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Perception Regarding Generic Drug Policy in Thailand to Ensure Patient Safety and Quality of Care: Mediating Role of Rational Drug Use

Sakapas Saengchai [1], Jintana Pattanapongthorn [2], Kittisak Jermsittiparsert [3, 4*]
[1] Faculty of Humanities and Social Science, Suan Sunandha Rajabhat University, Bangkok, Thailand
E-mail: sakapas.sa@ssru.ac.th
[2] Office of Expert Committee, Department of Health, Nonthaburi, Thailand
E-mail: jin_pattana@yahoo.com
[3] Department for Management of Science and Technology Development, Ton Duc Thang University, Ho Chi Minh City, Vietnam
[4] Faculty of Social Sciences and Humanities, Ton Duc Thang University, Ho Chi Minh City, Vietnam

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ABSTRACT

Generic drugs are the copy of branded drugs having same efficacy. Cost of generic drugs is much less than branded prescription drugs. The policy of generic drugs is not very well understood in Thailand. That's why economic gains are not achieved despite the availability of seven generic drugs purchased in Thailand. If clear policy of generic drugs will be implemented there will be positive impact on the quality care and patient safety keeping in view of rational drug use.

The aim of our study was to establish the perception of generic drugs by the people and its association with safety quality and patient care in Thailand's population.In this study, data of 296 citizens of Thailand of middle age group was collected. Structure survey questionnaire and purposive sample was used for the collection of data. IBM-SPSS and AMOS was used to analyze the data. Structural equation model (SEM) was the confirmatory method of analysis to check impact of generic drug policies on the quality care and patient health.

The results of our study showed the positive association of implementation of generic drug policies on the quality of care and patient safety mediated by rational drug use in Thailand.Our study confers the social, theoretical and practical benefits in regard to implementation of generic drugs policy in relation to rational drug use and quality care and patient safety in Thailand.

Keywords: Generic drugs, patient safety, quality care

Correspondance:
Kittisak Jermsittiparsert
Faculty of Social Sciences and Humanities, Ton Duc Thang University, Ho Chi Minh City, Vietnam
Email: kittisak.jermsittiparsert@tdtu.edu.vn

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INTRODUCTION

Private and public sector are involved in providing healthcare facilities in Thailand. Healthcare sector is a huge burden on the total GPD of the country making up to 2.6% of it. It is estimated that approximately 43% of the GDP is expended on the health care facilities and majority of the budget goes to the purchase of expansive prescription drugs. A study conducted in 2010, the medication consumption in Thailand (at purchaser cost) was around US $4517million.(Fathelrahman, Ibrahim, & Wertheimer, 2016). Thailand has a one of the best healthcare system where practically all patients are secured by protection for their wellbeing administrations (Rungsrisawat & Jermsittiparsert, 2019). The Universal Health Insurance Policy includes as part of their healthcare delivery, a well-functioning public distribution system of pharmaceuticals. Most of the essential drugs required, more than 90%, are available to public health care facilities with relatively small rates of stock-out. The stock of medications is appropriated where emergency clinics are provided legitimately with the vital drugs. Medical clinics and community hospitals deal with general wellbeing of healthcare. The accessibility of vital medications in public health facilities (including those categorized to be used in health facilities) is lower than in clinics, potentially because some health centers don't use a significant number of medications categorized in the regional EML to use at that scale.(Bandoophanit, Breen, & Barber, 2017)

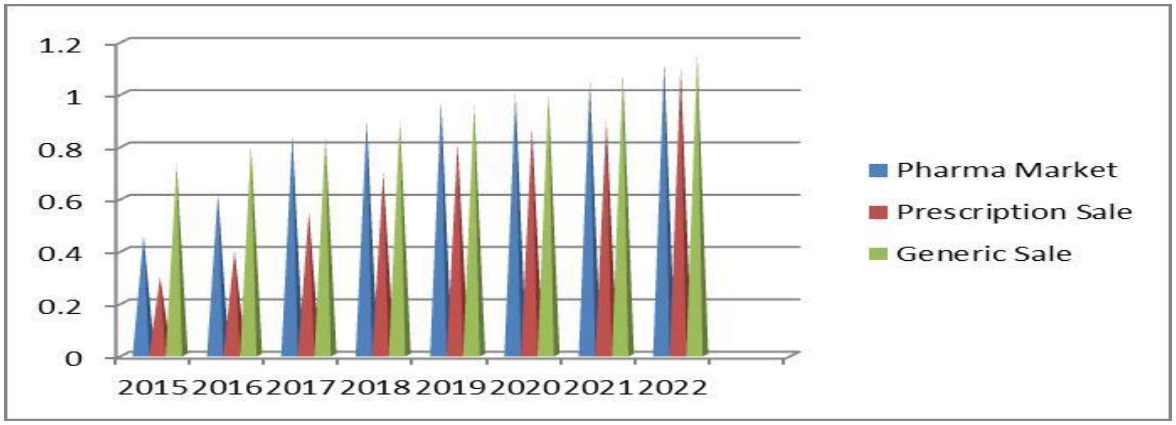

Figure 1. The increased sale of generic drugs is expected be equal to prescription sale by 2020 in Thailand. Source: Med Pharma Congress (2018).

The use of medicines that are sound, safe and practical is an important procedure. Only those medicines for the appropriate use should be included in the treatment and protection of safety. Since the last analysis in 2012 in Thailand, there has been generous progress towards promoting the rational use of medicines (Kar, Pradhan, & Mohanta, 2010). The commercial retail pharmacy prescription survey revealed that a total amount of drugs bought per patient was 1.64 (1.0-2.14), 8.6 percent bought antibiotics and 7.1 percent bought supplements. Generic drugs makes up to only 8.8 percent of medications are supplied / prescribed. The amount of these drugs prescribed in public sector is 35.8% more than in private sector due to its cost effectiveness. While efforts have been made to reduce costs, rising health care costs has always been a concern due to increasing health needs and public demands and rising technical and clinical advancements prices especially in developing countries (Tangcharoensathien, Witthayapipopsakul, Panichkriangkrai, Patcharanarumol, & Mills, 2018). That is why, in Thailand, the level of quality and quality of care are declining due to the unpredictable governmental policies. This ambiguous policy of government leads to the increase in mortality rates, thus declining the healthcare conditions due to unavailability of the drugs of increased prices. Mortality rate of minor diseases increases up to 71% of total death reported in the country. The increasing trend shows the alarming situation of availability of prescription drugs in public and private sectors (Riley & Cowan, 2014). Thailand is attributed for high prevalence of TB. The treatment of TB is long and medications are quite expansive. Therefore, studies shows the importance of availability of cost effective drugs like generic drugs of TB in Thailand (Gilpin, Korobitsyn, Migliori, Raviglione, & Weyer, 2018). Another widely prevalent disease in Thailand is AIDS. Estimations taken in 2015 showed that 440,000 people have HIV positive status. And number of deaths due to this disease are 14,000. If easily available and cost effective drugs would have been available then it will be easy to cope this deadly disease in Thailand (Organization, 2015).

An approximately 280 billion Indonesian Baht in 2013 has been the economic loss from significant NCDs to the Thai community (Organization, 2017). This is because of the way that prescription medications (Organization, 2017). This is because new medicines such as generics are not adequately applied in the health sector due to lack of clear policies of producing and sale of generic drugs, leading to low standard patient care and protection. This issue is widespread not just in Thailand but same situation is in developing and developed countries. Therefore, government of Thailand should focus on the implementations of law that will help to manufacture these drugs in the country and plays its important role in healthcare (Alfonso-Cristancho, Andia, Barbosa, & Watanabe, 2015; Psaty, Platt, & Altman, 2015).

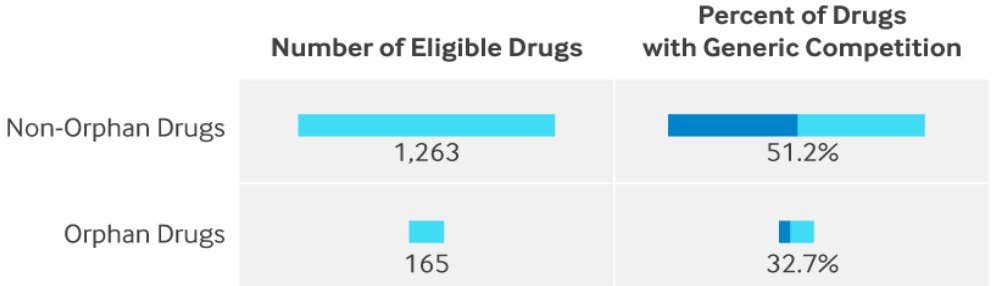

Figure 2: Diagram shows the competition given by generic drugs to small molecule drugs. Source: (Wellman-Labadie & Zhou, 2010)

Previous studies have been performed in quality and care but not in Thailand. Studies that are conducted to assess the impact of generic drugs policy on patient safety and care is uncertain and there results are unclear regarding this issue. Also, none of the study signifies the important role of mediator (rational drug use) with generic drug policy. Moreover, efficient statistical tools are not applied to assess the significance of these variables on the policy of generic drugs, therefore these gaps of previous studies will be filled in the present one.

The present study has following the objectives:

1: To analyze the impact of generic drugs policy in quality care in Thailand.

2: To assess the influence of generic drugs policy in Thailand.

3: To analyze the mediating role of rational drug use in relationship between generic drug use and patient safety in Thailand.

Previous studies signifies the role of efficient policy making for the generic drugs use thereby, improving quality of life and patient health in the individuals (Patel, Prajapati, & Paradkar, 2018). These studies suggest that, the cost of the drugs thereby health can be largely reduced if the policy of generic drugs are clearly explained and implemented so that the economic burden due prescription drugs can be reduced. In the present study, introduction and literature review elaborates the previous policies and there implementation in Thailand with regard to the quality care and rational drug use, then materials and methods discuss the conduction of the survey and then results and discussion leading to conclusion stating the findings of this research work.

LITERATURE REVIEW

Drug regulation had been first been implemented in Thailand in 1909 when certain pharmaceutical products and opiate substances were banned for sale. The current legislation is the B.E. Drug Act.2510(1967) and all its modifications governing animal and human medical products. MOPH is a body that appoints drug committee to that supervise Food and Drug Administration (FDA). FDA carried out the implementation of these acts (Ruxrungtham et al., 2016). The FDA teams up with other MOPH organizations, for example, the Department of Medical Science and Provincial Public Health Offices (PPHO), in particular regions all through the nation just as non-MOPH offices to guarantee viable administrative frameworks on drugs for both human and creature employments. There are very strict protocols regarding generic drugs and surety is made that the generic drugs have equal therapeutic intervention as its original quarter part. For this purpose, bioequivalent certification is required for the production of generic drugs whereas, the protocols for the regular prescription drugs are easily accessible to the company (Chaiyakunapruk, Jones, Dhippayom, & Sumpradit, 2016). Jirawattanapisal et al., reported that Thai MOPH has lately approved the utilization of only generic types of seven medicines for government and non-commercial purposes. This have been done under the Thai Patent Act (1992) B.E.2535 (Article 51), that conforms with Article 31 (b) of the World Trade Organization Pact on TRIPS as well as the Doha Declaration IPPH (Jirawattanapisal, Kingkaew, Lee, & Yang, 2009). Tansitpong et al., (2018) did a survey in 2018 to assess the awareness of generic drugs. For this purpose, questionnaires were filled by the pharmacists working in the health institutes. In the view of above mentioned studies, government should take into account the importance of generic drugs and new policies should be made so that investment in these drugs can be enhanced and its good impacts can be transferred to the patients of every financial background.

Generic drug policy and quality care

Study found that maximum pharmacists were aware to benefits of generic drugs making up to 88.1%. 84.7% pharmacist also added that after admiration of generic drugs in the presence of proper healthcare providers, their efficacy should be monitored and then analyze for its efficacy and safety purpose. This information will be helpful be the other healthcare providers in regard with the importance and efficacy of these drugs. Tansitpong et al. (2018), asserted that basically generic drug is administered to three major diseases including CVD, chemotherapy and neurological drugs in Thailand. The prevalence of these diseases make the major portions of overall diseases in Thailand. Accordingly, enabling generic replacement, encouraging generic prescription in clinics (in which generic prescription is still restricted), and encouraging generic therapeutics to patients and the population in general will help tackle the rising prices of medications (Tansitpong & Chaovalitwongse, 2018). Due to decline in prescription drug use and increase generic use, the quality of care will become better and more available to the people.

H1: Generic drug policy has significant impact on the quality of care.

Generic drug policy and patient safety

Sapsirisavat et al., (2016) studied the impact of generic drugs with healthcare of HIV subjects. Research further states that HIV therapy in Thailand currently relies on and has been conducted on generic antiretrovirals (ARV), quality control monitoring of many generic ARVs obtainable from multiple sources in Thailand. Evaluation would include a drug identification experiment, a chemical structure assay to directly measure its active compounds in-vitro and in-vivo. Correlations to the requirements mentioned throughout the global pharmacopeia of who have been rendered. A strategy of permitting nonexclusive generic substitution is applied in the developed nations. Although, in the conventional substitutions, is definitely not an essential and adequate condition for high generic use. For example, most of the developing countries are exceptional in accomplishing a significant level of conventional drug use, regardless of not utilizing a policy of generic substitution. Their strategy of utilizing conventional medication names in restorative instruction projects is credited with setting set up an endorsing conduct over the profession of the doctor with generous effect on expanding nonexclusive recommending. The elevated level of conventional recommending in the developing countries represents that other strategy instruments, especially at endorsing level, are powerful and warrant thought by approach making errs wishing to build the utilization of nonexclusive drugs (Rego, Brandão, Melo, & Nunes, 2002).

King et al., (2002) proposed in the stud that it can be seen that systems that either facilitate early market entry of generic pharmaceuticals or put in place financial incentives for their use, are best able to achieve the dual aims of increasing the consumption of generic drugs and creating a competitive market in which substantial differences in prices exist between the generic and branded, originator versions of a pharmaceutical product. Therefore, government of Thailand should take measure to ensure the flexible policies for generic drugs. This will not only improve quality care but also patient safety for the people (King & Kanavos, 2002). It is the concept among people that generic drugs due to less cost are also less efficient. But the above mentioned studies showed that these drugs are equally efficacious as prescription drugs. Thus, we can say that the generic drugs play a significant part in the patient safety.

H2: Generic drug policy has significant impact on patient safety

Mediating role of rational drug use with quality care

Perehudoff et al (2010) argued that, according to the international law, availability of necessary medications and treatment as part of the basic human right to a highest achievable quality of wellbeing ("the right to health") has been well established. The 1966 International Covenant on Political, Sociocultural Protection calls on states members to take measures to ensure accessibility for everyone to health services (Perehudoff, Laing, & Hogerzeil, 2010). A study by Mohammad et al., (2017) cited that, according to World Health Organization (WHO), the proportion of the population without sufficient access to vital medicines is less than 1% in developed countries, 24% in middle-income countries, and 39% in developing countries (Mohammad, 2017). In the least developed countries like Asia and Africa, this percentage increases up to 50 percent. Khatib et al (2016) and Ongarora et al., (2019) attributes this least accessibility of live saving medications to the increase cost of these drugs (Khatib et al., 2016; Ongarora et al., 2019). Kaló et al (2015) and Mendelson et al. (2016) discussed the comparison of the prescription drugs by the brand name the generic drugs and found that generic drugs have proved to be cost effective and easily accessible. And these feature of generic drug highly impact on the quality care (Kaló et al., 2015; Mendelson et al., 2016). Another study conducted by Bell et al (2018) asserted that the counterpart of branded medicine are equal in effectiveness and several times cheaper than original one (Bell et al., 2018). Ferrario et al. (2017) studied the economic impact of using generic drugs and found that the branded prescription medicine are huge burden of country's GDP (Ferrario, Humbert, Kanavos, & Pedersen, 2017). Fadare et al. (2016) suggested that it was reported that the change towards licensed drugs to the least expensive generic versions in the private industry in 17 low income countries can lead to an average savings of 60 percent. Above mentioned studies suggest that an efficient generic drug policy implication due to rational drug use of have positive role in the quality care.

H3: Rational drug use has significant role in generic drug policy and quality care

Mediating role of rational drug use with patient safety

Shrank et al; taking into account on CVD illness showed that anticipation with the fitting utilization of generic meds, shows up definitely more financially economical than recently reported, and it might even save money on costs. For instance, a prior examination evaluated that diminishing medication for non-diabetic and BP patients cost an expected $52,983 per quality-adjusted life-year, if a brand-name medication was utilized but without a brand name it cost decrease up to $7,753. (Shrank, Choudhry, Liberman, & Brennan, 2011). The rational drug use of generic medications also plays a key role in the patient safety protocols. As these drugs are equally beneficial for the patients also, less cost of this drug makes them easily accessible for people from all the financial backgrounds. This makes these drugs safety for the patients.

H4: Rational drug use has significant role in generic drug policy and patient safety

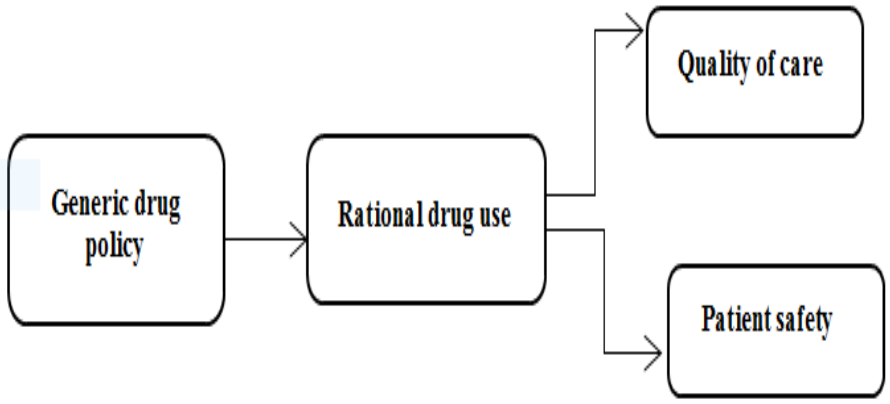

Figure 3: Diagram shows that rational drug use acts a mediator between generic drug policy and quality of care and patient safety.

RESEARCH METHODOLOGY

Population and Sampling

Researcher conducts this specific research study for observing the role of generic drug policy for ensuring the patient safety and quality of care, in mediating role of rational drug use. Population of study in this research study is Thailand because researcher observed the drug abuse as the increasing problem in Thailand. According to previous surveys, 4000 heroin addicts have been estimated in Bangkok alone and it has also been estimated that Yaba is the most used drug by Thai peoples between the age of 12 to 65. Due to these reasons, researcher considered it mandatory to evaluate that what will be the perception of Thai people regarding the role of generic drug policy in ensuring the quality of care and patient safety. In general, generic drug has been considered most authentic medication for drug abuse and it save up to 80% life's but to know the Thai people perspective researcher conducts this study. Researcher chooses the pharmacies of three big cities of Thailand such as Bangkok, Phuket and Chiang Mai through convenient sampling technique, as it enables to selects those which can easily be assessed for data collection. Further, sample respondents are the pharmacist working in these pharmacies, they have been selected through purposive sampling technique because researcher has to select only those who have knowledge about generic drug policy and its possible outcomes. For data collection, researcher distributes the 350 questionnaires among respondents, out of which only 319 have been received but researcher considered only 296 as valid response because 25 responses have been rejected due to incompleteness and invalidity.

Data collection Procedure

For quantitative, objective and primary data collection, researcher selects the survey questionnaire as best suitable survey instruments, it has to be composed of closed ended questions because researcher required objective response, despite of subjective opinion. Researcher asked the respondents two kinds of closed ended questions such as variable scale items and demographic questions. Moreover, researcher verified that questionnaire language has to be Thai while data collection and researcher ensured the content validity of measurement items through industrial practitioners. Further, researcher used pretest approach for identifying mistakes in questionnaire and to collect feedback regarding understandability of items from specific 30 respondents. For administration of questionnaire, researcher accompanied self-administering technique, as researcher self-visit the respondents and demonstrate them questionnaire filling procedure and tried to solve their queries regarding specific term.

Measures

In this research study, researcher takes into account the previous literature for the adaption of survey items for the measurement of proposed variables of the study because many other authors have already been conducted the research study on them and also have already been verified the reliability and validity of measures. Researcher has been adapted the 10 survey items for the measurement of generic drug policy, from work of (Xanthopoulou & Katsaliaki, 2019). For the measurement of patient safety, 5 measurement items have been taken from (Burke, 2003) and for the measurement of quality of care, researcher adapts the 3 survey items from (Van Bogaert et al., 2017). Further, researcher takes into account research work of (Yang, Liu, Ferrier, Zhou, & Zhang, 2012), for adapting 3 survey items for the measurement of rational drug use. All these measurement items responses have been measured on the bases of 5-point Likert scale, in which responses ranges from 1 (strongly disagree) to 5 (strongly agree).

Data Analysis

SPSS and AMOS software have been accompanied for evaluating the reliability and validity, by examining different criteria. Researcher evaluates the reliability through SPSS and examined two criteria such as Composite reliability and Cronbach's alpha, for ensuring the internal consistency of data and items reliability, both must have the values greater than threshold range 0.70. Further, AMOS has been accompanied for accessing convergent validity and discriminant validity, such as for convergent validity two criteria have been examined (1) average variance extracted, its values have to be greater than 0.50 and (2) factor loading, its values must exceed the 0.70 cutoff value. For evaluating discriminant validity, square root of AVE has to be greater than all other corelated constructs. Researcher has also been accompanied AMOS for running diagnosis of structure equation modeling, which performed hypothesis testing for reporting that which hypothesis get accepted or which get rejected.

Analysis of Data and Interpretation

The current study targeted 296 participants and out of those, 123 were male and 173 were female. Education wise, 23 were graduated, 142 were post graduated, 121 were masters and 10 had other degrees. The age of 41 people was between 21-30 years, the age of 184 people was between 31-40 years, the age of 52 people was between 41-50 years and 19 people were 50+.

Table 1: Descriptive statistics

	N	Minimum	Maximum	Mean	SD	Skewness	
	Statistic	Statistic	Statistic	Statistic	Statistic	Statistic	SE
RatDrugUse	296	1.00	5.00	3.5642	1.09287	-.819	.142
QualCare	296	1.00	5.00	3.3941	1.19983	-.543	.142
PatSafity	296	1.00	5.00	3.5101	1.16545	-.511	.142
GenDrPolicy	296	1.00	5.00	3.4453	1.10663	-.599	.142
Valid N (listwise)	296						

The above table one is showing the descriptive statistics of the study, the descriptive statistics detailed explanation about the variables if the study and they showing that the descriptive coefficients that give a complete summary of data. This set of data represent the entire sample of the population. The data is showing that there is no outlier in given data because maximum values are in the threshold range of 5-point Likert scale and the value of skewness is between -1 to 1, which is the threshold range of normality so, the given data is normal and valid. The data is valid to go for further testing.

Table 2: Rotated Component Matrix

	Component			
	1	2	3	4
RD1				.782
RD2				.794
RD3				.836
QC1			.833	
QC2			.857	
QC3			.834	
PS1		.875		
PS2		.895		
PS3		.884		
PS4		.873		
PS5		.887		
GD1	.848			
GD2	.863			
GD3	.871			
GD4	.896			
GD5	.891			
GD6	.887			
GD7	.867			
GD8	.841			
GD9	.853			
GD10	.856			
GD11	.819			

The above table two of rotated components matrix is showing that, almost all of the indicators are having factor loading more than 0.7, it means that all indicators are eligible to be exposed to further hypothesis testing techniques, because all the factors are in suitable threshold level and all the factors in suitable and valid sequence and range. So, this data is good to go for further testing techniques. There is no cross loading in the data shown in RCM so, the data is reliable.

Table 3: Convergent and Discriminant Validity

	CR	AVE	MSV	MaxR(H)	GD	QC	PS	RD
GD	0.914	0.771	0.288	0.976	**0.878**			
QC	0.903	0.756	0.282	0.980	0.459	**0.869**		
PS	0.922	0.834	0.331	0.987	0.380	0.527	**0.913**	
RD	0.895	0.740	0.331	0.989	0.537	0.531	0.575	**0.860**

The validity master sheet was used in order to confirm the convergent and discriminant validity for the research model variable. The discriminant validity provided the discrimination between variables while the convergent validity was measured with the help of composite reliability and average variance extracted. The results of the validities are shown in the table three. The results and convergence of each variable is more than 70%. The average variances extracted are more than 50%, while the discriminate validity showed that, loading of each variable discriminates

form each other. Every variable has maximum loading with itself as compared with others. So, these validities prove the authenticity of the collected data.

Table 4: Confirmatory factor analysis

Indicators	Threshold range	Current values
CMIN/DF	Less or equal 3	2.529
GFI	Equal or greater .80	.864
CFI	Equal or greater .90	.960
IFI	Equal or greater .90	.960
RMSEA	Less or equal .08	.072

Table four is of CFA, which is the confirmatory factor analysis used to confirm the fitness of hypothetical model before structural equation modeling, current results are showing that CMIN is less than 3, GFI is more than 0.80, CFI is more than 0.90, IFI is more than 0.90, and RMSEA is less than 0.08. All of the results showed that the data is in valid range and is good to go for further testing. Following is the screen shot of CFA in figure one.

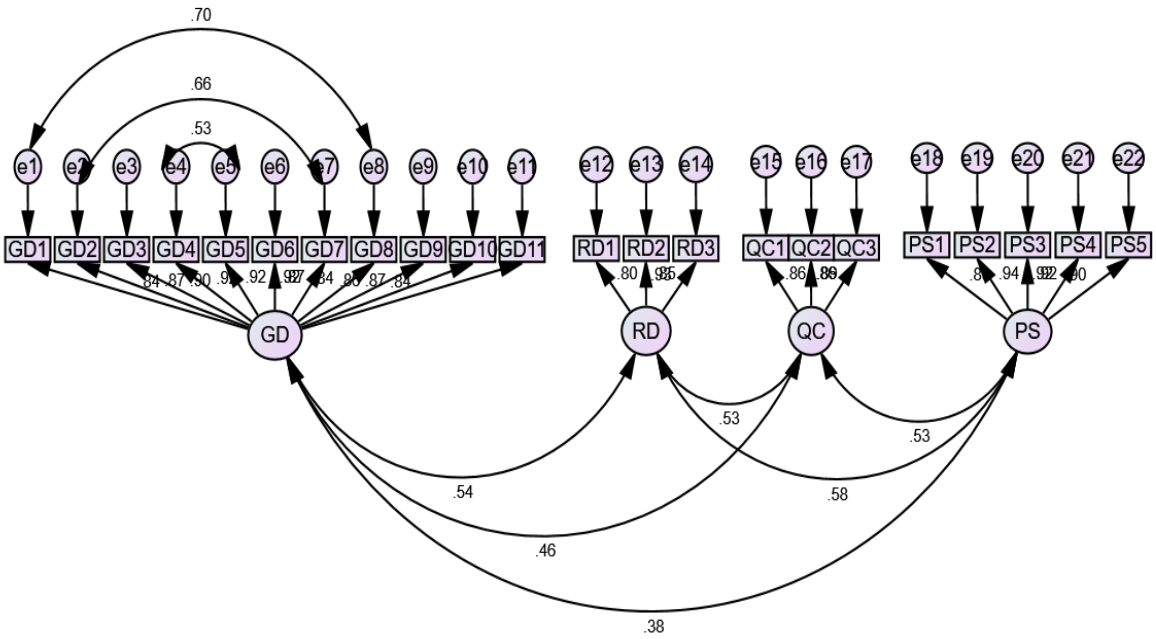

Figure 4: CFA

Table 6: Structural Equation Modeling

Total Effect	**GenDrPolicy**	**RatDrugUse**
RatDrugUse	.485***	.000
PatSafity	.369***	.484***
QualCare	.430***	.349***
Direct Effect	GenDrPolicy	RatDrugUse
RatDrugUse	.485***	.000
PatSafity	.134**	.484***
QualCare	.260**	.349***
Indirect Effect	GenDrPolicy	RatDrugUse
RatDrugUse	.000	.000
PatSafity	.235**	.000
QualCare	.169**	.000

The SEM table is showing the results of the relationships between different variables and the impacts of different variables. The impact of GDP on RDU, PS and QC is significant and positive. The impact of RDU on QC and PT is significant and positive as well.

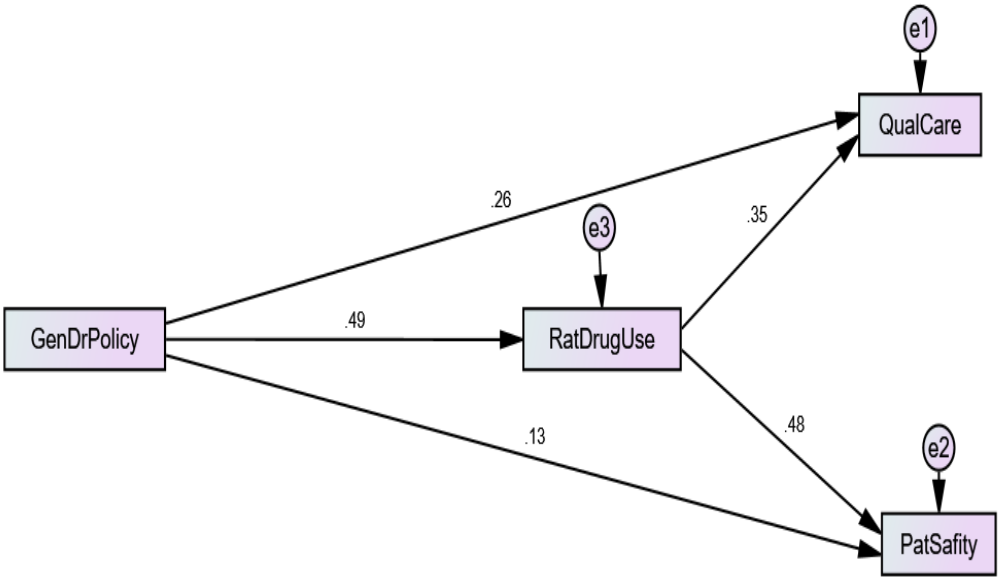

Figure 5: SEM

DISCUSSION AND CONCLUSION

Discussion

The aim of the study is to know impact of Generic Drug Policy (GDP) on Quality of Care (QOC) and Patient Safety (PS) with the mediating role of Rational Drug Use (RDU). The first hypothesis introduced was 'the impact of Generic Drug Policy on Quality of Care is positive and significant' this hypothesis was accepted. According to the writer (Guennif, 2017) the care which is shown in the generic policy which ensures the safety of drugs has made the life safe of people. The second hypothesis proposed was 'the impact of Generic Drug Policy on Patient Safety is positive and significant' this hypothesis was accepted. According to the writer (Lu, Emmerick, Stephens, Ross-Degnan, & Wagner, 2015), the patient feels secure and feel safe to buy that drugs that are originated by the authorities and they are also answerable to the community in the happening of any misleading event or when a patient is not safe. The third hypothesis proposed was 'the mediating role of Rational Drug Use between Generic Drug policy and Quality of care is positive and significant' this hypothesis has been accepted. According to the writer (MacNaughton & Forman, 2015), the policies which are introduced have make sure that drug is used in a proper way for medical treatment and automatically it has ensured the safety of the patient. The fourth hypothesis introduced was 'the mediating role of Rational Drug use between Generic Drug Policy and Patient Safety is positive and significant' this hypothesis was accepted. According to the writer (Raka & Liangrokapart, 2017), the safety of patient and not only patient but also other people who are affected by the irrational use of the drugs are marked safe by the rational usage of drugs which is done by the policies that are governed by law (Sruamsiri, Ross-Degnan, Lu, Chaiyakunapruk, & Wagner, 2015).

CONCLUSION

The aim of the study is to know impact of Generic **(**GDP) on (QOC) and (PS) with the mediating role of (RDU). This study was conducted in Thailand from 300 people through questionnaire. The study concludes that how the PS has been ensured by the policy makers of drugs. The RDU marks the safety and GDP ensures the PS. the impact of the policy has not only affected the patient person but also the normal people who consume drugs like cigarette and other forms of alcohol. This study sums that the RDU determines PS and QOC and all the variables are dependent on each other that how these factors are interrelated with each other and how much of difference does it make in a country's population or citizens. The country is also rated high when the safety of the citizens is ensured by the policies

Implications of the study

This study has enlightened the theory the with need of such policies that provoke the RDU which will ensure and emphasis on PS. this study has ensured the life of patients and they have put their trust in pharmaceutical companies because this study has made them realize to initiate the registration and authorization of the GDP. The government has also gained the trust of general public by making these authorized GDP by drug selling companies and retailers

Limitations and future research recommendations

This study has only focused on one mediating role RDU, other variables that highly play vital mediating role should also have been mentioned the future researcher is advised to cater more than one mediator by targeting a larger sample. The sample taken in the study was small as compared to the topic, the sample should be widening in order to get more precise and detailed data to reach to a conclusion in a better way.

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