CLINICAL PATHWAY EVALUATION MODEL FOR ST ELEVATION MYOCARDIAL INFARCTION OPTIMAL PATIENT CARE

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A thesis submitted in fulfilment of the
requirements for the award of the degree of
Doctor of Philosophy (Health Science)

Faculty of Biosciences and Medical Engineering
Universiti Teknologi Malaysia

MARCH 2017

ACKNOWLEDGEMENT

In preparing this thesis, I was in contact with many hospitals, researchers, acadcmicians, and practitioners. They have contributed towards my understanding and thoughts. In particular, I wish to express my sincere appreciation to my thesis supervisor, Professor. Ir. Dr. Ing Eko Supriyanto, for encouragcment, guidance, critics and friendship. Without his continued support and interest, this thesis would not have been seen as presented here.

I am also indebted to National Cardiovascular Disease center (NCC) in Jakarta and the National Heart Institute (IJN) in Kuala Lumpur for their assistance in supplying the relevant data. My sincere appreciation also extends to all my colleagues and friends who have provided assistance at various occasions. Their views and tips are useful indeed. Unfortunately, it is not possible to list all of them in this limited space.

I am grateful to my family members for the support and encouregment to reach my goal which used to be their goal. My parent, my real inspiration, should be recognised as they have been always my mentors to handle life and to keep going on to success. Special thanks to my husband and my kids for their patience and continuous support.

ABSTRACT

Recently, clinical pathway (CP) has been used to reduce the variation and optimise the ST-elevation myocardial infarction (STEMI) process of care. The evaluation domains of STEMI CP quality remain inconsistent information. The aim of this research is to develop an evaluation model to guide the decision making on the optimal STEMI clinical pathways content and design. A qualitative and quantitative (mixed method) was used to generate and analyse the data of this research. First, the initial research STEMI clinical pathway concept has been developed from theory and practice. Second, the concept was tested in subsequent questionnaires distributions (pilot and actual study). Third, a clinical pathway quality evaluation model for STEMI (STEMICPQ) has been proposed and then assessed by structural equation modelling (SEM) path analysis using smart PLS version 3.0 software. Fourth, the sensitivity and specificity of the proposed model were tested in comparison to three quality criteria performance in 138 retrospective trial records. The results of the two stages questionnaire demonstrated an agreement on the items grouping and classification by the experts on most of the items of the questionnaire. A total of 186 responses from the second questionnaire have been returned involving 84 specialists and 76 nurses. The items content validity index (ICVI) is greater than 80%, and the construct reliability (Cronbach Alpha) is 0.85. This research proposes a model consisted of three STEMI CP quality domains (Design and Content, Process and Activity, and Outcome and Variance) with total 30 items and 60 sub-items and proven its ability to evaluate the quality of STEMICP. The STEMICPQ model validation results have established strong composite reliability, predictive relevance and power of explanation. The hypothesis testing revealed that the outcome and variance is a strong predictor of the STEMI clinical pathway quality with path coefficient (β) = 0.65, t statistics (t) = 17.4 and item loadings significant (p) = 0.000. From a retrospective CP trial study, the overall predictive power of the STEMICPQ shows high sensitivity of 0.915, specificity of 0.942 and area under the curve accuracy (AUC) of 0.93 in comparison to the length of stay criterion (LOS) of STEMI patients. As a conclusion, this model revealed suitable to be implemented in the health care institution to improve the quality of healthcare for STEMI patients. Also, it provides the experts with a valid, feasible and practical decision-making tool to be used in the hospitals during the design stage of STEMI CP. This work does not cover the organisational or human factors.

ABSTRAK

Kebelakangan ini, laluan klinikal (CP) telah digunakan untuk mengurangkan perubahan dan mengoptimumkan proses penginfarkan miokardium elevasi segmen ST (STEMI). Kajian ini bertujuan untuk membentuk satu model penilaian yang optimum sebagai panduan membuat keputusan ke atas isi kandungan aliran klinikal STEMI dan reka bentuk. Kaedah campuran kualitatif dan kuantitatif telah digunakan untuk menjana dan menganalisis data kajian ini. Pertama, konsep tinjauan semula dilakukan bagi teori yang sedia ada (ulasan peninjauan semula) dan amalan perubatan (temu duga pakar-pakar dan analisis dokumen STEMI CP). Penyelidikan awal kajian telah dilaksanakan dalam fasa ini dan telah diuji melalui pengagihan borang soal selidik (kajian rintis dan sebenar) yang seterusnya pada fasa yang kedua. Ketiga, model penilaian kualiti aliran klinikal STEMI (STEMICPQ) telah dibangunkan seterusnya dinilai oleh analisis laluan permodelan persamaan struktur (SEM) dengan menggunakan perisian PLS pintar versi 3.0. Keempat, kepekaan dan kekhususan model yang dicadangkan telah diuji secara perbandingan dengan tiga kriteria kualiti yang telah ditaksir dalam 138 rekod kajian retrospektif. Keputusan daripada dua peringkat soal selidik menunjukkan persetujuan oleh pakar-pakar pada kebanyakan perkara dalam borang soal selidik dari segi pengumpulan dan pengelasan perkara. Sejumlah 186 maklumbalas dari borang soal selidik kedua telah diterima yang melibatkan 84 orang pakar dan 76 orang jururawat. Indeks kesahan isi kandungan perkara (ICVI) ialah melebihi 80% dan keutuhan binaan (Cronbach Alpha) ialah 0.85. Kajian ini mengusulkan model yang terdiri daripada 'tiga' bidang kualiti STEMI CP (Reka Bentuk dan Kandungan, Proses dan Aktiviti serta Hasil dan Perbezaan) dengan sejumlah 30 perkara dan 60 sub-perkara dan dibuktikan kebolehannya untuk menilai kualiti STEMI CP. Keputusan kesahan model STEMICPQ telah mewujudkan keutuhan komposit yang kukuh dan ramalan yang relevan dan kuasa yang penting. Hasil dari pengujian hipotesis mendapati keputusan dan perbezaan adalah peramal yang kukuh bagi kualiti aliran klinikal STEMI dengan koefisien laluan (β) = 0.65, statistik t (t) =17.4 dan ketaraan beban perkara (p) = 0.000. Dari kajian percubaan CP secara retrospektif, kuasa peramalan keseluruhan STEMICPQ menunjukkan kepekaan 0.915, kekhususan 0.942 yang tinggi dan kawasan di bawah lengkungan ketepatan (AUC) 0.93 kriteria berbanding tempoh penginapan (LOS) pesakit-pesakit (STEMI). Kesimpulannya, model ini didapati sesuai untuk dilaksanakan dalam institusi penjagaan kesihatan untuk meningkatkan kualiti penjagaan kesihatan untuk pesakit STEMI. Selain itu, ia juga menyediakan alat membuat keputusan yang sah, boleh dilaksanakan dan praktikal kepada pakar-pakar untuk digunakan di hospital semasa peringkat reka bentuk STEMI CP. Kerja ini tidak melibatkan faktor-faktor organisasi atau faktor manusia.

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LIST OF ABBREVIATION

ACC	-	Accuracy
ADR	-	The Adherence Rate
AGREE	-	Appraisal of Guidelines, Research, and Evaluation
ASA	-	AcetylSsalicylic Acid
AUC	-	Area Under the Curve
CAD	-	Coronary Artery Disease
CFA	-	Confirmatory Factor Analysis
CN	-	Condition Negative
COPD	-	Chronic Obstructive Pulmonary Disease
CP	-	Clinical Pathway
Cp	-	Condition Positive
CPGs	-	Clinical Practice Guidelines
CR	-	Composite Reliability
CVDs	-	Cardiovascular Diseases
CVI	-	Content Validity Index
DES	-	Design and Content Section
DOR	-	Diagnostic Odds Ratio
EBTs	-	Evidence-Based Treatments
ECG	-	Electrocardiogram
EFA	-	Exploratory Factor Analysis
FDR		False Discovery Rate
FN		False Negative
FOR		False Omission Rate
FPR	-	False Positive Rate

GoF	-	Global Fit Measure
GRACE	-	The Global Registry of Acute Coronary Events
HTMT	-	Heterotrait-Monotrait Ratio of Correlations
HUKM	-	Hospital Universiti Kebangsaan Malaysia
ICP	-	Integrated Care Pathway
ICPAT	-	Integrated Care Pathways Appraisal Tool
ICPUS	-	Integrated Care Pathways Users Scotland
ICU	-	Intensive Care Unit
I-CVI	-	Item content validation index
I-CVI	-	Item Content Validation Index
IJN	-	Institute Jantung Negara in Malaysia
KMO	-	The Kaiser-Meyer-Olkin measure
LBB	-	Left Bundle Branch
LOS	-	Length of Stay
LR-		Negative Likelihood Ratio
LR+	-	Positive Likelihood Ratio
LV	-	Latent Variable
MI	-	Myocardial Infarction
MOH	-	Ministry of Health, Malaysia
MV	-	Manifest Variable
NCC	-	National Cardiovascular Centre, Jakarta, Indonesia
NPV	-	Negative Predictive Value
NSTEMI	-	Non-ST Segment Elevation Myocardial Infarction
OMT	-	Optimal Medical Treatment
OUT	-	Outcomes and Variances Section
PAF	-	Path Axis Factoring
PCA	-	Principle Component Analysis
PCI	-	Percutaneous Coronary Intervention
PCN	-	Predicted Condition Negative
PCp	-	Predicted Condition Positive
PDSA	-	Plan- Do-Study-Act
PLS	-	Partial Least Square
PMA	-	Process of Medication and Activities Section

PPV	-	Positive Predictive Value
R^2	-	Goodness-of-Fit of Linear Regression
ROC	-	Receiver Operating Characteristics
S-CVI	-	Scale Validity Index
SEM	-	Structural Equation Modelling
SOP	-	Standard Operation Procedures
SPSS	-	Statistical Package for Social Sciences
SRMR	-	The Standardized Root Means Square Residual
STEMI	-	St-Elevation Myocardial infarction
STEMICPQ	-	STEMI Clinical Pathway Quality
TNR	-	True Negative Rate
TPR	-	True Positive Rate
UNU	-	United Nation University

LIST OF SYMBOLS

w	-	MV Weight
$\boldsymbol{X}$	-	MV variable
β	-	Path Coefficient
ε	-	Residual Term for Reflective Model
ζ	-	Residual term for Structural Model
ξ	-	LV variable
π	-	Parameter Loading
δ	-	Residual term for Formative Model

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CHAPTER 1

INTRODUCTION

1.1 Research Background

ST-elevation myocardial infarction (STEMI) disease happens due to the full thickness damage of the heart muscle (Thygesen *et al*., 2012). STEMI continues to be one of the most common reasons for hospitalisation worldwide (O'Gara *et al*., 2013 and Hall *et al*., 2016). Furthermore, it continues to contribute to 80% of the mortality rate worldwide STEMI contribute to 25-40% of the overall cardiovascular disease (CVD) morbidity in Malaysia (World Health Organisation, 2014) (Figure 1.1). As simplified in Figure 1.2, the progress of the myocardial infarction (MI) after blockage of the coronary artery leads to oxygen deprivation causing heart muscle deaths and will be manifested by ECG St-segment elevation.

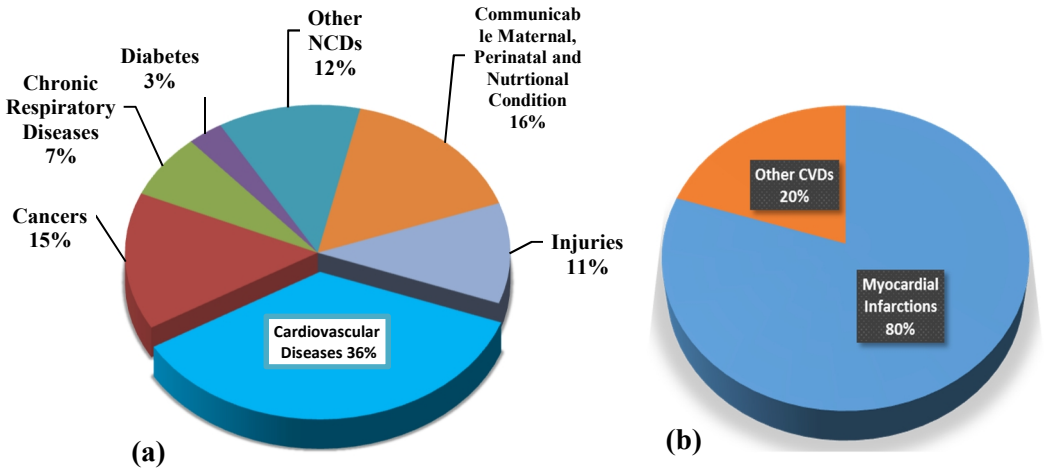

Figure 1.1 (a) Percentage of the total death by age and sex in Malaysia *(WHO Malaysia non-communicable disease country profile, 2014)*. (b) Myocardial infarction mortality worldwide *(World Health Organization, 2016)*

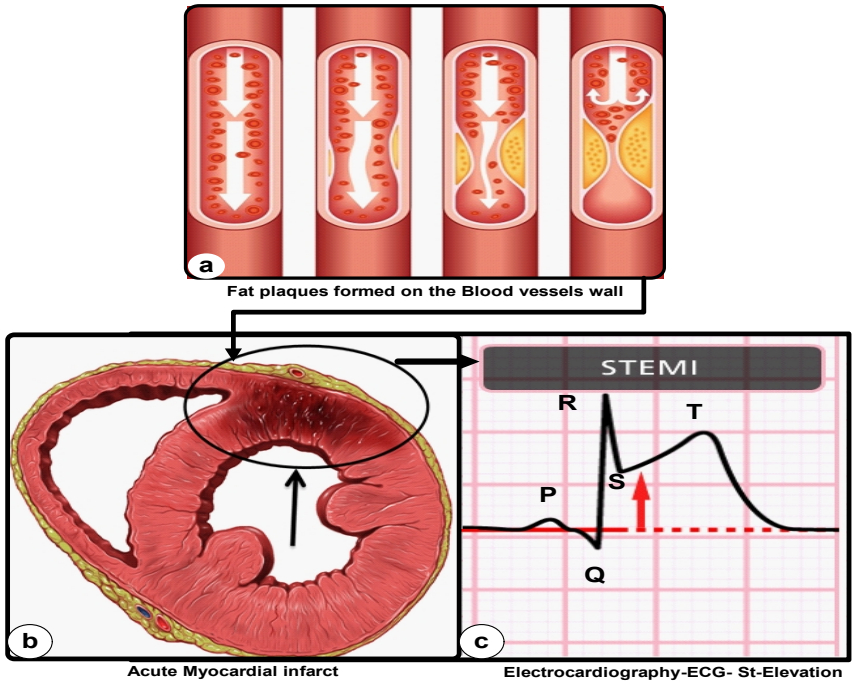

Figure 1.2 (a) Plaque formed on the wall of the arteries causing *(Anatomy Medicine, 2016)*. (b) Acute myocardial infarct and (c) ECG ST-segment elevation (*Emergency Medicine Ireland, 2016)*

The management of STEMI depends on standard diagnostic and therapeutic measures following the clinical practice guidelines (CPGs). CPGs are statements

reached after expert's consensus and rigorous review of the evidence from randomised trials. CPGS considered as the source for optimal care and improve the quality of patient care (Mehta, 2002). For example, Malaysia STEMI clinical guidelines (Robaayah Zambahari *et al.*, 2014) changed the death rate among STEMI patients minimally and similarly worldwide. Variations in the process of care remain as a significant quality issue in health care, and the patients may not yet receive the optimal care (Steg *et al*., 2012; Chan *et al*., 2016 and De Boer and Zijlstra, 2015). Various research studies have attributed that to the poor CPGs compliance due to its subjective nature and lengthy statements (Chan *et al*., 2015; Hansen *et al*., 2015; Lelgemann and Ollenschlager, 2006 and Lip *et al*., 2015).

The drawback in STEMI management as mentioned above, lead to the use of "Clinical pathway" (CP) in health care to ease the use of CPGs and enhances adherence to its standards (Young, 2002). Clinical pathway (CP) functions as an operational tool to integrate the clinical evidence to the practice and standardise the process of care. Clinical pathway defined as "a complex intervention for the mutual decision-making and organisation of care processes for a distinct group of patients during a well-defined period." (Vanhaecht, K. *et al.*, 2007). Queensland health clinical pathways board (2012) defined clinical pathway as "multidisciplinary management plans, which identify an appropriate sequence of clinical interventions, timeframes, milestones and expected outcomes for specific patient group".

Clinical pathways evolved as a solution for the variation in care issues improve efficiency and effectiveness. Consequently, clinical pathway enhances the quality of care process and support different diseases. Furthermore, it alleviates the guideline limitations such as lengthy content, variances in actions and procedures (Geleris and Boudoulas, 2011). Clinical pathway has adopted important features from the clinical guideline, the 'easy to access' feature from protocols, timeline and logical order from the algorithm. Besides, it is unique by having a focus on the quality and coordination of care. Indeed, CPs has been mainly attracting attentions to standardise the process of care and to ensure benefits for the patient and hospitals (Woolf *et al.*, 1999).

A clinical pathway is a complex intervention aims to assist in several functions such as decision-making, an organisation of care processes, and implementation of evidence and integrate quality indicators into clinical practice. Also, it helps in continuous monitoring and data evaluation (variance analysis) and potentially reduces healthcare costs. (Lawal *et al.*, 2016; Lodewijckx *et al.*, 2012; Marrie *et al.*, 2000; Rotter *et al.*, 2010; Rotter *et al.*, 2012 and Vanhaecht and Witte, 2007).

Clinical pathway development pass through several steps life cycle using 'plan, do, study and act' (PDSA) theory (Vanhaecht *et a.l*, 2007). It starts by identifying the need to the clinical pathway and end with implementation and analysis as illustrated in Figure 1.3 (Heiden, 2012). The life cycle of the clinical pathway had an average of 1-3 years according to National Health service England (NHS) (2011) and could be shortened to only one year depending on the management process (Vanhaecht *et al.*, 2007). Figure 1.3 shows the life cycle of STEMI clinical pathway from development to redesign according to PDSA cycle.

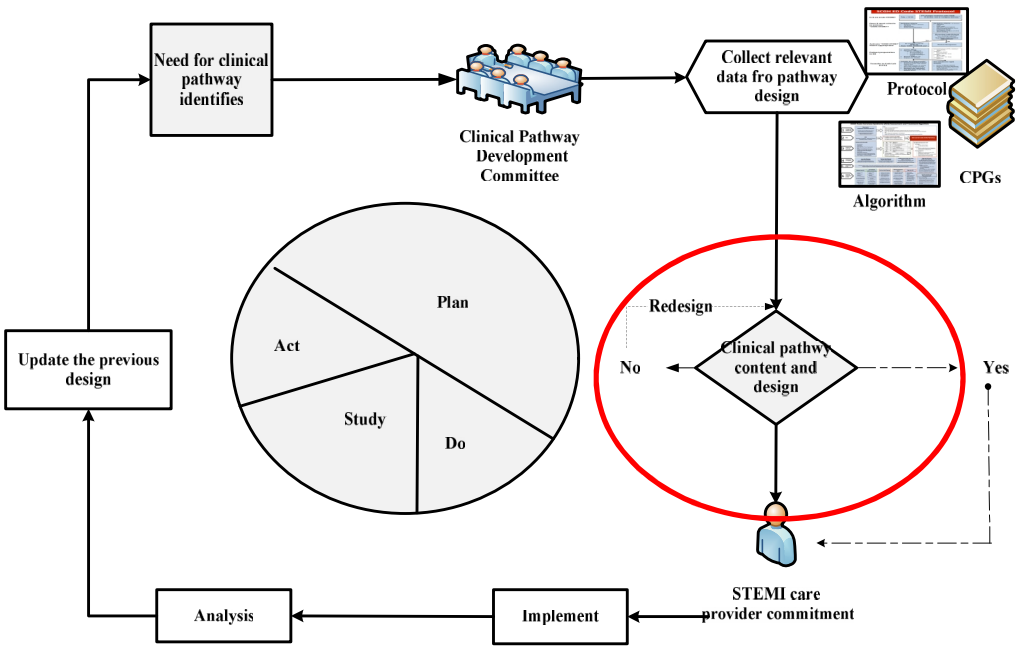

Figure1.3 Depict the clinical pathway lifecycle integrated with PDSA theory modified from Queensland health clinical pathways (2005)

The development of the clinical pathway depends on the consensus of the experts in the field; each organisation (hospital) has its clinical pathway based on the standard operation procedures (SOP) and the guideline for the health ministry's publications of the regions as a source for optimal care. The patients are the main target for the clinical pathway usage, and it is proofed to improve patient outcomes, safety, and optimise the use of clinical resources (Jernberg *et al*., 2011and Jollis *et al.*, 2012).

However, the current literature evidence show suboptimal adherence to clinical pathway and variability in the quality of care (Lawal *et al.*, 2016). The quality indicators description in the guidelines is missing in most of the guidelines and several factors lead to variation in clinical pathway design (Coffey *et al.*, 2005 and Coffey *et al.*, 1992). De Boer and Zijlstra (2015) explained that the quality should not be measured using only the time as an indicator to improve the outcome or the performance of physicians, but presenting the best treatment options available to the patient should also be considered as an indicator of success.

Various quality indicators under different themes do exist as highlighted by Rogers (2015). However, it becomes difficult to decide the most appropriate indicators for the purpose of measurement. For example, the existing research focuses on the outcome as an indicator of CP quality with less focus on the other quality attributes such as design and process. Nevertheless, the study by Mallock and Braithwaite (2005) has highlighted some criteria to select the core component of the clinical pathway. Also, Ovretveit (2010), Panella *et al*. (2003) and Hamilton *et al*. (2008) considered the involvement of the clinicians as a major factor in the development of clinical pathway. There is variation in the clinical pathway design due to the variability in concepts, methods and groups responsible for the design beside the existence of competing pathways among specialist and the hospitals (Aeyels *et al.*, 2014; Chatterjee and Joynt, 2014 and Demartino and Larsen, 2012).

1.2 Problem Statement

The variation in the process of care represents a serious quality issue which has been standardised by the clinical pathway. However, there are variations in STEMI CP development and evaluation methods. The current CPs evaluations tools would usually measure different components from various aspects, various domains and consider different outcome (Audimoolam *et al.,* 2005; Aziz *et al.,* 2012 and Van Herck *et al.*, 2010).

Furthermore, it is not clear whether the STEMI CP evaluation tools or models exist and if any, are they suitable to evaluate the STEMI CP quality or not. In practice, when experts decide to choose the best evidence to include in the CP, a revision of many publications needs to be ensured. This difficulty attributed to the variability in CPs definitions concepts and functions. Consequently, the development of clinical pathway depends on the consensus of the experts in the field, guidelines and each hospital has its designed clinical pathway. This discrepancy added to the sources of variation in care as each hospital will have a different plan with no standard for designing the STEMI CPs. Also, there is a lack of standardisation of ST-elevated myocardial infarction pathway documents (Aeyels *et al*., 2014; Mallock and Braithwaite, 2005).

Moreover, in the existing literature, most of the studies have been looking at the implementation aspect of the clinical pathway with pre-post CP implementation comparison to examine the effect of the CPs on the improvement of the outcome. However, little if any of these studies only focused on the first planning stage of the CPs. There are weak methodological designs in most of the current CP development studies lead to an indefinite evidence regarding the clinical pathway effectiveness and consequently weak CP design quality (El Baz *et al*., 2007).

From the aforementioned issues, the elements and the component of the optimal STEMI clinical pathway that could make it more practical and keep its quality perspective are still lacking with lack in developments guidance and variability in evaluation methods. Thus, it has become essential for the clinical pathway users to have a tool that could measure CP information quality and provides direction to what should be improved in clinical pathway and provide quick suggestions effectively. This contribution would ultimately save time and efforts of trying different options and plans with no definite result.

1.3 Research Objectives

The focal aim of this research was to develop STEMI CP Evaluation tool to assist in decisions making on the best STEMI clinical pathway design to be implemented for high quality and optimal patient care. Specifically, the objectives of this research are:

1. To investigate the evidence on the STEMI clinical pathway evaluation methods.
2. To identify the essential components of the STEMI clinical pathway that contribute to optimal STEMI patient care as a base for an evaluation tool for the STEMI clinical pathway quality.
3. To develop and validate a STEMI clinical pathway quality evaluation model.

1.4 Research Scope and Limitations

This research addresses STEMI clinical pathway. Besides, three quality dimensions for the STEMI clinical pathway quality characteristics ('Design and Content', 'Process Medication and activities' and Outcome and Variances) have been determined and tested: Yet, in this research the organisational and managerial dimensions were beyond the scope.

The primary intervention of this research was on the stage of design and content decision by providing a decision-making tool to predict the quality of the STEMI CP design before its implementation. This research focuses mainly on providing simple, reliable and optimal STEMI clinical pathway evaluation model that could be used during the by the experts and benefit the patients.

Two volunteered hospitals in Kuala Lumpur Malaysia, and Jakarta Indonesia that has the clinical pathway with at least one trial run in the hospital made the primary cohort for study besides the randomises online survey recruitments. The second was the scope of the study as the study only focused on STEMI patients. Other diseases could be considered in future research. Moreover; the research was limited to developing a model and using structural equation modelling (SEM) and partial least square regression (PLS) as well as to prove its validity by the use by experts and retrospective trial evaluation study. The time and context of this research restricted the developed model.

One practical limitation was the type of respondents (STEMI and CP experts), which is essential to perform a larger size for this research. Their busy schedules and difficulties in reaching them hinder the sample size. The research was limited to experts' opinion and reviews using semi-structured interviews and survey. Consents and ethical approval constrained the approach and sample size. These responses used to establish the STEMI CP quality evaluation model in an iterative way. Another

practical limitation was the volume of data produced from the evidence synthesis and the rating by the experts, and finally, the quality of clinical pathway has been seen previously as difficult to be measured. The additional practical limitation is the changing evidence according to the latest guidelines could not be claimed under this study as a revision for the newest evidence for the process and medications still needed.

1.5 Research Significant and Contributions

The current research study extends our knowledge of clinical pathway properties and the domains of qualities. The current finding adds to the growing body of literature by merging the quality indicator measures with the CP general characteristics to quantify the quality of STEMICP. The proposed STEMICPQ model would work as a base for future research where other dimensions of quality could be integrated and improved.

1.5.1 Theoretical Implications

Although the current study is based on a small group of respondents the study suggests a model with predictive power and accuracy of 85%. It also contributes to a new understanding of the sub-constructs used to evaluate STEMI clinical pathway and a tool for measuring the STEMI clinical pathway quality in healthcare that could be used to assist in decision making. In general, this research contributes to the knowledge by adding information on the characteristics of the STEMI clinical pathway and covers the gap between the result of the literature reviews and the empirical studies.

This study is one of the scarce that covered the clinical pathway in a modeling approach and bringing the macro quality dimensions to the clinical pathway class concept. That contributes to enhancing the research viewpoint in this STEMI CP specific field. This study also contributes by identifying the elements of STEMI CP that mostly contribute to the CP quality and also identified the association between three essential characteristics of the clinical pathway. The significant of this research to the medical field is the details method that has been used for creating the optimal criteria of STEMI clinical pathway.

1.5.2 Practical Implications

Considering the three quality domains in this study the quality is possible to be measured by the experts themselves which is different than auditing. The practical significance of this research can be brief in the following points:

- Healthcare quality implications: It is evident that the manner that any tool is designed would affect its performance. The developed model in this study is unique in considering the quality domains according to the CP content, process and outcome. And the proposed criteria and component are unique to provide guidance in the selection of the best STEMI CP design.

- Healthcare cost implications: The life cycle of the clinical pathway is long; therefore, to avoid the waste of time and effort that may occurred in the time of trials and implementation, this research STEMICPQ model is proposed to be used them for decision making before implementation. That could assist the users before they deploy the clinical pathway and give an insight on how good or bad is the STEMI clinical pathway design and reduce the cost of faulty trials.

- Procedural implications: Simple, user-friendly scoring computer based tool for the STEMI CP criteria has been proposed. The model is suitable for decision making and would also easy for the expert's work. Although the design of clinical pathway in many settings follows the plan- Do-Study-Act (PDSA) cycle which is a branch of management's theory, the clinical decision makers do not use the measurement techniques employed in the management's field.

- This work has combined both. The tool in this study would resolve the tension during the revision of all the publications before the design of clinical pathway. I believe that this research would improve the clinical pathway user's view on the analytic approach and modelling techniques that may help in advancing the research in this area and encourage the improvement of this field.

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