Carlos City, Pangasinan	261[a]	261[a]	261	290	399	372
Palo, Leyte	123	123[a]	137	61	160	199
Batangas City, Batangas	433	534	738	702	841	924
Dipolog City, Zamboanga del	202	238	390	494	410	390
NorteCaloocan City	2,560	3,142	3,390	4,127	4,527	4,214
TOTAL	**3,579**	**4,298**	**4,916**	**5,674**	**6,337**	**6,099**

[a] Values were imputed from available data

Table 4. *Interrupted Time Series Analyses Results*

Location[a]	Prior to PDI implementation		During PDI implementation	
	Coefficient	**p-value**	**Coefficient**	**p-value**
Palo, Leyte	-70.67	0.071	69.00	0.0301
Batangas City, Batangas	-162.00	0.088	111.00	0.0104
Dipolog City, Zamboanga del Norte	18.67	0.779	-52.00	0.0577
Caloocan City	385.17	0.293	43.50	0.7932
Overall	**222.83**	**0.516**	**212.50**	**0.3673**

[a] Estimates for San Carlos, Pangasinan could not be produced due to sparseness of data
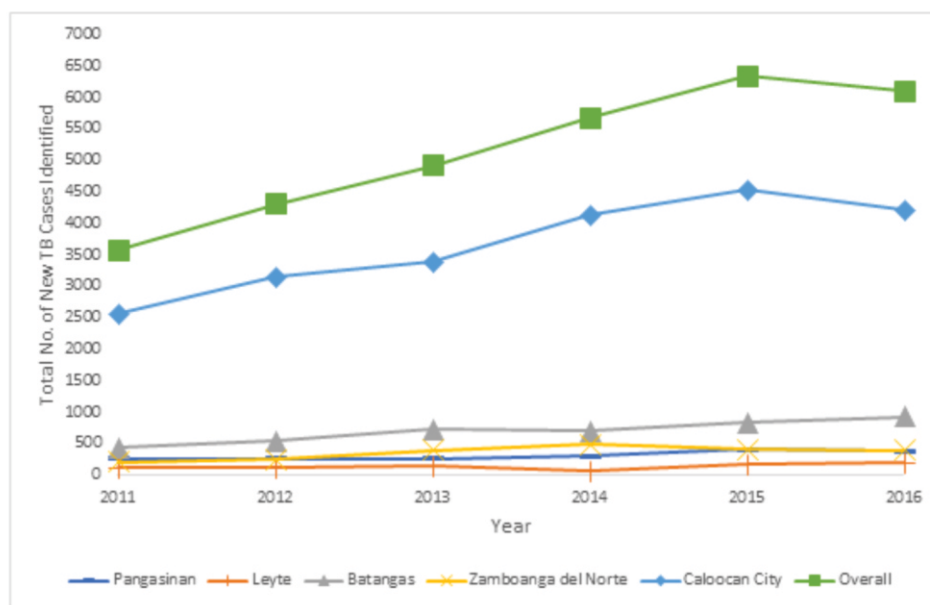
Figure 1. *Number of new TB cases identified from 2011-2016*

validation of the data provided by the pharmacy representatives in the SAQs cannot be performed for all pharmacies because the TB Referral Logbook was unavailable or, where available, the TB Referral Logbook did not tag referrals from the pharmacies engaged in the PDI.

TB Case Detection

Table 3 shows the number of new TB cases identified from 2011 to 2016 in the implementation sites assessed in this study. Although there appears to be an overall increasing trend

in the number of new TB cases identified (Figure 1), findings of the interrupted time series analysis showed no statistically significant immediate effect on the total number of new TB cases identified after the PDI was implemented in the year 2014 (p=0.516). There was also no statistically significant change over time in the total number of new TB cases identified after the PDI was implemented (p=0.3673). (Table 4)

Discussion

The main findings of the study show that the PDI was able to achieve two target outputs: (1) 60% of engaged pharmacies participating in the initiative, and (2) at least 20 presumptive TB cases referred monthly by the participating pharmacies. There was no sufficient evidence, however, to support the claim that PDI attained its target outcome of increasing the number of new TB cases seen by local TB programs before and after the implementation of PDI.

Eighty percent (83 out of 104) of engaged pharmacies in the pre-identified implementation sites of the program were classified as I/SMC community pharmacies. This is consistent with the 2012 Philippine Food and Drug Administration (FDA) report stating that 82% of the 49,447 pharmacies in the country were composed of small to medium-chain pharmacies [9]. Twenty seven (27) of these engaged I/SMC pharmacies were no longer in operation and were thus excluded from the study. This indicates that I/SMC pharmacies have shorter life spans compared to LC drugstores in the Philippines. This phenomenon is not limited to developing countries, but also applies to countries like the United States where a decrease in the number of independent community pharmacies was observed in the recent years [10]. A systematic review by Konduri et al. that examined the engagement of the private pharmaceutical sector for TB control emphasized the need for tailored strategies and considerations in scaling up the engagement of retail drug outlets nationwide. Their findings demonstrate that aside from setting a target percentage of pharmacies to be engaged, the volume of patients being served per engaged drug outlet or pharmacy must also be considered to ensure efficiency [11]. These suggest that although engagement of small to medium-chain pharmacies should be targeted, involvement of large-chain drugstores must also be strongly encouraged for the continued, sustainable and efficient implementation of initiatives like PDI.

Only 41% of pharmacy representatives reported that they received training related to the engagement of pharmacies in DOTS for patients with TB in the last five years while their reported average duration of employment of the pharmacy personnel was 5.4 years (with a standard deviation (SD) of 64.9 months). Relating the duration of employment with the response to participation in training on the engagement of pharmacies in DOTS chemotherapy, it is not surprising that majority of the pharmacy representatives indicated that they have not received PDI training. Nonetheless, pharmacies participating in the PDI were found to have met the target of at least 20 clients referred to the local TB DOTS facility monthly.

These findings were similar with that of another evaluation performed in Cambodia wherein the National Centre for Tuberculosis and Leprosy Control (CENAT) was shown to be successful in implementing a public/private mix (PPM-DOTS) TB Referral Program with 11.6% of TB cases detected attributed to private provider partners over the periods 2005-2012 [12]. The largest contributing provider in the Cambodia TB PPM Network were pharmacies which accounted for 61% (1,047) of all private provider partners (1,713) that also included laboratories and private clinics. Supportive supervision and regular meetings among the key players of the private-public mix played a crucial role in the PPM-DOTS implementation in Cambodia wherein conscientious monitoring and consistent feedback ensured that the participating pharmacies maintain their high commitment in the achievement of the set referral goals. According to the participating pharmacists, one strong motivator and compelling incentive for their continuous participation in the program is knowing that they were contributing to finding more TB cases and that the confirmed cases that they referred were receiving free treatment because of the program [13].

Lastly, the assessment did not find evidence to demonstrate that PDI contributed to an increase in TB case detection in some of the communities where it was implemented. Findings of the interrupted time series analysis showed no statistically significant immediate effect on the total number of new TB cases identified after the PDI was implemented in the year 2014 (p=0.516). This can be attributed to patient-related factors not measured in the study, specifically those that occur between the time the patients are given the referral slip in the pharmacy up to the time they access the NTP facility for further diagnosis. In a study done in two districts in Ho Chi Minh, Vietnam, pharmacists stated that suspected TB patients who are given referral slips can either turn to another pharmacy or remain untreated because they are not able to visit the NTP facility [14].

Several limitations were encountered, particularly in terms of validating the reported number of referrals by the

pharmacy representatives due to either unavailability of the TB Referral Logbook or the lack of entries in the TB Referral Logbook, if available. Recall and response bias should also be accounted for as the reported number of pharmacy referrals made for the past 30 days were only based on the memory and subjective judgment of the pharmacy representative. Moreover, for the interrupted time series analysis for the TB case detection contribution of PDI, data collected from the NTP on some of the inclusive years were not available. In order to perform the analysis, the missing data were assumed to be the same with that of the previous or succeeding year (Table 3). Finally, success indicators measured were only based on data collected from the participating pharmacies and from the NTP, and patient-related data and factors were not captured in this assessment.

Overall, it was found that achieving PDI's target outputs in terms of number of pharmacies engaged and number of pharmacy referrals generated did not necessarily translate to its target outcome of increasing new TB cases detected in the identified implementation sites. It is recommended to conduct a focused evaluation on patient behaviour and factors to be able to gain more insight and to further improve the implementation of the PDI.

Acknowledgements

Declaration of Interest

CTA, ACB and KLC received professional fees and grants from Johnson & Johnson (Philippines), Inc. outside of the submitted work. All other authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

References

1. Department of Health. (2013) The 2013 Philippine Health Statistics. Manila: Epidemiology Bureau

2. World Health Organization. (2015) Global Tuberculosis Report 2016. Geneva: World Health Organization, 2016.Institute for Health Metrics and Evaluation. GBD Compare. [Online] Institute for Health Metrics and Evaluation, University of Washington, Seattle, WA.

3. Perla, Isagani M. (2003) Pharmacy-based TB DOTS Implementation Plan. s.l.: Chemonics International Inc.

4. Department of Health. (2010) 2010-2016 Philippine Plan of Action to Control Tuberculosis (DOH HSRA Monograph No. 11). Manila: Department of Health.

5. Vianzon, Rosalind, *et al.* (2013) The tuberculosis profile of the Philippines, 2003–2011: advancing DOTS and beyond. 2, Western Pacific Surveillance and Response, Vol. 4.

6. USAID. (2016) Innovations and Multi-Sectoral Partnerships to Achieve Control of TB (IMPACT).

7. National Statistics Office and ICF Marco. (2009) National Demographic and Health Survey 2008. Calverton, Maryland: National Statistics Office and ICF Marco.

8. Tiu MY. Pharmacist's Role in Reducing the Burden of Tuberculosis: Pharmacy DOTS Initiative. n.d.

9. Nejar EM, Rempillo MG. (2014) Tax Contribution of the Philippine Pharmaceutical Industry. [Online] NTRC Tax Research Journal. Volume XXVI.2.

10. Hussain A, Malik M, Rutta E. (2015) Barriers and Opportunities to Effectively Engage Retail Pharmacies as DOTS Centers in Pakistan. Systems for Improved Access to Pharmaceuticals and Services (SIAPS). Pharmaceutical and Health Technologies Group. Management Sciences for Health (MSH).

11. Konduri N, Delmotte E, Rutta E. (2017) Engagement of the private pharmaceutical sector for TB control: rhetoric or reality?. Journal of Pharmaceutical Policy and Practice. : 10:6. DOI 10.1186/s40545-016-0093-3

12. Kingdom of Cambodia Ministry of Health. (2012) Tuberculosis Report 2012. Phnom Penh: National Centre for Tuberculosis and Leprosy Control.

13. Mihalea H, Richardson R. (2012) Public-Private Mix involving Pharmacies and Other Providers in TB Control – A Cambodia Case Study.

14. Lonnroth K, Lan K, Buu TN, Dieu TT. (2003) Referring TB suspects from private pharmacies to the National Tuberculosis Programme: experiences from two districts in Ho Chi Minh City, Vietnam. International Journal of Tuberculosis and Lung Disease. 7(12):1147-53.