Clinical Pathways – An Evaluation of its Impact on the Quality of Care in an Acute Care General Hospital in Singapore

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ABSTRACT

A critical or clinical pathway defines the optimal care process, sequencing and timing of interventions by healthcare professionals for a particular diagnosis or procedure. It is a relatively new clinical process improvement tool that has been gaining popularity across hospitals and various healthcare organisations in many parts of the world. It is now slowly gaining momentum and popularity in Asia and Singapore. Clinical pathways are developed through collaborative efforts of clinicians, case managers, nurses, and other allied healthcare professionals with the aim of improving the quality of patient care, while minimising cost to the patient. Clinical pathways have been shown to reduce unnecessary variation in patient care, reduce delays in discharge through more efficient discharge planning, and improve the cost-effectiveness of clinical services. The approach and objectives of clinical pathways are consistent with those of total quality management (TQM) and continuous clinical quality improvement (CQI), and is essentially the application of these principles at the patient's bedside. However, despite the growing popularity of pathways, their impact on clinical outcomes and their clinical effectiveness remains largely untested and unproven through rigorous clinical trials.

This paper begins with an overview of the nature of clinical pathways and the analysis of variances from the pathway, their benefits to the healthcare organisation, their application as a tool for CQI activities in direct relation to patient care, and their effectiveness in a variety of healthcare settings. The paper describes an evaluation of the impact of a clinical pathway on the quality of care for patients admitted for uncomplicated acute myocardial infarction (AMI) through an analysis of variances. The author carried out a one year evaluation of a clinical pathway on uncomplicated AMI in Changi General Hospital (CGH) to determine its effectiveness and impact on a defined set of outcomes. A before and after non-randomised study of two groups of patients admitted to the Hospital for uncomplicated AMI was done. A total of 169 patients were managed on the clinical pathway compared to 100 patients in the control (historical comparison) group. Outcomes were compared between the two groups of patients. Restriction and matching of study subjects in both groups ensured that the patients selected were comparable in terms of severity of illness.

The results showed that the patients on the clinical pathway and the comparison group were similar with respect to demographic variables, prevalence of risk factors and comorbidities. There was a statistically significant reduction in the average length of stay after implementation of the clinical pathway. This was achieved without any adverse effect on short term clinical outcomes such as in-hospital mortality, complication rate and morbidity. There were no significant difference in readmission rates at 6 months after discharge. The paper concludes that clinical pathways, implemented in the context of an acute care general hospital, is able to significantly improve care processes through better collaboration among healthcare professionals and improvements in work systems.

Keywords: Processes of care, variance analysis, evidence-based medicine, multidisciplinary

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INTRODUCTION

As we proceed towards the end of this century, healthcare is undergoing tremendous change at a rapid rate. Foremost on the policy agenda of many countries is the debate on quality of care and cost-containment. There are also increasing demands for more appropriate uses of technology, more coordinated care and enhanced care-giver-to-patient communication. Recent trends show an increasing tendency for the public to question professional practice and competency. There is also a disturbing trend towards an increase in malpractice litigation for medical negligence. Clinical audit and

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risk management have assumed increasing importance for many healthcare organisations. In view of all these pressures, health care organisations have devised strategies that reduce resource utilisation while maintaining the quality of care[1-4].

Some of the underlying causes of the above problems can be traced to the current care delivery process. The absence of a formal care planning system leads to errors of omission with the consequence that crucial steps in the care process are forgotten or not followed through. Furthermore, a team approach is often lacking, resulting in poor discharge planning and inadequate patient education. There is a growing disenchantment among patients and their families who are unaware of the plan of medical care. Hospital staff are also unhappy over unplanned discharges.

The challenge in health care today is to engineer the efficient use of shrinking resources while maintaining or even increasing quality outcomes in patient care. Clinical pathways or critical pathways or care paths is one such popular disease management tool that has recently been developed to address this problem. Clinical pathways are essentially multidisciplinary management plans that display goals for patients and provide the corresponding ideal sequence and timing of staff interventions to achieve those goals with optimal efficiency. Interest in clinical pathways has increased tremendously during the past decade as early anecdotal reports of their cost saving potential have been disseminated, usually outside peer reviewed scientific journals[5,6]. In Singapore, clinical pathways have been increasing in popularity partly because of the government's new healthcare financing policy initiatives such as casemix implementation. Clinical pathways are considered as casemix tools that facilitate the use of appropriate resources for homogeneous groups of patients (eg within a Diagnosis Related Group or DRG).

CLINICAL PATHWAYS – WHAT, WHY, HOW

A clinical (or critical) pathway is an optimal sequencing and timing of interventions by clinicians, nurses and other healthcare professionals for a particular diagnosis or procedure, designed to minimise delays and resource utilisation and to maximise the quality of care[7]. The often stated goals of implementing clinical pathways usually include the following:

1. Selecting a "best practice" when practice styles are known to differ significantly and unnecessarily.
2. Defining standards for the expected duration of hospitalisation and for the utilisation of clinical tests and procedures.
3. Examining the interrelationships among the different steps and stages in the care process and to engineer strategies to coordinate or decrease the time spent in the rate limiting steps.
4. Giving all involved staff common goals and to understand their roles in the entire care process.
5. Providing a framework for collecting and analysing data on the care process so that providers can understand how often and why patients do not follow an expected course during their hospitalisation.
6. Decreasing clinical documentation burdens.
7. Improving patient satisfaction through improved patient education – eg better care giver to patient communication on the plan of care.

A clinical pathway is essentially a plan of care that reflects best clinical practice and the expressed needs of the patient on the pathway. It describes the pattern of care for the usual patient. It represents the minimum standard of care and ensures that the essentials are not forgotten and are performed on time. Conventionally, pathways are written in the form of a grid (or matrix) which displays aspects of care on one axis and time intervals on another. The time intervals are typically in the form of a day by day clinical order and documentation sheet. However, this may vary, depending on the nature and progression of the illness or procedure being performed. Pathways designed for chronic conditions could have timelines in the form of weeks or months.

Clinical pathways integrate medical treatment protocols, nursing care plans and the activities of allied healthcare professionals into a single care plan, which clearly defines the expected progress and outcomes of a patient through the hospital system. Typically, pathways are developed for high-volume, high-risk and high-cost diagnoses and procedures. While pathways have been developed in hospitals in the USA for over a decade now, they are also gradually being introduced in other healthcare settings such as nursing homes and home healthcare.

VARIANCES

Flexibility is the key in using clinical pathways. They are guidelines and maps, not inflexible dictates for care or treatment. Because clinical pathways reflect the care needed by most, but not all patients within a defined population, situations arise in which there are differences from the anticipated plan of care. A well designed clinical pathway should capture between 60 to 80 percent of patients within a defined population. This is because a clinical pathway can only be designed for the "usual" patient. Some patients will fall off the pathway during the course of their hospitalisation. Some patients will encounter problems in the course of their hospitalisation, causing variation in the interventions and outcomes.

Variances are the unexpected events that occur during patient care – events that are different from what is predicted on the clinical pathway. Despite the intent to define the essential components of care, there still is variation in how care will be delivered and how patients will respond. Variances can be positive or negative. Positive variance occurs when the patient progresses towards projected outcomes earlier than expected, when pre-selected interventions such as pain medication administration are unnecessary, or when interventions such as patient education can successfully begin at an earlier stage. Negative variance occurs when either the patient fails to meet projected outcomes, there is a delay in meeting the outcomes, or there is a need for additional interventions previously unplanned.

An essential part of the use of clinical pathways is the collection and analysis of information obtained when patients deviate from the pathway. Analysis of variation provides useful and accurate information on the frequency and causes of variations in patient care. The analysis encourages members of the multidisciplinary healthcare team to adhere to the guidelines and standards set in the pathway, or justify the reasons for variations. In this way, clinical pathways compel doctors and healthcare providers to critically evaluate and understand about the basis of clinical decisions. Several authors have shown that using clinical pathways and clinical practice guidelines can improve clinical outcomes and the quality of patient care by reducing avoidable variation in the clinical process[8-10]. Analysis of variance is also a powerful clinical audit tool as all aspects of patient care are constantly reviewed and revised. Improvements in the quality of care are achieved through continuously redefining the pathways to reflect current best practice. This is the essence of continuous quality improvement incorporated into clinical practice. Variance data are used most effectively as a means of educating clinicians and enabling them to make considered changes to their practice based on emerging trends and the results of that care. The clinicians and the clinical pathway development team are intimately involved as they determine whether the variance data indicate that changes are needed in the clinical pathway itself or whether other system changes are required. This is the essence of evidence-based medicine in practice, ie using clinical data and evidence to plan the best possible treatment for the patient.

Variance analysis is often complicated by the sheer volume and magnitude of data. Furthermore, there is a lack of statistical independence among specific variances – multicollinearity and this arises because many activities prescribed on the pathway are related to one another. As such, a variance that occurs early in the pathway may affect the timing of subsequent activities, causing a "cascade" effect through the rest of the care delivery process, resulting in variances in other activities later in the pathway. A statistical model based on the concepts of the critical path method (CPM) and programme evaluation and review technique (PERT) has been developed to make variances more amenable to analysis and avoids the problem of multicollinearity[11].

The collection, analysis and reporting of variances constitutes a variance management system (VMS). Currently, the literature does not provide clear, consensus guidelines on how best to document, collect, analyse and report on variances. Zander[12] defined 4 categories for classifying variances: patient/family variance; caregiver/clinician variance; hospital/system variance; and community variance. This classification system has been widely adopted by many hospitals across the USA and is used in Singapore as well. Other authors have used similar classification systems for variance management[13]. Hoffman[14] took a different approach to variance classification. He used the categories often found on the left hand side of the pathway (eg evaluations, tests, consults, treatment, medication, education) and tabulated the frequency of variances within each category. The advantage of this method is that staff are already familiar with the standardised pathway categories and the variances are specified according to these categories.

Collecting variances may be carried out either prospectively or retrospectively through case notes review. Prospective variance collection provides a mechanism for addressing the problems encountered in the care delivery process as it occurs. As such, a more proactive approach to managing variance can be established. A retrospective approach tends to foster a more reactive type of problem solving and changes that need to be made may be delayed. The current literature provides very little detail on the mechanics of variance documentation directly on the pathway. However, the author's experience is that many hospitals utilise this approach. Hoffman[14] outlined a method where nurses write variances on a variance tracking tool attached to the pathway. Nurses follow up on these variances and address them during each shift. Thereafter, the tracking tool is sent to the quality management department or its equivalent for analysis and reporting. Hampton[15] used a tool separate from the pathway to document both the variances that occur and how they are addressed. In this approach, all disciplines involved in the care of the patient may document variances. However, unlike the paper by Hoffman, Hampton did not provide any examples of improved quality or cost-effectiveness associated with this approach. In addition, both authors did not address issues of variance data integrity and accuracy.

Another issue in variance collection is the use of computers. Paper based systems for variance collection are still the norm in most hospitals. However, computer based systems do exist. DiJerome[16] described a computerised clinical pathway and variance management system (VMS) that has been successfully implemented. The advantage of such a system is that it has the ability to adapt the pathway to changes in the patient's condition that are normally seen as variances. This flexible, computerised system for the use of pathways avoids the problem of patients "falling off the pathway". Computers also removes the problem of manual data collection and analysis. It appears that many organisations are now heading towards automation of pathways and variance management. Some authors have observed that while many hospitals still track variances manually, automation and links to centralised clinical information systems are often needed as the dataset grows[17]. Many hospitals use spreadsheet based data entry systems. There is also a growing number of information technology companies that have developed variance management software systems (Q-Works™, PAVAS®).

Many case reports have been published on variance analysis and reporting[18-24]. However, none of these reports have shown the relationship between the use of pathway variances and effective resource utilisation and patient outcomes. Much of the existing literature focuses on the qualitative aspects of developing a VMS and the need for case managers in this endeavour.

The relationship between clinical pathways, variance management and continuous quality improvement (CQI) have been discussed by several authors[11,24]. Variance management requires long term goals, objectives and commitment from all staff involved. The importance of linking the hospital's CQI effort to pathways and VMS can be understood from the paper by Falconer et al[25]. In this controlled study, a clinical pathway was developed for stroke patients and the outcomes were compared with a similar cohort of patients. They found that using a clinical pathway for stroke patients failed to provide any improvement in the cost of care and clinical outcomes. However, it is important to note that the pathway programme that was developed by these authors was not integrated with any CQI effort. If the researchers had used a CQI approach to follow up and resolve the variances detected, they might have been able to demonstrate incremental improvements in care. In addition, their sample size of 53 may have been too small to detect small but significant changes in outcomes. Other authors have reported positive outcomes and resource savings from the use of variance data for CQI efforts[7,26].

The recording, collection and analysis of variances provides continuous audit data on the care being delivered. Such audit information is specific to each case-type on the pathway being analysed. This regular analysis of the care processes, practices and outcomes through the analysis of variances and the feedback of the team is a vital component of the entire clinical pathway programme. Analysis can highlight deficiencies in the care process due to problems arising from the hospital system, such as reasons for delayed discharges, inavailability of sufficient operating theatre time, etc. Clinical pathways are also an ideal tool for outcome audit analysis because the documents can be retrieved and studied to ascertain whether or not the interventions resulted in the desired clinical outcomes as stated on the pathway.

There are few published evaluations of clinical pathways. The effectiveness of clinical pathways remains largely anecdotal. There are little published data on variances, and how the use of variance information has improved the quality of care. Despite this, the use of clinical pathways is increasing. The remainder of this paper illustrates how variance collection, aggregation and analysis have contributed to the quality of care in Changi General Hospital (CGH).

METHODOLOGY

The Case Management Unit and the Department of Medicine in Changi General Hospital (CGH) developed a clinical pathway for uncomplicated acute myocardial infarction (AMI) as part of the Hospital's quality improvement efforts. The pathway was developed by a multidisciplinary team comprising of doctors, nurses, cardiac rehabilitation specialists, and a case manager. A thorough literature search was undertaken by the clinical pathway development team to review the current management of AMI and recent evidence of effectiveness of various treatment modalities. The pathway was implemented on 25 Nov 96 and variances were collected prospectively through review of clinical notes and the pathway documents, for all patients who were admitted for AMI and satisfied the inclusion criteria for the pathway. Quality indicators such as the timing of initiation of thrombolysis were collected to allow objective evaluation of quality of care and clinical audit after the pathway has been fully implemented. All the variance and clinical data were collected and aggregated using a Microsoft EXCEL® software. Statistical analysis was carried out using a SPSS® Windows 7.0 software.

Baseline data and information was collected to determine the average length of stay for AMI patients over a one year period prior to implementation of the pathway. As a randomised controlled trial to assess the effectiveness of pathway versus non-pathway

patients may not be ethical and was not administratively feasible, a historical cohort of patients admitted in 1996, but prior to the start of the pathway was used for future comparison of outcomes. Other important data from the medical records to determine practice patterns and variation was helpful in determining the content of the pathway, which would in turn affect its acceptance by the clinicians. Based on the above, it was determined and decided that the appropriate target length of stay should be 7 days.

A prospective non-randomised and uncontrolled study was carried out on all patients admitted and put on the AMI clinical pathway during the period 25 Nov 96 to 31 Dec 97. Inclusion criteria for patient selection included the following:

1. All patients diagnosed with uncomplicated AMI at the emergency department. Diagnosis of AMI is on the basis of typical history of chest pain, raised cardiac enzymes and typical ST elevation on the ECG. Cardiac enzymes were available in the emergency department 24 hours of the day and results could be provided within minutes.
2. Patients admitted for chest pain and diagnosed to have AMI within 24 hours of admission into the the ward. The diagnosis would be based on serial ECG changes and/or raised cardiac enzymes. These patients would still be considered for thrombolytic therapy.
3. Patients with inactive but concommittent comorbidities such as diabetes mellitus, hypertension, renal disease or lung diseases were included in the study. Age alone was not an exclusion criterion.

Exclusion criteria included the following:

1. Patients with significant complications upon admission such as hypovolaemic shock, cardiogenic shock, pulmonary oedema, significant arrhythmias, cardiac arrest prior to arrival at the emergency room, significant heart failure and hypotension.
2. Patients admitted for chest pain but diagnosed to have AMI after 24 hours from admission. This is because these patients would not be considered for thrombolytic therapy.
3. Patients who were admitted for other unrelated clinical conditions, but developed AMI in the ward.
4. Patients with clear contra-indications for thrombolytic therapy.

The above inclusion and exclusion criteria were selected based on the necessity for a relatively homogeneous group of patients for this study. The criteria were also necessary to ensure that both groups of patients (before and after the pathway) were similar with respect to the type of treatment received (eg thrombolysis).

The case manager is informed of each admission for either suspected or confirmed AMI. The pathway starts at the emergency department and the case manager confirms the diagnosis with the doctor, and suitability for inclusion into the AMI pathway when the patient is in the intensive care unit or ICU (as a matter of clinical policy, all patients with confirmed AMI are admitted to the ICU). She collects and collates the variances during her daily ward rounds. Specific variance collection forms were designed and used for patients on the AMI pathway. The data are entered into a Microsoft EXCEL^{R} database and updated continuously.

A historical cohort of 100 patients previously admitted during the period 1 Nov 95 to 31 Oct 96 for uncomplicated AMI was randomly selected from the hospital patient information database. These patients were admitted before the AMI clinical pathway was implemented and serve as a comparison group for evaluation. All patients in this group were matched and selected according to the same inclusion and exclusion criteria as those in the study group. As such, the patients in the historical cohort would have been suitable for inclusion in the study group if the clinical pathway was in use at that time. This form of matching and restriction serves to ensure that both groups of patients are comparable in terms of casemix or type of patients, and severity of illness.

For both groups of patients, demographic data, comorbidities, coronary disease risk factors, length of stay (in days, based on hospital midnight census), hospital bill sizes, mortality and complication rates were collected through case notes review. In addition, the author retrospectively reviewed all the case notes and pathways of both groups for readmissions, complications, and other outcomes. Both groups of patients received the same thrombolytic agent (Strep tokinase) and other treatments (eg aspirin, beta-blockers and sublingual nitro glycerin). The two groups differed only in that one group was cared for using the clinical pathway while the other group did not have the pathway.

Distribution of continuous variables was reviewed for normality within each of the groups and the data collected. For each continuous variable, comparison of means between the two groups was carried out using either the Student's t-test or the Wilcoxon Rank Sum Test for non-parametric analysis. Dichotomous variables were compared using the Chi Square test. A "p value" of less than 0.05 was considered statistically significant. Statistical analysis was performed using Microsoft EXCEL^{R,} SPSS for Windows (version 7.5), Epistat and P-C Size softwares where appropriate.

DEFINITIONS

The following definitions for the various study variables were used:

1. **Source of Referral:**
   This refers to the permanent place of residence that the patient was in prior to admission. "Nursing Home" includes residences other than private homes such as homes for the aged, welfare or private nursing homes. "Others" refers to patients admitted through any other means and in this case, all were patients admitted from the Changi International Airport. CGH is the nearest hospital to the Airport.
2. **Average Length of Stay (ALOS):**
   This is the mean length of stay and is calculated by dividing the sum of the total length of stays by the total number of patients who completed the clinical pathway. For the comparison group, the same figure is calculated by dividing the sum total of all length of stays by the number of patients who would have completed the pathway if it was available during that period of hospitalisation. The length of stay is defined as the calculated difference between the admission date and discharge date. Discharges or deaths within one day of admission were taken as one day LOS. The distributions of the LOS for both groups were unimodal and slightly skewed to the right.
3. **Risk Factors:**
   The coronary risk factors which were recorded and collected for data analysis included the following:
   A) Smoking – defined as a documented history of cigarette smoking within 10 years of the current admission for AMI.
   B) Hyperlipidaemia – defined as a total fasting plasma cholesterol of more than 250 mg/dl. A documented history of hyperlipidaemia prior to admission was also recorded as positive for that risk factor even if the patient did not have a lipid profile done during the current admission for AMI.
   C) Hypertension – defined according to the World Health Organisation (WHO) criteria or a documented history of raised blood pressure prior to admission.
   D) Obesity – defined as a body mass index (BMI) of more than 25. Mild, moderate and severe obesity were not differentiated in this study.
   E) Past History of AMI – this was considered only if the patient had a clear history of a previous admission for AMI and was managed as for AMI. Patients with a past history of undetected silent myocardial infarction or evidence of an old myocardial infarct on resting ECG but never admitted to hospital for treatment of the infarct were excluded from this category.
   F) Known History of Ischaemic Heart Disease (IHD) – this includes only those patients who had a clear and documented history of IHD with evidence based on clinical symptoms, previous ECG findings, exercise stress test, thallium scanning or angiography. Patients with vague, undocumented and unconfirmed history of IHD, but with suggestive features of the disease were excluded from this category.
4. **Co-morbidities:**
   These were recorded as a means to estimate the potential confounding effect of comorbidities on the outcome of the patients. The various comorbid conditions recorded were:
   A) Diabetes Mellitus – this is defined according to the standard WHO criteria. A documented history of diabetes with evidence of medication given for the disease was taken to be positive for that comorbidity. Diabetes mellitus is also a known risk factor for AMI.
   B) Past History of Stroke – this included only those patients with a clearly documented history of a cerebrovascular accident (CVA) who were admitted to hospital for treatment. Patients with a history of transient ischaemic attack (TIA) were not included due to inconsistency of clinical documentation for both patient groups. Patients who had clinical signs suggestive of an old CVA, but were not admitted previously for that condition were investigated for that condition (by a CTscan) and were recorded as positive for that risk factor if the radiological findings corroborate with the clinical features.
   C) Renal Disease – this category included only those patients with a clearly defined and documented history of concurrent renal impairment or failure. Patients with a past history of renal disease but with normal renal function during the current admission were excluded from this category. Newly diagnosed renal impairment during the current admission for AMI were included. However, there were no such patients admitted in either groups.
   D) Gout – this included only those patients with a clearly documented history of acute gouty attacks or clinical evidence of tophaceous gout.
   E) Chronic Pulmonary Disease – this category included only those patients with a clearly documented history of confirmed chronic obstructive airway disease (COAD) on follow up and treatment, or with prior admission to hospital for that clinical problem. Patients with clinical features suggestive of COAD but not

investigated or treated for the disease were excluded from this category.

RESULTS AND DISCUSSION

Summary of Main Outcomes

A total of 182 patients were admitted to the Hospital for an initial diagnosis of uncomplicated acute myocardial infarction (AMI) and satisfied the inclusion criteria for the clinical pathway. Of these, 13 patients were confirmed to have unstable angina pectoris or some other diagnosis, and were taken off the pathway. This gives 169 patients admitted to the Hospital for confirmed AMI on the basis of ECG findings, typical history of chest pain and raised cardiac enzymes. Of the 169 patients with confirmed AMI, 153 (90.5%) completed the pathway while 16 (9.5%) were either taken off the pathway at some point of their stay or died during the hospitalisation.

Outcome Evaluation

A) Average length of stay

The average length of stay (ALOS) for the historical comparison group was 8.51 days. The ALOS after implementing the pathway was 7.10 days – a statistically significant reduction of 16.5% from the original figure (using Wilcoxon's Rank Sum Test; $p < 0.001$). When adjusted for differences in demographic variables, prevalence of risk factors and comorbidities between the study and comparison groups, the difference was still highly significant ($p < 0.001$). In the pathway group, the shortest length of stay was 5 days. The longest stay was 16 days, from a patient who developed urethral obstruction during his hospitalisation, unrelated to the AMI episode.

B) Morbidity and Mortality

In the study group, of the 169 patients who were confirmed to have AMI, 10 (77%) developed major complications compared to 153 (92.3%) patients who had a relatively smooth stay. 3 patients died, giving an inpatient mortality rate of 1.77%. The low mortality rate is not unexpected because the patients put on the clinical pathway were mainly suffering from uncomplicated AMI. All cases of complicated AMI on admission (eg with concomittent significant heart failure or major arrhythmias) were excluded from both groups of patients for this study. The results for the study group compared favourably with the historical cohort of patients. There was no statistically significant difference in the mortality rate between the two groups of patients (2% for the comparison group vs 1.77% for the pathway group).

There was a difference in the complication rate for the two groups – 9% in the comparison group vs 5.92% in the pathway group. The Chi Square test did not reveal any statistically significant difference ($p = 0.480$). However, this may be because of inadequate power to detect a true difference due to the relatively small sample size, resulting in a Type II or beta error. Using the "PC-Size" statistical software, the required sample size for the study group in order to detect a true difference would be 1209 patients (assuming an alpha error of 0.05 and a power of 80%). The power of this study is only 0.38 (or 38% chance of detecting the difference if it was true), which is very low.

From the above data, it can be reasonably concluded that the AMI clinical pathway did not result in any adverse effect on the immediate clinical outcomes of patients despite a reduction in the length of stay.

C) Readmission Rates

Readmission rates at 6 months after discharge were computed for both the historical comparison cohort and the study group. Patients were considered to be readmitted only if they were admitted for clinical problems primarily related to the initial episode of AMI (eg complications such as arrhythmias, congestive cardiac failure, Dressler's syndrome, or post-AMI angina pectoris) or as a result of the treatment given. There were no significant differences in the readmission rates between the two groups. It can therefore be concluded that the pathway had no adverse effect on intermediate clinical outcomes such as readmission rates.

However, it was difficult to ascertain the true readmission rates as some patients in both groups were lost to follow up after discharge. A summary of the results are in Table I.

In terms of average bill sizes payable, there was a reduction of 14% for non-subsidised patients for the pathway group and 2.5% for subsidised patients in the pathway group. This was so despite increases in the hospital fees (ward charges and laboratory tests) during 1997. The author was not able to standardise the figures because the increase in itemised charges was not uniform across the board. During the period of study, the overall hospital ALOS remained stable at 5.6 days.

Variance Analysis

An analysis of variances was carried out with the aim to understand variation in the care delivery process and determine the need to revise the pathway to suit the majority of the patient population. Another objective for variance analysis was to develop a hospital-wide standardised approach for evaluating pathways. The following section describes an analysis of variances and relates how quality improvement resulted from the use of the data.

Variances were collected for patients on the clinical

Table I. Summary Indices of Study and Comparison Groups.

Variables	Pre-Implementation	Post-Implementation	Difference
Sample size (n)	100	169	NA
Mean Age (in years)	57.8 (SD 11.6)	57.3 (SD 12.4)	p=0.751
Male : Female Ratio	2.84 : 1	3.12 : 1	p=0.863
Ethnic Distribution	Chinese: 62% Malays: 22% Indians: 14%	Chinese: 58% Malays: 26% Indians: 9%	p=0.383
Referral Source:			
- Patients' Home	94 (94%)	160 (95%)	p=0.441
- Nursing Home	6 (6%)	7 (4%)	
- Others	0%	2 (1%)	
Risk factors:			
- Hypertension	60 (60%)	98 (58%)	p=0.844
- Hyperlipidaemia	58 (58%)	115 (68%)	p=0.125
- Obesity	56 (56%)	105 (62%)	p=0.388
- Smoking	65 (65%)	105 (62%)	p=0.733
- P/H AMI	6 (6%)	7 (4.4%)	p=0.695
Co-existing Morbidity			
- Diabetes Mellitus	38 (38%)	74 (44%)	p=0.422
- P/H Smoke	2 (2%)	6 (3.3%)	p=0.725
- Chronic Pulmonary Disease	10 (10%)	22 (13%)	p=0.586
- Chronis Renal Disease	2 (2%)	6 (3.3%)	p=0.725
- Any one of the above risk factors	82 (82%)	149 (88%)	p=0.222
- Any one of the above co-morbidities	20 (20%)	30 (18%)	p=0.767
Type of Infarct:			
- Anterior/Anteroseptal	65 (65%)	98 (58%)	p=0.263
- Inferior	20 (20%)	47 (28%)	
- Combined	6 (6%)	15 (9%)	
- NonQ Infarct	9 (9%)	9 (5%)	
Complication Rate	9%	5.92%	p=0.480
Mortality Rate	2%	1.77%	p=0.737
Average Length of Stay (ALOS)	8.51 (SD 1.41)	7.10 (SD 1.59)	p<0.001

- *Differences in risk factors and comorbidities were assessed by the non-parametric Chi Square test without adjustment*
- *Differences in continuous variables (with assumption of a normal distribution) such as age was assessed using the 2 sample independent t-test*
- *The difference between the ALOS of the two groups was assessed by using the one factor analysis of covariance test, adjusting for age, gender, ethnicity, presence of co-morbidities and prevalence of risk factors*

pathway and were classified under the following categories:

- System variance
- Clinician /caregiver variance
- Patient variance

As the amount of variance data collected was very large, only those variances that were deemed to be important for the management of the patients on the AMI pathway which may affect the quality of care provided are discussed. The team agreed that the following issues that affect the quality of care should be monitored and tracked - diagnostic accuracy at the emergency department (clinician related), referral for cardiac rehabilitation (caregiver and system related), and the time to thrombolysis (system related).

Diagnostic accuracy at the emergency department

Fig. 1 illustrates the initial diagnosis of the patients who were misdiagnosed in the emergency department. In total, 13 out of 182 patients were misdiagnosed. The diagnostic accuracy rate for AMI at the emergency department in the pathway group during the period of observation was 92.8%. Local comparative data were not available. As such, it is difficult to provide any conclusion on the diagnostic competence of the doctors at the emergency department. However, if one takes the ideal "gold standard" of 100% diagnostic accuracy, there is obviously room for improvement. The most frequent misdiagnosis at the A&E is unstable angina, followed by ischaemic heart disease. Feedback and clinical audit of missed cases of AMI were provided to the Head of the Emergency Department and this served as a useful educational tool for the resident doctors.

Time to thrombolysis

The Hospital already had in place, a standard protocol for thrombolysis and management of AMI in the Intensive Care Unit. This was reviewed and updated after searching through the latest randomised controlled clinical trials, meta analysis and systematic reviews. After a situational assessment, it was realised that while the clinical staff utilised the appropriate drugs and techniques for the treatment of AMI, there was a problem in the time to thrombolysis from arrival at the emergency department to the receipt of streptokinase. Several of the large scale studies have established that early use of thrombolysis reduces overall mortality by about 20% - 30%. Thrombolysis should therefore be given as soon as possible[27].

The commonly accepted goal for thrombolytic therapy is treatment within 60 minutes once a patient enters the emergency department with chest pain associated with AMI[28]. Unfortunately, fewer than 5% of patients receive thrombolytic therapy within the first hour of onset of symptoms[29]. Clinical pathways and treatment protocols can only address the time to treatment once the patient seeks medical assistance.

In theory, in-hospital time to treatment can be shortened through collaborative efforts to develop protocols for treatment of chest pain, rapid and efficient methods for assessment and triage, the use of clinical pathways, standing orders and ready availability of drug therapy and diagnostic testing. In CGH, the usual

process after diagnosis of AMI at the emergency department is immediate transfer of the patient to the intensive care unit where thrombolytic therapy is then given. Fig. 2 shows the average time to I/V Streptokinase therapy for patients on the pathway in 1997. This was calculated as the time interval from registration at the emergency department to infusion of I/V Streptokinase in the intensive care unit. This crude measure reflects the summation of times taken for triage and diagnosis of AMI in the emergency department, transfer of the patient from the emergency department to the MICU and infusion of the drug after confirmation of diagnosis by the resident clinician in the intensive care unit. Prior to this study, there had been no locally published hospital evaluation of time to thrombolytic therapy. As such, local comparative data are not available. Similar data from the comparison group were also not available for this study.

145 (86%) patients had I/V Streptokinase infusion given between 1 hour to 2 hours of arrival to the Hospital. 3% of patients had I/V Streptokinase started within 30 to 40 mins from the time of registration at the emergency department. About 5% of the patients had Streptokinase started more than 3 hours after arrival at the emergency department due to the following reasons:

- 3 patients and their family members were initially unconvinced of the effectiveness of thrombolysis and therefore did not give consent for I/V Streptokinase therapy earlier.
- 4 patients had their initial diagnosis changed after review by the resident cardiologist. The initial diagnosis for these patients was angina pectoris. Repeat ECGs showed hyperacute changes, hence the decision for I/V Streptokinase therapy.
- 1 patient had a history of recent surgery and the decision for thrombolytic therapy was delayed because of the uncertainty of the margin of safety.

Not all patients were agreeable to I/V Streptokinase therapy. 2 patients still refused because of the risks involved. The above data showed that there was room for improvement in decreasing the time to thrombolytic therapy. Experience in the USA has shown that thrombolysis in the emergency department is cost effective and safe. A change in clinical practice by starting thrombolytic therapy in the emergency department could significantly reduce the delay in infusing I/V Streptokinase to patients with AMI, resulting in better outcomes and improved survival. The aim is to ensure that all patients receive thrombolysis within 60 minutes of arrival at the emergency department.

The development and implementation of the clinical pathway enabled the clinical staff to critically evaluate and analyse the situation with regards to thrombolytic therapy. While the pathway itself did not result in a shorter time to thrombolysis, it enabled the clinical staff to collect the relevant data that identified the problem area for improvement so that quality improvement efforts could be instituted. In this case, arising from the data collected, the emergency department and the cardiologist involved worked out a system and protocol and for the infusion of thrombolytic therapy at the emergency department. 18 months after the pathway was implemented, the emergency department started to infuse I/V Streptokinase for patients with confirmed uncomplicated AMI, resulting in a dramatic reduction in the time to thrombolysis. The 1998 data (not included in this paper) showed that 43% of patients received thrombolytic therapy within 1 hour of arrival at the A&E Department compared to 3% in 1997. In 1998, 48% of patients received thrombolytic treatment within 1 to 2 hours compared to 86% in 1997. This shows that through the implementation of the clinical pathway, improvements in quality can be achieved through the rational collection and analysis of data.

Fig. 1 Patients Misdiagnosed at the Emergency Department.

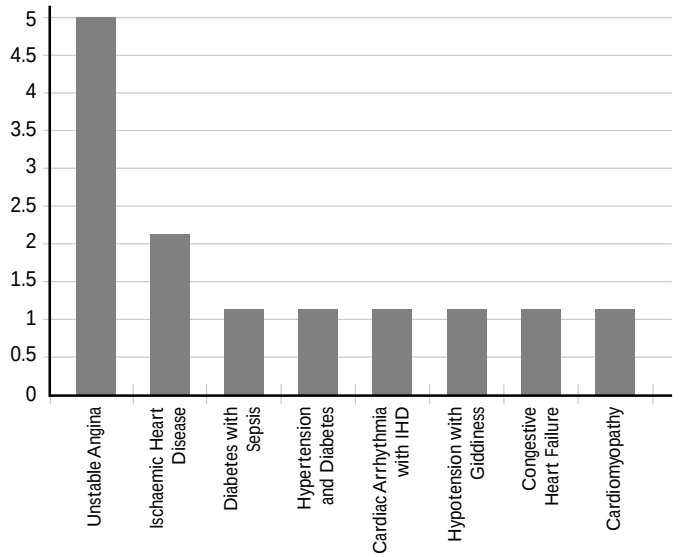
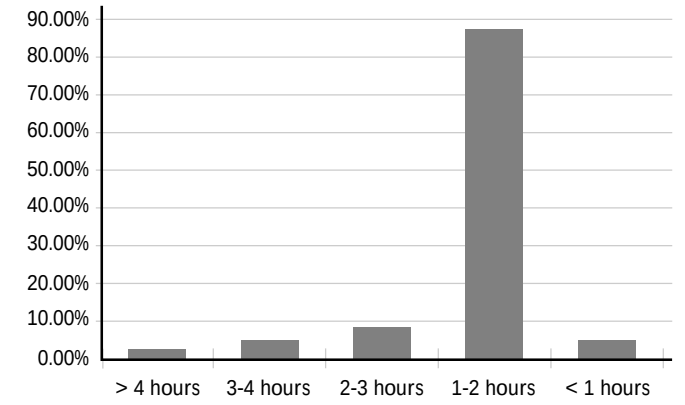


Fig. 2 Time to Thrombolytic Therapy.

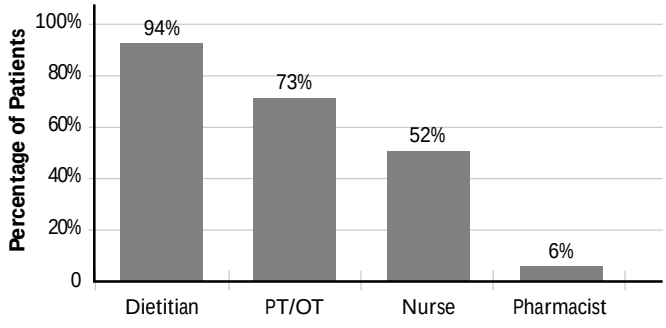


Referral for Cardiac Rehabilitation Programme (CRP)

The Hospital started a cardiac rehabilitation programme (CRP) in 1995 for patients admitted with AMI or heart failure. The aim was to provide a comprehensive programme for the tertiary prevention of coronary heart disease and for coronary risk stratification and behaviour modification in patients who survived a myocardial infarct. In this programme, a multi-disciplinary group consisting of a cardiologist, dietitian, physiotherapist, pharmacist, nurse counsellor and social worker (if necessary) plans the long term care of the patient after a myocardial infarct and provide the necessary medical, nursing, functional and social support for the patient after discharge. The programme also includes educational sessions for both patients and their relatives. A "Heart Saver" programme, which is essentially an educational session for family members on basic life support is an integral part of the CRP. The CRP was deemed to be of importance for the long term outcome of patients with AMI. Prior to the commencement of the pathway programme, the CRP team had not evaluated the process or outcome of the programme. The development and implementation of the AMI pathway therefore provided a means for the CRP team to evaluate the programme. This was still in progress at the time of writing this paper. In this study, only process measures were analysed.

The CRP team had previously set goals and objectives for the programme. These were used by the researcher to evaluate the process of the programme. One important process indicator is the timing of the referral for CRP during admission and when the CRP team member first established contact with the patient. The goal was to ensure that each patient admitted for AMI is seen by all CRP members at least once during hospitalisation. This initial contact is important in order to establish rapport with the patient and to encourage him or her to participate in the programme. During the AMI pathway development, it was agreed that the optimal time for referral for CRP would be on day 2 to day 3 of hospitalisation. The target day for the patient to be seen by the first CRP member was day 3 or 4.

Fig. 3 Patients seen by members of the CRP team.



Of the 153 patients who completed the pathway, 144 (94%) were referred to and seen by at least one member of the CRP team during their entire hospitalisation. This means that 6% of the patients were not seen by any of the CRP members during their stay in hospital. This could be attributed to the non-awareness of the doctors and nurses with the CRP referral system and the benefits that could be derived from the programme.

Fig. 3 illustrates the number of patients seen by various members of the CRP team. Dietitians saw the highest number of patients – 94% of the 153 patients who completed the pathway. This could be explained by the fact that routine referral to the dietitian is scheduled on Day 3 of hospitalisation. Moreover, routine fasting blood lipid profiles were done for almost all patients and the majority of them (68%) showed hyperlipidaemia. As such, these patients were independently referred to the dietitian for counselling on their dietary habits.

Routinely, all patients are counselled on their discharge medication by the pharmacist on the day of discharge. However, almost all the pharmacists failed to document their actions on the pathway. This issue was highlighted to the pharmacy manager, which resulted in an improvement in the compliance rate in documentation towards the end of the study period.

In terms of achieving the target time for patients to be seen by the CRP team members, of the 144 patients referred for CRP, 124 (86%) were seen within the targeted time, i.e. between Day 2 and Day 4 of hospitalisation. 2% of the patients were seen on Day 1 of hospitalisation, which is a positive variance. The reason was because these patients were pain-free and well enough to be assessed by the physiotherapist who happened to be in the intensive care ward during the time of referral. 12% of the patients were seen after the targeted time between Day 5 and Day 7, which is a negative variance. Reasons given included referral over a weekend or public holiday and insufficient staff during peak work periods (refer to Fig. 4).

In view of the variance data, and the need to improve the referral system for the CRP, the CRP team worked to improve the system of referral to the programme. It was noted that patients on the AMI clinical pathway were sometimes not referred to some members of the CRP team because there was no person designated to coordinate the referral system. After some brainstorming and problem solving, it was agreed that the physiotherapists would initiate the referral system to the other CRP team members once the patient is referred for the programme. The ward nurse would send the referral form to the physiotherapist, who would then inform all other team members through the Hospital's electronic mail system. In this way, the system

of referral for CRP is made more efficient and effective. This is an illustration of how a VMS can result in real improvements in the care delivery process by providing useful data which is then utilised for continuous quality improvement (CQI).

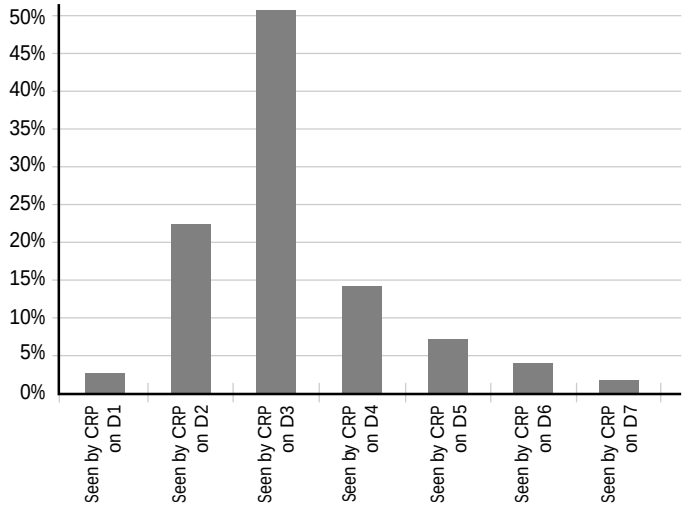
CONCLUSION

Current trends clearly show that clinical pathway programmes are being launched throughout the world. As a potential tool for quality improvement, pathways have tremendous appeal because of their multidisciplinary methods, their focus on process and outcomes of care, and on reducing unnecessary variation in treatment. Clinical pathways have much to offer the healthcare organisation and the individual practicing clinician. It provides a proactive, locally owned facility by which the multidisciplinary team can critically review and improve their processes and practices of care delivery towards the achievement of agreed clinical outcomes through the provision of best possible practice within the available resources. Pathways are also a means towards efficient resource management, provision of more information to patients and a clinical audit tool.

However, there are still serious concerns regarding their effectiveness and questions remain about the development, implementation and costs of clinical pathways. Methods to develop pathways remain unstudied and are still evolving with wide variations seen among institutions in their approach to topic selection, team composition, documentation on the pathway and variance management systems. Considerable research is needed to explore which methods of pathway development and implementation are most likely to provide benefits. As the technology of clinical pathways and their application expands, an important challenge for researchers will be to develop rigorous methods of evaluation techniques to assess their impact.

Through a study of the impact of the AMI clinical pathway, it has been shown that pathways can decrease the length of stay and possibly, resource use, with no concurrent adverse clinical outcomes. The paper has also shown that an analysis of variances can highlight important system issues that can then be dealt with in a timely manner. Details on the system and organisational effects of clinical pathways are beyond the scope of this paper. In view of the current paucity of evidence concerning the effectiveness of clinical pathways, hospitals and healthcare organisations should be encouraged to publish their evaluations of pathways. National and professional associations should also be encouraged to establish standardised criteria for evaluations of clinical pathways. Comparisons of the results of evaluations may be difficult because of differences in casemix and practice environments. However, this should not detract clinicians and health service researchers from evaluating the local impact of pathways because ultimately, such evaluations form part of the practice of evidence-based medicine.

Fig. 4 Percentage of patients first seen by CRP team (Distributed by day of hospitalisation).



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