EVALUATION OF CLINICAL PATHWAY FOR LAPAROSCOPIC APPENDICECTOMY IN HUSM

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DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF MEDICINE (GENERAL SURGERY)

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EVALUATION OF CLINICAL PATHWAY FOR LAPAROSCOPIC APPENDICECTOMY IN HUSM

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Introduction: A clinical pathway is a multidisciplinary plan of care based on best clinical practice for a specified group of patients with a particular diagnosis. It is designed to optimize resource utilization, and maximize quality of care. The efficacy and benefit of clinical pathway has been studied extensively in a few surgical fields and proven to be beneficial. However, the efficiency and benefit of clinical pathway implementation for laparoscopic appendicectomy in HUSM has yet to be studied. A clinical pathway for laparoscopic appendicectomy for acute appendicitis was developed in 2012 by the surgical team of HUSM in collaboration with the nursing staff, with a target length of stay of 3 days.

Objectives: The aim of this study was to determine the cost of treatment of appendicitis patients under implementation of standard CP for laparoscopic appendicectomy in HUSM and to evaluate spectrum of variance in treatment of appendicitis under this clinical pathway.

Methodology: All patients aged 12 or more, who were admitted to HUSM for suspected acute appendicitis and undergone treatment according to the clinical pathway from June 2014 until June 2016 was included in this study. Patients who had laparoscopic appendicectomy as part of other procedure, who were found intra-operatively to have diagnosis other than acute appendicitis, with significant co-morbid, and who require ICU care

were excluded. The datasheet documents of the clinical pathway were collected, data on the treatment, cost of treatment, and variances in length of stay (LOS), cost and treatment were analysed.

Result: 121 samples were collected and analysed. The mean cost of treatment was RM 1736.02. The mean LOS was noted to be 2.75 days, with standard deviation of 0.933 days. Only 12.4% of patients had LOS of more than 3 days (negative variance), while 41.3% of patients actually had positive LOS less than 3 days. This means only 46.3% of patients had LOS of 3 days as per the pathway. Majority of the cause for negative LOS were due to delay of surgery for more than 1 day after patient was posted for surgery. Another major variance is in initiation of antibiotics, whereby only around 12% of patients receive antibiotics upon admission as per pathway.

Conclusion: This study has identified the cost of treatment, and major variances in length of stay and certain treatment. Several modifications in the clinical pathway and changes in its implementation may be needed to improve its efficiency and benefit.

Supervisor: Dr. Zaidi Bin Zakaria

Co-supervisor: Dr Rosminah Mohamed

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ACKNOWLEDGEMENTS

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ABSTRAK

Haluan klinikal adalah pelan jagaan pesakit yang melibatkan pelbagai kepakaran, berdasarkan praktis terbaik untuk sesuatu kumpulan pesakit dengan sesuatu penyakit tertentu. Ia adalah direka untuk memastikan pengurusan optima sumber, di samping mencapai kualiti jagaan pesakit terbaik. Efikasi and kebaikan haluan klinikal telah dikaji dengan menyeluruh dalam pelbagai bidang pembedahan, dan didapati memberikan pelbagai manfaat. Walaubagaimanapun, tahap keberkesanan dan manfaat haluan klinikal untuk pembedahan appendisektomi secara laparoskopik di HUSM belum lagi dikaji. Pada tahun 2012, Jabatan Pembedahan HUSM, bersama pasukan jururawat, satu haluan klinikal untuk appendisektomi secara laparoscopik telah direka bentuk pada tahun 2012, dengan sasaran tempoh dalam wad selama 3 hari. Tujuan kajian ini adalah untuk mengenalpasti kos rawatan untuk pesakit akut appendicitis di bawah perlaksanaan haluan klinikal untuk pembedahan appendisektomi secara laparoskopik; dan juga untuk menilai spektrum variasi dalam rawatan apendisitis berdasarkan haluan klinikal ini. Semua pesakit berumur 12 dan ke atas, yang diwadkan di HUSM, disyaki mengidapi apendisitis akut, dan dirawat di bawah haluan klinikal ini daripada Jun 2014 sehingga Jun 2016, telah dimasukkan dalam kajian ini. Manakala pesakit yang menjalani pembedahan laparoskopik apendisektomi sebagai sebahagian daripada pembedahan lain, ataupun didapati mengidap penyakit selain daripada apendisitis akut, mempunyai penyakit utama lain, ataupun memerlukan penjagaan rapi ICU adalah dikecualikan daripada kajian ini. Borang pengumpulan data haluan klinikal yang disi telah dikumpul, dan kos rawatan dikenalpasti; variasi tempoh dalam wad, kos rawatan, dan variasi dalam rawatan turut dianalisa. Sebanyak 121 subjek telah dikenalpasti, dikumpul dan dianalisa. Purata kos rawatan adalah sebanyak RM 1736.02 berdasarkan hasil kajian ini. Purata tepoh dalam wad didapati adalah 2.75 hari dengan deviasi standard 0.933 hari. Cuma 12.4% pesakit diwadkan lebih daripada sasaran 3 hari(variasi negative), manakala 41.3% pesakit diwadkan kurang

daripada 3 hari (variasi positif). Ini bermakna sebanyak 46.3% pesakit mengenai sasaran tempoh dalam wad selama 3 hari. Punca utama yang menyebabkan perlanjutan tempoh dalam wad adalah kerana kelewatan pembedahan dijalankan lebih daripada sehari selepas pembedahan dirancang. Manakala untuk rawatan antibiotic, cuma 12% pesakit menerima antibiotic pada masa pesakit diwadkan. Kajian ini telah dapat mengenal pasti kos rawatan, dan juga variasi utama dalam tempoh dalam wad serta variasi dalam rawatan tertentu. Beberapa ubahsuain dalam haluan klinikal dan juga cara perlaksanaannya mungkin diperlukan untuk menambahbaikkan efikasi dan manfaat daripada haluan klinikal ini.

ABSTRACT

A clinical pathway is a multidisciplinary plan of care based on best clinical practice for a specified group of patients with a particular diagnosis. It is designed to optimize resource utilization, and maximize quality of care. The efficacy and benefit of clinical pathway has been studied extensively in a few surgical fields and proven to be beneficial. However, the efficiency and benefit of clinical pathway implementation for laparoscopic appendicectomy in HUSM has yet to be studied. A clinical pathway for laparoscopic appendicectomy for acute appendicitis was developed in 2012 by the surgical team of HUSM in collaboration with the nursing staff, with a target length of stay of 3 days. The aim of this study was to determine the cost of treatment of appendicitis patients under implementation of standard CP for laparoscopic appendicectomy in HUSM and to evaluate spectrum of variance in treatment of appendicitis under this clinical pathway. All patients aged 12 or more, who were admitted to HUSM for suspected acute appendicitis and undergone treatment according to the clinical pathway from June 2014 until June 2016 was included in this study. Patients who had laparoscopic appendicectomy as part of other procedure, who were found intra-operatively to have diagnosis other than acute appendicitis, with significant co-morbid, and who require ICU care were excluded. The datasheet documents of the clinical pathway were collected, data on the treatment, cost of treatment, and variances in length of stay (LOS), cost and treatment were analysed. 121 samples were collected and analysed. The mean cost of treatment was RM 1736.02. The mean LOS was noted to be 2.75 days, with standard deviation of 0.933 days. Only 12.4% of patients had LOS of more than 3 days (negative variance), while 41.3% of patients actually had positive LOS less than 3 days. This means only 46.3% of patients had LOS of 3 days as per the pathway. Majority of the cause for negative LOS were due to delay of surgery for more than 1 day after patient was posted for surgery. Another major variance is in initiation of antibiotics, whereby only around 12% of

patients receive antibiotics upon admission as per pathway. This study has identified the cost of treatment, and major variances in length of stay and certain treatment. Several modifications in the clinical pathway and changes in its implementation may be needed to improve its efficiency and benefit.

A. Study Protocol

I. Document submitted for ethical approval

Introduction and Literature Review

The vermiform appendix is a blind end hollow organ with base opening into the posteromedial wall of the cecum 2cm below ileocecal valve. It is variable in length, commonly about 6 to 9 centimetres. The submucosa of appendix contains many lymphoid mass and irregularly narrowed. The lumen is wider in children and may be obliterated in old age. The location of the base of the appendix is usually constant however the position of the other part of it can be variable. The commonest location of the appendix is retrocecal, followed by pelvic position. The appendix is attached to the terminal ileum by the mesoappendix which contains appendicular artery, vein and lymphatics. The appendicular artery is usually a branch of the inferior division of ileocolic artery. The appendicular artery is an end artery, and may be thrombosed in appendicitis, leading to ischemic necrosis and rupture of the appendix. (Sinnatamby, 2011)

Acute appendicitis is a common cause of abdominal pain and has a lifetime incidence of 8.6% in men, and 6.7% in women, typically occurring within the second and third decades of life.(ADDISS *et al.*, 1990) In the United States alone, acute appendicitis affects 250,000 individuals annually.(Kim *et al.*, 2015) Factors predisposing to acute appendicitis include fecolith, food residues, foreign body, lymphoid hyperplasia in viral infection, and rarely carcinoid tumour, typhoid disease, actinomycosis and tuberculosis. (Raftery, 2008)

The first appendicectomy occurred in 1735 by Claudius Amyand, Sergeant Surgeon to George II, performed the first known appendectomy. It was done during right scrotal hernia repair, during which he found a fistula from the appendix which was perforated by a pin. The appendix was

ligated and removed.(Shepherd, 1954) The term appendicitis was not coined until 1886 when Reginald Heber Fitz, pathologist of Harvard University presented a paper entitled "Perforating Inflammation of the Vermiform Appendix: With Special Reference to Its Early Diagnosis and Treatment."(FITZ 1935)In 1889, McBurney published the first of several important papers regarding theappendix. He suggested early operative intervention and developed themuscle-splitting incision that bears his name and is commonly used today.(McBurney, 1894)

For over a century, open appendicectomy has been the gold standard of treatment for appendicitis.(Katkhouda *et al.*, 2005) However in recent years, laparoscopy technique has been gaining attention and is used in treatment of appendicitis. Laparoscopic surgery is a form of minimal access surgical technique. It creates less surgical trauma compared to conventional open technique. It is achieved by insertion of rigid endoscope through a port in the abdominal wall to obtain access into the peritoneal cavity, which will be inflated with inert gas, usually carbon dioxide to create pneumoperitoneum. Further ports then can be placed, through which further surgical instruments can be inserted. (Darzi, 2004)A Cochrane review in 2010 involving 67 studies comparing laparoscopic to open appendicectomy in adults concluded that use of laparoscopy and laparoscopic appendicectomy is patients with suspected appendicitis is recommended, especially in the young female, and obese. Hospital stay was shorter by 1.1 day and return to work and sports activity was earlier in patients who undergo laparoscopic appendicectomy. However, the duration of surgery is longer than open procedure by 10 minutes and cost of surgery is higher than open surgery. (Sauerland *et al.*, 2010)

Clinical pathway, also known as integrated care pathway, is a financial management tool that was initiated under Casemix System in the United States with the aim to reduce length of stay and reduce healthcare cost. (Takegami et al., 2003)

A Clinical Pathway (CP) is a multidisciplinary plan of care based on best clinical practice for a specified group of patients with a particular diagnosis. A CP is designed to minimize delays, optimize resource utilization, and maximizes quality of care (Reid et al., 2000) CPs support the implementation of Casemix by reducing variations of care, increasing homogeneity of cases, improving quality of Casemix data, and enhancing costing analysis in Casemix. (Aljunid et al., 2011)

(Rotter et al., 2010) further suggested the use of five criteria to for definition of clinical pathway, namely (1) the intervention was a structured multidisciplinary plan of care; (2) the intervention was used to channel the translation of guidelines or evidence into local structures; (3) the intervention detailed the steps in a course of treatment or care in a plan, pathway, algorithm, guideline, protocol or other inventory of actions; (4) the intervention had time frames or criteria-based progression (that is, steps were taken if designated criteria were met); and (5) the intervention aimed to standardized care for a specific clinical problem, procedure or episode of healthcare in a specific population.

They are used to translate clinical guidelines into local protocols and clinical practice and are now common place, particularly in the management of surgical conditions including appendicitis. (Campbell et al., 1998) Tan et al. had found significant reduction in readmission rate and postoperative morbidity rate in 204 patients undergoing major colorectal surgery managed using clinical pathway in 2001 in Singapore. There is also a reduction in length of stay by two days although not statistically significant (Tan et al., 2005) In a more recent study by Kulkarni, clinical pathway for endocrine surgery procedures, i.e. unilateral thyroid lobectomy, total thyroidectomy and parathyroidectomy, they achieved significant reduction in length of stay for all three procedures, and concurrent reduction of total cost for all procedures. However the post

operative morbidity was not assessed, although readmission rate within 72 hours post discharge had no significant difference. (Kulkarni et al., 2011)

Clinical pathway is a vital component to be implemented in HUSM for a more cost effective management of cases in HUSM. Healthcare managers are always facing the challenge to provide acceptable service quality while keeping costs at a minimum, and in order to achieve this, knowledge of the actual cost of treatment of each patient is vital.(Javid *et al.*, 2016) With reliable cost level estimates, only then can the hospital managers measure resource utilization and allocate accurately to eliminate inefficiency, promote transparency while maintaining productivity.(Porter, 2010; Vogl, 2013) unfortunately, cost analysis is not a simple task. Many factors affect cost estimation, namely patient characteristics, clinical activity, and of utmost significance, the costing method used. (Cartwright, 1999)

The efficacy and benefit of clinical pathway has been studied extensively in a few surgical fields (Müller et al., 2009) and proven to be beneficial. The reduction in length of hospitalization and also total cost of treatment had also been found in several studies, including (Uchiyama, 2002) who studied patients who undergo biliary and stomach laparoscopic surgery, (Quaglini, 2004) who studied on economic effects of clinical pathway in stroke patient management, and (Choong, 2000) who conducted prospective study on patients with femur fracture. However, the efficiency of its implementation for acute appendicitis and laparoscopic appendicitis in our centre has yet to be studied.

Casemix system has been implemented in HUSM since 2011. It was first initiated in United States of America by Professor Robert Fetter of Yale University in late 1970s, conceptually to simplify the complexity of patient specific diagnoses, by grouping similar diagnostic categories

into clinically meaningful diagnostic clusters, where resource use was also similar(Thompson *et al.,* 1979)Case-Mix system is a classification of patient treatment episodes designed to create classes which are relatively homogenous in respect of the resources used and which contain patients with similar clinical characteristics.(Reid *et al.,* 2000) Casemix system "provides a means for examining the product of the hospital, since patients within each class are expected to receive a similar product"(Fetter *et al.,* 1980)Casemix system has been first implemented in Malaysia in Universiti Kebangsaan Malaysia in 2002(Rohaizat, 2005), and has been launched officially in HUSM in 9 June 2013. Currently in HUSM, the main use of casemix system is for clinical quality measurement and improvement.

Problem Statement

Clinical pathway has never been initiated in HUSM Surgical Department. The feasibility and benefit of having such a pathway had not been studied in this institution. In fact in Malaysia only HUKM had published data on studies of clinical pathway (Aljunid, 2011). While many papers had been published on clinical pathway for a variety of disease, (Kulkarni, 2011) (Müller, 2009) its implementation and success in Malaysian hospital in general and specifically in HUSM had not been studied. More ever, it is in the principle of clinical pathway, that it is vital to tailor the pathway to suite a centre. Therefore in the process of developing a practical and beneficial clinical pathway, it is vital that the designed clinical pathway is evaluated systematically, and redesigned if necessary to ensure its practicality and efficacy. Findings from this study will give answer to the above problem.

Target Research Questions

In initiating use of clinical pathway, a few questions will need to be addressed in the process of its development. Number one is if the clinical pathway is acceptable to the clinical staff. This question will be evaluated by documenting the variance rate of the patient management compared to the standard clinical pathway. Another question is the cost of management of patients undergoing laparoscopic appendicectomy, and with this standard clinical pathway, how much is the average cost of treatment.

General Objective:

To evaluate the effectiveness of a standard clinical pathway for laparoscopic appendicectomy developed based on the consensus in HUSM.

Specific Objectives:

I. To determine the cost of treatment of appendicitis patients under implementation of standard CP for laparoscopic appendicectomy in HUSM.

II. To evaluate spectrum of variance in treatment of appendicitis under implementation of standard CP for laparoscopic appendicectomy in HUSM

Study Area

Data collection for this study will be done in Hospital University Sains Malaysia (HUSM) Kubang Kerian, Kelantan.

Study Population

Study population for this study will be all patients who are admitted to HUSM for suspected acute appendicitis, from June 2014 until June 2016.

Inclusion Criteria:

1. Patients aged more than 12 years old.
2. Patients presenting to or referred to HUSM for suspected acute appendicitis
3. Patients who undergo laparoscopic appendicectomy

Exclusion Criteria:

1. Patients who undergo appendicectomy as part of other procedure
2. Patients who undergo open appendicectomy or interval appendicectomy
3. Patients with complicated chronic condition or who require ICU care
4. Patients who is found to have perforated appendix, appendicular abscess, normal appendix, or other pathology noted intraoperatively
5. Patients with significant post operative complications such as bowel obstruction requiring parenteral nutrition.

Sample Size Estimation

Sample size is estimated based the average of cases of acute appendicitis treated in HUSM from 2014 to 2016. The average cases per year are 248. Based on calculation using Raosoft, with margin of error of 5%, confidence level of 90%, sample size required for this study is 130.

Sampling Method

Simple random sampling method will be used; all patients admitted and treated according to the laparoscopic appendicectomy clinical pathway from June 2014 till June 2016 will be randomised for simple random sampling using SPSS.

Data Collection

Study Design and study population:

This is a retrospective cross sectional study.

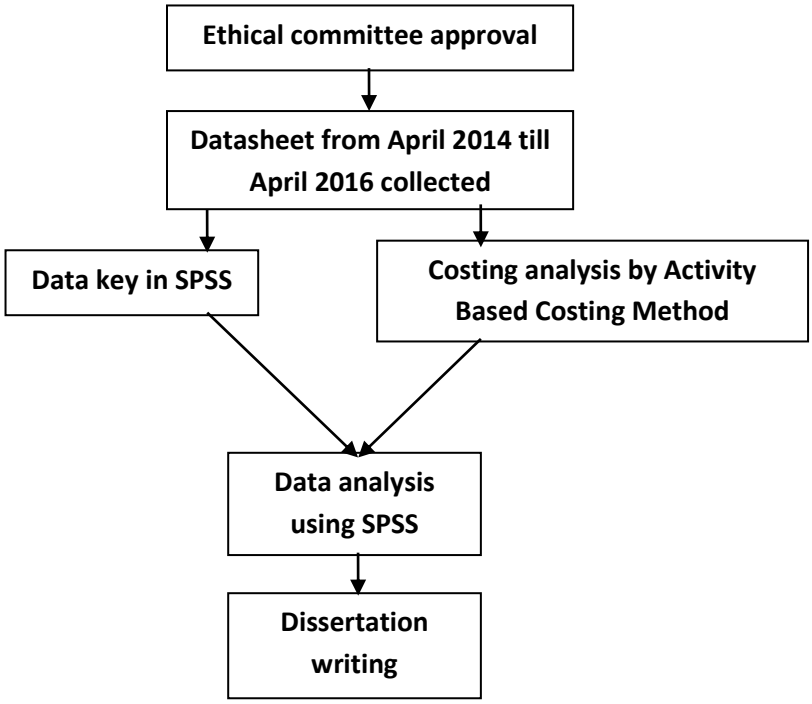
A clinical pathway was developed in 2012 in HUSM. It was a designed mainly by the Surgical team of HUSM in collaboration with the nursing staff. The clinical pathway was implemented in 2012. Each clinical pathway patient details and variation was recorded either by in charge staff nurse or doctors. The completed documents will be periodically collected by a Sister in charge as case manager.

For this review, patients who had been admitted and treated according to this clinical pathway from April 2015 till April 2016 will be included. The datasheet documents will be collected from case manager and data key in using SPSS version 22 and analysed.

Data Analysis

SPSS Statistical software, version 22 will be used for data analysis. Descriptive, prevalence and univariate analyses are among analyses will be conducted in order to accomplish the outlined specific objectives in this study. Costing analysis will be done by using Activity Based Costing method. All treatment activity, including staff salary, cost of blood and radiological investigation, medications, and cost of surgery will be taken into account. Variance in cost will be recorded and analysed.

Study Flow Chart



References

ADDISS, D. G., SHAFFER, N., FOWLER, B. S. & TAUXE, R. V. (1990). THE EPIDEMIOLOGY OF APPENDICITIS AND APPENDECTOMY IN THE UNITED STATES. *American Journal of Epidemiology,* **132(5)**, 910-925.

Cartwright, W. S. (1999). Methods for the economic evaluation of health care programmes, second edition. By Michael F. Drummond, Bernie O'Brien, Greg L. Stoddart, George W. Torrance. Oxford: Oxford University Press, 1997. *J Ment Health Policy Econ,* **2(1)**, 43.

Darzi, A. (2004). Minimal Access Surgery. In*:* Kirk, R. M. and Ribbons, W. J. (eds.), *Clinical Surgery In General RCS Course Manual* 4 ed. Edinburgh: Churchill Livingston, pp 237-240.

Fetter, R. B., Shin, Y., Freeman, J. L., Averill, R. F. & Thompson, J. D. (1980). Case mix definition by diagnosis-related groups. *Med Care,* **18(2 Suppl)**, iii, 1-53.

FITZ , R. (1935). On Perforating Inflammation of the Vermiform Appendix with Special Reference to Its Early Diagnosis and Treatment. *New England Journal of Medicine,* **213(6)**, 245-248. doi: doi:10.1056/NEJM193508082130601

Javid, M., Hadian, M., Ghaderi, H., Ghaffari, S. & Salehi, M. (2016). Application of the Activity-Based Costing Method for Unit-Cost Calculation in a Hospital. *Global Journal of Health Science,* **8(1)**, 165-172. doi: 10.5539/gjhs.v8n1p165

Katkhouda, N., Mason, R. J., Towfigh, S., Gevorgyan, A. & Essani, R. (2005). Laparoscopic Versus Open Appendectomy: A Prospective Randomized Double-Blind Study. *Annals of Surgery,* **242(3)**, 439-450. doi: 10.1097/01.sla.0000179648.75373.2f

Kim, D. Y., Nassiri, N., Saltzman, D. J., Ferebee, M. P., Macqueen, I. T., Hamilton, C., Alipour, H., Kaji, A. H., Moazzez, A., Plurad, D. S. & de Virgilio, C. (2015). Postoperative antibiotics are not associated with decreased wound complications among patients undergoing appendectomy for complicated appendicitis. *Am J Surg,* **210(6)**, 983-987; discussion 987-989. doi: 10.1016/j.amjsurg.2015.07.001

McBurney, C. (1894). IV. The Incision Made in the Abdominal Wall in Cases of Appendicitis, with a Description of a New Method of Operating. *Ann Surg,* **20(1)**, 38-43.

Porter, M. E. (2010). What is value in health care? *N Engl J Med,* **363(26)**, 2477-2481. doi: 10.1056/NEJMp1011024

Raftery, A. T. (2008). *Applied Basic Science for Basic Surgical Training* (Second international edition ed.). Edinburgh: Churchill Livingston Elsevier.

Reid, B., Palmer, G. & Aisbett, C. (2000). The performance of Australian DRGs. *Aust Health Rev*, **23(2)**, 20-31.

Rohaizat, Y. (2005). Proposed National Health Care Financing System For Malaysia: The Role Of Case-mix. *Malaysian Journal of Public Health Medicine*, **5(2)**, 91-98.

Sauerland, S., Jaschinski, T. & Neugebauer, E. A. M. (2010). Laparoscopic versus open surgery for suspected appendicitis. *Cochrane Database of Systematic Reviews***(10)**. doi: 10.1002/14651858.CD001546.pub3

Shepherd, J. A. (1954). Acute appendicitis: a historical survey. *Lancet*, **267(6833)**, 299-302.

Sinnatamby, C. S. (2011). *Last's Anatomy* (12 ed.). Edinburgh: Churchill Livingstone Elsevier.

Thompson, J. D., Averill, R. F. & Fetter, R. B. (1979). Planning, budgeting, and controlling--one look at the future: case-mix cost accounting. *Health Services Research*, **14(2)**, 111-125.

Vogl, M. (2013). Improving patient-level costing in the English and the German 'DRG' system. *Health Policy*, **109(3)**, 290-300. doi: 10.1016/j.healthpol.2012.09.008

Research Gantt Chart

	2016								2017					
Action	February	March	April	May	June	July	August	September	January	February	March	April	May	June
Literature review														
Proposal preparation														
Proposal presentation								5/9/2016						
Ethical Approval														
Data collection														
Data analysis														
Thesis writing														
Submission														

II. Ethical approval letter

Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM)
Human Research Ethics Committee USM (HREC)

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Kampus Kesihatan,
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5th June 2017

Dr. Chong Yi Chin
Department of Surgery
School of Medical Sciences
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan.

JEPeM Code : USM/JEPeM/17010052
Protocol Title : Evaluation of Clinical Pathway for Laparoscopic Appendicectomy.

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code **USM/JEPeM/17010052**, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid from **5th June 2017** until **4th June 2018.**

Study Site: Hospital Universiti Sains Malaysia.

The following researchers also involve in this study:
1. Assoc. Prof. Dr. Zaidi Zakaria
2. Dr. Rosminah Mohamed

The following documents have been approved for use in the study.
1. Research Proposal

In addition to the abovementioned documents, the following technical document was included in the review on which this approval was based:
1. Data Collection Form

Attached document is the list of members of JEPeM-USM present during the full board meeting reviewing your protocol.

While the study is in progress, we request you to submit to us the following documents:
1. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2015: Continuing Review Application Form.** Subsequently this need to be done yearly as long as the research goes on.
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using **JEPeM-USM FORM 3(A) 2015: Study Protocol Amendment Submission Form.**
3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2015: Study Protocol Amendment Submission Form.**
4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2014: Adverse Events Report.**
5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2015.**
6. Any event which may have ethical significance.

7. Any information which is needed by the JEPeM-USM to do ongoing review.
8. Notice of time of completion of the study using **JEPeM-USM FORM 3(C) 2014: Final Report Form.**

Please note that forms may be downloaded from the JEPeM-USM website: **www.jepem.kk.usm.my**

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.

"ENSURING A SUSTAINABLE TOMORROW"

Very truly yours,

PROF. DR. HANS AMIN VAN ROSTENBERGHE
Chairperson
Jawatankuasa Etika Penyelidikan (Manusia) JEPeM
Universiti Sains Malaysia

Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM)
Human Research Ethics Committee USM (HREC)

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Date of meeting : 23rd March 2017
Venue : Meeting Room, Division of Research & Innovation, USM Kampus Kesihatan.
Time : 9.00 a.m – 3.00 p.m
Meeting No : 356

Members of Committee of the Jawatankuasa Etika Penyelidikan (Manusia), JEPeM Universiti Sains Malaysia who reviewed the protocol/documents are as follows:

	Member (Title and Name)	Occupation (Designation)	Male/ Female (M/F)	Tick (✓) if present when above items, were reviewed
Chairperson :	Professor Dr. Hans Amin Van Rostenberghe	Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	M	✓ (Chairperson)
Secretary:	Mr. Mohd Bazlan Hafidz Mukrim	Science Officer	M	✓
Members :				
1.	Professor Dr. Lee Yeong Yeh	Lecturer, School of Medical Sciences	M	✓
2.	Associate Professor Dr. Mohtar Ibrahim	Lecturer, School of Medical Sciences	M	✓
3.	Professor Dr. Nik Hazlina Nik Hussain	Lecturer, School of Medical Sciences	F	✓
4.	Associate Professor Dr. Nor Azwany Yaacob	Lecturer, School of Medical Sciences	F	✓
5.	Mrs. Norleha Mohd Noor	Executive Secretary, School of Dental Sciences	F	✓
6.	Associate Professor Oleksandr Krasilshchikov	Lecturer, School of Health Sciences	M	✓
7.	Associate Professor Siti Hawa Ali	Lecturer, School of Health Sciences	F	✓
8.	Mrs. Zawiah Abu Bakar	Community Representative	F	✓
9.	Professor Dr. Zeehaida Mohamed	Lecturer, School of Medical Sciences	F	✓

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

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Chairperson
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B. BODY CONTENT

Introduction

Introduction

The vermiform appendix is a blind end hollow organ with base opening into the posteromedial wall of the cecum 2cm below ileocecal valve. It is variable in length, commonly about 6 to 9 centimeters. The submucosa of appendix contains many lymphoid mass and irregularly narrowed. The lumen is wider in children and may be obliterated in old age. The location of the base of appendix is usually constant however the position of the other part of it can be variable. The commonest location of the appendix is retrocecal, followed by pelvic position. The appendix is attached to the terminal ileum by the mesoappendix which contains appendicular artery, vein and lymphatics. The appendicular artery is usually a branch of the inferior division of ileocolic artery. The appendicular artery is an end artery, and may be thrombosed in appendicitis, leading to ischemic necrosis and rupture of the appendix. (Sinnatamby, 2011)

Acute appendicitis is a common cause of abdominal pain and has a lifetime incidence of 8.6% in men, and 6.7% in women, typically occurring within the second and third decades of life.(ADDISS *et al.*, 1990) In the United States alone, acute appendicitis affects 250,000 individuals annually.(Kim *et al.*, 2015) Factors predisposing to acute appendicitis include fecolith, food residues, foreign body, and lymphoid hyperplasia in viral infection, and rarely carcinoid tumour, typhoid disease, actinomycosis and tuberculosis. (Raftery, 2008)

The first appendicectomy occurred in 1735 by Claudius Amyand, Sergeant Surgeon to George II, performed the first known appendectomy. It was done during right scrotal hernia repair, during which he found a fistula from the appendix which was perforated by a pin. The

appendix was ligated and removed.(Shepherd, 1954) The term appendicitis was not coined until 1886 when Reginald Heber Fitz, pathologist of Harvard University presented a paper entitled “Perforating Inflammation of the Vermiform Appendix: With Special Reference to Its Early Diagnosis and Treatment.”(FITZ 1935)In 1889, McBurney published the first of several important papers regarding theappendix. He suggested early operative intervention and developed themuscle-splitting incision that bears his name and is commonly used today.(McBurney, 1894)

For over a century, open appendicectomy has been the gold standard of treatment for appendicitis.(Katkhouda *et al.*, 2005) However in recent years, laparoscopy technique has been gaining attention and is used in treatment of appendicitis. Laparoscopic surgery is a form of minimal access surgical technique. It creates less surgical trauma compared to conventional open technique. It is achieved by insertion of rigid endoscope through a port in the abdominal wall to obtain access into the peritoneal cavity, which will be inflated with inert gas, usually carbon dioxide to create pneumoperitoneum. Further ports then can be placed, through which further surgical instruments can be inserted. (Darzi, 2004)A Cochrane review in 2010 involving 67 studies comparing laparoscopic to open appendicectomy in adults concluded that use of laparoscopy and laparoscopic appendicectomy is patients with suspected appendicitis is recommended, especially in the young female, and obese. Hospital stay was shorter by 1.1 day and return to work and sports activity was earlier in patients who undergo laparoscopic appendicectomy. However, the duration of surgery is longer than open procedure by 10 minutes and cost of surgery is higher than open surgery. (Sauerland *et al.*, 2010)

Clinical pathway, also known as integrated care pathway, is a financial management tool that was initiated under Casemix System in the United States with the aim to reduce length of stay and reduce healthcare cost. (Takegami et al., 2003)

A Clinical Pathway (CP) is a multidisciplinary plan of care based on best clinical practice for a specified group of patients with a particular diagnosis. A CP is designed to minimize delays, optimize resource utilization, and maximizes quality of care (Reid et al., 2000) CPs support the implementation of Casemix by reducing variations of care, increasing homogeneity of cases, improving quality of Casemix data, and enhancing costing analysis in Casemix. (Aljunid et al., 2011)

(Rotter et al., 2010) further suggested the use of five criteria to for definition of clinical pathway, namely (1) the intervention was a structured multidisciplinary plan of care; (2) the intervention was used to channel the translation of guidelines or evidence into local structures; (3) the intervention detailed the steps in a course of treatment or care in a plan, pathway, algorithm, guideline, protocol or other inventory of actions; (4) the intervention had time frames or criteria-based progression (that is, steps were taken if designated criteria were met); and (5) the intervention aimed to standardized care for a specific clinical problem, procedure or episode of healthcare in a specific population.

They are used to translate clinical guidelines into local protocols and clinical practice and are now common place, particularly in the management of surgical conditions including appendicitis. (Campbell et al., 1998) Tan et al. had found significant reduction in readmission rate and postoperative morbidity rate in 204 patients undergoing major colorectal surgery managed using clinical pathway in 2001 in Singapore. There is also a reduction in length of stay by two days although not statistically significant (Tan et al., 2005) In a more recent study by Kulkarni, clinical pathway for endocrine surgery procedures, i.e. unilateral thyroid lobectomy, total thyroidectomy and parathyroidectomy, they achieved significant reduction in length of stay for all three procedures, and concurrent reduction of total cost for all procedures. However the post operative morbidity was not assessed, although readmission rate within 72 hours post discharge had no significant difference. (Kulkarni et al., 2011)

Clinical pathway is a vital component to be implemented in HUSM for a more cost effective management of cases in HUSM. Healthcare managers are always facing the challenge to provide acceptable service quality while keeping costs at a minimum, and in order to achieve this, knowledge of the actual cost of treatment of each patient is vital.(Javid *et al.*, 2016) With reliable cost level estimates, only then can the hospital managers measure resource utilization and allocate accurately to eliminate inefficiency, promote transparency while maintaining productivity.(Porter, 2010; Vogl, 2013) unfortunately, cost analysis is not a simple task. Many factors affect cost estimation, namely patient characteristics, clinical activity, and of utmost significance, the costing method used. (Cartwright, 1999)

The efficacy and benefit of clinical pathway has been studied extensively in a few surgical fields (Müller et al., 2009) and proven to be beneficial. The reduction in length of hospitalization and also total cost of treatment had also been found in several studies, including (Uchiyama *et al.*, 2002) who studied patients who undergo biliary and stomach laparoscopic surgery, (Quaglini *et al.*, 2004) who studied on economic effects of clinical pathway in stroke patient management, and (Choong *et al.*, 2000) who conducted prospective study on patients with femur fracture. However, the efficiency of its implementation for acute appendicitis and laparoscopic appendicitis in our centre has yet to be studied.

Casemix system has been implemented in HUSM since 2011. It was first initiated in United States of America by Professor Robert Fetter of Yale University in late 1970s, conceptually to simplify the complexity of patient specific diagnoses, by grouping similar diagnostic categories into clinically meaningful diagnostic clusters, where resource use was also similar(Thompson *et al.*, 1979)Case-Mix system is a classification of patient treatment episodes designed to create classes which are relatively homogenous in respect of the resources used and which contain patients with similar clinical characteristics.(Reid *et al.*, 2000) Casemix system "provides a means for examining the product of the hospital, since

patients within each class are expected to receive a similar product"(Fetter *et al.*, 1980)Casemix system has been first implemented in Malaysia in Universiti Kebangsaan Malaysia in 2002(Rohaizat, 2005), and has been launched officially in HUSM in 9 June 2013. Currently in HUSM, the main use of casemix system is for clinical quality measurement and improvement.

Study Objective

General Objective:

To evaluate the effectiveness of a standard clinical pathway for laparoscopic appendicectomy developed based on the consensus in HUSM.

Specific Objectives:

III. To determine the cost of treatment of appendicitis patients under implementation of standard CP for laparoscopic appendicectomy in HUSM.
IV. To evaluate spectrum of variance in treatment of appendicitis under implementation of standard CP for laparoscopic appendicectomy in HUSM

Rationale for Study

Clinical pathway has never been initiated in HUSM Surgical Department prior to 2012. The feasibility and benefit of having such a pathway had not been studied in this institution. In fact in Malaysia only HUKM had published data on studies of clinical pathway (Aljunid, 2011). While many papers had been published on clinical pathway for a variety of disease, (Kulkarni, 2011) (Müller, 2009) its implementation and success in Malaysian hospital in general and specifically in HUSM had not been studied. Moreover, it is in the principle of clinical pathway, that it is vital to tailor the pathway to suite a centre. Therefore in the process of developing a practical and beneficial clinical pathway, it is crucial that the designed clinical pathway is evaluated systematically, and redesigned if necessary to ensure its practicality and efficacy. Findings from this study will give answer to the above problem.

Methodology

Study Area

Data collection for this study was done in Hospital University Sains Malaysia (HUSM) Kubang Kerian, Kelantan.

Study Population

Study population for this study was all patients who were admitted to HUSM for suspected acute appendicitis and treated according to the clinical pathway, from June 2014 until June 2016.

Inclusion Criteria:

4. Patients aged more than 12 years old.
5. Patients presenting to or referred to HUSM for suspected acute appendicitis
6. Patients who undergo laparoscopic appendicectomy

Exclusion Criteria:

6. Patients who undergo appendicectomy as part of other procedure
7. Patients who undergo open appendicectomy or interval appendicectomy
8. Patients with complicated chronic condition or who require ICU care
9. Patients who is found to have perforated appendix, appendicular abscess, normal appendix, or other pathology noted intraoperatively
10. Patients with significant post operative complications such as bowel obstruction requiring parenteral nutrition.

Sample Size

Sample size was estimated based the average of cases of acute appendicitis treated in HUSM from 2014 to 2016. The average cases per year were 248. Based on calculation using Raosoft, with margin of error of 5%, confidence level of 90%, sample size required for this study is 130. After datasheet collection, only 145 completed clinical pathway datasheet were available, and after applying exclusion criteria, only 121 data were eligible for analysis. This will still give a confidence level of 87% with 5% margin of error.

Study Design and Data Collection

A clinical pathway for acute appendicitis treated by laparoscopic appendicectomy was developed in 2012 in HUSM. It was a designed mainly by the Surgical team of HUSM in collaboration with the nursing staff. It outlines all investigation and management of a patient with suspected acute appendicitis, from arrival to the Accident and Emergency Department, till surgery laparoscopiccally, until patient is discharged. All investigation, management and variance in management of the patient were recorded on the data collection sheet by the staff nurse incharge. The data collection sheet is as attached in the appendix. The completed documents will be periodically collected by a Sister in charge who acts as the case manager. In this study, all the available datasheet were collected from the case manager, and analysed. The full clinical pathway is attached in appendix.

Costing Analysis

Costing of the treatment was done using Activity Based Costing method. All treatment activity, including staff salary, cost of blood investigation and radiological investigation, medications, and cost of surgery was taken into account. For staff salary, pay of staff per