

Evidence for the Contemporary Clinical Pathway Quality Measures: Literature Review

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Abstract

Objectives: Clinical pathway effect on improving the healthcare quality still underestimated. An overview on clinical pathway current practice overview will be presented in the context of this paper. **Methods/Statistical analysis:** A search for the medical literature was conducted to screen the contemporary evidence. We focused on finding the gold standard for clinical pathway quality measures and the current status of clinical pathway in Malaysia. Various databases (MEDLINE, EMBASE, Pub Med, COHRANCE library and CINAHEL) have been screened for 2000 to 2015 studies. Checklist of the preferred reporting items for systematic reviews and meta-analyses has been used as a guide for reporting. **Findings:** The search has identified 720 documents, of which 315 (44%) met the inclusion criteria of this study. Twenty meta-analysis studies have been found, while only nine have completely fulfilled the search inclusion criteria. Mostly they discussed the length of stay, patient outcome and cost from RCT (randomized clinical trial) or EXP (experimental design) evidence as a quality indicator for the clinical pathway which may underrepresent the complexity nature of clinical pathway and ignored many aspects of care. The majority of publications in Malaysia found from (UKM) with similar heterogeneous focus on the outcome measures to what have been found in the overall literature. Interestingly, we found that no meta-analysis study has been conducted in Malaysia for clinical pathway. **Application/Improvements:** Current research on clinical pathway still limited. More Studies on the effect of clinical pathway on quality of care still needed with emphasize on the cofounding factors.

Keywords: Clinical Pathway, Literature Review, Quality and Evidence based Medicine

1. Introduction

From an ideal point of view, the clinical care is applying the clinical guidelines which are basically a high trusted level of evidence. The clinical guideline evidence is gained from the scientific methods such as Randomized Controlled Trials(RCT), up-to-date information from relevant and valid research. The evidence based clinical guideline used for implementing the best care and guiding the decision making Process¹. Meta-analysis is another trusted high level of evidence. It combines the results from RCTs and assess the previous research systematically and

give quantitative conclusion^{2,3}. Meta-analysis provides us with a precise estimate for the effect of treatment or the outcomes. It is as first source for evidence based Medicine⁴.

In the new era, clinical pathway has become a central issue for quality improvement⁵. Clinical pathway turned out a solution to standardize the care, decrease the medical error and improve the quality of care. Clinical pathway increased the capacity of health care providers to describe each patient plan with variance characteristics consideration, moving us to more tailored health care service. Clinical pathway ultimately has been used to reach the maximal care and to improve the quality.besides

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it is used to guarantee the patient safety, raise the patient satisfaction and optimize the resources utilizations ⁶.

Clinical pathways are used as the tools for guiding evidence-based healthcare that have been implemented since the 1980s in international level. Majority of the studies on the development and implementation of clinical pathway carried out in the United States, Canada, Australia, Netherlands and the United Kingdom. There are only few known studies have been started in Asia, including Singapore ⁶. There is no one definition for a clinical pathway, and no one standard to be used for clinical pathway development. Even though, the clinical guideline is used for extracting the activities in clinical pathway, yet, a lot of variations in care have been found in many studies ⁷⁻¹¹. Clinical pathway proved significant in reducing the length of stay and medical cost, in addition to the improving the efficiency of resource utilization and minimizing unnecessary documentation ¹².

Clinical pathways are being used worldwide but more in developed countries, while sporadic evidence in Asia about the clinical pathway deployment and studies on its impact on outcome and quality of care is found. Moreover, evidence about clinical pathway usefulness has been unclear ¹³. They believe that their study was the first of its kind in Malaysia, which is pioneers in developing and implementing the clinical pathway in Malaysia. So, the development and implementation of clinical pathway could be considered in still in infancy in the country healthcare system ¹⁴. In addition, it is well known that the development of any standard should rely on strong contemporary source of evidence.

In fact, in Malaysia, there are a lot of efforts to improve the quality of health care service using of clinical pathway as a guideline, protocols etc. That was highlighted in many of ministry of health reports and publications; however, the academic focus on the clinical pathway is limited. Various studies that tackled the different type of diseases in Malaysia exist such as the 'dental pathway' that has been developed by the Oral Health Division in collaboration with the University of Malaya Community Dentistry Department and 'neonatal jaundice pathway' ¹⁵. However, the researches interest to cover the rigors of the implemented methods is limited. Hence, in this study scope we specifically intended to appraise the available contemporary evidence studies about clinical pathway quality, meta-analysis, and for Malaysian studies on clinical pathway.

2. Method and Search Strategy

Initially, a search was done in order to understand the concept of the systematic review and meta-analysis. After that, PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analysis) checklist was used to derive our search criteria and guided us on reporting the systematic review and meta-analysis ⁴.

2.1 Search Sequence

Using the University Technology Malaysia open access database website for journal and publication, we searched for the keyword of meta-analysis and the number of paper found related to meta-analysis journal is n=2,212. Then, we made the search term more specific by using the term "meta-analysis" "clinical pathways" and specifying the search on quality. The papers have been downloaded for review process for the content by two investigators. The suitable paper to be included in our study was retained for further analysis.

Table 1. Criteria of Journal Selection in Literature Search

Eligibility	Exclusion	Inclusion
The articles that mention clearly the effect of clinical pathway on quality	Different language other than English	Year 2000-2015
	Abstract only	Journal/Articles/ Full text
	No outcome measures	All diseases
	Protocol	With quality, outcome and Indicator
	Guidelines	"critical care" "meta-analysis", "clinical pathway", "meta-analysis", "critical pathway"
	literature review and Meta-analysis	The study sample represents the design of interest or partly (Meta-analysis)
	Telemedicine	
	Demographic effect	

2.2 Study Selection

The criteria of inclusion and exclusion criteria were listed as shown in Table 1. For maintaining the contemporary nature of this study, we search for the new evidence by considering studies published in between 2000 and 2015. The electronic databases have been screened (MEDLINE, PUBMED, CINAHL, EMBASE and COCHRANE library) for the key terms “meta-analysis”, “clinical pathway”, “meta-analysis”, “critical pathway”, “quality” and “Malaysia”.

2.3 Evidence Extraction and Statistical Consideration

The information on clinical pathway quality aspects was collected. Descriptive analysis for the frequency of occurrence of certain themes has been conducted and reported within the analysis section in this paper. Descriptive statistics using SPSS version 22(IBM corporation, USA) was used for the analysis of some of the parameters besides the Microsoft excel. Tabulated results and graphs presented in the subsequent section.

3. Results and discussion

3.1 Clinical Pathway and Meta-analysis

We have conducted the search for the studies that contain our search keyword in order to answer three questions about this study. A search using the key term of “clinical pathway”, Meta-analysis” and “Quality” was used to examine the medical literature in order to review what is already known about the quality of clinical pathway? How clinical pathway quality is reported in the current evidence? And to investigate studies that used meta-analysis to report the effect of clinical pathway on quality. The studies that presented the evidence of measures that have been used in most of the literature to report the effect of clinical pathway on quality has been extracted.

Another search for the key word “Malaysia” was included to find all current peer reviewed publication about clinical pathway in Malaysia. The results obtained from the search are shown in Figure 1. It is apparent that after an iterative exclusion for literature for the un-eligible studies that have literature review and or meta-analysis in their study design only few studies (twenty) remain for analysis. There were another fifteen records recruited

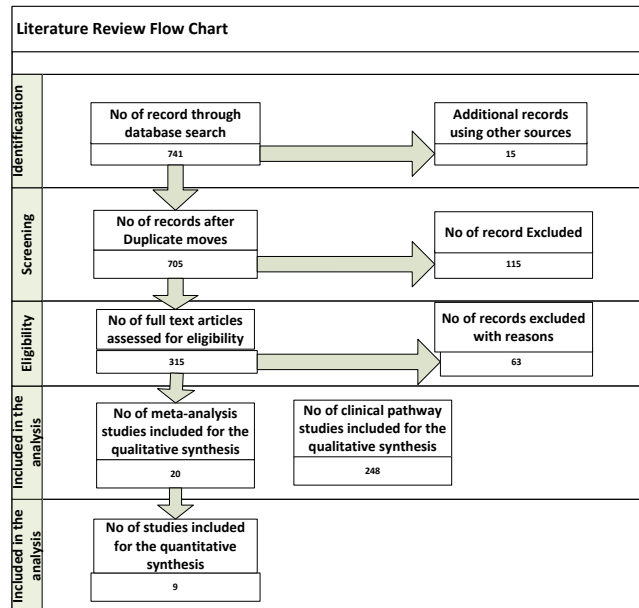


Figure 1. The Literature Review Search Result Using Keyword ‘Meta-Analysis’

from WHO reports and guidelines but excluded from the analysis.

The eligible papers have been downloaded for the content review process by two investigators. The suitable papers to be included in our study were retained for further analysis. The results obtained from the search using the meta-analysis and clinical pathway terms are presented in Figure 1. A number of records through database searching were 741 in which 315 were eligible to study and 248 have been included in qualitative analysis while only 9 were about meta-analysis. After finalizing the review for the found paper, we filtered the paper according to the impact of the clinical pathway. The selected journal was then extracted and put in excel to be observed.

The nine founded studies about meta-analysis were studies from Australia, UK, China, Sweden, Netherland, etc. as shown in Figure 2. China has the highest number of studies, and Canada was the second highest, while no meta-analysis studies were found to be done in Malaysia yet. On the other hand, the study design in the meta-analysis studies was not consistent in using the randomized controlled trial as a source of scientific evidence, but they also use other weak design or sometimes the study design not mentioned in the context.

We found that the meta-analysis studies themes aggregated around three common clinical disorders, general disorders, cancer and Surgery. Then we have plotted

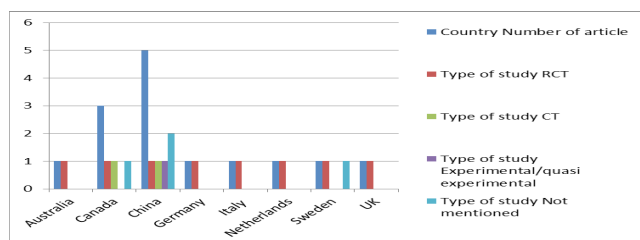


Figure 2. The Literature Review Search Result For A Meta – Analysis At Different Country Of Study

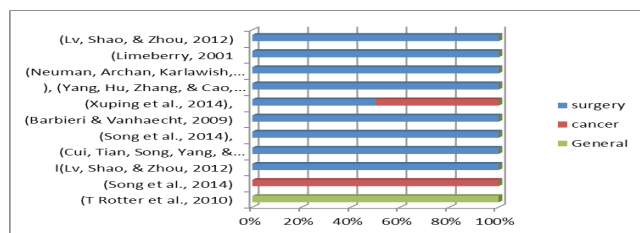


Figure 3. Meta-Analysis Studies Focus On Clinical Pathway Scope Of Treatment

frequent literature topics, scope with the name of the authors as shown in Figure 3. There were three common scopes for most of the studies of Meta-analysis, surgery, general and cancer as shown in Figure3 and surgery is the most studied clinical pathway 96%.

If we look now at the quality outcomes that have been reported on the results of the pooled meta-analysis studies, we will find that the identified studies have mentioned some of quality of factors but not specify major categories or classifications. The discrete clinical outcome measure was included, such as the study by ¹⁶. The distribution of outcomes quality measures of the studies in the nine meta-analysis papers has been plotted against the frequency of reporting that specific outcome in each study. In other word, the used measure in each study and its distribution in the 9 recruited studies shown in Figure4. Some of the recruited studies reported the effects of clinical pathways on length of stay, hospital costs and patient outcomes ¹⁶⁻²³. However, other aspect also considered as an outcome for the meta-analysis studies, such as ‘infection’ ²⁴. Sometimes a pre and post operational mortality and patient satisfaction, the readmission rate in the surgical clinical pathway were reported as an outcome too. In cancer patient, they considered the inpatient expenditure, patient satisfaction ²⁵ as a quality measure. While post-operative self-care behavior, effect of clinical pathways on professional practice, patient outcomes, length of hospital

stay, and hospital cost has been also a focus for study in²². The collected parameters of the outcome quality measures revealed some common outcomes were the quality of interest in most of the pooled meta-analysis studies (Length of stay, patient outcome, and cost).

It is important to highlight that there were no standard frame used in all the recruited studies that highlight the clinical pathway quality effect; rather, we find discrete measures for have been used. Besides, we found that randomized clinical trial or clinical trial with pre and post design was used in most but not all the studies Figure 4. Despite the importance of the Meta-analysis research for getting reliable results and evidence³. There were some studies not specifying the type of study design that they follow in their research. It's important to highlight that only China and Australia as ASEAN counties have done the meta-analysis of clinical pathway.

3.2 Clinical Pathway Research in Malaysia

After extracting the themes of quality focus in the aforementioned subsection, we started to screen the databases for the studies in Malaysia. As a result of systematic search in the database until July 2015, we found only few manuscripts about clinical pathways in Malaysia. All the studies that were related to clinical pathway and the studies conducted in Malaysia are summarized and extracted into the table to study the scope of studies, meta-analysis presence and the quality outcome that have been reported.

A total of 11 publications were found to be related to our search criteria. Mostly survey and consensus, pre and post, while one study was randomized controlled trials. The outcome measured were length of stay, complication, Cost and Knowledge. Interestingly, no meta-analysis study was done in Malaysia regarding the clinical pathway effect on quality of medical care. That could be justified by the low number of clinical pathway meta- analysis study in all countries as revealed from our database search and shown in Figure3.

The scanned Malaysia clinical pathway publications have revealed that the studies on clinical pathway started in 1999 by ²⁶ in the same trend with other studies in the other countries. However, the ups and downs in reporting studies in Malaysia were clear as shown in Figure 5. Every two years there was a study to be published in Malaysia from 2006 until early 2015. That might be due to the prospective nature and consensus design of the studies which inherently take long time to be executed.

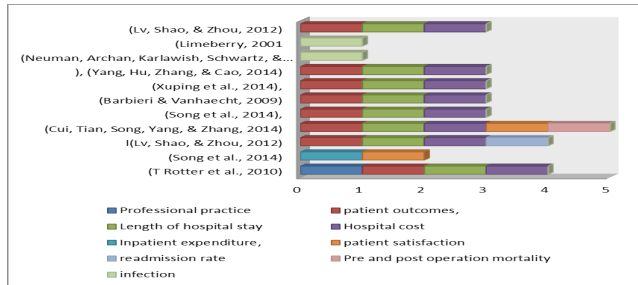


Figure 4. Meta-analysis studies quality outcome measures focus

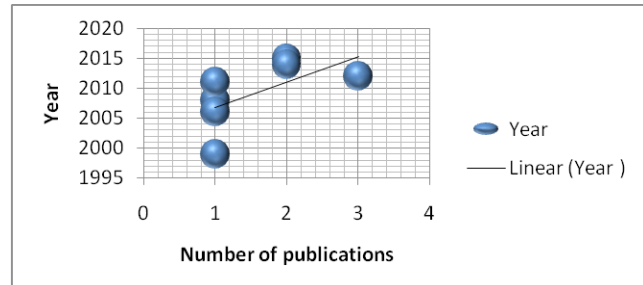


Figure 5. Clinical pathway studies in Malaysia by year of publication.

Table 2. Extracted Manuscripts from Malaysian clinical pathway Publications.

Study Title	CPs publications in Malaysia			
	Authors, Year	Focus/ settings	Method, sample size, statistical method	Problem They solved
The Evaluation of Knowledge and Practice on CP Among Health Care Workers at UKM Medical Centre Malaysia	In ¹⁴	Evaluation for the level of knowledge and practices and identifying the determinant factors. UKM Medical Centre. Target: healthcare workers.	Survey, for 3 departments and 12 wards A total of 127 respondents are acquired based on universal sampling method. , Methods used for analysis are by Chi Square for statistical analysis & logistic regression for multivariate analysis.	No evidence for the presence of study on the evaluation of the knowledge level about CP and its practice among healthcare workers at medical Centre prior to that time.
Development of CP for Mild Cognitive Impairment & Dementia to Quantify Cot of Age-Related Cognitive Disorders in Malaysia	In ¹²	Mild Cognitive Impairment & Dementia disease. Kuala Lumpur City for 3 days in September 2013	An expert group discussion, EGD among selected experts The experts is including psychiatrist specialists and public health medicine specialists.	There is no clinical pathway for Mild Cognitive Impairment (MCI) and Dementia
Clinical Pathways of Metastatic Spinal Cord Compression: Orthopedics experience based on hospitals admissions.	In ¹²	Orthopedics: Metastatic spinal cord compression. Orthopedic Unit in public teaching hospital	Review the previous year document of admissions cases	The pressures on healthcare system that caused by healthcare resource utilization or morbidity.
Clinical pathway as a strategy in improving healthcare quality and cost containment	In ¹²	The benefits of CP in enhancing healthcare quality and medical cost control. Faculty of Medicine, UKM	Literature review of the selection of relevant articles about the benefits of clinical pathways.	Based on the reviewed articles, what can be measured from clinical pathway? What are benefits of clinical pathway?

continue

Clinical pathways: Development and implementation at a tertiary hospital in Malaysia	In ¹²	CPs for ST Elevation Myocardial Infarction, Total Knee Replacement, elective Lower Segment Caesarean Section & Chronic Obstructive Airway Diseases. Meetings & workshop at UKM Medical Centre	Construct written consent for respondent which consist of assessment, investigations, treatment, medications, diet, teaching, referral, outcomes and, discharge plan based on time-task matrix in Gantt Chart format.	Intense pressures and challenges in reducing the healthcare cost while maintaining its quality.
Impact of clinical pathway on clinical outcomes in the management of COPD exacerbation.	In ²⁹	Chronic Obstructive Pulmonary Disease (COPD) at UKM Medical Centre, UKMCC	Non-randomized study with historical controls on patients admitted for COPD exacerbation. , two groups of selected patients: non-CP group (288 patients) & CP group (212 patients) Method: Compare the length of stay (LOS), complication rates, readmissions, and mortality rates to evaluate clinical outcomes.	Inconsistencies between guidelines and their application in daily clinical practice.
Standard Processes of Electronic Clinical Pathways that Support Decision Making and Teamwork Communication.	In ¹⁶	Health Information System (HIS) This study was held at Faculty of Computing, UTM Skudai	Review	Review how IT support and improve CP and medical process how to support decision making processes.
Integrated care pathway (ICP) on management of occupational related chronic low back pain (OCLBP) in Malaysia: A critical Review.	In ^{14, 15}	Occupational Related Chronic Low Back Pain (OCLBP) This study was carried out at Department of Community Health, Faculty of Medicine, UKM supported by UKM and Social Security Organization of Malaysia (SOCSO).	Reviews from local and international industrial laws that related to the topic as well as the established guidelines.	ICP has not yet being used for managing occupational disease.
Direct Medical Cost of Stroke: Findings from a Tertiary Hospitals in Malaysia.	In ¹²	UKM Medical Centre Disease: acute stroke Focus: Length of Stay(LOS) & cost of care per patient	In-patient data maintained by the Case Mix Unit are used. , Universal sampling of sampling method was used which all patients with cerebrovascular diseases recorded in Case Mix data base include in study. , Top-down costing method is also used.	Lack of investigations on economic impact of stroke as well as increasing hospital admissions due to this disabling condition.
Developing the cost for uncomplicated acute ST elevated Myocardial Infarction (STEMI primary percutaneous coronary intervention) using step down and activity based costing at UKMMC.	In ³²	Disease: Acute Uncomplicated ST Elevated Myocardial Infarction & percutaneous coronary intervention (PCI) Focus: cost of patient treatment UKM Medical Centre, UKMMC	Step down costing method which consists of “per-diems” costing & “case mx” costing, Activity based costing using CP which measures the cost of every resource used by a specific patient., Patient with diagnosed STEMI and PCI admitted to Coronary Care Unit (CCU), Coronary Rehabilitation Ward (CRW) & Cardiology Ward (CW).	The number of cardiovascular disease increases in Malaysia and thus the cost treatment also increased.

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Clinical Pathways in dental care in Malaysia: Clinicians' Knowledge, Perceptions and Barriers Faced.	In ^{13,27}	Primary Dental Care Community Dentistry Department with collaboration of the Oral Health Service Division, Ministry of Health Malaysia.	Self-administered questionnaire is used. The respondents are all the dentists and dental nurses (N=191)	CP developed was still new for routine oral health services even though it was reported had been used in hospital settings for a few decades.
The Role of Nutritional Support in Acute Pancreatitis: A Review and Proposal of a Clinical Pathway for Management	In ²⁶	UM/ surgery department	critical review	acute pancreatitis is heterogeneous and clinical pathway needed so they will use review to develop CP

More studies have been published in 2014 and 2015 consecutively, that most probably due to the exploratory nature of the latest studies^{6,13,23,27-32}. Table 2 shows the details of extracted manuscripts from Malaysian studies.

In summary, clinical pathway is not a new field in Malaysia, however, interest in reporting the contemporary scientific evidence is scanty. In this study it has been revealed that the golden source of evidence which is randomized controlled trials, have been used by most of the retrieved Meta-analysis studies, while the percentage of the low quality design still significant. In Regards to quality measures that has been used in the evidence there were no standard frame for quality measurement, with a focus on the traditional system measure as an outcome of implementing clinical pathway.

However, the clinical pathway is not for hospital system only, it is patient centered. We argue that, a standard framework for the quality dimension would be more useful to study all variables and variances involved in quality for clinical pathway. Ironically, in Malaysia, we found a gap in the body of knowledge in literature on clinical pathway. Further research on clinical pathway would be beneficial in providing sources for future Meta-analysis. The effect of Clinical pathway on quality of care in Malaysian context and ASEAN still needed. That would support the contemporary improvement of clinical care process through using contemporary scientific evidence.

4. Conclusion

Even though, clinical pathway supposed to be a contemporary evidence-based care process, we find a lack of scientific evidence that come from a strong level of evidence type of studies such as Meta-analysis is disap-

pointing. Therefore, difficulties in healthcare quality can arise when they are not based on contemporary scientific evidence. The presence of some meta-analysis studies was clearly toward the traditional measure of the direct impact of Implementation of clinical pathway. The studies that discuss the latent impact of structure and design were almost absent. In order to be able to conduct the meta-analysis of the studies that discuss the pre-mentioned objectives, we have to find the studies with suitable sample size and similar objective.

There is a limitation in this study, especially in the coverage of the health care database as a bias source. There is a need to find other sources of evidence in order to support clinical pathway toward standard development. Indicating that there is lack in the gold standard (high level of evidence that could be used in synthesizing evidence-based clinical pathway. Besides, may enlighten the researchers to the necessity of improving the research in the clinical pathway incorporating its operational and scientific evidences.

5. Acknowledgements

We appreciate all the support given by research assistance to make this work successful. We acknowledge the role of Ministry of Higher education (MOHE) and University Technology Malaysia (UTM) in financially supporting the study by TRGS grant R.J130000.7845.4L843 and Tier 1 funding Q.J130000.2545.10H29. This study has been conducted in conjunction of study under ethical approval from Ministry of Health (MOH) ethical approval board with NMRR registration number NMRR-15-1209-27004.

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