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The Thai Journal of Pharmaceutical Sciences
39 (3), July-September 2015: 110-118



Economic impact assessment on good pharmacy practice regulation in Thai community pharmacy

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Abstract

Good Pharmacy Practice (GPP) in community and hospital pharmacy setting is a crucial standard for pharmacy services. The Thai Food and Drug Administration (Thai-FDA) realized the benefit of GPP and tried to implement this concept as a regulation for every community pharmacy. As a result, the Ministerial Regulation on Application and Issuance of License to Modern Pharmacies was implemented, so the new community pharmacies which open after the issue of this regulation must abide by it if they open after 26th June 2014. However, the Thai-FDA gave a period within eight years for old pharmacies to adapt to this new regulation. Thus, this study aimed to explore the economic impact in terms of cost-benefit of the Ministerial Regulation on Application and Issuance of License to Modern Pharmacies. This regulation was revised to improve the quality and standard of community pharmacies. The data was obtained from self-administered questionnaires sent to Type I pharmacy owners, excluding the accredited pharmacies, and from the published literature and expert opinion. This study was performed from a societal perspective. The result showed that the total 8-year cost was \$1,317.90 million dollars (48,639.61 million baht) and total 8-year benefit was \$3,672.34 million dollars (136,027.69 million baht). NPV and benefit to cost ratio were \$ 2,087.79 million dollars (68,458.75 million baht) and 2.79 benefit: cost, respectively. The one-way best case and worse case sensitivity result presented that the net benefit ranged from -\$856.14 million dollars to \$20,815.45 million dollars (- 28,072.91 to 682,538.71 million baht). Cost of pharmacy closing down was the least sensitive variable in this model. Cost of Drug-Related problem (DRP) per case and number of DRPs in community pharmacies were the important factors which might contribute to an impact on net benefit. The implementation of this regulation seems to have provided positive financial return on investment to Thai society.

Key Words: Community Pharmacy, Drugstore, Regulation, Good Pharmacy Practice, Thailand

Introduction

Good Pharmacy Practice (GPP) in community and hospital pharmacy setting is a standard for pharmacy services. GPP was first developed by the International Pharmaceutical Federation (FIP) in 1992. The joint FIP/World Health Organization guideline on good pharmacy practice was issued in 1999. The objective of FIP is to improve the standards of pharmacy services by using the FIP/WHO guidelines on GPP as a framework. WHO and FIP define a definition of Good Pharmacy Practice (GPP) as "the practice of pharmacy that responds to the needs of the people who use the pharmacists' services to provide optimal, evidence-based care" [1]. WHO and FIP recommended that it is essential to establish national frameworks of GPP standards and guidelines to support this practice [1]. The current number of pharmacies has increased dramatically in Thailand. The

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Received: 20 April 2015

Revised: 3 June 2015

Accepted: 22 July 2015

Academic Editor: Puree Anantachoti

total number of Type I pharmacies in 2008 was 10,063 and has increased to 13,088 in 2013 [2].

Modern pharmacy in Thailand can be classified into two categories, Type I and Type II pharmacy. Type I pharmacy is the pharmacy that has at least one registered pharmacist working. All types of medicine (i.e. dangerous medicines, controlled substances and psychological medicines) are permitted to be sold in these types of pharmacy. There is no need to have registered pharmacist working in Type II pharmacy which can sell only non-dangerous, OTC (over the counter drugs)[3]. However, it has also been found that there are many major problems that need to be urgently solved. For example, selling drugs illegally or without permission, selling of prescription or controlled substances without a pharmacist who has responsibility for providing pharmaceutical care, and no pharmacist on duty at the operational time. These inappropriate dispensing practices may cause irrational use of medication and also affect to consumer safety [3-6].

Even though, there is the Drug Act, B.E. 2510 (1967) in Thailand, it is a broad principle and there was no standard set of guidelines to comply with it until 2003, when the Thai Food and Drug Administration collaborated with the Thai Pharmacy Council to start a, "Community Pharmacy Development and Accreditation" program (CPA). This is a voluntary program that promotes pharmacies to improve under the Good Pharmacy Practice (GPP). The vision of this program is to emphasize on safety and rational use of medicine by improving the quality in community pharmacy service [7]. The voluntary change of community pharmacy to follow GPP guideline will occur due to the market competitive pressure because people are more likely to concern about the quality issue. The CPA program has been started since 2003 and 316 pharmacies have been accredited by the Pharmacy Council and ten years later these have increased only to 547 stores.

Although the CPA program as a social intervention is a useful and valuable program for patients, there are still small numbers of pharmacies which are accredited [8]. With the obligation of the ASEAN Economic Community (AEC) which has a goal of regional economic integration by 2015, the Thai-FDA needs to use legal intervention for type I community pharmacy by revising "The Ministerial Regulation on Application and Issuance of License to Modern Community Pharmacy" in order to get all pharmacies to comply to Good Pharmacy Practice (GPP). Eventually, it was approved by the Royal Gazette on 27th December 2013 and became effective on 26th June 2014. The purpose of revising this regulation was to improve the standard of community pharmacies using GPP principles in terms of place and equipment, personnel, effective drug management and pharmacy service regarding safety and efficacy standards to customers. The new community pharmacies which open after this regulation became effective (26th June 2014) must abide by GPP regulation. The main context in this regulation is requiring all new community pharmacies to pass Good Pharmacy Practice (GPP) standard before renewing their pharmacy license. The benefit of complying with this new regulation will

bring good pharmacy practice to patient which in turn can reduce Drug-related problems (DRP) [6, 9, 10]. On the other hand, old community pharmacies who cannot comply with this new regulation have to be closed down which can be a cost to society also. With the concern about the survival of old community pharmacies which is a cost to society, Thai-FDA delayed eight years for old community pharmacies which opened before issuing this new regulation for the development to pass GPP standard in order to get renewal of their license [11].

Before any legislation, the legislator or government needs to ensure that the regulation they develop and implement has high quality because poor quality regulation will have substantial cost to society. In addition, poor quality regulation will increase compliance cost for business and others. In order to systematically identify and assess the expected effects of the regulation, reliable analytical methods such as benefit/cost analysis can be used [12]. There are many studies which have examined the compliance to standard for accredited pharmacies. There is only one study which has examined the possibility to comply to the GPP standard for community pharmacies under the Ministry of Public Health notification [13]. However, there is no study which has examined the benefit/cost analysis of this regulation. Therefore, this study is conducted to explore the economic impact in terms of benefit/cost analysis of the Ministerial Regulation on Application and Issuance of License to Modern Community Pharmacy. The result of this study can support the Thai-FDA decision making in legislation of the GPP regulation and also convince community pharmacies to comply with this regulation.

Methods

Study design: Full economic evaluation should compare between reasonable comparators. Since this regulation has been implemented, it was not practical to find other alternatives to compare. Therefore, we did not use full economic evaluation in this study and aimed to evaluate only a cost-benefit analysis of implementing the Ministerial Regulation on Application and Issuance of License to Modern Community Pharmacy in Thailand. Cost-benefit analysis is an analytical method in order to systematically identify and assess the expected effects of a regulatory proposal. The main outcome measure was net present value during the 8-year period since 2014 of this regulation. This study was conducted from societal perspective which was pharmacy's owners, patients, and government sector (FDA). We did not include Pharmacy council in the government sector because there is no cost or benefit which occur to them. All costs and benefits were converted to 2014 Thai baht, the year of implementing the regulation. Data on costs and benefits were obtained from self-administered questionnaires sent to Type I pharmacy owners excluding the accredited pharmacies, and from the published literature and expert opinion.

Costs: Cost is any resource that is used in the project to produce goods or services for achieving the objective of

the project. Therefore, the Cost of implementing the GPP was all direct costs that occurred when the GPP regulation was implemented from societal perspective, see **Table 1**. Cost from government (FDA) perspective included 1) Cost of issuing law and regulation 2) Cost of GPP training for FDA officer and outsource authorities 3) Cost of GPP information distribution and 4) Cost of GPP handbook for FDA officer. Cost from pharmacies' owners' perspective included eight incremental costs which occurred after the GPP regulation implementation: 1) Cost for renovating the place and equipment, 2) Cost for adapting stock management, 3) Other variable costs after the GPP implementation, 4) GPP handbooks for pharmacies, 5) Full time pharmacists' fees, 6) Opportunity cost of a pharmacy closing when renovating the stores, 7) Cost of pharmacy close down and 8) Assessment cost for renewing pharmacy licenses.

The purpose of implementing GPP regulation was to improve the standard of the primary health care system in society through the pharmacies. When community pharmacies close down because of not complying with the regulation, patients have to go to the new community pharmacies which can be a cost in patient's perspective, but we assumed that there is no change in overall transportation cost. Therefore, our assumption in this model was no cost from the patients' perspective.

Benefits: Benefits of implementing the GPP was defined as all direct benefits which occur when implementing the GPP regulation from the societal perspective. All benefits have been transferred to monetary value, see **Table 1**. The benefit from government (FDA) perspective was cost saving by the reduction of surveillance costs. Even though the Drug Act, B.E.2510 (1967) stated that the pharmacies must have a full time pharmacist available during the operating time, absent pharmacists are still a major problems in Thailand [4]. Absence of pharmacists on duty has increased the risk of inappropriate dispensing of medication and directly affected patients' health. The government could control this problem by randomly inspecting the remaining pharmacies. Thus, implementation of GPP regulations would save the cost of surveillance. In this model, FDA expert opinion reported based on their database in 2013 that the surveillance cost would reduce 50 % after the GPP regulation implementation.

Benefit from pharmacies' owners' perspective was the cost saving by reducing the waste of expired drugs each year, which cost was obtained from the questionnaire. Benefit from patient's perspective was cost saving from reducing drug-related problems (DRPs). A pharmacy is the primary health care service for people, because it is inexpensive, convenient and time saving. The survey data on health and welfare found that the number of people self-medicating had increased from 20.9 % in 2008 to 30.7 % in 2012 [14]. Even though, the patients gain advantages from pharmaceutical care services, adverse results from drug utilization may occur any time such as drug-related problems. The crucial role of the pharmacist in a community pharmacy is medication

history taking. This activity can help pharmacists to dispense the appropriate medication to patients and can avoid the undesirable result such as dispensing antibiotic medication to a patient who is allergic to that kind of medicine. Drug related problems (DRPs) can occur due to the incomplete information from the patients about their history, before dispensing the medication in the community pharmacy. It was found that 27.59 % to 29.3 % of patients would exhibit at least one DRP if there was no history taking before dispensing the medication [6]. Directly asking about patient's history would prevent DRPs occurring by between 18.75 % and 23.81 % [6]. Therefore, the benefits of medication history taking from the patient is the important issue to be considered in order to identify and prevent drug related problems in community pharmacies.[6].

There were studies which showed that the cost involved with drug-related problems (including total cost of drug-related morbidity and mortality) was more than the expenses for primary drug therapy [15, 16]. Drug-related problems are gradually becoming known as a serious issue of concern, but most DRPs are preventable such as medical problems. There was a lack of availability of published literature in terms of DRP-related cost in community pharmacies in Thailand. Two studies in India examined cost avoidance per case from DRP which accounted for US\$ 180 to US\$ 428 in 2013 [17-19]. In the United State, DRPs contributed to the economic burden which increased from \$76.6 billion in 1995 to \$177.4 billion in 2000 [16]. There was a study which calculated the average cost of each adverse drug reaction at Thai Northern Regional Hospital which accounted for US\$ 53 [20]. However, this study focused on drug-related problem, thus cost per case related to DRP from India was used as a proxy of cost avoidance of DRP in Thailand due to similarity of situation in our base case. The data from US and Thai case were used for the sensitivity analysis. The survey data on health and welfare found that the number of people self-medicating had increased from 20.9 % in 2008 to 30.7 % in 2012 [14]. Therefore, the number of patients who can avoid DRP after the GPP implementation was 1,240,189 cases which was calculated from the Thai population of people who went to pharmacies in Thailand, (Thai population 64,785,909 people in December, 2013 [21]), the probability of DRP prevention from GPP regulation (0.21) and the probability of DRP in pharmacy (0.29) [6]. As a result, the total cost saving from reducing drug-related problems (DRP) was \$179.94 million (5,900.19 million baht) in 2014. This cost will recur every year.

Sensitivity analysis: One-way (univariate) sensitivity analysis and best case-worse case analysis were performed by changing one variable at a time and the value of others were constant and were presented as Tornado diagram (**Figure 1**). Both cost and benefit in this study were converted to the present value by using 3% percent discount rate.

Table 1 Source of information used to obtain data on cost and benefit from government (FDA), from pharmacies' owners' perspective and from patients' perspective

Variable	Source of information	Base case	Sensitivity analysis (range)
Costs			
<i>Government (FDA) perspective</i>			
Cost of issuing law and regulation (USD/regulation)	FDA report, 2012 [25]	6,457.76	-
GPP Training for FDA officer (USD/person/hour)	FDA expert opinion, FDA Resource [25]	33.01	-
GPP information distribution (USD/newsletter)	FDA expert opinion, Literature review [26]	3.05	-
GPP handbook for FDA officer (USD/handbook)	FDA expert opinion, Literature review [26]	30.50	-
<i>Pharmacies' owners' perspective</i>			
Cost for renovating place and equipment (USD/year)	Literature review, expert opinion, survey	3,204.65	609.94 – 11,906.23
- Eight square meter area	Expert opinion	914.91	
- Counseling area	Literature review [27], expert opinion	1,168.04	
- Air conditioning	Literature review [28]	505.52	
- Closing area for dangerous medication	Literature review [28]	152.49	
- Thermometer	Literature review [28]	3.64	
- Refrigerator	Literature review [28]	200.03	
- Tray	Literature review [28]	9.09	
- sphygmomanometer (automatic)	Literature review [28]	72.74	
- weighing apparatus	Literature review [28]	21.82	
- stadiometer	Literature review [28]	10.91	
- fire extinguisher	Literature review [28]	21.82	
- pharmacist sign with picture	Literature review [28]	18.18	
- pharmacist uniform	Literature review [29]	14.55	
- storage for keeping documents	Literature review [28]	90.92	
Cost for adapting stock management (USD/year)	Literature review [27, 28, 30], expert opinion, Survey	1,585.82	280.57 – 2,146.97
- cabinet			
- pharmacy management program			
Other variable costs from GPP	Literature review [27, 28], expert opinion, survey	165.48	30.50 – 914.91
- staff (USD/year)			
- document, paper, sticker			
- lights			
- cost of maintenance program			
GPP handbook for pharmacy owner (USD/handbook)	Literature review [31], expert opinion	6.10	
Full time pharmacist (USD/year)	Literature review [32, 33], expert opinion	13,174.75	4,391.58 – 16,658.01
Opportunity cost from pharmacy renovation (USD/year)	Survey	224.92	89.97 – 1,480.87
Assessment cost for renewing pharmacy license (USD/license/year)	expert opinion	45.75	
Cost of pharmacy close down (USD/pharmacy close down)	Survey	40,984.14	15,248.55 – 102,515.05
<i>Patient's perspective</i>			
No cost	-		

Note: There were 12,544 pharmacies in 2011. Exchange rate of 1 US dollar was 32.79 baht (1 April, 2014). Discounted rate used in this study was 3 % [36]. The average inflation rate in Thailand was 4.5 % from 1977 until 2014 [37].

Table 1 (*Continued*) Source of information used to obtain data on cost and benefit from government (FDA), from pharmacies' owners' perspective and from patients' perspective

Variable	Source of information	Base case	Sensitivity analysis (range)
Benefits			
Government (FDA) perspective			
Cost saving from reducing of surveillance cost (USD/Rx/year)	Literature review. [2, 4], expert opinion	35.53	-
- Probability of reducing surveillance pharmacy			0 – 0.8
Pharmacies' owners' perspective			
Cost saving from reducing waste of expired drug (USD/Rx/year)	Survey	707.51	60.99 – 4,574.57
Patient's perspective			
Cost saving from reducing of DRP (USD/case)	Literature review [34]	447.26	81.58 – 1,041.96
- Probability of DRP in community pharmacy	Expert opinion, Literature [6, 35]	0.29	0.04 – 0.50
- Probability of DRP prevention due to history taking	Expert opinion, Literature [6, 35]	0.21	0.18 – 0.76

Note: There were 12,544 pharmacies in 2011. Exchange rate of 1 US dollar was 32.79 baht (1 April, 2014). Discounted rate used in this study was 3 % [36]. The average inflation rate in Thailand was 4.5 % from 1977 until 2014 [37].

Results

The results of the value of implementing the GPP regulation in terms of cost and benefit from three perspectives were presented in **Table 2**. Total costs for the entire eight-years of implementing the GPP regulation were \$1,317.90 million dollars (48,639.61 million baht). Cost incurred by the government perspective was \$171,535.45 dollars (5.62 million baht) which included cost of issuing law and regulation, cost of GPP training for FDA officers and outsource authorities and cost of GPP information distribution. The cost from pharmacies' owners' perspective accounted for \$1,483.19 million dollars (48,633.99 million baht). There was no cost from patient's perspective. Total benefit was equal to \$3,672.34 million dollars (136,027.69 million baht). The benefits included in the analysis were cost saving by reducing surveillance costs, cost saving by reducing waste of expired drug each year and cost saving by reducing DRP. Cost saving from reducing DRP showed the largest proportion of the benefits which accounted for \$4,080.87 million dollars (133,811.59 million baht). The net benefit from cost-benefit model when implementing GPP regulation was \$2,354.49 million dollars (77,203.82 million baht) from societal perspective. The benefit to cost ratio was 2.79.

Sensitivity analyses: The result showed that net benefit ranged from -\$856.14 million dollars to \$20,815.45 million dollars (– 28,072.91 to 682,538.71 million baht). Cost of pharmacy closing down was the least sensitive variable in this model (NPV varied from \$2,338.74 - \$2,356.19 million dollars), whereas costs of DRP per case and number of DRPs in community pharmacies were the important factors which might contribute to an impact on net benefit.

Discussion and Conclusion

The result presented that implementing the GPP regulation was cost beneficial which provided 2.79 fold benefits higher than cost and NPV accounted for \$ 2,354.49 million dollars (77,203.82 million baht). Even though, the benefits in this model were limited to three cost-saving 1) reducing pharmacy surveillance, 2) reducing expired medicine, and 3) reducing drug-related problems (DRP), the result of NPV was a very large amount. It did not cover other intangible benefits which are not easily measureable in monetary value. There were other benefits of GPP implementation, but it was difficult to convert into monetary value. For example, providing pharmaceutical care can improve patient outcome, reduce adverse drug events (ADE), improve appropriate use of medicine, improve intermediate outcome (i.e. blood pressure) and reduce drug costs [10]. There was a positive effect of pharmacist counseling such as improving quality of life in patients with dyspepsia [9, 10], and 43 % of patients changing their decision of medicine purchasing in non-prescription medicine, in which 4.2 % of patients were referred to a doctor and 7.3 % of patients could be prevented from ADE, [10, 22] while 63 % of patients reported that their symptom improved, and 85 % of patients thought that it was not essential to see the physicians when they had minor health problems [10, 23, 24]. When comparing to the proportion of all of these benefits, it was found that the benefit from patients' perspective or cost saving from reducing DRPs was the highest proportion. Cost and benefit in this model was based on questionnaire survey, published literatures and expert opinions. To strengthen the results, best-case and worse-case sensitivity analysis were performed. The result of implementing the GPP regulation showed cost benefit

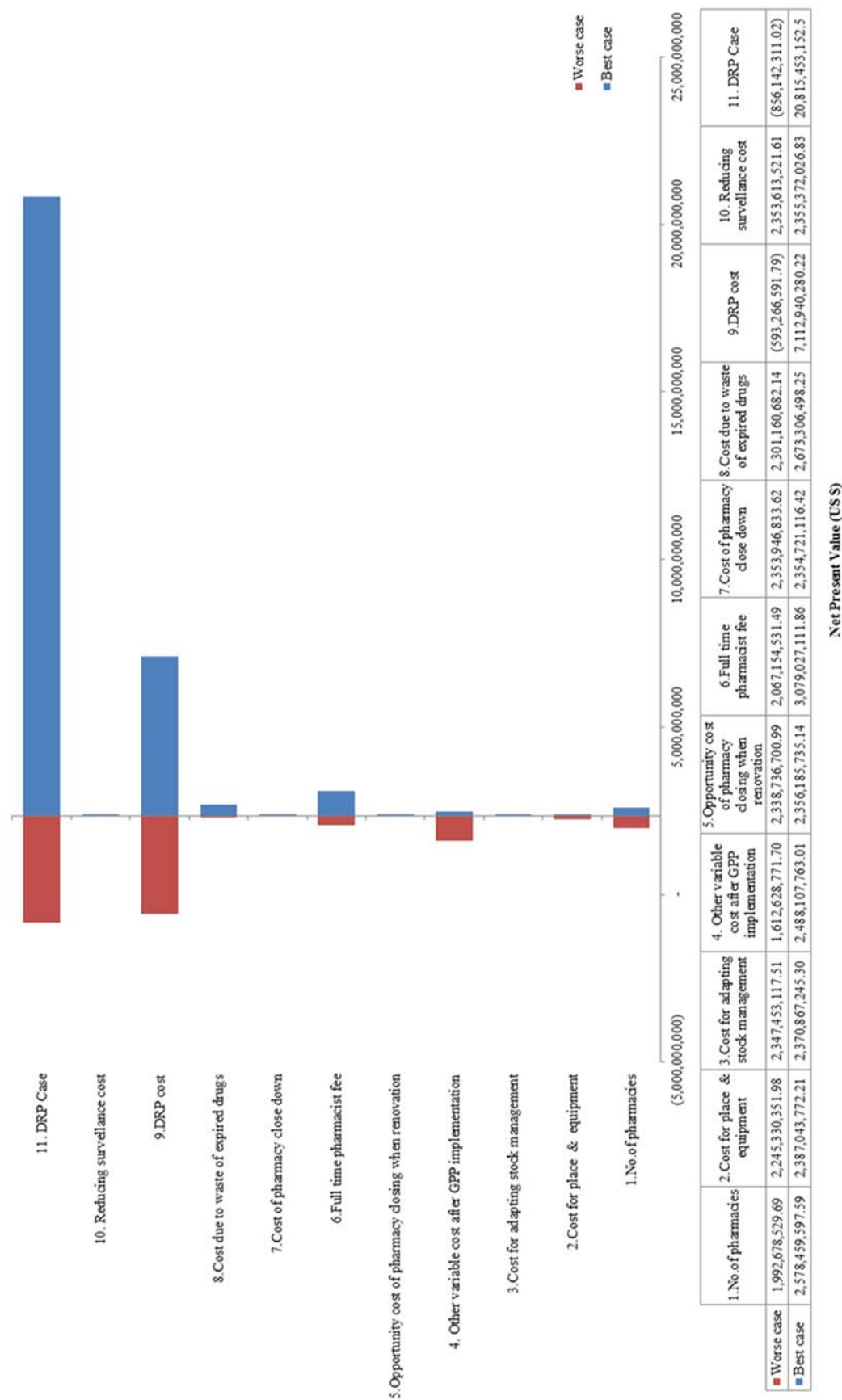


Figure 1 One way sensitivity analysis of 8-year implementation of the GPP regulation in community pharmacies

except when the two variables of DRP cost and number of DRP cases were varied. Varied DRP cost provided NPV ranged from -\$593.27 million dollars to \$7,112.94 million dollars (-19,453.211 to 233,233.31 million baht), whereas varied DRP cases provided NPV which ranged from -\$856.14 million dollars to \$20,815.45 million dollars (-28,073.91 to 682,538.71 million baht). Both of these variables showed negative NPV in the worse-case scenario. In conclusion, the results indicated that implementing the GPP regulation in community pharmacies in Thailand was cost beneficial and provided positive financial return on investment to the society since the first year. Our recommendation is the lag time for old community pharmacies should be less than eight years and it might be better to implement to all community pharmacies before the integration of AEC in 2015.

Acknowledgement

The authors would like to thank Thai-FDA for the funding and Assoc. Prof. Sathipong Thanaviriyakul for his valuable comments. Our manuscript has already been proofread to 'International English' by a native English speaker experienced in medical English, Stephen Pinder.

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