

## DESIGN STANDARD IN HEALTH CARE TO FOLLOW OR NOT? AN INSIGHT FROM CLINICAL PATHWAY

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### Abstract

Clinical pathway is a management tool utilized in hospitals in order to reduce variation in medical care as well as control health quality. Poor adherence to the clinical pathway documents most probably leads to deficiency in quality of care. This paper presents the result of an investigation for the role of clinical pathway document component (design) on the use of the clinical pathway tool in practice. We checked the content of three clinical pathway designs using the Integrated Care Pathway Appraisal Tool (ICPAT). Negative correlation between the compliance to ICPAT indicators and the completeness of third clinical pathway design has been obtained. Standard criteria in designing clinical pathway shows discrepancy which might be due to reluctances among the users to follow the lengthy procedure. In conclusion, user's preferences need to be considered for more practical use of clinical pathway beside the standard documentation perfection in order to achieve its objectives.

Keywords: STEMI Clinical Pathway, quality indicators, standard compliance

### Abstrak

laluhan klinikal merupakan alat pengurusan yang digunakan di hospital-hospital bertujuan mengurangkan kepelbagaian dalam rawatan perubatan serta mengawal kualiti kesihatan. Pematuhan yang lemah terhadap dokumen-dokumen laluhan klinikal akan mengurangkan kualiti kesihatan. Kertas kerja ini membentangkan hasil penyelidikan ke atas peranan komponen (rekabentuk) dokumen aliran klinikal dan mengenai kegunaan dokumen aliran klinikal dalam pelaksanaan. Pemeriksaan isi kandungan rekabentuk aliran klinikal menggunakan Alat Penilaian Penjagaan Bersepadu (ICPAT). Hubungkait yang negatif di antara penyesuaian indikator ICPAT dan kesempurnaan rekabentuk aliran klinikal diperolehi. Kriteria yang ditetapkan dalam merekabentuk aliran klinikal menunjukkan percanggahan mungkin diakibatkan oleh keengganan para pengguna untuk mengikuti prosedur yang panjang. Kesimpulannya, pilihan pengguna perlu dipertimbangkan untuk kegunaan aliran klinikal yang lebih praktikal di samping kesempurnaan dokumentasi piawai dalam mencapai objektif.

Kata kunci: Laluhan Klinikal STEMI, petunjuk kualiti, pematuhan standard

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## 1.0 INTRODUCTION

A Clinical pathway (CP) has been used as a management tool to standardize the care process, improve time to care access and improve health care quality [1]. Furthermore, European Pathway Association (2011)[2], defines the clinical pathway as: 'an intervention plan for the mutual decision making and organization of care processes for a well-defined group of patients during a well-defined period'. During the past 30 years, much more information has been available on the clinical pathway development and implementation [3]–[5]. Since the adoption of the operational methodology from industries to health care, it has been proved effective and efficient in tackling the cost and time management. What we know about clinical pathway is largely based on pre and post implementations evaluative studies that investigate the impact of clinical pathway on cost and quality. On the other hand, interestingly, quality as an important endpoint to clinical pathway still not clearly identified and defined. It has been tackled in many research as an outcome efficacy of the used document. However, what is not yet clear is the impact of clinical pathway design on the completeness of the document, and its effect on quality.

## 2.0 RELATED STUDIES

A key aspect of medical care is the quality of service and its outcome. In health service, one of the less tackled points in quality is the design. For better care, we need to emphasize on the design and its effect on improving the care [6]–[8]. Quality has been undertaken as 'the end measurement of the process and activities that have been deployed during the patient treatment in hospital. The outcome such as mortality has been mostly undertaken as the endpoint measure for the quality despite the importance of the structure as an important indicator for medical care quality[9]–[12]. That might be due to what have been pointed out by Dondbedian (2005), as he mentioned that "there is still an unclear relation between the structure with the other two quality indicators process and outcome".

Clinical pathway as an operational management tool has a unique characteristic. Rather than what traditionally have been viewed, the component of the structure just the adequacy of equipment's, human resource the operation of the program etc, there are some other less praised characteristics. For example, the effect of development component with considering the dynamic nature of the process of care which could lead to variation in practice.

Besides that, an important characteristic is 'the professional users'. They have their opinion, which may be opposing to the use of the clinical pathway. Consequently, the Use of clinical pathway could be

considered by the professionals as "cookbook" that limits their decisions freedom [13]. Although, some studies have been carried out on the development of clinical pathway, there have been few empirical investigations into the design and evaluating its quality [14]–[17].

Some studies failed to specify whether they follow the standard in clinical pathway development other than guidelines. Furthermore, not clear what are the tools they use in clinical pathway development, and whether it has improved the quality of care or not.

While, much of the current literature on quality of care pays particular attention to the process and outcome measures [18], the design measure not mentioned in most of the studies [19]–[23].

Patients on clinical pathway have a shorter average length of stay and a lower rate of complications compared to patients, not on the clinical pathway [22]–[24]. However, evidence shows that there are variation in the use of health services for conditions and circumstances that are quite similar. These variations could be a result of some influencing factors that have been explored in several studies, and has been found to have effect on quality of medical care [14], [25]–[27]. While most of the affecting factors are related to patients, organization, and clinical pathway development.

The effect of clinical pathway design on the quality of care have been out of sight. There has been little agreement on what is the exact definition and standard for development of clinical pathway for along time. Although, the aspects for compliance to treatment process or clinical care after using clinical pathway documents implementation have been the focus of several studies [28]–[31]. Thus far, there are a few studies have engage in the document component and design as an indicator for quality care [9], [30], [32], etc. In auditing, completeness of records might be used as an indicator for quality improvement.

According to Nicholson (2013), the idea of complete and accurate patient record documentation has come to advance the quality and continuity of care. Similarly, it builds a mean of exchange between providers and between providers and members about health status, preventive health services, treatment, planning, and delivery of care [33]. It represent the compliance to the standard that oftenly used in health care to promote quality improvements, i.e. to achieve changes in organizational structures or processes, health care provider behavior and patient outcomes.

It is not clear what is the impact of clinical pathway design on the completeness of the document, and its effect on quality. The success of the implementation of the clinical pathway could be known from the completeness of document 'medical record'. From literature study conducted in this study, it is observed that, the tools that discuss design factor are scanty in relation to the prevalence of clinical pathway use.

One of the appraised tool to analyze the design of clinical pathway has dragged our attention 'Integrated Care Pathway Appraisal Tool' (ICPAT) as the most appropriate audit tool to assess clinical pathway documents by [8], [16]. Also, it consists of section that consider the design of clinical pathway document, that was a very important inclusion criteria for this study. Therefore, it have been selected to be used in evaluation of clinical pathway compliance to its indicators. The component of clinical pathway thought to be the optimal care that required for better medical care outcome. Therefore, deviation from the clinical pathway will lead to low quality. In this paper, we argue that the design of the clinical pathway document has a role in the usability of its components and ultimately that would be an important factor in the quality of medical care [9]. The main objective of this study is to determine the correlation between design and completeness of the document. To investigate whether the documents that follow standard will has more usability or not. In the following sections, the method and results for analysis of three clinical pathway designs and the completeness of the clinical pathway retrospective documents will be described. It will finally go on to the discussion and conclusion.

### 3.0 METHODOLOGY

In this study, we adopted the descriptive case study design. We used two sources of evidence: documents (three clinical pathway documents with different design Clinical pathway 1 (CP1), clinical pathway 2 (CP2) and Clinical Pathway 3 (CP3) for the same disease and retrospective filled clinical pathway documents). The data collected from a tertiary hospital which based on some inclusion criteria. The hospital should be a referring hospital for STEMI patients with at least one trial in the clinical pathway. Generally, this research was conducted in two phases. In the first phase, we conducted a literature review to identify the studies that have discussed the design of the clinical pathway in its scope. After that, only one that mainly discusses the design was used in benchmarking the design of CPs and the tool indicators has been used as standard variables for this study. We have explored the context and described the clinical pathway in real settings. Prior to commencing the study, ethical clearance was sought from the ethics board. The mutual agreement to access the data was reached based on a memorandum of agreement between the hospitals and the research group. In the second phase, a retrospective analysis was performed to investigate the completeness of 297 filled clinical pathway documents. Due to the time constraint and the cost that could affect this study, it was difficult to do a prospective randomized study. Therefore, the sample was collected from an eligible collaborated hospital. In this study, the population of interest was the ST-Elevation Myocardial Infarction (STEMI) clinical

pathway design. Three designs from a hospital were collected. Statistical analysis was performed using SPSS software (version 22). The final explanation of the significance of the finding follows the descriptive nature. Statistical significance was analyzed using Spearman correlation tests as appropriate. Ranking for the best design was done and critical description of the factors underlies the preference is explained within the context of the discussion section.

## 4.0 RESULTS AND DISCUSSION

### 4.1 Compliance to ICPAT

As a result of a literature search for the available tools or standard to evaluate the design of the clinical pathway document, we found the Integrated Care Pathway Appraisal Tools (ICPAT) [8], [16] which has been developed within the West Midlands region of the UK assessing the quality of the integrated clinical pathway (ICPs). It has been considered as one of the few available tools that check the design of CP. It gives a standard for the design of any clinical pathway. The researchers have analyzed the clinical pathway compliance to the checklist tool indicators. The optimal design is defined in our study as 'the design or model of the clinical pathway that have the majority of the Integrated Care Pathway Appraisal Tools (ICPAT) tool component'. ICPAT have been considered as a valid tool to assess the design of the clinical pathway in several researches regardless of its focus on the document structure. We have only chosen the tool that has some focus on the documentation as an important eligibility criterion to include this tool in our study. We follow the evidence in the literature [8], [16] to justify our selection. The first set of analyses compared the indicators in the ICPAT checklist to the three STEMI clinical pathway designs.

**Table 1** Standard design documentation indicators in ICPAT tool

No	Element
1	Front page
2	Abbreviation section
3	Reference section
4	Version control
5	Clearly defined patient group and scope
6	A plan of expected/anticipated care along some form of timeline
7	Sequential order
8	Documentation from all the discipline involve
9	Evidenced-based practiced and guidelines
10	Included process and outcome
11	Variances-recording framework
12	Risk management tools
13	Place the patient at the center of the care cycle
14	Facilitate and promote continuous quality improvement

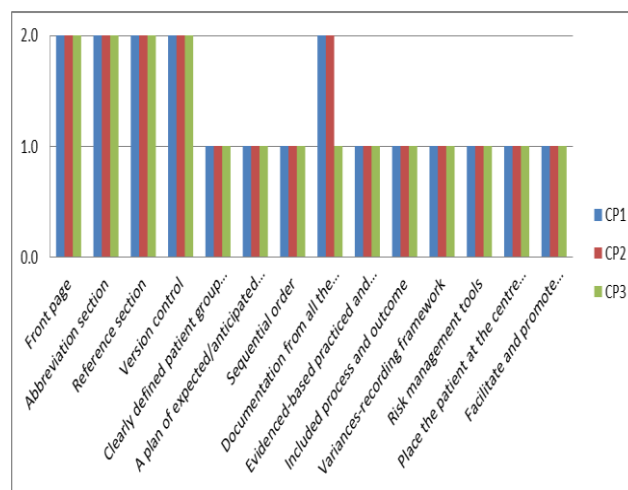
Adapted from de Luc & Whittle (2002) ICPAT [8]

The indicators of benchmarking tool are shown in Table 1. It shows the fourteen indicators of the Checklist of the Integrated Care Pathway Appraisal Tools (ICPAT) that was used to benchmark the design of the three clinical pathways.

**Table 2** Clinical Pathway Compliance to Checklist

Clinical Pathways version (CP)1				
		Frequency	Percent	Cumulative Percent
Valid	Yes	9	64.3	64.3
	No	5	35.7	100.0
Clinical Pathways version(CP) 2				
		Frequency	Percent	Cumulative Percent
Valid	Yes	9	64.3	64.3
	No	5	35.7	100.0
Clinical Pathways version(CP) 3				
		Frequency	Percent	Cumulative Percent
Valid	Yes	10	71.4	71.4
	No	4	28.6	100.0

As shown in Table 2 the frequency of hits was calculated for each clinical pathway version. The percentage of completeness was similar in clinical pathway 1 and 2 with 64.3% while it was 71.4% for clinical pathway 3. All the 3 pathways stated patient group and they differ in arranging the activities. Even though, both Clinical pathway 1 and Clinical pathway 2 were equals in term of compliance to the ICPAT standard indicators, there were differences in the arrangements of activities and details of process components. From Figure 1 it can be seen that all the three clinical pathway models have no front page, abbreviation section, reference section and version control, while Clinical pathway 3 was the only model that includes the (documentation from all the discipline involve) indicator. The frequency of using the checklist indicators and compatibility with ICPAT was calculated. We found that Clinical pathway 3 was the most compliance version to ICPAT standard with the percentage of 71.4 as shown in Figure 2.

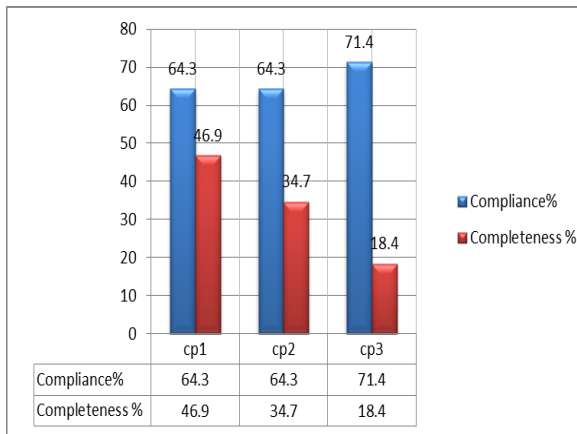


**Figure 1** Compliance of Different Clinical pathway Documents Designs with ICPAT Tool Indicators. **Note:** 2= have, 1=do not have, CP1= clinical pathway design number one, CP2= clinical pathway design number two, CP3= clinical pathway design number three

#### 4.2 Clinical Pathway Designs Completeness

Initially, 500 documents collected for a clinical pathway for STEMI (ST-Elevation Myocardial Infarction) patients. However, only 294 documents were valid from the three STEMI clinical pathways designs, the rest were excluded to avoid the bias in the comparison. We excluded the documents that have been un-readable, not STEMI or not used at all.

The data were collected from the hospital records for the year 2012 until the year 2014 for both STEMI patients' genders, male and female and for 18 years and above. The frequency of completeness of the three Clinical Pathway shows that the Clinical Pathway 1 has the most usage among the other designs. As noticed from the analysis of retrospective CPs documents clinical pathway 3 had the lowest percentage of documents completeness with only 18.4%, regardless its highest compliance to the ICPAT standard while, Cp1 owned the highest value of completeness with 46.9%. These results show that compliance to the clinical path standard (ICPAT) had a negative influence on the documents completeness.



**Figure 2** Clinical pathway completeness by user's versus compliance to the standard. **Note:** CP1= clinical pathway design number one, CP2= clinical pathway design number two, CP3= clinical pathway design number three

Although; CP1 and Cp2 had the same value of compliance to standards they differ in term of completeness which indicate that there are other factors might affect this measure. The estimations of clinical pathway completeness according to the discrepancy above are shown in the Figure 2. Mostly, in all designs the statistics show no significant deviation from the mean and that most probably due to using the data from the same source and setting for the same type of disease as shown in Table 3.

**Table 3** Clinical Pathway Completeness Description

statistics	N	Mean	Std. Deviation	Std. Error Mean
Clinical pathway design	294	1.7143	.75722	.04416

### 4.3 Correlation Analysis

By using the medians for the two aforementioned analyses and doing Spearman correlation test we tried to find the correlation between the clinical pathway design and its completeness. Descriptive analysis has been conducted through CP1, CP2 and CP3 as shown in Table 4.

**Table 4** Descriptive Statistics for Clinical Pathway compliance to ICPAT Components in three designs

		Clinical Pathways version 1	Clinical Pathways version 2	Clinical Pathways version 3
N	Valid	14	14	14
	Missing	0	0	0
Mean		1.3571	1.3571	1.2857
Std. Error of Mean		.13289	.13289	.12529
Std. Deviation		.49725	.49725	.46881

As presented in Table 5, the significance of the association between the completion of three clinical pathway designs (CPd) and the compliance to standard design to the ICPAT (CPC) was negative.

In this study, we consider the correlation if  $p < 0.05$ . The highest correlation was negative in Clinical pathway 3 compliance with standard (ICPAT) with value of  $p = -0.784$ , while same value '-0.721' found for another two Clinical pathway designs.

Interestingly, despite the incompliance of the CP3 to the ICPAT, less completeness was observed, which most likely could infer that the adherence to the standard in designing the clinical pathway might lead to not use it.

A possible explanation for this could be that the design which is structured is time demanding or complex and would lead to losing interest in filling it.

**Table 5** Spearman correlation between Clinical Pathways completeness and Clinical Pathways compliance

Correlation			Clinical Pathways version 3	Clinical Pathways version 2	Clinical Pathways version 1
Spearman's rho	Element of clinical pathway	Correlation Coefficient	-.784**	-.721**	-.721**
		Sig. (2-tailed)	.001	.004	.004
		N	14	14	14
	Clinical Pathways version 3	Correlation Coefficient	1.000	.849	.849
		Sig. (2-tailed)	.	.000	.000
		N	14	14	14
	Clinical Pathways version 2	Correlation Coefficient	.849	1.000	1.000
		Sig. (2-tailed)	.000	.	.
		N	14	14	14
	Clinical Pathways version 1	Correlation Coefficient	.849	1.000	1.000
		Sig. (2-tailed)	.000	.	.
		N	14	14	14

We tried to explain more the result that we found in the correlation analysis. We used the clinical pathway 1 as a benchmark and compared its component, and its arrangement and sequence with clinical pathway 2 and 3. We found that sequence of tasks was different in most of the components and sometimes is absent, such as in clinical pathway 1 and the variance record was more detailed and framed in the clinical pathway 3.

That might give insight to the reason in the high completeness of clinical pathway 1 regardless its incompatibility to standard as shown in Table 6. In general, there was a quite high compliance to the indicators mentioned in the ICPAT in designing the clinical pathway documents. Even though the three tested designs were almost similar in term of compliance to standard, it is important to mention that the only difference was the "documentation indicator" which presented only in clinical pathway 3rd design.

**Table 6** Individual Variation in the Clinical Pathway Tasks Arrangement and Sequence

CP1	CP 2	Arrangemen t	CP 3	Arrangeme nt
Medical assessment	√	5, 6 & 1	√	3
Nursing	x	-	√	2
Nutrition	√	8	√	6
Pharmacy (Medication)	√	7	√	4
Rehabilitation	√	9	√	7
Consultation	√	4	√	8
Education	√	11	√	9
Outcome	√	10	√	8
Variance	√	12	√	Additional sheet
Nurse and Doctor in charge	√	14	√	10
cost	√	13	x	-

Most likely, that was the reason for the incompleteness of this document. By looking at the presence of variance framework in CP 3, we relate that to its incompleteness, assuming that the presence of more complex variance record was a time-consuming task that contributed to CP 3 incompleteness. Furthermore, the reason for the difference between clinical pathway 1 and 2 in completeness could be explained if we look at the content of each one. The individual variation is shown in Table 6.

For example, in the process component certain tasks that should be provided to STEMI patient was absent or integrated with another section in the clinical pathway. Some were not given importance in the layout of the design, such as nursing tasks was absent from the Clinical Pathway 1 in the STEMI treatment process, and the variant record.

We are considering the reality analysis is our strength in this study. To some extent, the finding of this study were limited by the small size for each type of documents especially the third clinical pathway or the time of implementation which might affected the results i.e. the three designs were implemented in different years. This finding, though are preliminary, suggests that design of clinical pathway could affect the users compliance to use it. Interestingly, following the standard in designing document is not enough to reassure the people will use it.

However, these findings are rather disappointing, however, it is important to know that the results of this study do not explain how the time effect, the user type, is or other factors may affect the use of the documents. Not to omit the presence of some shortcoming in this study, such as the 'source of data'. The data collection was done in the same hospital, while the same clinical pathway committee were the personnel who improved the versions of clinical pathway from one to three. That may explain

the close correlation between the three designs results although it has been designed in different time. Therefore, to develop a full picture of the factors that affect the incompleteness, further data collection to clarify this limitation was done and will be presented in another publication.

## 4.0 CONCLUSION

The main goal of the current study was to describe and correlate the standard design with the completeness of the documents in the real setting. We found that the compliance has a quite significant relation to using clinical pathway in reality. However, that relation has shown negative whenever the compliance to standard has been achieved. From the researcher's opinion, these results could be explained by two ins and outs, the time of the trial and the complexity of the design. Further inferential analysis should be done to study the effect of other factors on the use of clinical pathway in hospitals and therefore patient care.

In short, there is a reluctance to use certain CP. The result of this study is in agreement with what have been found in quality literature, as the standard is rigid may lead to low quality [9]. Improvement of care should consider the construct design factor and the user's preferences.

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