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The International Journal of Public Health and Health Sciences (IJPHS) aims to publish original articles and contributions relevant to public health and medical sciences. IJPHS is published by the Praboromajchanok Institute for Health Workforce Development (PBRI), Ministry of Public Health, Thailand. It is a non-profit, peer-reviewed, open-access, international, scientific journal that publishes articles in areas of health sciences disciplines. The scope of the IJPHS is broad, covering the following categories: original articles, reviewed articles, special articles, case reports, correspondence, and others in the fields of public health, medical sciences and related allied health, especially the following areas:

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Three issues will be published annually: January - April, May - August, and September - December. Authors from all areas of health and medical sciences are invited to submit scientific papers and contribute in this journal. Please find more details at https://he01.tci-thaijo.org/index.php/ijphs/index

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Editorial Statement

The Global Health Security Index (GHS Index) 2021 has been announced Thailand health 5th globally by Nuclear Threat Imitative Researchers, Center for Health Security, Bloomberg School of Public Health, Johns Hopkins University, USA and Economist Impact ranked countries with health security. The indices were the assessment of the readiness to cope with the epidemic of communicable diseases 2021 by assessing 6 factors covering issues epidemic prevention infection detection, follow-up care for patients coping with the epidemic, public health system compliance with international standards, managing political, and economic and social risks. Thailand was ranked fifth with an overall score of 68.2 out of 100, and ranked No. 1 in Asia. Thailand received the highest score for detection and tracking of cases at 91.5 points, with the top 10 countries being: 1. United States 2. Australia 3. Finland 4. Canada 5. Thailand 6. Slovenia 7. United Kingdom 8. Germany 9. South Korea and 10. Sweden (https://www.ghsindex.org/country/thailand/)

COVID-19 infections are decreasing in Thailand, with 12,992 new infections reported on average each day. That's 50% of the peak. There have been 4,271,815 infections and 28,701 coronavirus-related deaths reported in the country since the pandemic began. For vaccination, Thailand has administered at least 133,209,540 doses of COVID vaccines so far. Assuming every person needs 2 doses, that's enough to have vaccinated about 95.7% of the country's population. If you are traveling to Thailand, please visit Department of Disease Control, Ministry of Public Health's website; from here you will find Thailand Ministry of Public Health travel advisories and other useful information. You may also consult the Tourism Authority of Thailand (TAT) Press Releases, Civil Aviation Authority of Thailand and Thai Embassy or consular. ICAO also updates Global COVID-19 airports status. They also provide useful information for travelers.

The editorial board of IJPHS sincerely hope that the members, faculty members, researchers, industrious students, medical, nursing and public health personnel as well as alumni who are interested in obtaining more detail from original articles, reviews, and other to use or transform research information into teaching and research fields. In this issue, IJPHS is consisting of four interesting topics covering public health and medical sciences which you can download articles in the journal at the website https://www.tci-thaijo.org/index.php/ijphs.

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Content

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Original article

Factors Affecting Intention to Wear Face Masks among Thai People

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Abstract

This study examined the factors influencing Thais' intention to wear face masks. The predictors of intention to wear face masks included attitude, face mask cost, the pandemic risk perceptions, perceived benefits and face mask availability. This study gathered data using online questionnaires among 391 respondents recruited through convenience sampling. The conceptual framework was examined with the partial least squares path modelling and structural equation modelling (PLS-SEM) using the ADANCO software program (version 2.2.1) and SPSS (version 27). The empirical findings show the relationship between factors and intention to wear face masks. The results revealed that attitude had the most significant influence on intention to wear a face mask, followed by the perceived benefit of a face mask, pandemic risk perceptions, availability of face masks, and face mask cost. The respondents' pandemic risk perceptions significantly influenced attitude. Also, their attitude was a significant mediator between their pandemic risk perceptions and their intention to wear face masks. Our study assists healthcare policymakers in developing strategies to encourage wearing face masks as part of infection prevention protocols. Policy makers can better understand the public's factors that may increase their intention to wear a face mask during the COVID-19 pandemic by predicting the power of attitude, face mask cost, the pandemic risk perceptions, perceived benefits and face masks availability.

Keywords: Attitude, perceived benefit of face masks, the pandemic risk perceptions, face mask availability

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Introduction

Since the first coronavirus disease (COVID-19) patient was identified in December 2019 in Wuhan, Hubei Province, China, the virus has spread globally, resulting in a new public health crisis (Zhao, 2020; Zhou et al., 2021). Furthermore, the outbreak of a novel coronavirus (COVID-19) has become a substantial public health concern worldwide (Irfan et al., 2021). To cope with COVID-19, countries worldwide have implemented various containment and mitigation strategies to slow the increase in patient surges and flatten the curve so that the number of new cases is spread out over a larger amount of time. These actions allow the healthcare system more time to prepare for and handle the current confirmed patients (He, 2021). Also, most scientists have developed epidemiological models based on the little that was known about COVID-19 at that time (Stevens, 2020). Regular handwashing with soap or sanitisers, and wearing masks in public places are simple, cost-effective ways to reduce the spread of COVID-19. Wearing a face mask is recommended to prevent the spread of COVID-19 and respiratory disease (Chu et al., 2020; Tso & Cowling, 2020). Before the Covid-19 pandemic, medical face masks were primarily used by public health personnel. Now, the general public requires these single-use masks to protect themselves daily (Thampanishvong & Wibulpolprasert, 2020). Wearing masks in public places is an effective way to prevent the spread of COVID-19. This solution is highly recommended in several countries worldwide (Tran, 2021). Irfan et al. (2021) stated that it is crucial to assess public willingness to wear face masks during the COVID-19 pandemic. Numerous factors influence people's desire to wear face masks, including perceived behavioural control, attitude toward face masks, social norms, cost of face masks, risk perceptions of the pandemic, and availability of face masks (Irfan et al., 2021; Tran, 2021). Thus, factors affecting people's intention to wear a face mask during the COVID-19 pandemic are a crucial topic to study.

Problem Statement

COVID-19 has presented the world with a new and compelling challenge in the present era. As a result, the purchase of anti-corona virus products, such as face masks and hand sanitisers, are increasing (Shah et al., 2020). In Thailand, it is mandatory to wear a face mask when leaving the house to prevent the spread of Covid-19 (Wancharoen, 2021). Thus, it is critical and beneficial to understand individuals' intention to wear face masks during the COVID-19 pandemic.

Research Objective

This study identifies the main factors affecting the general public's intention to wear a face mask during the COVID-19 pandemic in Thailand.

Research Question

What are the main factors affecting the Thai general public's intention to wear a face mask during the COVID-19 pandemic?

Factors Affecting Intention to Wear Face Masks During COVID-19

Wearing a face mask is a simple and effective way to protect against the spread of many diseases, including COVID-19 (Chaabna et al., 2021; Tran, 2021). Therefore, it is critical to assess the public's willingness to wear face masks in response to the COVID-19 pandemic by analysing the factors influencing people's intention to wear them (Irfan et al., 2021).

Attitude was defined as a person's positive or negative evaluation of specific behaviour. It is a crucial component of the theory of planned behaviour (Ajzen, 2001). Previous research has found a positive relationship between attitude and willingness to wear face masks (Irfan et al., 2021).

Cost information is a critical factor in the economic losses associated with the purchasing process (Al-Marri et al., 2018). There is a correlation between the face mask

cost and the intention to wear them (Irfan et al., 2021; Kesselheim, 2013)

Risk perceptions are critical for taking preventive measures, but they are frequently biassed. Effective management of new epidemic infectious disease risks in the absence of treatment or vaccination relies heavily on population precautionary behaviour. Many health behaviour theories include risk perception as a critical component (Brug & Richardus, 2009). The pandemic risk perceptions significantly influence individuals' intention to wear face masks (Ahmad et al., 2020; MacIntyre & Chughtai, 2020; Irfan et al., 2021).

The perceived benefits of face masks refer to people's understanding and awareness of the benefits that face masks provide in controlling and preventing the transmission of infectious viral diseases (MacIntyre et al., 2009). Perceived benefits of face masks have a significant influence on individuals' intention to wear face masks (Burnett & Sergi, 2020; Feng et al., 2020; Shukman, 2020)

Significant numbers of individuals had to purchase protective tools, such as face masks, on their own because they were not provided by the hospitals or the government (Bhargava et al., 2021). Face mask availability significantly influences individuals' intention to wear face masks (Bhargava et al., 2021; Irfan et al., 2021).

Intention to Wear Face Masks

Wearing a face mask is a simple and effective way to protect against the spread of many diseases, including COVID-19 (Chaabna et al., 2021; Tran, 2021). However, the use of face masks remains contentious, with international variation in practice. Egan et al. (2021) investigated the effects of visual representations of guidance or infographics on knowledge of appropriate face mask usage in a representative UK cohort. That study enrolled a total of 4,099 adult participants. The findings revealed that there was a high willingness to use a mask. In addition, to ensure that face masks are used correctly, as required by UK law, guidance should provide sufficient information while remaining understandable. According to Irfan et al. (2021), it is critical to assess the public's willingness to wear face masks in response to the COVID-19 pandemic by analysing the factors that influence people's intention to wear face masks. Attitudes, pandemic risk perceptions, and perceived benefits of face masks significantly impact the public's willingness to wear face masks. In contrast, the face mask's cost and the limited availability can make face mask usage prohibitive.

Research Hypotheses

H1: The participants' risk perceptions of the pandemic significantly affect intention to wear face masks.

H2: Face mask availability significantly affects intention to wear face masks.

H3: Face mask cost significantly affects intention to wear face masks.

H4: Perceived benefits of face masks significantly affect intention to wear face masks.

H4: Attitude significantly affects the intention to wear face masks.

H5: Pandemic risk perceptions significantly affect attitude.

H6: Attitude is a significant mediator between participants' risk perceptions of the pandemic and intention to wear face masks.

Research Methodology

Closed-end online questionnaires (Likert's Rating Scale) were used to collect data in this study. The questionnaire items were based on previous research. The dependability and validity of the measurement instruments were assessed. Validity refers to how well an instrument measures the researcher's concept to quantify (Zikmund, 2003). The main variables in this study were measured using a five-point Likert Scale, ranging from 1 (strongly disagree) to 5 (strongly agree). Questions about respondents' demographics were

derived from the study conducted by Siripipatthanakul & Vui (2021). The questionnaire items about factors affecting intention to wear face masks were based on a previous questionnaire created by Irfan et al. (2021). The questionnaire was developed from reliable sources and content validity was proved by three experts in business, healthcare and education fields.

Study Population and Sample

Initially, the study's target population was unknown. The researchers conducted a typical survey that has a confidence level of 95%, following the recommendation of Zikmund (2003). A minimum of 385 cases at p=0.5 must be collected using convenience sampling from Thailand's five different geographical regions (Northern, Southern, Eastern, Central and Northeastern), with a sample error of 5% and a precision level of 95%. The study included 391 participants in total.

Data Collection

Self-administered questionnaires were used to collect data. The researchers used convenience sampling to recruit participants. Before delivering online questionnaires, it was critical to inform respondents about the study's objectives and solicit their participation.

Data Analysis

The collected data were analysed using the SPSS program (version 27) and the partial least squares-structural equation modelling program, called ADANCO, (version 2.2.1). The researchers calculated descriptive statistics for the demographic characteristics of the respondents, and found the mean and standard deviation for each variable and questionnaire item. Reliability tests and factor loadings were used to determine the data's reliability and validity.

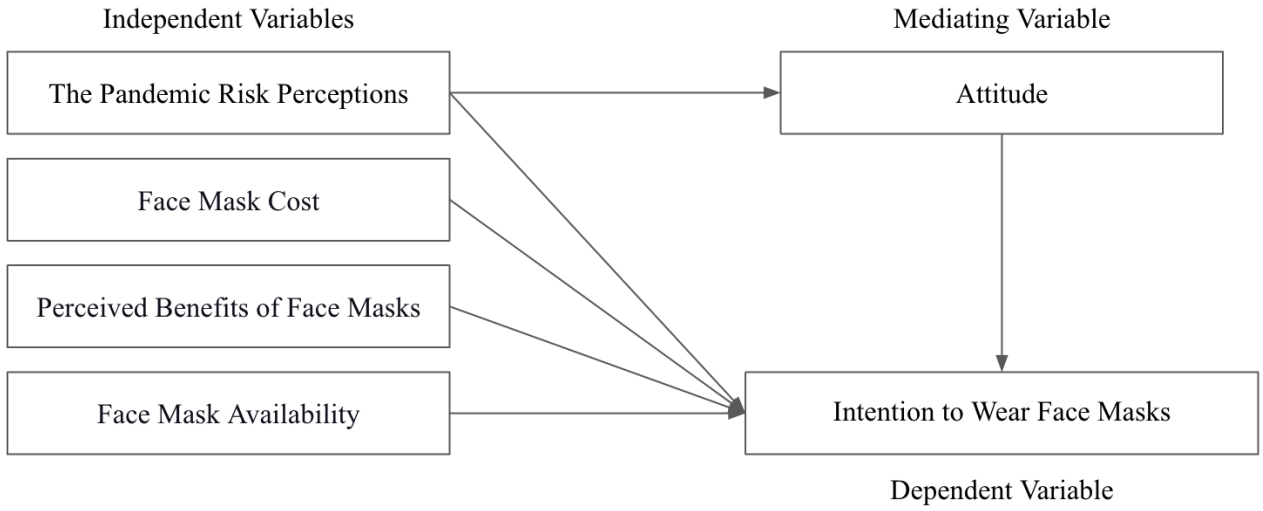

Figure 1. Conceptual Framework of the Study.

Results

Three hundred and ninety-one (391) respondents completed questionnaires. Most respondents were female (69.1%), between the age of 18-25 years old (49.6%), single (83.4%), and earned monthly income below 10,000 baht. Most of them always wear a face mask when going outside (96.4%). Participants usually used 1-2 pieces of face mask (74.2%).

Table 1. Scale Reliability of Different Constructs Associated with Intention to Wear Face Masks Including Cronbach's Alpha and Average Variance Extracted

Construct	Cronbach's Alpha	Average Variance Extracted
Attitude	0.7513	0.6704
Face Mask Cost	0.8828	0.7399
The Pandemic Risk Perceptions	0.7936	0.6199
Perceived Benefits of Face Masks	0.8472	0.6842
Face Mask Availability	0.8191	0.7340
Intention to Wear Face Masks	0.7209	0.5435

Cronbach's Alphas were over 0.7 and AVE were over 0.5, following the recommendation of Jung et al (2014).

Table 2. Total Effects Inference Between Different Factors and Intention to Wear Face Masks

Effect	Original Coefficient	Standard Bootstrap Results					Percentile Bootstrap Quantiles			
		Mean Value	Standard Error	T-Value	P-Value (2-Sided)	P-Value (1-Sided)	0.5%	2.5%	97.5%	99.5%
Perceived Benefits → Intention to Wear Face Masks	0.2987	0.2987	0.0588	5.0802	0.0000	0.0000	0.1596	0.1917	0.4148	0.4478
Attitude → Intention to Wear Face Masks	0.3047	0.3009	0.0716	4.2522	0.0000	0.0000	0.1322	0.1716	0.4483	0.5017
Face Mask Availability → Intention to Wear Face Masks	0.1589	0.1603	0.0390	4.0715	0.0001	0.0000	0.0622	0.0855	0.2403	0.2751
Pandemic Risk Perceptions → Intention to Wear Face Masks	0.4031	0.4011	0.0694	5.8072	0.0000	0.0000	0.2163	0.2549	0.5303	0.5688
Pandemic Risk Perceptions → Attitude	0.7108	0.7053	0.0696	10.2091	0.0000	0.0000	0.4912	0.5546	0.8256	0.8484
Face Mask Cost → Intention to Wear Face Masks	-0.0627	-0.0634	0.0363	-1.7270	0.0845	0.0422	-0.1592	-0.1318	0.0193	0.0453

Table 3. Summary of Hypothesis Testing of Factors Associated with Intention to Wear Face Masks Based on Path Analysis from Structural Equation Modelling

Hypotheses	Results	Actions
H1: The pandemic risk perceptions significantly affect intention to wear face masks.	β=0.187 at p<0.01	Supported
H2: Face mask availability significantly affects intention to wear face masks.	β=0.159 at p<0.001	Supported
H3: Face mask cost significantly affects intention to wear face masks.	β= - 0.063 at p<0.05	Supported
H4: Perceived benefits of face masks significantly affects intention to wear face masks.	β=0.299 at p<0.001	Supported
H4: Attitude significantly affects the intention to wear face masks.	β=0.305 at p<0.001	Supported
H5: The pandemic risk perceptions significantly affect attitude.	β=0.711 at p<0.001	Supported
H6: Attitude is a significant mediator between the pandemic risk perceptions and intention to wear face masks.	R^2=0.505 at p <0.01	Supported
Overall, the relationship can be explained by 57.0% (R^2=0.570).		

Figure 2 shows the specific β coefficients, R^2 values, and p-values for the associations between different factors and intention to wear face masks based on the PLS-Structural Equation Model for our study. All factors the researchers examined were related to the intention to wear face masks (R^2=0.570, p<0.001). Attitude (AT) had the most influence on the intention to wear face masks among Thais (β=0.305, p<0.001), followed by perceived benefits of face masks (PB; β=0.299, p<0.001), the pandemic risk perceptions (RP; β=0.187, p<0.01), face mask availability (AVL; β=0.159, p<0.001). Face mask cost has a significant adverse effect on the Thais' intention to wear face masks (CST, β= -0.063, p<0.05). The participants' risk perceptions of the pandemic have a significant influence on the intention to wear face masks, which accounted for about 50.5% of the variability in intention to wear (β=0.711, p<0.001, R^2=0.505) Attitude was a mediator between participants' risk perceptions of the pandemic and their intention to wear face masks (β=0.305, p<0.001, R^2=0.505).

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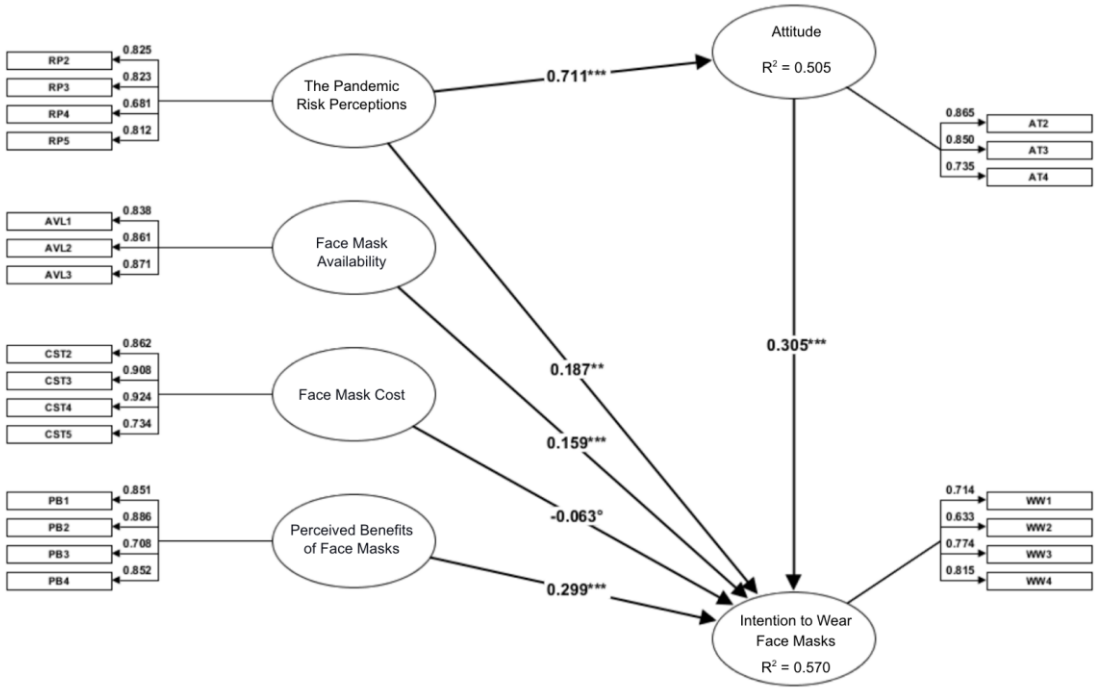

Figure 2. PLS-Structural Equation Model of the Study (SRMR=0.782).

RP=the pandemic risk perceptions; AVL=face mask availability; CST=face mask cost; PB=perceived benefits of face masks; AT=attitude; WW=intention to wear face masks.

Discussion

The study's main objective was to identify the factors affecting the general public's intention to wear a face mask during the COVID-19 pandemic in Thailand. All of our a priori hypotheses were tested and confirmed. The results from this study supported the previous research of Zhang et al. (2021) that residents' positive attitudes toward face mask-wearing influence their behavioural intention to wear face masks. Also, our results also supported the previous studies of Irfan et al. (2021) and Larebo & Abame (2021) that there is a positive relationship between attitude and the intention to wear face masks. Kesselheim (2013) found that wearing face masks has emerged as a critical policy issue globally. The costs of face masks strain people's budgets and contribute directly to adverse outcomes. Our results supported research by Irfan et al. (2021) that the likelihood of the general public wearing face masks decreases if the cost of purchasing face masks rises. Our results supported the previous research of Irfan et al. (2021) that face mask availability impacts the public's intention to wear them. In addition, our research findings supported findings from Bhargava et al. (2021) and Chughtai & Khan (2020) that the availability of face masks has a significant impact on individuals' intention to wear them. Our results supported the previous research of Ahmad et al. (2020), MacIntyre & Chughtai (2020), and Irfan et al. (2021) that the pandemic risk perceptions have a significant influence on individuals' intention to wear face masks.

Conclusion

Our empirical findings show the relationships between factors and intention to wear face masks. Our study reveals that participants' attitude, their risk perception of the pandemic, perceived benefits, and face

mask availability significantly impacts their willingness to wear them. However, increased face mask cost harms the intention to wear face masks. Furthermore, participants' risk perceptions of the pandemic have a significant impact on attitude. Thus, attitude is the mediator between participants' risk perception of the pandemic and the intention to wear face masks among the general public in Thailand.

Research Implication

To ensure that face masks are used correctly, guidance should provide adequate information while remaining understandable (Egan et al., 2021). Our research findings benefit healthcare policymakers in developing strategies to encourage the general public's awareness about wearing face masks to prevent the spread of COVID-19. Our research contributes to better understanding of how perceptions and different factors may increase the intention to wear a face mask among Thais during the COVID-19 pandemic. Specifically, we provide evidence that the general public's attitude, risk perception of the pandemic, perceived benefits of the face mask, as well as environmental factors including the cost of face masks and availability of face masks can affect intention to wear face masks.

Limitations and Recommendations

This study was a self-administered questionnaire. Qualitative research, such as interviews and focus groups could provide more insight into future research. Furthermore, numerous studies support that antecedents of willingness to wear face masks could include other factors, which may not be included in this study. Thus, further research is recommended. For example, Weiss et al. (2007) identified four barriers that may discourage people from wearing face masks: (1) discomfort, particularly in hot weather; (2) the presence of chronic lung disease; (3) inconvenience, due to the need to remove face masks when eating or drinking; and (4) youth, because face masks are not designed for children, and even if they were, children were found to be unlikely to wear them for long periods. The present study did not examine the negative effect of these barrier factors. These factors should be considered further. Moreover, the law and regulations may impact a willingness to wear face masks in Thailand. It is unclear whether other significant regulations and barriers may impact Thai people wearing face masks. Thus, future research will be required to investigate more variables influencing wearing face masks among Thais. Also, several demographic factors influence the public's willingness to wear face masks. As a result, the researchers should consider demographic factors as independent variables in future research.

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Original article

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Implication of Behavioural Change Theories in Occupational Health and Safety : A Systematic Review

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Abstract

Background: Occupational health behaviour is a critical factor that influences work-related health problems and injuries. Thus, it is increasingly important that health providers incorporate understanding of the complexity of behaviour change into programmes designed to encourage and promote healthy behaviour among workers. **Objective:** The objective of this systematic review is to explore the uses of behavioural change theories in relevant studies regarding occupational health and safety and suggests applications to facilitate altering problem behaviours. **Method:** A search strategy was utilised the PICO model together with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). **Results:** After the screening process based on inclusion and exclusion criteria, finally,18 studies were selected as the study selection. The theory of reasoned action (TRA) is commonly applied in occupational health research to investigate, explain, or predict individual intentions toward safety behaviours in a variety of different workplaces, while the theory of planned behaviour (TPB) was applied to investigate, explain, or predict individual intentions as well as perception of behavioural control toward occupational safety and health or to alter and improve different health behaviours in various kinds of workers. The transtheoretical model (TTM) is especially useful in developing programme or intervention. And finally, the health belief model (HBM) is useful for exploring perceived susceptibility, severity, benefits, barriers and self-efficacy, including cues to action towards self-protective behaviour. **Conclusions:** Health providers could apply these behavioural models in assisting employees to increase health promoting behaviours and, at the same time, conduct preventive interventions to minimise occupational injuries as well as work-related health problems.

Keywords: Behavioural Change Theories, Occupational Health and Safety

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Introduction

The principal missions of occupational health and safety aside from promoting workers' health are reducing their possibilities of, or preventing the workers from, experiencing work-related health problems as well as accidents and injuries (Suddin, Ani, Ismail, & Ibrahim, 2015). Consequently, studying in the field of occupational health and safety, especially worksite health promotion and disease prevention, touches on fundamental aspects of daily routine of working life (Pescud et al., 2015). Occupational health behaviour is a critical factor that influences work-related health problems and injuries (Moradhaseli, Ataei, van den Broucke, & Karimi, 2021). Thus, it is increasingly important that health providers incorporate understanding of the complexity of behaviour change into programmes designed to encourage and promote healthy behaviour among workers (O'Connell et al., 2015)

Behavioural change theories used in occupational health and safety are among the earliest theories of work health-related behaviours that remain the most widely used in current studies, comprised the Theory of Reasoned Action (TRA) (Ajzen, I., & Fishbein, 1980; Fishbein & Ajzen, 1975), Theory of Planned Behaviour (TPB) (Ajzen, 1985, 1991), the Health Belief Model (HBM) (Janz & Becker, 1984; Rosenstock, Strecher, & Becker, 1988), and the Transtheoretical Model's (TTM) (Prochaska & DiClemente, 1983).

This article aims to systematically review the uses of behavioural change theories, i.e., TRA, TPB, HBM, and TTM, in relevant studies regarding occupational health and safety and suggests applications to facilitate altering problem behaviours. oviders could apply these behavioural models in assisting employees to increase health promoting behaviours and, at the same time, conduct preventive interventions to minimise occupational injuries as well as work-related health problems.

Methodology

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) was undertaken to the literature retrieval strategy, evaluation method, data extraction, and result evaluation. The PRISMA statement consists of a four-phase flow diagram and a 27-item checklist comprised 1) searching relevant studies from databases, 2) screening based on inclusion and exclusion criteria, 3) coding of Studies, and 4) analysis and identify levels of evidence (Moher, Liberati, Tetzlaff, & Altman, 2009).

Searching relevant studies from databases

Literature review search strategy

A search of the relevant literature was undertaken using the following electronic databases: Cumulative Index to Medical Literature Analysis and Retrieval System Online (MEDLINE), Nursing and Allied Health Literature (CINAHL), Academic search premier, PsycINFO including Multidisciplinary databases, such as, Scopus and Web of Science.

Applying PICO framework as a method of search strategy

The PICO model or framework (Richardson, 1995), a method of search strategy applied to search for all possible combinations of search terms, was adopted because PICO framework is seen as successful search strategy which is usually highly structured (Glanville et al., 2006). The acronym PICO stands for P=Population, I=Intervention, C=Comparison and O=Outcome. The key words used to search the literature in this present study were underpinned by the PICO model (Richardson et al., 1995).

Screening based on inclusion and exclusion criteria

The second phase of the research selection process consists of examining each of the selected articles and excluding articles that meet the following exclusion criteria. In this study, inclusion criteria consisted of:

1. The details of relevant studies have the keywords specified by the study questions and the resources are only peer-reviewed journal or articles and presented in full text.
2. The relevant studies of the last ten years from 2011 to 2021 are included.
3. The relevant studies presented in the English and Thai language are only accepted.

And exclusion criteria comprised:

1. The details of literature are not relevant to the keywords specified by the study questions or the resources are presented in abstract.
2. Studies published before the year 2011 are excluded.
3. Other languages than English and Thai are excluded due to the potential risk of the misunderstanding from translations.

Coding of Studies

Each of the selected studies was analysed using the evaluation form described in table 1 according to the following characteristics: Author's name, and year published, methodology, theory(ies), application, as well as levels of evidence.

Analysis strategy and levels of evidence

Levels of evidence were identified based on Joanna Briggs Institute (JBI) (The Joanna Briggs Institute, 2014)

Results

Study selection

After searching the original database returned, the findings revealed as below diagram.

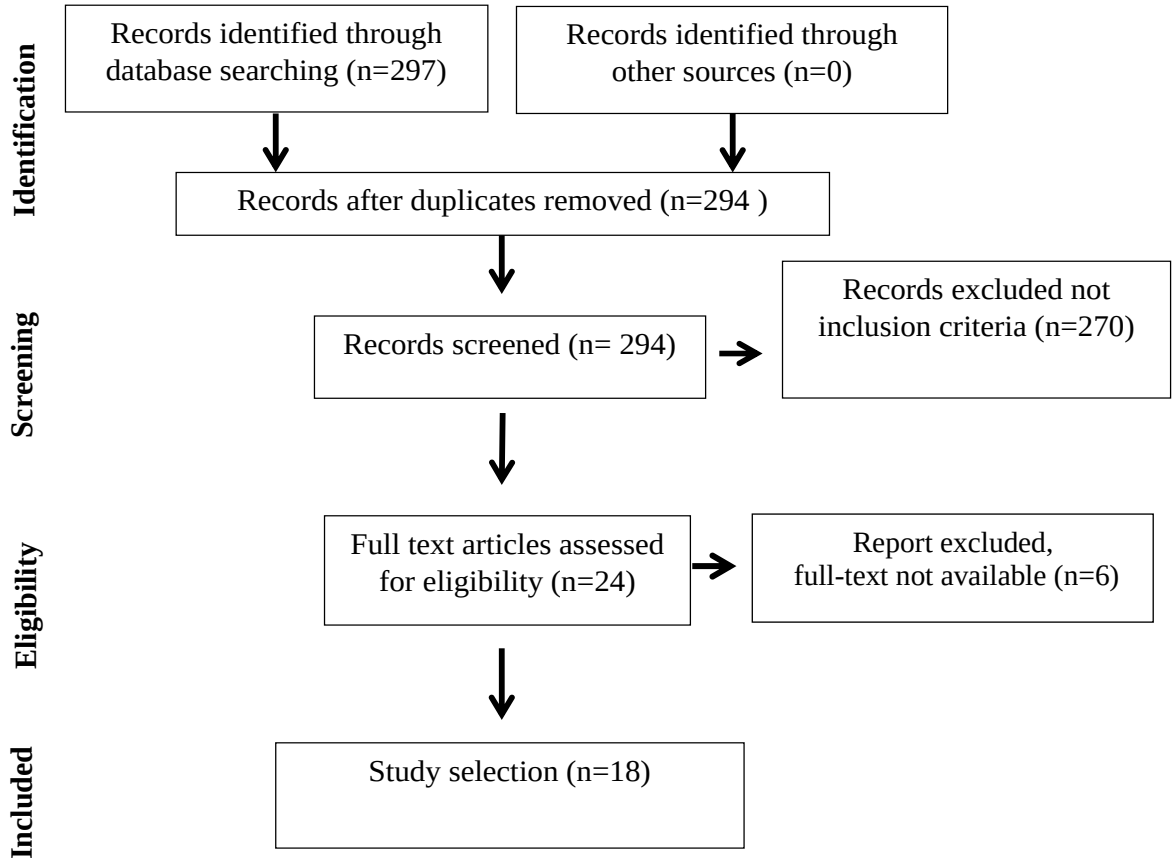

Figure 1 Study selection flow diagram

Figure 1 shows the flow chart for selecting the included studies. After searching the original database through Medical Literature Analysis and Retrieval System Online (MEDLINE), Nursing and Allied Health Literature (CINAHL), Academic search premier, PsycINFO including Multidisciplinary databases, such as, Scopus and Web of Science, 297 studies were records. After deleting duplicates, the researchers then screened the summaries and excluded studies that did not address behavioural change theories in occupational health. Finally, 18 studies were selected as the study selection.

Study Characteristics and Quality Assessment

After the screening process based on inclusion and exclusion criteria, the 18 included studies were analysed. Overall and study-level quality assessments were summarised based on Joanna Briggs Institute (JBI) presented as table 1.

Table 1 Overall and study-level quality assessments

Author(s)	Year of publication	Methodology	Theory(ies)	Application	Levels of evidence
Abdollahzadeh et al	2021	A cross-sectional study	HBM	To adopt the concepts of HBM as theoretical framework in predicting workers' intention to use	Level 4.b

Author(s)	Year of publication	Methodology	Theory(ies)	Application	Levels of evidence
				a personal protective equipment (PPE)	
Ginandhani et al	2021	A cross-sectional study	HBM	To determine factors that have a direct and indirect effect on the use of PPE	Level 4.b
Goh et al	2018	A cross-sectional study	TRA	To develop a survey instrument for examining factors influencing unsafe behaviours	Level 4.b
Gultekin and Kitis	2019	A cross-sectional study	HBM	To develop an instrument for assessing lead exposure	Level 4.b
Gupta et al	2021	A cross-sectional study	HBM	To examine factors underpinning workers' decisions to implement prevention and control measures	Level 4.b
Hinsz and Nickell	2015	A cross-sectional study	TRA and TPB	To develop a survey instrument for examining factors that contribute to the production of safe food	Level 4.b
Jafaralilou et al	2019	A controlled quasi-experimental study	TPB	to measure the impact of the TPB-based educational intervention on promoting helmet use among workers	Level 2.c
Kuchi et al	2016	A semi-experimental study	TPB	To adopt the concepts of intention and behavioral control for prediction of behaviour change	Level 4.b
Lopes et al	2019	A case study	TPB, An extended model of TPB	To develop an instrument for assessing industrial worker behaviour	Level 4.d
Moazzami et al	2016	A quasi-randomised trial (pseudo-randomisation)	TTM	To consider effect of an ergonomics-based educational intervention	Level 1.d
Moradhaseli et al	2021	A cross-sectional study	HBM	to explore the factors influencing workers' occupational health behaviour	Level 4.b
Nasir et al	2020	A cross-sectional study	HBM	To develop a survey instrument for assessing COVID-19 related perceptions and possible disparities between workers	Level 4.b

Author(s)	Year of publication	Methodology	Theory(ies)	Application	Levels of evidence
O'Connell et al	2015	A randomised controlled trial (RCT)	TPB	To develop a psychosocial measure for identifying behavioural self-efficacy	Level 1.c
Rezaei et al	2019	A cross-sectional study	TPB	To investigate the factors affecting workers' intention in using PPE	Level 4.b
Sanaeinasab et al	2018	A randomised controlled trial (RCT)	TTM	To determine the effect of a TTM-based educational programme on work-related ergonomic posture	Level 1.c
Siponen et al	2014	A cross-sectional study	TRA	To adopt the concepts of intention and actual behaviour as theoretical framework	Level 4.b
Wright et al	2019	A cross-sectional study	HBM	To determine wastewater worker's beliefs and practices on wearing PPE	Level 4.b
Zeidi et al	2011	A prospective randomised controlled trial.	TTM	To examine the effectiveness of ergonomic training on postural habits	Level 1.c

According to characteristics of the selected studies, the 18 studies were published from 2011 to 2021 with most done in Asia. Most of which were undertaken as a cross-sectional study. A various type of samples' occupations in the relevant studies included mine workers(Gultekin & Kitis, 2019), dental health personnel (Nasir, Elhag, & Almahdi, 2020), farmers (Abdollahzadeh & Sharifzadeh, 2021; Rezaei, Seidi, Science, & 2019), workers at a poultry producing facility(Hinsz, las, & 2015), construction workers (Goh, Ubeynarayana, Wong, & Guo, 2018; Jafaralilou, Zareban, Hajaghazadeh, Matin, & Didarloo, 2019), university staff (O'Connell et al., 2015), and industrial workers (Lopes, Kalid, Rodríguez, & Ávila Filho, 2019).

The uses of behavioural change theories in occupational health and Safety

Domain 1: The uses of theory of reasoned action (TRA) in occupational health and Safety

The theory of reasoned action (TRA) was first introduced in 1967 by Martin Fishbein, and then was extendedly developed by Fishbein and Icek Ajzen in the year 1975 and 1980 (Fishbein & Ajzen, 1975). The TRA is a behavioural theory with emphasis on behavioural and normative beliefs, attitudes, subjective norms, intentions, and behaviour sequence or series directed to a specific focus (M. Fishbein, 1980). A definitive element of the model is regarded as an individual intention to engage in a certain behaviour that is examined as the best predictor of subsequent behaviour — whether or not a person actually perform in that behaviour. Behaviour Intentions, in turn, could be predicted by attitudes and subjective norms. This means that the more positively an individual regards a certain action or behaviour and the more they perceive the behaviour as being crucial to others, such as

peers, family, or society, the more likely they are to form intentions to engage in that behaviour. Attitude is based on a set of outcome beliefs regarding the consequences of behaviour, i.e., how positive or negative each outcome is and how likely it is to occur. A perceived subjective norm is based on normative beliefs — the acceptance and evaluation of behaviours by other people (Fishbein & Ajzen, 1975)

Thus far, only three studies regarding the use of TRA in occupational health studies were selected according to the study selection processes. The TRA has been commonly applied in occupational health research to investigate, explain, or predict individual intentions toward safety behaviours in a variety of organisational settings, for instance, examining factors contributing the intentions of food processing workers to engage in food safety behaviours (Hinsz et al., 2015), determining intentions and the other cognitive factors within the TRA of workers in a tunnel construction project to perform behaviour-based safety (BBS) (Goh et al., 2018), and intentions of employees in Finland to comply with information security policies (Siponen, Adam Mahmood, & Pahnila, 2014). The relevant studies concluded that the reasoned action variables of TRA were all predictive of safety behaviours of food processing workers, and food safety intentions and behaviours of these participants were best predicted by the reasoned action approach (Goh et al., 2018; Hinsz et al., 2015). Intention and social norms were proved to be the biggest influence on work safety behaviours (Goh et al., 2018). Also, intention and social norms had a significant and positive effect on the employees' intention to comply with information and policies of their workplace (Siponen et al., 2014).

Furthermore, the TRA was also applied to predict a strong association of individual behaviour together with belief concerning the self-efficacy of procedures to assure safety (Didarloo et al., 2012; Leiter, Zanaletti, & Argentero, 2009; Siponen et al., 2014). Thus, the TRA could be applied as psycho-social measures to identify behavioural self-efficacy (O'Connell et al., 2015).

Domain 2: The uses of theory of planned behaviour (TPB) in occupational health and Safety

The theory of Planned Behaviour (TPB) (Ajzen, 1985, 1991), an extended theory of the TRA, included perceived behavioural control as an additional construct is assumed that behavioural intention determines behaviour directly and indicates that attitudes toward a behaviour, subjective norms, and perceived behavioural control (PBC) influence an individual's intention. The difference between the TRA and its companion, the TPB, is that the TPB allows for perceived control – as an additional component of intentions and behaviour – to affect behaviour directly, regardless of the behavioural intention.

For the above reasons, the TPB has been well-known and widely applied theoretical framework for describing and predicting individual behaviour (Ajzen, 1985, 1991). In occupational health and safety, the TPB was applied in this research area than the TRA. This is because the TPB was proposed to eliminate the limitations of the original TRA model in dealing with individual behaviour by including perceived behavioural control. Consequently, many relevant studies concluded that TPB has higher predictive power than TRA (Guo et al., 2007).

Most relevant studies applied TPB as theoretical framework by using the four subscales of the model – attitude, subjective norms, perceived behavioural control, and intention – to measure the outcomes of the TPB-based educational intervention or to investigate, explain, or predict individual intentions, as well as perception of behavioural control toward occupational safety and health or to alter and improve different health behaviours in various kinds of workers (Jafaralilou et al., 2019), e.g., applying TPB to assess the effect of a training intervention on helmet use of cement factory workers (Jafaralilou et al., 2019), to seek the

appropriate method of manual material handling among workers working in mining and metal Industries (Kuchi, Zare, & Aghamolaei, 2016), and to examine factors contributing the intentions of food processing workers to engage in food safety behaviours (Hinsz et al., 2015).

A variety of relevant studies indicated that the TPB was applied as an instrument for assessing or improving individual work-related behaviours. O'Connell et al. (2015), for instance, applied the concepts of TPB to develop a psychosocial measures for identifying behavioural self-efficacy to reduce workplace sitting time of NHS staff (O'Connell et al., 2015). Lopes et al. (2019) adopted the TPB constructs to develop an instrument for investigating the factors affecting workers' intention in using personal protective equipment (PPE), and to assess work behaviours regarding energy saving of industrial workers (Lopes, Kalid, Rodríguez, & Ávila Filho, 2019).

TPB is the foundation of the later framework, the extended theory of planned behaviour (TPB). The extended TPB is included an or some additional construct(s) depending on the relevant objectives and specific context of each study, for instance, adding descriptive norm and personal moral norm into the classic theory of planned behaviour to understand the determinants of energy saving behaviour of workers in their workplaces (Gao, Wang, Li, & Li, 2017), adding risk perception and moral norm to predict intention of farmers regarding safe use of chemical fertilisers (Savari & Gharechaee, 2020), or including knowledge and personal norm as additional variables to investigate factors associated with the construction waste reduction behaviour of contractor employees (Li, Zuo, Cai, & Zillante, 2018). The results of the relevant studies using the extended TPB explored that the extended TPB framework has significantly improved the explanation power of work behaviour than the original TPB model (Gao et al., 2017; Li et al., 2018).

Both TRA and TPB assume that the behavioural intention is the best predictor of a behaviour or, in another word, an intention to perform the behaviour is a determinant of that behaviour. Many studies regarding individual safety behaviours applied both TRA and TPB in order to explore relationships between attitude and risky behaviours as these two theories hypothesise that the influential effect from attitude to individual subsequent behaviour was mediated through intended behaviour (Ma, Yan, Huang, & Abdel-Aty, 2010).

Domain 3: The uses of transtheoretical model (TTM) in occupational health and Safety

The Transtheoretical Model (TTM), created by Prochaska and DiClemente, is a behavioural theory that illustrates behaviour change as occurring in five stages comprised: precontemplation, contemplation, preparation/determination, action/willpower, and maintenance (Prochaska & DiClemente, 1983). In the precontemplation stage, precontemplators are not seriously considered about changing their behaviour and do not seek any kind of help. People in this stage are less likely to change their behaviour than those in the other four stages. For contemplation stage, people are more aware of their negative behaviours affecting personal consequences. Even though contemplators are acknowledged and have the competence to consider the possibility of changing, they are prone to be ambivalent. For the stage of preparation/determination, people are ready for change by making a commitment to make a change. In action/willpower stage, people are actively engaged in taking steps to change their negative behaviours as they believe in their ability to change the behaviours by applying a variety of different methods. The last stage of change is maintenance, people in this stage are able to successfully maintain their positive behaviours and are aware of progression they have made (Prochaska & DiClemente, 1983; Prochaska, DiClemente, & Norcross, 1992). The concepts of the TTM could be especially useful in developing programme planning, curriculum development, and programme evaluation or

intervention to promote health or improve individual health behaviour (F. et al., 2017; Keshmiri et al., 2017; Leandro-França, van Solinge, Henkens, & Murta, 2016)

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In occupational health studies, TTM was applied as an effective health educational instrument or in the form of occupational health promoting programme for promoting health in a workplace (Moazzami, Dehdari, Taghdisi, & Soltanian, 2015). Most educational programmes or interventions based on TTM developed were associated with safer work habits or promoting healthy lifestyles in a variety of workplaces, particularly applying TTM to improve ergonomic postures or postural habits of workers. The three included studies revealed that their intervention groups receiving a TTM-based intervention had a significant improvement in ergonomic postures ($P < 0.05$) after finishing educational programme in comparison with before intervention. Their results could be concluded that TTM-based ergonomic programme was effective in improving ergonomic posture to prevent postural risk factors for musculoskeletal disorders (MSDs). Furthermore, individual guidance based on the TTM were effective in promoting long-term continuation of positive work habits or preventing work-related diseases. (Moazzami et al., 2015; Sanaeinasab et al., 2018; Zeidi, Morshedi, & Zeidi, 2011).

Domain 4: The uses of health belief model (HBM) in occupational health and safety

The original version of HBM was basically established as a systematic method in the early 1950s, at which time several social psychologists sought to understand the widespread failure or the infrequent acceptance of people being charged little or nothing for the health service to participate in health promotion programmes (Janz & Becker, 1984). Thus, the original objective of the HBM developers was to focus on understanding why people do not take personal protective equipment (PPE) to prevent themselves from health threats (Orji, Vassileva, & Mandryk, 2012). The six major components of the HBM comprised; perceived susceptibility, severity, benefits, barriers and self-efficacy, including cues to action. These six main constructs of HBM influence preventive health behaviours (Rosenstock et al., 1988).

Aside from some deliberation of HBM components, this behaviour change model is closely fit the determinants identified for personal protective equipment (PPE) (Abdollahzadeh & Sharifzadeh, 2021; Ginandhani, Kurniasih, & Rachman, 2021; Gupta, Fournié, Hoque, & Henning, 2021; Wright et al., 2019), the HBM does highlight some components that should be related to workplace self-protective behaviour, for instance, threat-related beliefs (hazard susceptibility and severity), self-efficacy, response efficacy (perceived benefit), and barrier (DeJoy, 1996). Consequently, the HBM was typically applied in studies regarding occupational health and safety to understand why people did or did not take preventive measures, such as mask, engage in a wide variety of preventive health behaviours (Abdollahzadeh & Sharifzadeh, 2021).

The HBM seems to be the most widely used theory in occupational health studies according to database searching. 7 out of 18 selected studies revealed that the HBM construct was applied as prevention and control measures to explore factors influencing workers' occupational health behaviours, particularly the uses of PPE (Abdollahzadeh & Sharifzadeh, 2021; Ginandhani et al., 2021). The relevant studies illustrated that perceived threats or risk perception, another word, as suggested by the theory of HBM, is one of the major component in understanding how workers become motivated to change their work-related behaviours (Nasir et al., 2020; Yousafzai, Siddiqui, & Janjua, 2013). A literature reviewed appears to suggest that perceived benefits particularly PPE effectiveness in reducing work exposure emerged as the strongest positive predictor (Abdollahzadeh & Sharifzadeh, 2021; Ginandhani et al., 2021; Gupta et al., 2021),

while perceived barriers emerged as the strongest negative predictor to enacting work-related behaviours (Abdollahzadeh & Sharifzadeh, 2021; Gupta et al., 2021; Nasir et al., 2020). Furthermore, the other variables mentioned in HBM such as fear, threat, or past experience is directly related to the health threat or risk perception of workers (Bishop, Baker, Boyle, & MacKinnon, 2015; Janz & Becker, 1984).

Discussion

Despite the fact that both TRA and TPB were commonly applied in occupational health research to investigate, explain, or predict individual intentions toward safety behaviours in a variety of different workplaces, the TPB was applied in this research area than the TRA. This is because the TPB was proposed to eliminate the limitations of the original TRA model in dealing with individual behaviour. The TPB was included perceived behavioural control, an additional construct, that allows for perceived control to affect behaviour directly, regardless of the behavioural intention. Consequently, many relevant studies concluded that the TPB has higher predictive power than the TRA. As Özer and Yilmaz (2011) illustrated, TPB has higher predictive power than TRA in predicting workers' intention to use information technology (Özer & Yilmaz, 2011). Consistent with the findings of Guo et al. (2007), despite the fact that both models are appropriated to predict smoking behaviours among Chinese student, the TPB had a significantly higher variance than TRA for predicting intention as well as smoking behaviours among adolescent (Guo et al., 2007). Sutton, McVey, & Glanz (1999), however, concluded that even though the TRA constructs were not the strongest predictors, TPB did not perform significantly better than the TRA. Also, the beliefs on which the study samples are based were potentially amenable to affect through educational-based programmes (Sutton, McVey, & Glanz, 1999).

According to the TTM, the stages of change from TTM illustrate individual intention and engagement to perform a targeted health-related behaviour. Consequently, this model is especially useful in developing programme or intervention. In occupational health studies, TTM was applied as an effective health educational instrument or in the form of occupational health promoting programme for promoting health in a workplace as the TTM-based interventions are effective in promoting behaviour change of the target population (Moazzami et al., 2015). Consistent with the conclusions of Moeini et al. (2010) and Zare et al. (2016), the educational programme based on the TTM had a statistically significant relationship with the whole TTM processes. Also, the experimental group had a significant positive progress after finishing educational programme in comparison with before intervention (Moeini, Rahimi, & Hazaveie, 2010; Zare, Aghamolaei, Zare, & Ghanbarnejad, 2016).

The HBM seems to be the most widely used theory in occupational health studies according to database searching. The model is useful for exploring perceived susceptibility, severity, benefits, barriers and self-efficacy, including cues to action towards self-protective behaviour (Abdollahzadeh & Sharifzadeh, 2021). This systematic review illustrated that, aside from some deliberation of HBM components, this behaviour change model is closely fit the determinants identified for personal protective equipment (PPE) (Abdollahzadeh & Sharifzadeh, 2021; Ginandhani et al., 2021; Gupta et al., 2021; Wright et al., 2019). As wall (2009) concluded that the results were particularly noteworthy that factors identified with the implication of PPE closely matched the construct of HBM (Wall, 2009). Consistent with the conclusion of DeJoy (1996), the HBM theory is the only one framework specifically developed to illustrate preventive health behaviour and this behaviour change model is closely fit the determinants identified for using in the field of occupational health, especially self-protective behaviour (DeJoy, 1996).

Conclusion

Application of the behavioural change theory, as a theoretical framework, in the field of occupational health and safety was valuable as all theories are useful for investigating antecedents of work-related health behaviours. Researchers could properly apply these behavioural change theories to design, test, or report studies or interventions. The TRA is commonly applied in occupational health research to investigate, explain, or predict individual intentions toward safety behaviours in a variety of different workplaces, while the TPB was applied to investigate, explain, or predict individual intentions as well as perception of behavioural control toward occupational safety and health or to alter and improve different health behaviours in various kinds of workers. If researchers plan to conduct intervention to improve health among workers, the TTM seems to be the most appropriated framework. And finally, the HBM is useful for exploring perceived susceptibility, severity, benefits, barriers and self-efficacy, including cues to action towards self-protective behaviour.

Suggestions for the further study

Due to the scarcity of literature related to the experimental studies such as randomised controlled trial (RCT), participatory action research (PAR), and qualitative studies, there should be more RCT, PAR, and qualitative work in occupational health using behavioural change theories as these methods are considered valuable for the future research.

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Cost-Benefit Analysis of Automatic Emergency Braking System Installation from Thailand Vehicle Market

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Abstract

The automatic emergency braking (AEB) is one of the advanced active vehicle safety features which is the most promising safety technology in recent years for reducing accidents. This study analyzes the impact of AEB system installation in vehicle market using Cost-benefit analysis from Thailand. The benefit gain mainly bases on number of lives saved under rear-end collision accident. The cost is calculated from number of AEB unit installed in new vehicle each year. Sensitivity analysis is applied by varying effectiveness of AEB system. The results suggest that AEB is not cost-effective even in optimistic scenario under prescribed circumstance. Other benefit gain from AEB in aspect of accident prevention should be further investigated.

Keywords: Cost-benefit analysis, Automatic emergency braking (AEB), Thailand vehicle market

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Introduction

World Health Organization (WHO) has reported that the number of road traffic deaths has reached 1.35 million a year. Up to 90% of this number is dominated by low- and middle-income countries and this number is still increasing every year (WHO, 2018). Thailand is categorized in the middle-income country group and has the highest traffic fatality rate among ASEAN and among the worst in the global level. Powered two-wheelers are the main proportion of the number of road fatalities following by pickup trucks and passenger cars respectively (Ministry of Public Health, 2021). In order to cope this problem, Thailand has to put many efforts into different strategies. One of the strategies is to improve vehicle safety standards (WHO, 2020) which can be achieved by using of the vehicle safety technologies.

The automatic emergency braking (AEB) system is one of the vehicle active safety technologies designed to prevent and mitigate rear-end and pedestrian collision accidents. The system constantly detects the objects ahead of the vehicle by using sensor which can be varied from cameras, radar, or combination of these sensors. It applies the brake automatically if the object ahead is approaching to the vehicle and the driver does not respond to the situation. Many studies reported the effectiveness of AEB system which can reduce the rear-end collision accidents by 25-50% (Cicchino, 2017) (Jeong & Oh, 2013) (Fildes et al., 2015) (Isaksson-Hellman & Lindman, 2016). However, cost of the system is very high (Sitthiracha & Koetniyom, 2021). Before issuing any policy, authorities or policy makers need information on feasibility of both technical and economic aspects. Then cost-benefit analysis (CBA), which is one of the useful economic analysis tools, can provide insight of the situation helping those governors.

There are few studies using CBA to analyze cost effectiveness of the vehicle safety technologies. Mohd Jawi, Ariffin, Ahmad, Abu Kassim, Mohamed & Voon (2014) demonstrated impact of electronic stability control and seat belt reminder systems through CBA and focuses only on Malaysia. European Commission Directorate General Energy and Transport (EC) (2006) used CBA to assess the cost effectiveness of 21 vehicle safety technologies across European region. Edwards, Nathanson, & Wisch (2014) estimated possible benefits of AEB system installation in vehicles sold in Europe and then used benefit-cost ratio (BCR) to determine range of the system costs for the break-even point. The parameters and scenarios, that were used by these studies for CBA, are summarized in Table 1.

Table 1 Summary of parameters and scenario using for CBA

Items	Mohd Jawi, Ariffin, Ahmad, Abu Kassim, Mohamed & Voon (2014)	EC (2006)	Edwards, Nathanson, & Wisch (2014)
Benefit	- Number of vehicles on road - Number of road crashes (casualties & damage only) - Technology effectiveness - Crash costs (casualties & damage only)	- Baseline casualties - Technology effectiveness - Vehicle market forecasting - Transport distance growth - Effect of Improvements of vehicles and roads - Casualty costs	- Injury risk curves - Impact speed distribution - Impact location - Crash scenarios - Driver braking behavior - AEB performance - Monetary casualty values - Baseline casualties for Great Britain and Germany - EU27 casualties
Cost	- System	- Installation	- System (as output)
Scenario	- 100% fitment on current vehicles with fixed number of the vehicles on road	- Do nothing - Retrofit all current vehicles - New vehicle penetration	- Nominal crash scene - Optimistic crash scene - Pessimistic crash scene
CBA	- BCR - Discount rate	- BCR - Discount rate	- BCR (as input)

This study demonstrates how to evaluate the impact of AEB system installation in Thailand vehicle market using CBA. The framework for CBA is presented. Possible benefits and costs are determined through parameters and assumptions. The scenario covers from year 2021 through 2030.

Methods

The main principle of CBA is comparison of total benefits and total costs of an interested issue which can be anything that investment is related (Layard, 1994). There is not only one way to determine benefits over costs as shown in Table 1. It depends on some assumptions and available data/information. In this study, the framework for CBA is shown in Figure 1.

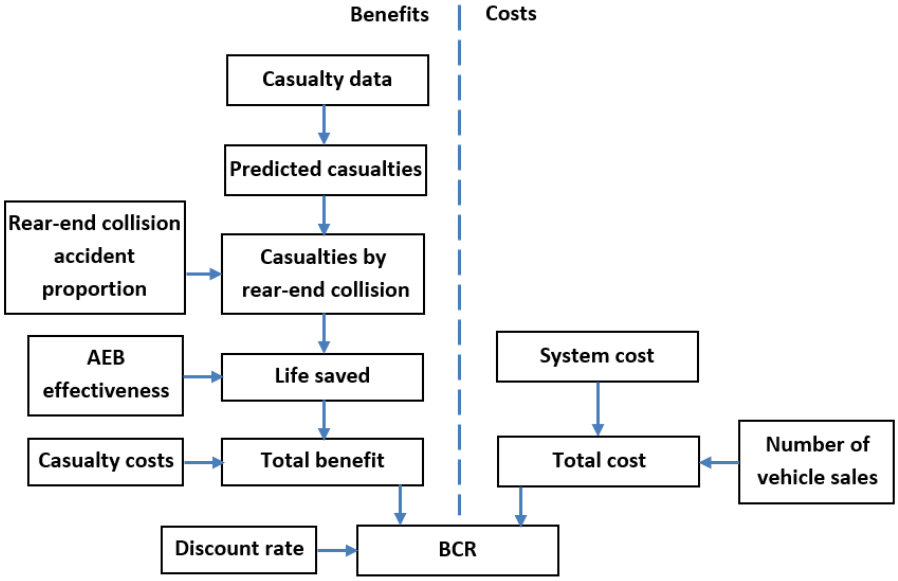

Figure 1 CBA framework

Casualty data and predicted casualties

The numbers of road traffic deaths and injuries by four-wheel vehicles in Thailand between 2015 and 2019 are shown in Figure 2 and 3 respectively. These data are compiled from the Injury Data Collaboration Center (Ministry of Public Health, 2021). The data are selected from top-three ranks of the four-wheel vehicle group only which are pickup truck, passenger car/taxi and van. The pickup truck is the major contribution to the number of deaths and injuries when comparing to the other two. Trends of both death and injury are increasing every year. However, the injury database has not yet distinguished into serious and minor injuries. The proportion of the serious and minor injuries are obtained from Juntarasup (2018) by 13.4% and 86.6% respectively for the pickup truck and 25% and 75% for passenger car.

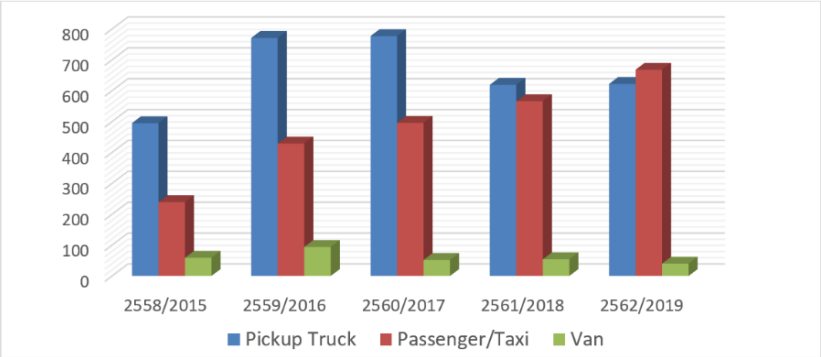

Figure 2 Number of road traffic deaths by four-wheel vehicles (Ministry of Public Health, 2021)

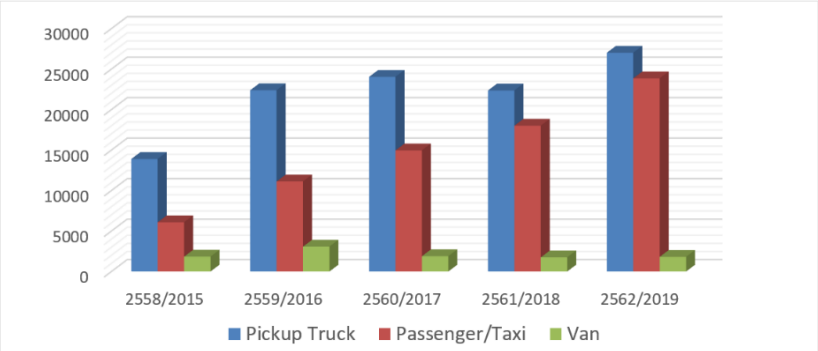

Figure 3 Number of road traffic injuries by four-wheel vehicles (Ministry of Public Health, 2021)

There are many methods to forecast the road traffic casualties. Jomnonkwao, Uttra, & Ratanavaraha (2020) has attempted to forecast the road traffic death by using different techniques, e.g., Time-series analysis, curve estimation, regression analysis, and path analysis. Many input data are used to develop the models including death rate per 100,000 population, national gross domestic product, number of registered vehicles, and energy consumption in transportation sector. However, all models could not predict properly after 10 years. These results might imply that more factors influencing the road traffic death were not considered. Since there is not any model to forecast the road traffic casualties perfectly, the linear regression of previous data is used instead under following assumptions.

- Rate of change in number of deaths and injuries is constant due to constant vehicle sale volume.
- Deaths and injuries contributed by the van are neglected due to small number when comparing to other vehicle types.
- There is not any change in the vehicle safety equipment fitment of all vehicles sold in the Thailand market throughout the period under consideration.
- Pandemic decease and lockdowns due to Royal Thai Government's orders, which affect movement of goods and people since 2020, are neglected.

Rear-end collision accident proportion

AEB system is very effective in reducing a certain type of accident, i.e., the rear-end collision. The rear-end collision data related to the number of road traffic deaths and injuries are obtained from the Transport Accident Management System (TRAMS) (Ministry of Transport, 2021). According to TRAMS, the rear-end collisions account for the number of road traffic deaths and injuries in average around 17.6% and 16.8% respectively. Thus, forecasting of the number of road traffic deaths and injuries by the rear-end collision case is based on these percentages and the baseline data from Figure 2 and 3.

AEB effectiveness

In this study, it is assumed that basic AEB system is installed in all new vehicles starting from 2021. The percentage of lives saved bases on the effectiveness of AEB ranges from 25-50% as mentioned in the introduction. This can be used as sensitivity analysis by setting different effectiveness in different scenarios, e.g., pessimistic, nominal, and optimistic scenarios. The effectiveness is set at 25%, 38% (Fildes et al., 2015), and 50% for pessimistic, nominal, and optimistic cases respectively.

Number of lives saved, casualty costs, and benefit gain

The number of lives saved can be determined by following equations.

$$N_{\text{lives saved}} = \eta_{AEB} \times \%\text{rear-end} \times (N_{\text{death},Y} - N_{\text{death},2020}) \quad (1)$$

$$N_{\text{injuries saved}} = \eta_{AEB} \times \%\text{rear-end} \times \%\text{minor/serious injury} \times (N_{\text{death},Y} - N_{\text{death},2020}) \quad (2)$$

Where η_{AEB} = AEB effectiveness for rear-end collision;
%rear-end = proportion of rear-end collision casualties;
%minor/serious injury = proportion of serious or minor injuries; and
Y = [2021, 2022, 2023, …, 2030].

The benefit gain of the road traffic casualties can be simply determined by multiplying the numbers of lives and injuries saved with the corresponding economic costs which are categorized into three groups: death, serious injury and minor injury. The cost of death and serious injury are 10 and 3 million baht/person in 2016 respectively (Thailand Development Research Institute,), while the cost of minor injury is 0.06 million baht/person in 2016 with inflation rate adjustment (Ministry of Transport, 2008). These values are necessary to be converted into true values corresponding each year by using inflation rate. The inflation rates obtained from Bank of Thailand are averaged and fixed at 0.6565% (Bank of Thailand, 2021).

Number of vehicle sales, system costs, and investment cost

The investment cost can be also simply determined by multiplying the number of vehicle sales in each year and AEB unit cost. The assumption is made on installation of AEB system in all new vehicle from 2021 through 2030 as a mandatory from Thai Government. Expected vehicle sale each year bases on the average of vehicle sales from 2012 to 2018 (Department of Land Transport, 2021) at about one million unit/year which are shown in Figure 4. The cost assumptions are made on the basic AEB system using single sensors which costs around 180 GBP (Thatcham Research, 2021) and is also adjusted by the inflation rate.

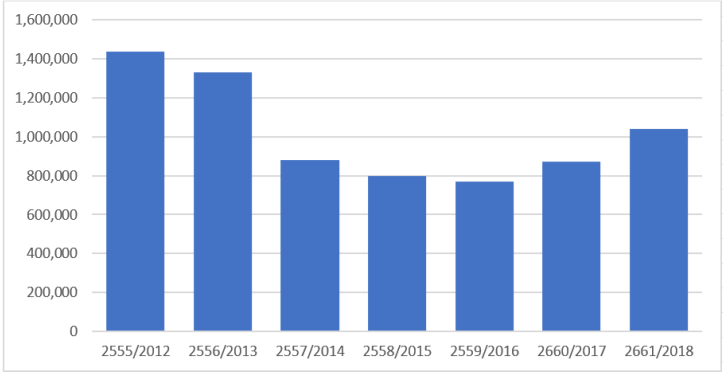

Figure 4 Number of vehicle sales in Thailand from 2012 – 2018 [19]

Benefit-cost ratio calculation

BCR can be calculated by Equation 3. Present values of total benefit and total cost can be calculated by Equation 4. Discount rate uses Social Rate of Time Preference (SRTP) which is based on what rate attract individuals to save their money rather than to consume them (University of Arizona, 2021). This concept corresponds to an assumption that there is not any subsidy or investment from the government. However, Thai government bond interest rate can be used instead of SRTP in practical (Royal Irrigation Department, 2012). Thai government 10-year bond interest rate is 1.873% (World Government Bonds, 2021).

$$\text{BCR} = \frac{Present\ value\ of\ total\ benefit}{Present\ value\ of\ total\ cost} \quad (3)$$

$$\text{Present value} = \text{Future value} \div (1 + \text{Discount rate})^{\text{No. of period}} \quad (4)$$

The criterion for deciding the cost effective is BCR > 1. If BCR is less than 1, that considered issue is not cost-effective (EC, 2006).

Results and discussion

Prediction of the road traffic casualties

Forecasted number of the road traffic casualties are shown in Figure 5 and 6. The number of road traffic deaths and injuries tends to be increased every year. When comparing to the historical data from 2015 to 2019 using the linear regression method, percentage errors are -16% and +22% for pickup truck and -11% and +17% for passenger car. After applying the proportion of the rear-end collision, the number of road traffic casualties by the rear-end collisions is forecasted as shown in Figure 7 and 8. The historical traffic accident data is crucial for identifying the specific accident and its casualties as shown in Figure 1. Thailand Development Research Institute (2020) has expressed a concern on the current Thailand traffic accident database which is not unified and is still far to be useful enough to identify the effective measures for the road safety problem. Different organizations involve the information collection with different purposes. It can be seen from the information used in this study have to be obtained from various sources. If the database is improved, the better prediction can be expected.

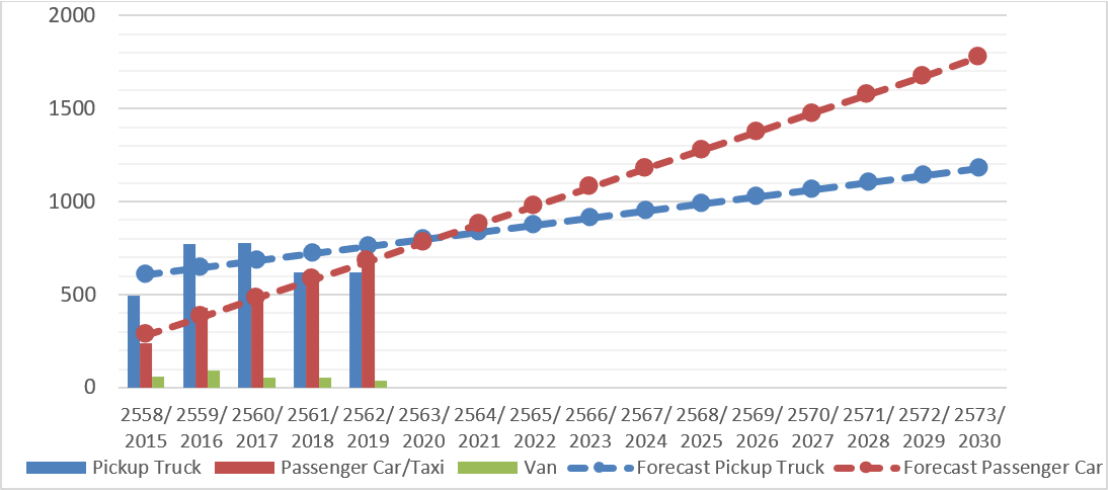

Figure 5 Forecasted number of road traffic deaths by four-wheel vehicles

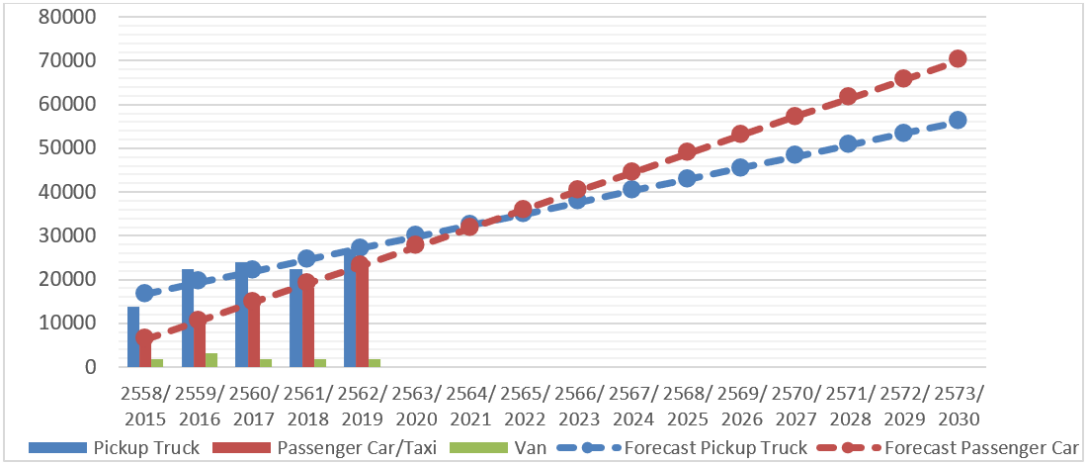

Figure 6 Forecasted number of road traffic injuries by four-wheel vehicles

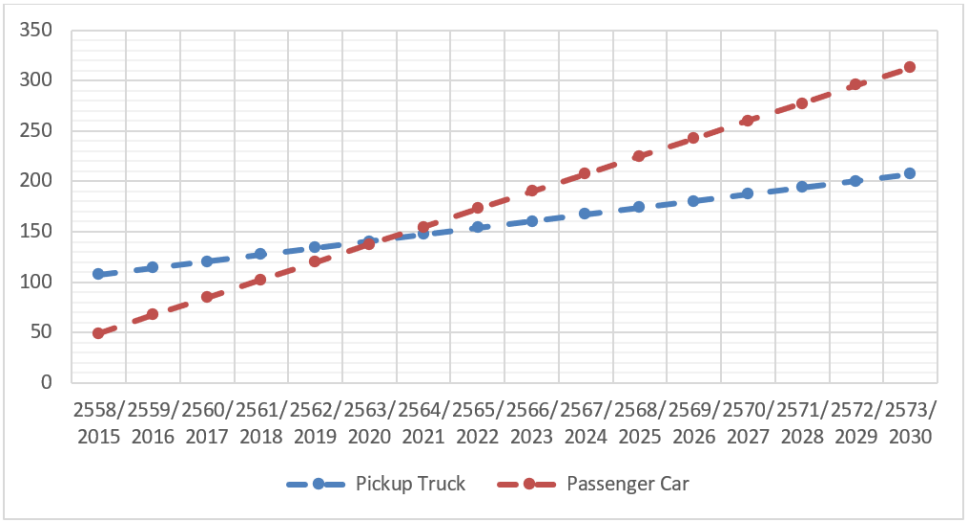

Figure 7 Forecasted number of road traffic deaths by rear-end collisions

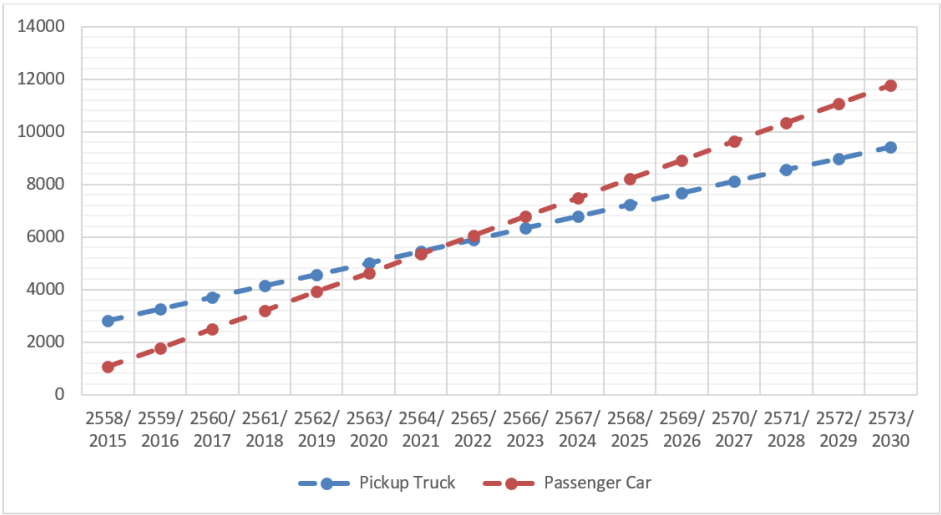

Figure 8 Forecasted number of road traffic injuries by rear-end collisions

AEB Cost-effectiveness

Detailed calculations of the benefits and costs in different scenarios including the final BCR are shown in Table 2 and 3. The results of BCR in all cases are less than 1 which suggest that the AEB installation is not cost-effective under an assumed circumstance even the best AEB effectiveness under the optimistic scenario. This may come from two main reasons: the number of road traffic casualties by the four-wheel vehicles in Thailand and the economic cost of road traffic casualties for Thai people. The number of road traffic casualties in the Western, European and many high-income countries comes mainly from the four-wheel vehicles, while it is only 20% in Thailand. The economic cost of road traffic deaths and injuries is also very different between the Western countries and Thailand. The accident costs of a fatality, a serious injury and a minor injury in European Union year 2006 are 1,018,200 € (~40 million baht), 143,100 € (~5.6 million baht) and 23,100 € (~0.9 million baht) respectively (EC, 2006), while they are only 10, 3, and 0.06 million baht respectively in Thailand year 2016.

Table 2 Benefit and cost calculations in different scenarios

	Years									
	2564/ 2021	**2565/ 2022**	**2566/ 2023**	**2567/ 2024**	**2568/ 2025**	**2569/ 2026**	**2570/ 2027**	**2571/ 2028**	**2572/ 2029**	**2573/ 2030**
Nominal scenario										
- Lives saved [person]	9	18	27	37	46	55	65	73	83	92
- Injuries saved [person]	439	878	1,317	1,756	2,195	2,634	3,072	3,512	3,951	4,389
Benefit [MTHB]	394	794	1,199	1,619	2,035	2,456	2,893	3,315	3,763	4,205
Present value [MTHB]	387	765	1,134	1,504	1,855	2,198	2,541	2,858	3,184	3,494
Total benefit [MTHB]					**19,920**					
Pessimistic scenario										
- Lives saved [person]	6	12	18	25	30	36	43	48	55	61
- Injuries saved [person]	289	578	867	1,155	1,444	1,733	2,022	2,310	2,600	2,888
Benefit [MTHB]	261	524	792	1,073	1,337	1,614	1,907	2,180	2,481	2,772
Present value [MTHB]	256	505	749	996	1,218	1,444	1,674	1,880	2,099	2,303
Total benefit [MTHB]					**13,123**					
Optimistic scenario										
- Lives saved [person]	12	25	36	48	61	73	84	97	109	121
- Injuries saved [person]	578	1,155	1,733	2,310	2,888	3,465	4,043	4,621	5,198	5,776
Benefit [MTHB]	520	1,058	1,582	2,123	2,683	3,238	3,790	4,371	4,949	5,534
Present value [MTHB]	511	1,020	1,497	1,972	2,445	2,897	3,329	3,769	4,188	4,597
Total benefit [MTHB]					**26,225**					
AEB cost [MTHB]	8,100	8,153	8,206	8,260	8,314	8,369	8,424	8,479	8,535	8,591
Present value [MTHB]	7,951	7,856	7,762	7,670	7,578	7,488	7,398	7,310	7,223	7,136
Total cost [MTHB]					**75,371**					

Table 3 BCR according to different scenarios

	Pessimistic	**Nominal**	**Optimistic**
BCR	0.17	0.26	0.34

This study focuses mainly on benefit gain from saved casualties. There might be other benefits that still are not taken into account, for example, property damage cost and accident scene management overheads. BCR results may be improved if these factors are included.

Conclusion

This study demonstrates how to analyze the cost-effectiveness of AEB installation in Thailand vehicle market using CBA for policy decision making aimed for casualty reduction from the road traffic accident. The results suggests that AEB is not cost-effective (BCR < 1). Thorough accident database is necessary for accurate prediction. It is suggested that further research should explore other benefits of AEB in aspect of accident prevention such as reductions of property damage and accident scene management overheads.

Acknowledgements

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Method Development and Method Validation for Residual Water Determination of Erythropoietin Pharmaceutical Formulations by Volumetric Karl Fischer Titration

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Abstract

The aim of this study is to develop and validate a water determination method for erythropoietin products using volumetric Karl Fischer (KF) titration technique. The external extraction technique using Hydranal™ formamide dry as an extraction solvent and using a mixture solution of Hydranal™ methanol dry and Hydranal™ formamide dry in a ratio of 60:40 as a solvent in the titration vessel was designed as a suitable method. The developed method was validated for specificity, repeatability, accuracy, and intermediate precision. The method was specific to the residual water contained in the erythropoietin pharmaceutical products as there was no effects from any interferences. Repeatability expressed the relative standard deviation (RSD) of six replicate samples as 4.6% (≤10%), which clearly revealed that the method was precise. The % recoveries obtained from three concentration points (lowest %residual water content, 100% and 120% of specification) were 101% , 104% and 105%, which were within the acceptable range of 90-110% . It obviously indicated that the method provided a very acceptable accuracy. The intermediate precision outcomes on different days and between analysts were shown in terms of % margin. % Margin was observed as an excellent value of 6% (≤25%). This indicated that the method was reproducible. In conclusion, it was indicated that the developed method was suitable for water determination in erythropoietin products since the validation results show that the method was specific, precise, accurate, and reproducible.

Keywords: Erythropoietin, lyophilized powder, method validation, residual water determination, volumetric Karl Fischer titration

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Introduction

Erythropoietin is manufactured by recombinant DNA technology in cell culture (Ifeanyl, 2015). The produced erythropoietin manifests the identical structure as the human erythropoietin, which composed of 165 amino-acid glycoproteins with molecular weight of 30,400 Daltons (Varas et al., 2018). Furthermore, the recombinant human erythropoietin also exhibits the equivalent activity as the endogenous erythropoietin which acts as a stimulator of red blood cell production in the bone marrow (Ifeanyl, 2015; Grampp et al., 2018). Erythropoietin is indicated for treatment of anemia in both adults and pediatric patients with various associate conditions due to chronic kidney disease, anti HIV infection and myelosuppressive chemotherapy (Bohlius et al., 2006; Henry et al., 1992; John et al., 2012). The erythropoietin pharmaceutical formulations in the market are available in two dosage forms; concentrated solution and lyophilized powder (Veiga et al., 2013). Among 44 erythropoietin products officially registered by Thai FDA, 10 formulations are lyophilized powder (Thai FDA, 2019).

Lyophilization is the process of removing water presented in the products under low temperature and pressure (Joseph E, 2019). Residual water in lyophilized drug products has a critical impact on stability of the active ingredient, particularly large molecules such as proteins (Joseph E, 2019). Increasing residual water content causes degradation of products via hydrolysis reaction. It results in not only physico-chemical stability (e.g., enhancing collapse of porous structure and altering reconstitution behavior), but also biological stability which can affect biological activity (Joseph E, 2019). Therefore, the content of residual water in finished products should be in a range of 2-3% (Chang et al., 2005). The residual water contained in the products mainly achieves from the inactive ingredients in the formulation. Amount of 4,000 international units (IU) of erythropoietin corresponded to 26.68 µg, which was less than 0.05% w/w in the formulation (Kato T, 2016). Owing to the hygroscopic property, lyophilized erythropoietin products easily adsorb moisture from the atmosphere leading to a false high value in water content (Joseph E, 2019). Therefore, an appropriate method to accurately and precisely determine residual water content of these products needs to be developed.

Karl Fischer (KF) titration is the recommended technique for water determination in the official pharmacopoeias such as British Pharmacopoeia and United States Pharmacopeia (British Pharmacopoeia, 2019; USP, 2019). Volumetric KF titration is preferred to measure the water content in the range of 0.01% to 100% or between 0.1 mg and 500 mg of water (Margreth et al., 2010). In general, water extraction from samples can carry out in two dissimilar ways; internal and external extraction (Margreth et al., 2010; Mettler Toledo, 2011). Regarding the internal extraction, the sample powder is directly transferred into the titration vessel and then the residual water is extracted out and titrated (Margreth et al., 2010; Mettler Toledo, 2011). On the other hand, the external extraction requires to dissolve the sample powder with a proper solvent prior to transferring into the titration vessel (Margreth et al., 2010; Mettler Toledo, 2011). The water content of the solvent used has to be determined and subtracted from the gross water content to provide the actual water content of the sample. As the concern of hygroscopic property, external extraction technique is interesting. A suitable solvent for complete water extraction therefore, is necessary to be investigated since the excess of some kinds of the solvents affect the stoichiometry of the KF reaction (Margreth et al., 2010; Mettler Toledo, 2011). The accomplishment of titration on solvent effect must consequently be evaluated as well.

In our experiment, we performed volumetric KF titration with external extraction to determine the residual water content of erythropoietin products. The objective of this study was to develop and validate an analytical method to determine the residual water content of erythropoietin

in the lyophilized products using the external water extraction and volumetric KF titration. We examined the ability and potential of this method to determine the amount of water in lyophilized erythropoietin products in terms of the resulting products' quality, efficacy and stability.

Materials and Methods

Chemicals and reagents

Two different organic solvents: Hydranal™ methanol dry and Hydranal™ formamide dry were purchased from Honeywell, Germany. Hydranal™ Composite 2 (KF reagent) and Water standard 10.0 (1%w/w) were also bought from Honeywell, Germany. Mannitol and human serum albumin (HSA) were acquired from Sigma Aldrich, USA. Sodium chloride, sodium phosphate monobasic monohydrate and sodium phosphate dibasic dihydrate were obtained from Carlo Erba, USA. Recombinant human erythropoietin products were received from the distributors.

Apparatus

Residual water content measurements were performed using a volumetric KF titrator (Metrohm Ltd., Switzerland) equipped with a 5-mL exchange unit. Other equipment and supplies employed included an analytical balance (Mettler, Switzerland), a hot air oven (Memmert, Germany), and syringes with needles (Nipro, Thailand).

Methods

Preparation of lyophilized matrix sample

Components of the matrix solution represent all excipients contained in the erythropoietin products marketed in Thailand. The matrix solution in the presence of mannitol, human serum albumin, sodium chloride, sodium phosphate monobasic monohydrate and sodium phosphate dibasic dihydrate were prepared in sterile water for injection. One milliliter of matrix solution was filled in each 5-mL glass vial and approached to the lyophilization process. The lyophilized matrix samples were stored in a desiccator at 2-8^{o}C.

Method development

Selection of external extraction solvent

Anhydrous methanol and anhydrous formamide are the desired solvent considered to dissolve lyophilized samples (Joseph E, 2019; Mettler Toledo, 2011). Thus, these two solvents were chosen as the preliminary solvents for studying the reconstitution of the lyophilized matrix samples and erythropoietin products. We evaluated the solubility of the lyophilized matrix sample in two different external extraction solvents; Hydranal™ methanol dry and Hydranal™ formamide dry. A vial of lyophilized matrix sample was reconstituted with each extraction solvent. The suitable solvent selected was then used to reconstitute the lyophilized erythropoietin products to examine its ability to act as an extraction solvent. If the reconstitution was successful, then the solution had a clear appearance.

Table 1. The study design for determination of the suitable external extraction solvent

Sample	External extraction solvent
Lyophilized matrix sample	Hydranal™ methanol dry Hydranal™ formamide dry
Erythropoietin product	Suitable solvent obtained from dissolving lyophilized matrix samples

Selection of solvent in titration vessel

We compared two different solvents, Hydranal™ methanol dry and a mixture of Hydranal™ methanol dry and Hydranal™ formamide dry in the ratio of 60:40, for use as the solvent in the titration vessel. Titration of each of 2-mL reconstituted matrix sample in the titration vessel containing each solvent studied was performed. The stoichiometry of the KF reaction indicated by the constant drift values of the titration using different solvent in the titration vessel was evaluated.

Determination of residual water content of external extraction solvent

In our method development process, first we found the suitable external extraction solvent for reconstituting the lyophilized sample. Next, we determined the residual water content of the selected extraction solvent for external extraction prior to assessment of the validation parameters. We subtracted the water content of the extraction solvent from the residual water content of the reconstituted samples to calculate the actual residual water content of the samples .

Approximately 2 mL of the extraction solvent was drawn into a syringe and the whole syringe was then accurately weighed. The solvent was quickly transferred into the titration vessel and the syringe with the remaining solvent was re-weighed. Residual water contained in the extraction solvent was titrated until reaching an end point. An average value of the residual water content of the solvent was obtained from triplicate measurements.

Method validation

Five validation parameters with respect to specificity, repeatability, accuracy and intermediate precision were utilized to assess the developed method.

Specificity

Interferences of air in the titration system and KF reagent on the measurement results were studied. Two samples, air and 0.5 mL of Water standard 10.0, were used as the samples for this study. The influence of air in the titration system was also evaluated by performing the titration with no sample added into the solvent in the titration vessel. The effect of KF reagent was evaluated by the titration of the known amount of water content contained in the Water standard 10.0. We directly quantified the water content of the air in the titration system was. We calculated the percent recovery of the residual water contained in the Water standard 10.0 as follows:

$$\%\text{Recovery} = \frac{\text{Water content found in Water standard 10.0}}{\text{Water content stated in the certificate of Water standard 10.0}} \text{ x } 100 \qquad \text{(Equation 1)}$$

Repeatability

Six lyophilized matrix samples were left at ambient temperature for 30 minutes. A whole vial of the matrix sample including the lyophilized powder, a glass vial, a rubber stopper, and an aluminum cap were weighed. The lyophilized matrix sample was completely reconstituted with 2 mL of the suitable extraction solvent. The residual water in the lyophilized matrix sample was extracted by gently mixing until a clear solution was obtained. We used a syringe with a needle to transfer the matrix solution from the vial to the titration vessel. Then we titrated the solution. The vial with remaining solution, the rubber stopper, and the cap were dried in an oven at 230°C. Then we cooled down the vial to the ambient temperature in a desiccator before re-weighing. The weight of the vial after drying was subtracted from the weight of the whole vial to calculate the weight of the remaining matrix sample. Percent residual water content of the lyophilized matrix sample was calculated. Six replicate determinations of % residual water content were performed. Then we calculated the % RSD. The average % residual water content obtained was assumed to be the lowest water content determined in the lyophilized matrix samples.

Accuracy

Accuracy testing was carried out by spiking the water standard 10.0 in the matrix solution at three concentration levels. Three levels were comprised of lowest %residual water content (obtained from repeatability), 100% and 120% of the specification (specification of the residual water content allowed to contain in the erythropoietin pharmaceutical formulations: not more than 4%) which covered the working range. Three replicate determinations of each level were carried out. The % recovery obtained from a comparison of water content found and water content added was calculated as follows:

$$\%\text{Recovery} = \frac{\text{Water content found}}{\text{Water content added}} \text{ x } 100 \qquad \text{(Equation 2)}$$

Intermediate precision

Intermediate precision was presented to measure within-laboratory variations resulting from performing the procedure being conducted by three different analysts on three different days. Three individual vials of the erythropoietin product were determined on each three different days by the major analyst. Also, the other 6 individual vials (3 each) of the erythropoietin product were demonstrated by the other two second analysts. The average value of the % residual water content and standard deviation (SD) of three different days and three different analysts were calculated. The following % margin was used for evaluation of the intermediate precision studies.

$$\%\text{Margin} = \frac{\text{SD in intermediate precision x } 2.575}{\text{Upper specification limit} - \text{Mean}} \text{ x } 100 \qquad \text{(Equation 3)}$$

Results and Discussion

Method development

Selection of external extraction solvent

The results show that the Hydranal™ formamide dry was superior to the Hydranal™ methanol dry in terms of the dissolving of lyophilized samples. Figure 1(a1) shows that the lyophilized matrix sample did not dissolve with the Hydranal™ methanol dry. A turbid suspension was obviously observed after reconstitution. This was associated with the prior reports, which explained that mannitol and human serum albumin were not able to dissolve in alcohol (Bouchard et al., 2007; Houen G, 1996; Yoshikawa et al., 2012). On the contrary, the lyophilized matrix sample was much soluble in the Hydranal™ formamide dry (Figure 1(a2)). Therefore, the Hydranal™ formamide dry was selected for the further step. The erythropoietin product was reconstituted with the Hydranal™ formamide dry. The clear solution obtained (Figure 1(b)) is evidence that the erythropoeietin product was completely reconstituted with Hydranal™ formamide dry. It was concluded that Hydranal™ formamide dry was the suitable solvent for using as the external extraction solvent for the lyophilized matrix sample and erythropoietin products.

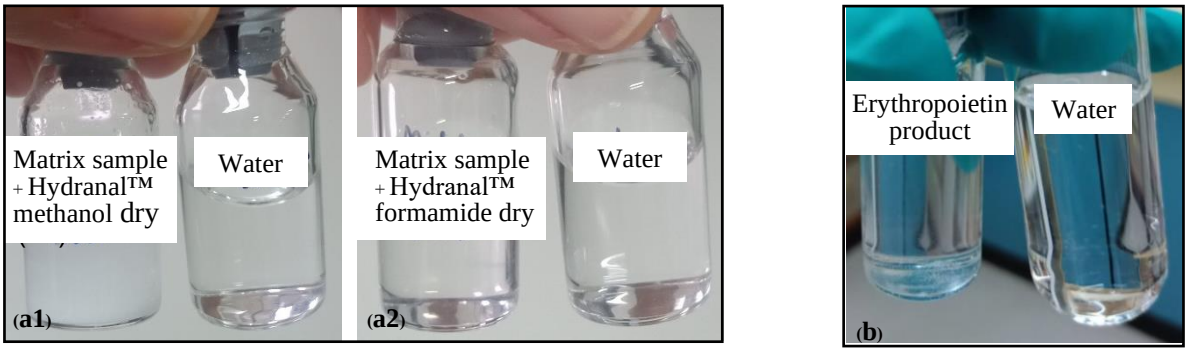

Figure 1. Clarity of the reconstituted solutions (a) lyophilized matrix samples reconstituted with the Hydranal™ methanol dry (1) and with the Hydranal™ formamide dry (2) and (b) erythropoietin product reconstituted with the Hydranal™ formamide dry

Selection of solvent in titration vessel

In the preliminary study, we noticed that using Hydranal™ methanol dry as a solvent in the titration vessel resulted in the precipitation of mannitol and HSA. This led to speedily reach the end point. It can be explained that the precipitates coated on surface of the electrode and blocked the titration reaction (Bouchard et al., 2007; Houen G, 1996; Yoshikawa et al., 2012). The water was not able to react with the KF reagent and the end point then was reached very fast resulting in incorrect volume of KF reagent consumed. Besides, the constant drift value, which is the value indicated the water amount entering to the titration system per unit time, reached to 0 uL/min (Margreth et al., 2010; Mettler Toledo, 2011). This extremely low value of the constant drift caused by the completely blockage of the precipitation of mannitol and HSA on the surface of the electrode. To overcome this challenge, the other solvents were required to improve the solubility of mannitol and HSA. Thus, we found that using of a mixture of Hydranal™ methanol dry and Hydranal™ formamide dry in the ratio of 60:40 as a solvent in the titration vessel did not affect the constant drift values and the end point. The mixture of solvents seemed solve the precipitation problem because the excipients

in matrix sample dissolved in this mixture (Margreth et al., 2010; Mettler Toledo, 2011). The result was in agreement with the literature reported that the addition of formamide (not more than 50%v/v) in the titration system improved the stoichiometry of the KF reaction (Margreth et al., 2010). The Hydranal™ formamide dry in the ratio of 40% of mixture solvent was designed in order to have some percent available of the Hydranal™ formamide dry in the system for the reconstituted samples added. Hence, the mixture of Hydranal™ methanol dry and Hydranal™ formamide dry in the ratio of 60:40 was proper to use as the solvent in the titration vessel.

Determination of residual water content of external extraction solvent

Even though the Hydranal™ formamide dry used as the extraction solvent is identified as "dry", the solvent still contained a small amount of water. This residual water could not be ignored, since it could affect the analysis of residual water of the sample. Therefore, we determined the residual water content of the extraction solvent before analyzing the sample. The residual water content of the extraction solvent was subtracted from residual water content of the reconstituted sample in order to calculate the true amount of residual water in the sample.

Method validation

Specificity

Firs, we evaluated whether aspects of the laboratory environment affected the titration system by titrating the air in the system. We found that air in the system contained only 0.077 mg water. This amount of water was insignificant since the detection limit of volumetric KF titration method was 0.1 mg water (Margreth et al., 2010). Consequently, water in environment of the titration system did not have an effect on the experiments and could be safely ignored. Next, Water standard 10.0 was titrated to ensure that there was no interference from the KF reagent. The recovery of the known amount of water content in the Water standard 10.0 was 100.6%. This % recovery was within the acceptance criteria of 97.5-102.5% (British Pharmacopoeia, 2019). The high accuracy for the %recovery indicated that KF reagent did not interfere with the titration system. We also concluded that the method was specific to only water.

Repeatability

Six individual lyophilized matrix samples were analyzed to determine repeatability. Average residual water content in the lyophilized matrix samples shown as 3.8% water and the %RSD was 4.6%. The results complied with the acceptance limits of 4.0% water (British Pharmacopoeia, 2019) and 10.0%RSD respectively (Incledon & Lam, 2004). Thus, we concluded that the method was repeatable for residual water content determination in the analyzed samples.

Accuracy

The accuracy data was presented in Table 2. The %recovery of the three concentration points (lowest %residual water content, 100% and 120% of the specification) was 101%, 104% and 105%, respectively. These %recovery values were all within the acceptance limits between 90% to 110% which was indicated that the water content found were very close to the true water content containing in the test solution (OECD, 2014). In conclusion, the method was able to determine the residual water content accurately.

Table 2. %Recovery of the accuracy study

Concentration of water content	%Recovery
3.8%	101%
4.0%	104%
4.8%	105%

Intermediate precision

Intermediate precision was performed by measuring residual water content in the erythropoietin product on the three different days and by the three different analysts. Erythropoietin product was used as the test samples in this study in order to ensure the usability of the developed method after the specificity, repeatability and accuracy of the method was satisfactorily validated. Table 3 shows the results of the intermediate precision. The average residual water content in the products on the three different days by the main analyst were 0.5%, 0.7%, and 0.5% , respectively. While the average residual water content in the products determined by the other two second analysts were 0.7 and 0. 5% , respectively. The results were excessively low with respect to the acceptance limit of 4. 0% water (British Pharmacopoeia, 2019) . The intermediate precision for three replicates each day and each analyst were evaluated using standard deviation (SD) (Chitsopa K, 2019) . Acceptable SD was defined as being 0.3 or smaller (Chitsopa K, 2019) . The results showed the SD values of the three different days by the main analyst as 0.09, 0.08 and 0. 11, respectively. The SD values for the other two analysts were 0. 10 and 0. 03 respectively. Due to the very low water content of erythropoietin products and inconsistency of water amount in different individual vials, we considered it acceptable to use % margin as acceptance criteria for intermediate precision testing. The results revealed the excellent % margin of 6% which was extremely lower than the acceptance criteria of 25% (Little TA, 2016).

Table 3. SD and % margin of the intermediate precision

Day	**Average water content [%]**	**SD**
1	0.5	0.09
2	0.7	0.08
3	0.5	0.11
Analyst 2	0.7	0.10
Analyst 3	0.5	0.03
Average water content [%]	0.6	
SD of water content	0.08	
Factor for SD	2.575	
Limit [%]	4	
% Margin	6	

Conclusion

The analytical method for water determination in the lyophilized erythropoietin products using external extraction and volumetric KF titration technique was developed and validated. Hydranal™ formamide dry and the mixture of Hydranal™ methanol dry and Hydranal™ formamide dry in the ratio of 60:40, were selected to be used as the external extraction solvent and the solvent in the titration vessel, respectively. The validation data shows that the method was specific, precise, accurate, and reproducible. Hence, the developed and validated method in this study is suitable for determination of the residual water content in the erythropoietin products in order to ensure the products' quality, efficacy and stability in routine analysis.

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Steps and Challenges of Problem-Based Learning

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Abstract

Problem-Based Learning (PBL) was designed to reduce the hours of conventional lectures in McMaster university, Canada. It is not only providing a lively learning process, but also student-centered approach. Therefore, PBL is considered a tool for the 21st Century skill development (Suwastini et. al., 2021). PBL is not only enabling students to gain their knowledge through self- direct learning, but also other necessary skills, such as, cooperative learning, critical thinking and problem-solving skills (Hung, Jonassen & Liu, 2008). This article aims to elaborate on the seven steps of PBL, roles of teacher and learners in the PBL process, its challenges and how to overcome obstacles for each step of PBL. Furthermore, the PBL implication is also presented in this article.

Keywords: Problem Based Learning, 21st Century skills, Student centered, Self- directed learning

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Background

Problem-Based Learning (PBL) is a student-centered approach which enables students to develop their problem-solving skills. PBL allows them to research relevant knowledge and evidence, as well as apply their findings to resolve a problem in practice (Savery, 2015). Although there are several PBL concepts available, the most popular one is from the medical school at McMaster University in Canada. The use of PBL at McMaster University was launched in 1960's by Howard S. Barrows, who aimed to improve teaching methods for medical students. Instead of conventional lecturing without patient context, he assigned a clinical problem with patient context. Therefore, students could learn from the PBL process by making a decision involving patients based on their knowledge, evidence, and problem-solving skills (Norman & Schmidt,1992; Savery, 2015; Puttiwanit et al., 2020).

It is vital for current education to prepare students for 21st century learning by teaching them self-directed and lifelong learning skills (Puttiwanit, et al., 2020). Furthermore, PBL could influence students to have more long-term knowledge retention than conventional lecture. PBL not only helps students to learn from real-life situations, but also enables them to gain problem-solving skills and experience working in teams (Murphy et al., 2011). Researchers found that learners significantly improve their cognitive skills more using PBL compared to those using usual, lecture-based learning styles ($t = 7.23$, $p < .001$) (Boonpleng et al., 2018).

The three main criteria for Problem Based Learning education

The Department of Chemical Engineering at McMaster University (2022) indicated the three main criteria for PBL education are small group learning, student self- directed learning (SDL), and student self-assessment. Here are more details on each of the three criteria:

1) Small group learning with a student and teacher ratio of 5-7: 1 is recommended (Department of Chemical Engineering, McMaster university, 2022). This is good for building rapport between students and teacher because they could know each other perspectives and preference in a small group discussion (Sybing, 2019). Furthermore, group learning could pressure students to actively do complete the self-study assignments and submit their works on time (Schmidt et al. 2011).

2) Self-directed learning (SDL) is crucial for influencing student centered learning (Department of Chemical Engineering, McMaster university, 2022). Teachers need to assess students regarding learning concepts, knowledge gaps, and missing concepts. This enables teachers to know which topics that students should be required to self-study (Strobel & Van Barneveld, 2009). Teachers act as facilitators who influence students to learn from a problem with real- life context. The teacher does not judge whether the students' decisions are right or wrong, but instead focuses on the students' learning process and building of skills afterwards (Savin-Baden, 2001; Savery, 2015). Evidence shows that PBL helps students to better understand and connect the PBL case to real-life, for example, using a case of psychiatric patient scenario based on a real patient case (Norman & Schmidt,1992). Therefore, students also better retain contents and improve their practice skills (Strobel & Van Barneveld, 2009; Lobuteva et al. 2019).

3) The PBL process also helps students develop the important 21st Century skills of self-assessment. The importance of this step is to improve student's learning by developing student self-motivation, self-confidence, helping students to see where they are (Woods, 1996). Specifically, students could practice their reflective thinking, analytical thinking, critical thinking, problem-solving skills, cooperative learning, and holistic thinking skills

(Blumhof et al. 2001; Savin-Baden, 2001; Hung, Jonassen, & Liu, 2008). Therefore, the key principles for student self-assessment should be a clear purpose and measurable as well as based on variety of performances and evidence (Woods, 1996).

Preparation for PBL process

The crucial preparation for PBL teaching could be categorized into four groups: 1) learner, 2) teacher, 3) infrastructure and learning resources, and 4) problem or scenario that students will address in the PBL process.

4.1 Learner

Learners should be informed about course objectives and course behavioral objectives. Therefore, they could prepare themselves for their roles in advance. This could help them to achieve learning outcomes more successfully than if they were not aware of expectations ahead of time (Puttiwanit, et al., 2020).

4.2 Teacher

Teachers should be trained in advance with regard to these topics:

1) Teachers need to emphasize the concept of problem solving as a starting point. They should encourage learners to combine existing knowledge with new knowledge in order to create a novel body of knowledge to solve problems together within their group. The teachers facilitate the learners to learn through PBL process, rather than focusing on the answer. Teachers encourage students to develop their skills in problem solving, creative thinking, critical thinking,cooperative learning, and self-directed learning. In this way, teachers promote authentic student-centered teaching and learning (Puttiwanit et al., 2020; Department of Chemical Engineering, McMaster university, 2022).

2) Teachers must adjust to being facilitators, instead of lecturers. Teachers create a non-threatening atmosphere and provide formative feedback to reduce possible group tension (Wood, 2003; Puttiwanit et al., 2020).

3) Teachers need practice in creating scenarios, piloting them with a PBL teaching team, and refining their scenarios. A team of teachers can write and give tutor notes to each other. Each teacher can revise their scenario incorporating peer feedback before implementing their scenarios with students (Wood, 2003, p.329).

4) The teachers are not only required to have a broad knowledge of the changes in the social context. They also need to have knowledge of health systems, society, culture, factors contributing to physical and/or psychiatric disorders (Puttiwanit et al., 2020). This will enable teachers to apply these concepts when planning their PBL activities in detail.

4.3 Infrastructure and learning resources

Teachers need reference lists regarding textbooks, hard copies of relevant nursing journal articles, databases for electronic health sciences journals, and websites that are relevant for self- directed learning. Teachers and students all need adequate computers and Internet access to complete online searches.

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4.4 Scenario that students will address during PBL process

Scenario design is crucial for assisting learners to acquire a variety of knowledge. Wood (2003) and Hmelo-Silver (2004) indicate seven criteria to develop a good scenario for the PBL process. The criteria are: 1) identifying learning objectives in advance, 2) using an authentic scenario, 3) adapting the scenario to the students' prior knowledge level, 4) engaging students in discussion, 5) leading students to identify appropriate issues that require more learning, 6) stimulating self-directed learning (SDL), and 7) creating an interesting scenario.

The seven steps of PBL process and roles of teachers and students

Teachers and students participate in the seven steps of the PBL process. We provide greater details about the teachers' role, students' role, as well as potential problems and solutions for each step in the tables below. We suggest weekly timeline in which these steps can be completed.

Week 1: Processing step 1- 5

Step 1: Clarifying unfamiliar terms of PBL

Teachers' role	Students' role	Potential problem and possible solution
Presenting the scenario by video clip or paper-based scenario.	Watching video clip or reading a paper-based scenario with other members in the group.	**Potential problem**: Teachers tend to be lecturer instead of a facilitator. **Possible solution:** Teachers provide students with prompt questions in a PBL manual instead of giving a lecture.

Step 2: Problem definition

Teachers' role	Students' role	Potential problem and possible solution
1. Emphasizing student centered learning by motivating students. Asking questions related to the scenario. Encouraging them to identify what they have observed and discuss observations among themselves. 2. Encouraging students to express their opinions and listen with intention. Provide them positive feedback when learners demonstrate the desired skills based on learning outcomes.	1. Assigning responsibilities within the group regarding head of the group, secretary, and members. 2. Identifying issues from the scenario. 3. Sharing and discussing opinions among group members.	1. **Potential problem**: Teacher centered learning. **Possible solution:** Providing a manual and prompt questions for in-depth discussions. 2. **Potential problem:** Students remain silent and find it difficult to have a group discussion. **Possible solution:** The teacher asks the students to share their previous experiences related to the scenario. For example: Have they encountered a

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	Teachers' role	Students' role	Potential problem and possible solution
3.	Summarizing and expanding on students' opinions.		situation similar to the PBL scenario? If yes, how was it similar?

Step 3: Brainstorming

The learners brainstorm to analyze the problems and to search for possible causes or contributing factors for the problem based on the group members' prior knowledge. This is collaborative learning that uses rational thinking. Students practice summarizing knowledge and concepts of the group members to solve their problem. Students create a reasonable proposal to solve problems and/or possible hypotheses for why their problem occurs. Students may use a mind map as a tool (Boromarajonani College of Nursing Sawanpracharak Nakhonsawan, 2018; Department of Chemical Engineering, McMaster university, 2022)

	Teachers' role	Students' role	Potential problem and possible solution
1.	Encourage students to express their opinions about problems they are interested in and want to learn.	Sharing opinions and asking questions. Encouraging each other to learn within the group.	**1. Potential problem:** Some questions and analytical information do not cover the key points. **Possible solution:** Teachers provide hints for students to give them possible directions, but do not lecture. 2. **Potential problem:** Some students are silent, but some are dominant. **Possible solution:** Teachers treat each student equally. Encourage silent members to speak up by using questions for all group members. For example, "Do you agree with your peers/group members? Why or why not?" Silent learners may not want to voice their opinions because they fear their opinions would be rejected. Thus, it may be helpful to explicitly ask for all members to provide feedback. Furthermore, the "think, pair, share" technique is a good option for encouraging group discussion (Vicki et al., 2016).
2.	Provide additional information for the scenario.		

Step 4: Analyzing the problem

The group of learners brainstorms, proposes possible solutions, and hypothesizes different reasons for the problem based on scenario. The group prioritizes solutions and hypotheses based on the learners' prior knowledge. This process should emphasize rational thinking and student expression. Furthermore, students can outline additional content that they need to research using a mind map. Therefore, this process helps students obtain accurate data and complete information before presenting it to the group members (Boromarajonani College of Nursing Sawanpracharak Nakhonsawan, 2018; Department of Chemical Engineering, McMaster university, 2022).

Teachers' role	Students' role	Potential problem and possible solution
1. Encourage students to make assumptions and propose learning topics. 2. Appraise mind maps and point out the similarities and differences of each mind map with learners. 3. Encourage learners to suggest what they need to explore further and search from different sources of knowledge.	1. Hypothesize the causes of the problem(s)/ topic(s) and the person(s) involved in the scenario. 2. Prioritize the interesting and important issues for 3-5 problems. 3. Indicate the learning topics and identify sources of knowledge. 4. Create and present mind map of the group. 5. Manage and assign topics for further information searches.	**Potential problem:** Students may identify missing issues or topics which require further study. **Possible solution:** The teacher gives an example of a hypothesis and learning topic or factors that may be related to the problem.

Step 5: Formulating learning objectives/issues

Students indicate learning objectives and issues for their PBL scenario. They use the objectives to search for relevant groups of information. In addition, the first round of student self-evaluation and reflection regarding on their work and the PBL learning process should be undertaken at this stage (Boromarajonani College of Nursing Sawanpracharak Nakhonsawan, 2018; Department of Chemical Engineering, McMaster university, 2022).

Step 5: Formulating learning objectives/ issues

Teachers' role	Students' role	Potential problem and possible solution
1. Assist learners to achieve learning objectives by designing the strategies that are focused, achievable, complete/ comprehensive and appropriate (Wood, 2003, p.329).	1. Evaluate the satisfaction of their own work, the PBL learning process, and behavior while working together in groups.	**Potential problem:** Learners are reluctant to assess the group teachers because of fear of bias in the assessment of scores. **Possible solution:** Use online survey and conceal the names and identity of the learners for

Teachers' role	Students' role	Potential problem and possible solution
2. Ask students to reflect on the PBL learning process and working in groups. 3. Ask students to evaluate and feedback themselves. 4. Give positive reinforcement, such as complimenting and encouraging learners based on their individual behavior.	2. Give feedback to the group teacher.	confidentiality and obtain information for further development.

Week 2: Processing step 6

Step 6: Self-study/ Self-directed learning

Learners collect information from the media and various learning resources related to the learning objectives before participating group discussion (Boromarajonani College of Nursing Sawanpracharak Nakhonsawan, 2018; Department of Chemical Engineering, McMaster university, 2022)

Teachers' role	Students' role	Potential problem and possible solution
Give advice and help students to examine learning resources which students search for.	Research for knowledge on assigned topics through information sources such as libraries, online media, experts, etc.	**Potential problem:** Learners choose information from untrusted sources of knowledge. **Possible solution:** Teachers suggest ideas on how to select trustworthy sources for credible references. During the first week that students are researching their problem, check resources and give advice to the students both face-to-face and online discussions.

Week 3: Processing step 7

Step 7: Reporting and group shares results of their private study

Learners present information obtained by researching various sources of information, media, and learning resources that are relevant to the learning objectives (Wood, 2003, p.329) . The students test their hypotheses by using the obtained information and connecting to new knowledge. They present and exchange knowledge including a comparison of research data related to their learning goals (Boromarajonani College of Nursing Sawanpracharak Nakhonsawan, 2018; Department of Chemical Engineering, McMaster university, 2022).

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Teachers' role	Students' role	Potential problem and possible solution
Arrange learners to present information that they have researched. Encourage the group members provide feedback on the missing parts that students need to address to achieve their learning objectives.	1. Present the information that has been assigned. 2. Do self-assessment regarding ones' own performance according to learning goals for validation and completeness of work.	**Potential problem:** Students do not research and/or present their work. **Possible solution:** The teacher askes for reasons to come up with a solution to the problem together, but do not blame the students.

PBL Learning evaluation by the instructor

After completing the PBL process, the instructor should do authentic assessment of the practice by evaluating the learners' behaviors while participating in the group activities. Teachers should observe systematically. They should assess the skills of student group members regarding their performance on expressing their opinions, group work collaboration, and punctuality (Puttiwanit et al., 2020).

Challenges and limitations of Problem Based Learning

The challenges of PBL comprise of transitioning learning process from conventional learning process to PBL; student-centered learning process. The teacher may explain and teach students if he/she found that the students lack of knowledge. Hence, the teachers need to be trained how to use appropriate prompt questions (Boromarajonani College of Nursing Sawanpracharak Nakhonsawan, 2018; Department of Chemical Engineering, McMaster university, 2022). Group dynamic could cause negative experiences during conducting PBL process, for example, blaming to each other (Ramlo, Salmon & Xue, 2021) and some students do not clear what they are required to do in PBL (Belland, Glazewski, & Ertmer, 2009). Furthermore, discrepancies of PBL assessment between students and teacher could be an issue because students tend to perceive their capabilities slightly higher than the teacher (Machado, Machado, Grec, Bollela, & Vieira, 2008). Therefore, the focus of assessment tool is crucial (Hung, Jonassen & Liu, 2008). Although PBL is recognized as a good process to improve student's knowledge retention, it may not suitable for a general education subject (Van den Bossche, Gijbels & Dochy, 2000). Evidence shows that basic knowledge scores of students with conventional learning are better than PBL students who are good at clinical reasoning skills (Nendaz & Tekian, 1999; Hung, Jonassen & Liu, 2008).

Conclusion

PBL is a learning tool to improve the 21st Century skills regarding critical thinking, problem solving, and communicative skills through resolving a realistic problem in a collaborative group setting (Ali, 2019; Suwastini et. al., 2021). In PBL, the teachers' role is not lecturing but facilitating the students to learn and achieve desired learning outcomes based on the scenario (Suwastini et. al., 2021). Our paper summarized seven steps necessary to achieve the desired goals of PBL. We also explained the different teacher and student responsibilities, roles, and actions needed to accomplish successful PBL. Finally, we indicated challenges and limitations of PBL. Therefore, it is necessary to well plan scenario, and train PBL teachers prior to apply it in a real class.

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Author Guideline and Instruction

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Originals

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Thesis/dissertation

Hom, K. E. (2018). *Association of Air Pollution with Longitudinal Changes in Arterial Stiffness and Correlated of Longitudinal Changes in Arterial Stiffness in the Multi-Ethnic Study of Atherosclerosis (MESA)*. A Dissertation Submitted in Partial Fulfillment of the Requirements for the Degree of Doctoral of Philosophy, University of Washington.

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