A SURVEY ON PATIENTS' POSTOPERATIVE PAIN EXPERIENCE

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ABSTRACT

Background

Pain is one of the major concerns of patients undergoing surgery. Unresolved postoperative pain can negatively affect a patient's well-being on many levels. Efforts have been made to address postoperative pain. However, throughout the years, studies have shown that moderate to severe postoperative pain is still undermanaged. The aim of this study is to examine the performance of postoperative pain management in UMMC from the patients' perspective.

Methods

150 patients who underwent elective surgery in UMMC were recruited to complete a questionnaire. The questionnaire explored the incidence and severity of postoperative pain, emotional and functional disturbances caused by pain as well as the patients' level of satisfaction towards their pain management.

Results

The incidence of moderate to severe pain on POD1 was 52%. Pain was found to be associated with functional and emotional disturbances. Younger age, ASA>1, and orthopedic surgery were found to be risk factors for moderate to severe pain. The patients were generally satisfied with the pain management given.

Conclusions

Acute postoperative pain remains prevalent despite various efforts. Opioids are still the mainstay of treatment for moderate to severe pain, but its undesirable side effect profile limits its usage. A new approach is needed to further improve patients' postoperative pain experience.

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LIST OF SYMBOLS AND ABBREVIATIONS

APS: Acute Pain Service

POD1: Post-Operative Day 1

ASA: American Society of Anesthesiologists

GA: General Anesthesia

IV: Intravenous

LIST OF APPENDICES

CHAPTER 1: INTRODUCTION

The International Association for the Study of Pain (IASP) defines pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. Acute pain is temporarily related to injury and that resolves during the appropriate healing period.

Though surgery is an effective method to cure certain diseases, it unavoidably involves skin incisions, tissue manipulations and resection of diseased organ/tissues, all of which contribute to acute pain. Anesthesia no doubt could provide pain-free experience during surgery, but it does not obliterate the aftereffect of surgery, that is acute postoperative pain. In fact, most patients undergoing surgical procedures experience acute postoperative pain despite adequate analgesics [1,2]

Pain is one of the major concerns of patients undergoing surgery. Efforts have been undertaken to reduce postoperative pain. This is not only for humanitarian reasons, but good pain control also has the potential to reduce postoperative morbidity and mortality. Unrelieved postoperative pain can negatively affect a patient's well-being on multiple levels [3]. It can interfere with sleep and physical functioning, delaying wound healing and possibly prolonging hospital stay.

To address this problem in a structured and systematic manner, the Acute Pain Service (APS) was introduced in the United States in 1988 by Ready et al [4]. Since then, there have been a widespread introduction of APSs in major hospitals around the world.

Over the years, with the development of newer analgesics, analgesia protocols, as well as more frequent usage of minimally invasive surgical techniques, patients' postoperative outcome was expected to improve. However, a survey by Apfelbaum JL et al [5] in 2003, when compared with survey by Warfield and Kahn in 1995, showed little difference in patients' postoperative pain experience. This finding is also supported by an analysis by Correll DJ [6].

In UMMC, APS was established in 1992. Around 20,000 surgeries are performed in UMMC annually [7]. Not all patients can be managed by the APS. It is therefore important that the primary team be responsible in providing pain relief after surgery. Most surveys look at the incidence and severity of pain from assessing patients' notes.

This survey focuses on determining what matters to patients by asking patients to complete a questionnaire in their own time regarding their pain experiences, in the hope of understanding ways to improve post-operative pain control.

CHAPTER 2: LITERATURE REVIEW

A comprehensive literature review by Sinatra in 2010 found that the treatment of acute pain remains suboptimal due to attitudes and educational barriers on the part of both physicians and patients, as well as limitations of available therapies [3]. For example, opioids are effective, but had undesirable side effects. Poorly treated acute pain can lead to impaired sleep and physical function, reduced quality of life and high economic costs.

In regards to postoperative pain, it has been assumed that sufficient pain control will improve surgical outcome, and there is a consensus that optimal pain relief is a prerequisite for early postoperative recovery. However, a systemic review by Werner et al in 1995 found that postoperative pain relief *per se* did not significantly improve postoperative outcome (morbidity and length of hospital stay) except for patient's satisfaction and pulmonary complications. Postoperative outcomes are, in fact, dependent on many factors [8].

As for the importance of postoperative pain control in patient's perspective, Macario et al conducted a survey in 1999 to quantify patients' preferences for postoperative outcomes. Pain was ranked as the third most undesired postoperative outcome (after vomiting and gagging on endotracheal tube). It goes on to show that pain remains a major concern for patients undergoing surgery [9].

The prevalence of postoperative pain varies considerably between studies. It ranges from 2.2%[5], 58%[10] to 70%[11]. Generally, most of the authors agree that postoperative pain continued to be undermanaged.

Murray et al conducted a study in a developing country referral hospital (Tygerberg Hospital, Western Cape, South Africa), surveying 1231 patients on POD1. 62% reported moderate to severe pain [12].

A study was done in year 2002-2003 at the University Hospital Maastricht, Netherlands, involving 1490 patients. Moderate and severe pain was reported by 41% of the patients 1 hour after surgery, 30% on POD1, 19%, 16 % and 14% on POD 2,3,4 respectively [13].

In the same survey, but looking in particular in day surgery patients (n=648), 26% reported moderate to severe pain on the day of surgery, and the number dropped to 21% on POD1 [14].

In 2009, in Aga Khan University Hospital in Nairobi, Kenya, 150 day-surgery patients were telephone interviewed at 24 and 48 hours after discharge. 55% of the patients had pain at 24 hours postoperatively. 13% was moderate to severe [15].

In the effort to improve postoperative pain management in developed, as well as in developing countries, a group of researchers from Germany started the PAIN OUT (Improvement in postoperative PAIN OUTcome) initiative. This is a large multi-national, non-interventional registry and benchmark project. It collects demographic, clinical and outcome data by using a validated questionnaire in multiple languages. It started in 2009 and is expected to continue until 2030. To date, more than 200 hospitals are taking part in PAIN OUT and more than 300,000 datasets have been collected altogether.

CHAPTER 3: METHODS

3.1 Aim

The overall aim of this study is to improve care for patients with postoperative pain. Many factors affect postoperative pain and we hope to identify factors that can be improved upon. The findings from this study will also serve as a benchmark for future quality improvement.

3.2 Study Design

This is a cross sectional study. Data were collected from patients' case notes as well as questionnaires (Appendix B &C)

3.3 Study Population

The study was conducted in University Malaya Medical Center from April till September 2016. The elective surgery operation list was examined daily, and patients who fulfilled inclusion criteria are compiled into a list. The patients are then randomly chosen and approached for participation (5 patients a day, from a list of approximately 30 patients).

Inclusion criteria

All patients aged 18 and above,

ASA 1-3

Patients who were admitted for at least 24 hours after surgery (inpatient)

Exclusion criteria

Mental retardation

Sedated and ventilated patients

Patients who have undergone surgeries involving:

Eye, ear, nose and throat

Cardiac surgery

Neuro surgery

3.4 Study procedure and measures

On POD1, the patients were approached in their bed, and given explanation regarding the purpose and methods of the study. A well validated questionnaire (PAINOUT questionnaire, see Appendix A) were used to assess postoperative pain experience.

The questionnaire, available in English and Malay, was composed of 13 questions that examined 5 key areas:

Incidence of Pain

Question 1: On a scale of 0-10, Please indicate the worst pain you had since surgery

Question 2: On a scale of 0-10, Please indicate the least pain you had since surgery

Question 3: On a scale of 0% -100%, how often were you in severe pain since your surgery?

All 3 questions were aggregated to form an overall pain score (PS), with the following formula:

$$PS = Q2 + Q3(Q1-Q2)$$

Most patients experience fluctuating level of pain throughout the day and during different activities. We feel that an aggregated score for pain is need to better represent the overall pain experience. This formula takes into account different pain levels as well as the frequency of severe pain.

Degree of functional disturbance (FD)

Question 4: On a scale of 0-10, how much does pain interfered with

a) Doing activities in bed (turning, sitting up)

b) Breathing deeply or coughing

c) Sleeping

d) Doing activities out of bed (walking, standing)

The score of all sub-questions were combined to form an overall degree of functional disturbance (FD) with the following formula

$$FD = (Q4a + Q4b + Q4c + Q4d)/4$$

Degree of emotional disturbance (ED)

Question 5: On a scale of 0-10 how much does pain caused you to feel

a) Anxious

b) Helpless

The score from these two questions were combined to form an overall score for emotional disturbance (ED) with the following formula

$$ED = (Q5a + Q5b)/2$$

Side effects (SE)

Questions 6a, 6b, 6c, 6d explored the degree of nausea, drowsiness, itching and dizziness respectively on 0-10 scales.

These are the side effects of opioids

Degree of satisfaction towards pain management

Question 7 explored the degree of relief the patient received from the pain treatment. Question 8 assessed if the patients have liked more pain treatment. Question 9 asked if the patient received information about pain treatment options.

Question 10 assessed the degree of patients' participation in pain management, whereas Question 11 asked how satisfied the patients are with the pain treatment on a 0-10 scale.

Demographic variables such as age, gender, weight and height were recorded for the patients. Additionally, the following data were collected from the anaesthetic record and case note: comorbidities, type and duration of surgery, method of anesthesia, dose of opioids and non-opioids received intraoperatively, in recovery room and in ward.

3.5 Statistical Analyses

Data were analyzed using descriptive statistics.

Fisher exact test and logistic regression were used to find associations or differences.

3.6 Ethical and Technical Considerations

All participants were provided with detailed information in English and Malay language, and were asked to participate. The purpose, risks and benefits were explained to the patients prior to participation of the study. The rights of the patient to refuse or withdraw from the study were also informed. The participation of the patients was voluntary and the identity of all the patients remained confidential. This study was approved by the Ethics Committee of University Malaya (MECID.NO: 201632229; Appendix G)

CHAPTER 4: RESULTS

4.1 Demographic Characteristics

This study included 150 patients of whom 100 (67%) were females and 50 (33%) were males. Their age ranged from 18 to 83 years, with the mean age being 49. 46% of the patients were class ASA1. Hypertension (30%), diabetes mellitus (20.7%) and cancer (16.7%) were the three most common comorbidities (Table 4.1)

Most of the patients underwent surgery under general anesthesia (73.3%), while the rest received regional anesthesia. 4 patients underwent a combined general and regional anesthesia. 30.7% of the patients underwent orthopedic surgery, 30.7% underwent gynecology surgery. 16%,10.7% and 9.3% patients underwent urology, breast, and general surgery, respectively.

Table 4.1: Demographic Data

Variables	
Age; years mean(SD)	49.6(15.24)
Gender; n(%)	
Male	50 (33)
Female	100 (67)
Weight; kg	67.9 (13.82)
Height; cm	159.1 (9.78)
Body mass index; $kg.m^{-2}$-	26.91 (5.47)
ASA 1	69 (46)
ASA>1	81 (54)
Comorbidities, n(%)	
Cancer	25(16.7)
HPT	45(30)
DM	31(20.7)
Dyslipidemia	5(3.3)
CVS	8(5.3)
Renal	1(0.67)
Gastrointestinal	4(2.67)
Respiratory	3(2)
Others	3(2)
Type of anesthesia; n(%)	
General Anesthesia (GA)	110 (73.3)
Spinal	22 (14.7)
CSE	6 (4)
Epidural	4 (2.7)
Nerve Block	4 (2.7)
GA + regional	4 (2.7)
Type of surgery; n(%)	
General surgery	14 (9.3)
Orthopedics	46 (30.7)
Gynecology	46 (30.7)
Urology	24 (16)
Breast	16 (10.7)
Thoracic	2 (1.3)
Duration of surgery; n(%)	
<30 mins	10 (6.7)
31-60 mins	50 (33.3)
61-120mins	26 (17.3)
>120mins	64 (42.6)

4.2 Incidence of pain

Of the 150 patients, 110(73.3%) indicated their worst pain since surgery to be moderate to severe; 67(44.7) moderate and 43(28.7%) severe. 25(16.7%) were in severe pain very often. To get an overall pain score (PS), we used the formula

$$PS = Q2 + Q3(Q1-Q2)$$

And we found that 72(48%) reported mild pain, 78(52%) were in moderate to severe pain; of which 64(42.7%) reported moderate pain and 14(9.3%) were in severe pain (Table 4.2).

Table 4.2: Incidence of pain

Worst pain since surgery?	n	%
No pain	4	2.7
Low	36	24.0
Moderate	67	44.7
Severe	43	28.7
Least pain since surgery?	**n**	**%**
No pain	16	10.7
Low	83	55.3
Moderate	49	32.7
Severe	2	1.3
How often were you in severe pain?	**n**	**%**
Not often	70	46.7
Sometimes	55	36.7
Very often	25	16.7
Overall Pain Score	**n**	**%**
Mild	72	48
Moderate	64	42.7
Severe	14	9.3

4.3 Degree of functional disturbance

We examined how much patients' physical activities were affected by postoperative pain. It was found that the pain interfered more with activities in bed such as turning and sitting up (mean score 4.31 ± 2.665) than with coughing (2.71±2.55) and sleeping (2.97±2.66).

Half of the patients reported mild functional disturbance, 72(48%) reported moderate disturbance and only 3(2%) were severely disturbed by pain (Table 4.3)

Table 4.3 Degree of functional disturbance

On a scale of 0-10, how much does pain interfere with:	mean	SD
a. Activities in bed (turning, sitting up)	4.31	2.665
b. Breathing deeply or coughing	2.71	2.555
c. Sleeping	2.97	2.663
d. Activities out of bed (standing, walking)	3.27	2.145
Overall Functional Disturbance score	**n**	**%**
Mild (0,1,2,3)	75	50
Moderate (4,5,6,7)	72	48
Severe (8,9,10)	3	2

Logistic regression analysis was done and moderate to severe pain score was a strong risk factor for functional disturbance as well as emotional disturbance (Table 4.4).

Table 4.4 logistic regression – Functional Disturbance vs Pain Score

Functional Disturbance	Odd Ratio	p value
Pain Score (moderate-severe vs mild)	7.636	<0.01

4.4 Degree of emotional disturbance

When asked about the feeling of anxiety, the patients reported a score of 3.3±2.73. Their mean score was 3.28±2.77 for the feeling of helplessness.

For overall emotional disturbance, 77(51.3%) reported mild disturbance, 59(39.3%) reported moderate disturbance and 14(9.3%) had severe emotional disturbance (Table 4.5).

Table 4.5 Degree of emotional disturbance

On a scale of 0-10, how much does pain cause you to feel:	mean	SD
a. Anxious	3.3	2.734
b. Helpless	3.28	2.771
Overall Emotional Disturbance score	**n**	**%**
Mild (0,1,2,3)	77	51.3
Moderate (4,5,6,7)	59	39.3
Severe (8,9,10)	14	9.3

Moderate to severe pain was associated with higher level of emotional disturbance (Table 4.6)

Table 4.6 logistic regression – Emotional Disturbance vs Pain Score

Emotional Disturbance	Odd Ratio	p value
Pain Score (moderate-severe vs mild)	4.636	<0.01

4.5 Level of Satisfaction

34% of the patients would have liked to have more pain treatment. 55% received adequate information regarding their pain treatments. The mean score for satisfaction is 7.23±2.3 (Table 4.7).

Table 4.7 Level of satisfaction

	mean	SD
How much pain relief have you received? (0-100%)	56.9	23.69
Would you have liked more pain treatment?	n	(%)
Yes	51	34
No	99	66
Did you receive information about your pain treatment	n	(%)
Yes	83	55.3
No	67	44.7
Were you allowed to participate in pain treatment decisions?	4.88	3.407
How satisfied are you with the pain treatment?	n	%
Not satisfied	10	6.7
Acceptable	61	40.7
Very satisfied	79	52.6

A logistic regression was performed to look for factors affecting degree of satisfaction. Pain score, age and gender did not affect degree of satisfaction in a statistically significant manner (Table 4.8)

Table 4.8 Logistic regression – Degree of satisfaction vs Pain Score, Age, Gender

Degree of satisfaction	Odd Ratio	p value
Pain Score	0.635	0.254
Age	1.416	0.3988
Female vs Male	2.041	0.12539

4.6 Comparison of pain score to identify risk factors

A logistic regression was performed to identify independent risk factors for pain score being reported as moderate or severe. Younger age, ASA>1 and orthopedics surgery were identified as statistically significant independent risk factors. Urology surgery was associated with lower incidence of moderate to severe pain. Duration of surgery was taken as a surrogate marker for grading of surgery, i.e. surgery that takes >120mins were considered major. However, it did not show any significant correlation with the pain score (Table 4.8).

Table 4.9 Logistic regression – Risk factors for High Pain Score

Variables	Odd Ratio	p value
Age <50 (vs >50)	2.400	0.0275 *
Female vs male	0.945	0.894
ASA 1 vs ASA>1	0.421	0.0283 *
GA vs non-GA	0.941	0.876
Type of surgery		
Breast surgery	0.472	0.1683
Urology	0.253	0.0175 *
Gynecology	1.235	0.595
General Surgery	2.186	0.261
Orthopedics	3.417	0.0237 *
Duration of surgery		
<120min vs >120min	1.056	0.893

4.7 Opioids, non-opioids and side effects

Only 114 patients who underwent general anesthesia were included in this section. In UMMC, the common opioids used were fentanyl and morphine intraoperatively, with morphine and tramadol being the most commonly used opioids post operatively. For easy calculation, all opioids were recorded in equipotent dose to morphine.

1 mg of morphine = 10mcg of fentanyl = 10mg of tramadol

Non-opioids used were paracetamol, parecoxib, celecoxib and diclofenac acid. From the table below, we see that 73% of the patients were given non-opioids intraoperatively, and most of the patients (92.1%) were given non-opioids in the ward. The mean total doses of opioids given postoperatively were around 7.3±10 mg over 24 hours (Table 4.9)

Table 4.10 Analgesics received during surgery

	n = 114
Received non-opioids intraoperatively, n(%)	73 (64)
Received non-opioids in RR, n(%)	6 (5.3)
Received non-opioids in ward, n(%)	105 (92.1)
Cumulative dose of opioids intraoperative, mean (SD)	14.23 (4.418)
Cumulative dose of opioids in RR, mean (SD)	2.71 (4.394)
Cumulative dose of opioids in ward, mean (SD)	7.29 (10.844)

While comparing patients who received non-opioids intraoperatively to those who did not, it was found that the mean pain score reported was lower in those who were given non-opioids (Table 4.10)

Table 4.11 Opioids + non-opioids vs Opioids only intraoperatively

	n	mean	SD
Opioids + non-opioids intraoperatively	73	3.67	2.085
Opioids only intraoperatively	41	4.11	2.525

Regarding the side effects of opioids, most patients experienced mild discomfort. The mean score for the side effects were given in the table below (Table 4.11)

Table 4.12 Side effects of opioids

On a scale of 0-10, how severe are these side effects:	mean	SD
Nausea	2.31	2.752
Drowsiness	3.23	2.888
Itching	1.17	2.005
Dizziness	2.57	2.691

CHAPTER 5: DISCUSSION

The 0-10 pain scale is a widely-used method to assess pain. A pain score of >4 is generally considered moderate, and >7 is considered severe. Both moderate and severe pain require immediate actions from the healthcare service providers.

A meta-analysis by Dolin SJ (2002) involving 165 papers (nearly 20,000 patients) found that 29.7% of the patients reported moderate to severe postoperative pain [16]. Depending on the method of assessment, most studies reported the incidence of moderate-severe pain within the range of 40-70% [5,6,12,13,14,15,16,17]. From our study, the incidence of moderate-severe postoperative pain in UMMC is 52% in the population of patients surveyed.

When the incidence of postoperative pain is looked at from multiple studies, it can be said that postoperative pain continues to be undermanaged. The establishment of APS was expected to improve postoperative pain management, but an analysis in 2012 (20 years after the introduction of APS) found no real progress in acute pain treatment [6].

From this survey, we see that opioids were being under prescribed. Among patients who received GA, the mean total dose of intraoperative opioid is 14.23mg morphine-equivalent. Considering virtually all of these patients were given 100mcg of fentanyl (10mg morphine equivalent) prior to induction of anesthesia, the effective long acting opioid dose is only around 4mg on average. This might have contributed to higher incidence of postoperative pain. Considering that patients generally experienced very little side effects of opioids, there might still be room for a higher dose of opioids. The core problem here is the clinicians' fear of side effects.

One factor that leads to the under management of postoperative pain is the lack of patient education. Admittedly, some degree of pain is to be expected after any surgery, but a patient might be experiencing moderate to severe pain and yet think it is normal, hence do not raise it to the attending doctors. The patients may also choose to be silent to avoid being labelled as "difficult".

Another barrier to good pain management is the attitude of doctors and nurses in the primary teams [17]. In the postoperative wards, patients are taken care of by house officers. Very often, the focus of care is on level of functional recovery i.e. passing of flatus after bowel surgery or the ability to weight bear after a knee replacement. Lab results also received considerable attention and efforts are made to "correct the numbers". Pain is often not addressed adequately.

There is growing evidence that the efficacy of analgesics differs between different surgical procedures [18]. An initiative was created (PROSPECT, procedure specific postoperative pain management) to collect and review data in order to formulate recommendations of pain relief methods for different types of surgical procedure.

Recently there are new and exciting methods to deal with acute postoperative pain. Advances in the knowledge of molecular mechanisms have led to the development of multimodal analgesia and new pharmaceutical products to address postoperative pain [19]. New products, such as capsaicin, ketamine, gabapentin, pregabalin and dexmedetomidine, have shown promising results when used as adjuvants. Some existing drugs, such as paracetamol (in intravenous preparation), clonidine and adenosine, have also regained popularity as adjuncts to opioids in intraoperative and postoperative pain management [20]. In UMMC, ketamine and IV paracetamol are occasionally used

intraoperatively, while gabapentin and pregabalin are used mainly to treat chronic neurogenic pain.

From this survey, higher pain score is associated with higher functional and emotional disturbance. Though we cannot conclude that pain is the reason for all the functional and emotional disturbances, it still makes sense to keep pain as low as possible. With pain under control, the patients may be able to sleep better and mobilize earlier, all of which contribute to faster recovery [21,22].

LIMITATIONS

The main theatre of UMMC was closed for renovation starting from July 2016. Surgeries were conducted in periphery operation theatres (Menara Timur, Menara Selatan, Woman & Child Health Complex, Trauma Centre, CIGMIT). This has caused our data collection to be difficult.

Questionnaire survey requires cooperative and relaxed respondents. The inherent flaw in assessing pain via questionnaire is that, a patient might be in so much pain and distress that he will just refuse to answer any question. This might contribute to a falsely low prevalence of postoperative pain.

We obtained information from GA forms regarding analgesics. From our experience, local anesthetics were often injected around surgical incision sites, but this was never recorded. Thus, we were unable to examine its effect on pain experience.

CHAPTER 6: CONCLUSION

Acute postoperative pain remains prevalent worldwide despite increased awareness, newer analgesics and improved surgical techniques. Fortunately, this problem is being recognized and efforts are underway to address it.

Opioids are still the mainstay of treatment for acute postoperative pain of moderate-severe intensity. Multimodal pain management methods may achieve its opioid sparing effect, thereby reducing side effects, but it has little effect on the overall pain experience. There are some exciting new products that show promising results as analgesic adjuncts, but the usage is still very limited.

Opioid use is associated with many undesired side effects, making it difficult for healthcare providers to achieve satisfactory pain relief with minimal side effects. Careful titration of opioids and close monitoring may be able to achieve this goal, but it is labour intensive and probably not financially feasible. To improve patients' postoperative pain experience from here, a newer approach is needed.

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APPENDICES

Appendix A: Data Collection Form - Page 1/7

PAIN OUT DATA COLLECTION FORM

A. DATE:	D. RESEARCH ASSISTANT CODE
B. TIME:	PATIENT CODE
C. WARD:	ROOM NUMBER

SCREENING – INCLUSION CRITERIA		
	yes	no
S1 Time of data collection is POD1 AND patient is 6 hrs (minimum) in the ward		
S2 Patient is consenting age or over		
S3 Patient has given his consent to participate		

DEMOGRAPHIC INFORMATION	
D1 Gender ☐ Male ☐ Female	**D2** Year of birth:
D3 Weight:	**D4** Height:
D5 Nationality:	**D6** Country of birth:
D7 Language of Outcome questionnaire:	

Mark medications *given* to patient; record *cumulative* doses.

MEDICAL HISTORY

H1 Comorbidities ☐ yes ☐ no

If yes, which (check all that apply);

Cancer	☐ Cancer
Renal	☐ Dialysis ☐ without dialysis
Psychiatric	☐ Affective disorders (depression, anxiety, phobia, PTSD, bipolar) ☐ Schizophrenia ☐ Alcohol use disorder ☐ Substance abuse of drugs (legal and illegal)
Cardiovascular	☐ HPT ☐ CAD ☐ CVA
Hematology	☐ Sickle cell disease
GI disease	☐ Liver cirrhosis ☐ GI ulcer disease ☐ Irritable bowel disease (Crohn's, ulcerative colitis)
Pulmonary disease	☐ Asthma ☐ OSA ☐ COPD
Neurologic	☐ Fibromyalgia
Steroid use	☐ Regular usage of oral or parenteral corticosteroid
Multiple trauma	☐ At least 1 fracture(s)/laceration(s)/tissue damage in addition to the current reason for surgery
Other surgery	☐ Patient has already undergone another surgery during current hospitalization
	☐ Other, specify:

H2 Existing condition

☐ Pregnancy, Week: _____

☐ Lactation

H3 Did the patient receive any opioid(s) before the current admission?

☐ Yes ☐ no ☐ not possible to obtain the information

If yes, which:

Name	Dosage/day	remark

PRE – MEDICATION

M1 Sedatives (pre-medication)

☐ Yes ☐ no ☐ not possible to obtain the information

If yes, which:

Name	dosage	remark
midazolam	mg	

M2 Non-opioids (pre-medication)

☐ Yes ☐ no ☐ not possible to obtain the information

If yes, which

Name	Dosage	Route
Celecoxib (Celebrex)	mg	PO / IV / IM / SC / Supp
Diclofenac (Voltaren)	mg	
Etoricoxib (Arcoxia)	mg	
Parecoxib (Dynastat)	mg	
Paracetamol	mg	
Gabapentin	mg	
Pregabalin (Lyrica)	mg	
Other,specify:		

M3 Opioids (pre-medication)

☐ Yes ☐ no ☐ not possible to obtain the information

If yes, which

Name	Dosage	Route
Morphine	mg	PO / IV / IM / SC / Supp
Oxycodone	mg	
Oxycodone + naloxone (Targin)	mg	
Tramadol	mg	
Fentanyl	mcg	
Other,specify:		

SURGICAL PROCEDURE(S)

P1 Surgical procedure(s) *use ICD-9 codes link* http://icd9cm.chrisendres.com/index.php?action=procslist

ICD-9 Procedure Code	Text
1.	
2.	
3.	
4.	

P2 Duration of surgery

Start surgery: Date: ____/____/____ Time: ____:_____

End surgery: Date: ____/____/____ Time: ____:_____

INTRA-OPERATIVE

M4 General anaesthesia (intra-op)

☐ Yes ☐ no ☐ not possible to obtain the information

If yes, which

☐ Inhalational ☐ IV

M5 Regional anaesthesia (RA) (intra-op)

☐ Yes ☐ no ☐ not possible to obtain the information

If yes, which

☐ Epidural	☐ Spinal	☐ Brachial Plexus	☐ Femoral
☐ Sciatic	☐ Other:	☐ Other:	☐ Other:

M6 Non-opioids (intra-op)

☐ Yes ☐ no ☐ not possible to obtain the information

Name	Dosage	Route
Ketamine	mg	PO / IV / IM / SC / Supp
Diclofenac (Voltaren)	mg	
Parecoxib (Dynastat)	mg	
Paracetamol	mg	
Other,specify:		

M7 Wound infiltration (intra-op)

☐ Yes ☐ no ☐ not possible to obtain the information

If yes, which

☐ Single shot by surgeon ☐ Indwelling catheter

☐ Other, specify:

M8 Opioids

☐ Yes ☐ no ☐ not possible to obtain the information

If yes, which

Name	Dosage	Route
Fentanyl	mcg	PO / IV / IM / SC / Supp
Morphine	mg	
Oxycodone	mg	
Pethidine	mg	
Tramadol	mg	
Remifentanil	mcg	
Other,specify:		

RECOVERY ROOM

M9 Non-opioids (recovery room)

☐ Yes ☐ no ☐ not possible to obtain the information

If yes, which

Name	Dosage	Route
Ketamine	mg	PO / IV / IM / SC / Supp
Diclofenac (Voltaren)	mg	
Parecoxib (Dynastat)	mg	
Celecoxib (Celebrex)	mg	
Etoricoxib (Arcoxia)	mg	
Paracetamol	mg	
Other,specify:		

M10 Regional anaesthesia (recovery room)

☐ Yes ☐ no ☐ not possible to obtain the information

If yes, which

☐ Epidural	☐ Spinal	☐ Brachial Plexus	☐ Femoral
☐ Sciatic	☐ Other:	☐ Other:	☐ Other:

M11 Opioids

☐ Yes ☐ no ☐ not possible to obtain the information

If yes, which

Name	Dosage	Route
Fentanyl	mcg	PO / IV / IM / SC / Supp
Morphine	mg	
Oxycodone	mg	
Pethidine	mg	
Tramadol	mg	
Other,specify:		

WARD

M12 Non-opioids (ward)

☐ Yes ☐ no ☐ not possible to obtain the information

If yes, which

Name	Dosage	Route
Celecoxib (Celebrex)	mg	PO / IV / IM / SC / Supp
Diclofenac (Voltaren)	mg	
Etoricoxib (Arcoxia)	mg	
Parecoxib (Dynastat)	mg	
Paracetamol	mg	
Gabapentin	mg	
Pregabalin (Lyrica)	mg	
Other,specify:		

M13 Regional anaesthesia (ward)

☐ Yes ☐ no ☐ not possible to obtain the information

If yes, which

☐ Epidural	☐ Spinal	☐ Brachial Plexus	☐ Femoral
☐ Sciatic	☐ Other:	☐ Other:	☐ Other:

M14 Opioids

☐ Yes ☐ no ☐ not possible to obtain the information

If yes, which

Name	Dosage	Route
Fentanyl	mcg	PO / IV / IM / SC / Supp
Morphine	mg	
Oxycodone	mg	
Pethidine	mg	
Tramadol	mg	
Other,specify:		

M15 Measurement of pain: Was pain documented as defined in the SOPs?

☐ Yes ☐ no ☐ not possible to obtain the information

PATIENT CODE:

PATIENT OUTCOMES QUESTIONNAIRE

The following questions are about pain you experienced since your surgery.

P1. On this scale, please indicate the **worst pain** you had since your surgery:

0	1	2	3	4	5	6	7	8	9	10

no pain — **worst pain possible**

P2. On this scale, please indicate the **least pain** you had since your surgery:

0	1	2	3	4	5	6	7	8	9	10

no pain — **worst pain possible**

P3. How often were you in **severe pain** since your surgery?
Please circle your best estimate of the percentage of time you experienced **severe pain:**

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

never in severe pain — **always in severe pain**

P4. Circle the one number below that best describes how much, since your surgery, **pain interfered with or prevented you from ...**

a. doing **activities in bed** such as turning, sitting up, changing position:

0	1	2	3	4	5	6	7	8	9	10

did not interfere — **completely interfered**

b. **breathing deeply** or **coughing**:

0	1	2	3	4	5	6	7	8	9	10

did not interfere — **completely interfered**

c. **sleeping**:

0	1	2	3	4	5	6	7	8	9	10

did not interfere — **completely interfered**

d. Have you been **out of bed** since your surgery?

☐ No ☐ Yes

If yes, how much did **pain interfere or prevent you from doing activities out of bed** such as walking, sitting in a chair, standing at the sink:

0	1	2	3	4	5	6	7	8	9	10

did not interfere — **completely interfered**

PATIENT CODE:

PATIENT OUTCOMES QUESTIONNAIRE

P5. Pain can affect our mood and emotions.
On this scale, please circle the one number that best shows how much, since your surgery, **pain caused you to feel ...**

a. **anxious**

0	1	2	3	4	5	6	7	8	9	10

not at all **extremely**

b. **helpless**

0	1	2	3	4	5	6	7	8	9	10

not at all **extremely**

P6. Have you had any of the following **side effects** since your surgery?
Please circle "0" if no; if yes, circle the one number that best shows the severity of each:

a. **Nausea**

0	1	2	3	4	5	6	7	8	9	10

none **severe**

b. **Drowsiness**

0	1	2	3	4	5	6	7	8	9	10

none **severe**

c. **Itching**

0	1	2	3	4	5	6	7	8	9	10

none **severe**

d. **Dizziness**

0	1	2	3	4	5	6	7	8	9	10

none **severe**

P7. Since your surgery, how much **pain relief** have you received?
Please circle the one percentage that best shows how much relief you have received from all of your **pain treatments** combined (medicine and non-medicine treatments):

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

no relief **complete relief**

P8. Would you have liked **MORE pain treatment** than you received?

☐ No ☐ Yes

P9. Did you receive any **information** about your **pain treatment** options?

☐ No ☐ Yes

Version 2a 10.1.201

PATIENT CODE:

PATIENT OUTCOMES QUESTIONNAIRE

P10. Were you **allowed to participate in decisions** about your **pain treatment** as much as you wanted to?

0	1	2	3	4	5	6	7	8	9	10

not at all **very much so**

P11. Circle the one number that best shows how **satisfied** you are with the results of your **pain treatment** since your surgery:

0	1	2	3	4	5	6	7	8	9	10

extremely dissatisfied **extremely satisfied**

P12. Did you use or receive any **non-medicine methods** to relieve your **pain**?

☐ No ☐ Yes

If yes, **check all** that apply:

☐ cold pack ☐ meditation ☐ deep breathing
☐ heat ☐ acupuncture ☐ prayer
☐ talking to medical staff ☐ walking ☐ massage
☐ talking to friends or relatives ☐ relaxation ☐ imagery or visualization
☐ TENS (Transcutaneous Electrical Nerve Stimulation)
☐ distraction (like watching TV, listening to music, reading)
☐ other (please describe):

P13. Did you have a **persistent painful condition for 3 months** or more before coming into hospital for this surgery?

☐ No ☐ Yes

a. If yes, **how severe** was the **pain** most of the time?
Please circle the number that indicates this.

0	1	2	3	4	5	6	7	8	9	10

no pain **worst pain possible**

b. If yes, **where** was this **persistent pain** located?

☐ site of surgery ☐ elsewhere ☐ both (site of surgery and elsewhere)

Thank you for your time and feedback

To be filled in by the research assistant

Research assistant code:

Patient was interviewed: ☐ No ☐ Yes

If yes, please mark the reason(s):

☐ Too ill / weak ☐ Too much pain ☐ Requested assistance ☐ Did not understand scales
☐ Technical reasons (patient has no eyeglasses / is blind; can not sit up; is illiterate; arm is in cast; etc)

Version 2.6.101201

Appendix C: PAINOUT outcome questionnaire (Bahasa Melayu) – Page 1/3

patient code:

SOAL SELIDIK PESAKIT

Berikut adalah soalan-soalan mengenai kesakitan yang anda alami semenjak anda menjalani pembedahan.

P1. Menggunakan skala di bawah, sila pilih tahap kesakitan **paling teruk** yang anda alami semenjak anda menjalani pembedahan:

0	1	2	3	4	5	6	7	8	9	10

tiada kesakitan — **kesakitan paling teruk**

P2. Menggunakan skala di bawah, sila pilih tahap kesakitan **paling minima** yang anda alami semenjak anda menjalani pembedahan:

0	1	2	3	4	5	6	7	8	9	10

tiada kesakitan — **kesakitan paling teruk**

P3. Berapakah kerap anda merasa **kesakitan yang teruk** semenjak anda menjalani pembedahan?
Sila bulatkan anggaran yang terbaik dari segi peratusan masa dimana anda mengalami kesakitan yang teruk:

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

tidak pernah mengalami kesakitan yang teruk — **selalu mengalami kesakitan yang teruk**

P4. Sila bulatkan salah satu nombor di bawah yang paling tepat menggambarkan sejauh mana, semenjak anda menjalani pembedahan, kesakitan tersebut, **mengganggu atau menghalang anda daripada ...**

a. Melakukan **aktiviti di atas katil** seperti memusingkan badan, duduk, menukar posisi badan:

0	1	2	3	4	5	6	7	8	9	10

tidak mengganggu — **sangat mengganggu**

b. **Bernafas secara mendalam atau batuk:**

0	1	2	3	4	5	6	7	8	9	10

tidak mengganggu — **sangat mengganggu**

c. **Tidur:**

0	1	2	3	4	5	6	7	8	9	10

tidak mengganggu — **sangat mengganggu**

d. Adakah anda **meninggalkan katil** anda semenjak menjalani pembedahan?

☐ Tidak ☐ Ya

Jika ya, sejauh manakah **rasa sakit tersebut mengganggu atau menghalang anda daripada melakukan aktiviti-aktiviti di luar katil** seperti berjalan, duduk di atas kerusi, berdiri di singki?

0	1	2	3	4	5	6	7	8	9	10

tidak mengganggu — **sangat mengganggu**

SOAL SELIDIK PESAKIT

P5. Rasa sakit boleh menjejas ragam angina (mood) dan emosi kita.

Menggunakan skala ini, sila bulatkan satu nombor yang paling tepat menggambarkan sejauh mana, semenjak anda menjalani pembedahan, **kesakitan telah menyebabkan anda berasa:**

a. gelisah

0	1	2	3	4	5	6	7	8	9	10

Langsung tidak — teramat sangat

b. tidak berdaya

0	1	2	3	4	5	6	7	8	9	10

Langsung tidak — teramat sangat

P6. Adakah anda mengalami **kesan-kesan sampingan** yang berikut semenjak menjalani pembedahan? Sila bulatkan "0" jika tidak; jika ya, bulatkan satu nombor yang paling tepat menggambarkan tahap keterukan setiap keadaan tersebut:

a. Rasa loya

0	1	2	3	4	5	6	7	8	9	10

tiada — teruk

b. Mengantuk

0	1	2	3	4	5	6	7	8	9	10

tiada — teruk

c. Rasa gatal

0	1	2	3	4	5	6	7	8	9	10

tiada — teruk

d. Pening

0	1	2	3	4	5	6	7	8	9	10

tiada — teruk

P7. Semenjak anda menjalani pembedahan, sejauh mana kelegaan kesakitan yang telah anda terima? Sila bulatkan peratusan yang paling tepat menggambarkan tahap keredaan yang anda terima daripada kesemua rawatan untuk **menahan kesakitan** (rawatan menggunakan ubat dan rawatan tanpa ubat):

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

tidak meredakan kesakitan — meredakan kesakitan sepenuhnya

P8. Adakah anda inginkan **LEBIH BANYAK rawatan menahan kesakitan** daripada yang anda terima?

☐ Tidak ☐ Ya

P9. Adakah anda menerima sebarang **maklumat** tentang pilihan-pilihan **rawatan menahan kesakitan** yang sedia ada?

☐ Tidak ☐ Ya

SOAL SELIDIK PESAKIT

P10. Adakah anda **dibenarkan melibatkan diri dalam membuat keputusan tentang rawatan untuk menahan kesakitan** anda seperti mana yang anda ingini?

0	1	2	3	4	5	6	7	8	9	10

Langsung tidak **tentu sekali**

P11. Sila bulatkan salah satu nombor di bawah yang paling tepat menggambarkan tahap **kepuasan** anda dengan hasil **rawatan menahan kesakitan** anda semenjak menjalani pembedahan:

0	1	2	3	4	5	6	7	8	9	10

amat tidak puas hati **amat puas hati**

P12. Adakah anda menggunakan atau menerima sebarang **rawatan tanpa ubat** (non-medicine method) untuk meredakan kesakitan anda?

☐ Tidak ☐ Ya

Jika ya, **tandakan semua** yang berkenaan:

☐ pek sejuk
☐ Rawatan haba
☐ Bercakap dengan kakitangan perubatan
☐ Bercakap dengan kawan/saudara-mara
☐ TENS (Transcutaneous Electrical Nerve Stimulation
☐ Alihkan perhatian (seperti menonton TV, mendengar muzik, membaca
☐ lain-lain (sila nyatakan):
☐ Meditasi
☐ Akupunktur
☐ Berjalan
☐ bersantai
☐ Bernafas secara mendalam
☐ Sembahyang
☐ Urut
☐ Imejan atau pembayangan

P13. Adakah anda mengalami **kesakitan yang berterusan selama 3 bulan** atau lebih daripada 3 bulan sebelum datang ke hospital untuk menjalani pembedahan ini?

☐ Tidak ☐ Ya

a. Jika ya, apakah **tahap kesakitan** tersebut pada kebanyakan masa?

0	1	2	3	4	5	6	7	8	9	10

tiada kesakitan **kesakitan paling teruk**

b. Jika ya, **di manakah kesakitan berterusan** ini dirasai?

☐ di tempat yang dibedah ☐ di tempat selain daripada tempat yang dibedah
☐ kedua-dua sekali (di tempat yang dibedah dan tempat selain daripada tempat yang dibedah)

Terima kasih kerana meluangkan masa untuk memberikan maklum balas

---

To befilled in by the research assistant Research assistant code: ☐

Patient was interviewed: ☐ No ☐ Yes

If yes, please mark the reason(s):

☐ Too ill / weak ☐ Too much pain ☐ Requested assistance ☐ Did not understand scales
☐ Technical reasons (patient has no eyeglasses / is blind; can not sit up; is illiterate; arm is in cast; etc)

Appendix D: Patient Consent Form (English)

UNIVERSITY MALAYA MEDICAL CENTRE

CONSENT BY PATIENT FOR CLINICAL RESEARCH

Please create Version No. and Version Date for this document:

Version No.: 1.03
Version Date: 7/3/16

I, ...
Identity Card No.....
(Name of Patient)
of .....
(Address)
hereby agree to take part in the clinical research (clinical study/questionnaire study/drug trial) specified below:

Title of Study: A Survey on Patients' Postoperative Pain Experience

the nature and purpose of which has been explained to me by
Dr. .....
(Name & Designation of Doctor)

and interpreted by .....
(Name & Designation of Interpreter)

..... to the best of his/her ability in ..... language/dialect.

I have been told about the nature of the clinical research in terms of methodology, possible adverse effects and complications (as per patient information sheet). After knowing and understanding all the possible advantages and disadvantages of this clinical research, I voluntarily consent of my own free will to participate in the clinical research specified above.

I understand that I can withdraw from this clinical research at any time without assigning any reason whatsoever and in such a situation shall not be denied the benefits of usual treatment by the attending doctors.

Date: ..... Signature or Thumbprint .....
(Patient)

IN THE PRESENCE OF

Name .....)
)
Identity Card No. .....) Signature
(Witness for Signature of Patient)
Designation .....)

I confirm that I have explained to the patient the nature and purpose of the above-mentioned clinical research.

Date ..... Signature .....
(Attending Doctor)

CONSENT BY PATIENT
FOR
CLINICAL RESEARCH

R.N.
Name
Sex
Age
Unit

BK-MIS-1117-E02

Appendix E: Patient Consent Form (Bahasa Melayu)

UNIVERSITY MALAYA MEDICAL CENTRE

KEIZINAN OLEH PESAKIT UNTUK PENYELIDIKAN KLINIKAL

Sila letakkan Nombor Versi dan Tarikh Versi untuk dokumen ini:

Nombor Versi: 1.03
Tarikh Versi: 7/3/16

Saya,.....
No. Kad Pengenalan .....
(Nama Pesakit)

beralamat.....
(Alamat)

dengan ini bersetuju menyertai dalam penyelidikan klinikal (pengajian klinikal/pengajian soal-selidik/percubaan ubat-ubatan) disebut berikut:

TajukPenyelidikan: A Survey on Patients' Postoperative Pain Experience

yang mana sifat dan tujuannya telah diterangkan kepada saya oleh Dr.....
(Nama & Jawatan Doktor)

mengikut terjemahan .....
(Nama & Jawatan Penterjemah)

..... yang telah menterjemahkan kepada saya dengan sepenuh kemampuan dan kebolehannya di dalam Bahasa / loghat.....

Saya telah diberitahu bahawa dasar penyelidikan klinikal dalam keadaan methodologi, risiko dan komplikasi (mengikut kertas maklumat pesakit). Selepas mengetahui dan memahami semua kemungkinan kebaikan dan keburukan penyelidikan klinikal ini, saya merelakan/mengizinkan sendiri menyertai penyelidikan klinikal tersebut di atas.

Saya faham bahawa saya boleh menarik diri dari penyelidikan klinikal ini pada bila-bila masa tanpa memberi sebarang alasan dalam situasi ini dan tidak akan dikecualikan dari kemudahan rawatan dari doktor yang merawat.

Tarikh: ..... Tandatangan/Cap Jari .....
(Pesakit)

DI HADAPAN

Nama .....)
)
No. K/P.....) Tandatangan
.....
) *(Saksi untuk Tandatangan Pesakit)*
Jawatan .....)

Saya sahkan bahawa saya telah menerangkan kepada pesakit sifat dan tujuan penyelidikan klinikal tersebut di atas.

Tarikh: ..... Tandatangan .....
(Doktor yang merawat)

KEIZINAN OLEH PESAKIT
UNTUK
PENYELIDIKAN KLINIKAL

No. Pend.
Nama
Jantina
Umur
Unit

BK-MIS-1117-E02

MEDICAL ETHICS COMMITTEE
UNIVERSITY MALAYA MEDICAL CENTRE

PATIENT INFORMATION SHEET

Please create Version No. and Version Date for this document:

Version No.: 1.03
Version Date: 7/3/16

Attention to the investigator: Please fill in simple layman language as you would speak to research subjects.

Please read the following information carefully, do not hesitate to discuss any questions you may have with your Doctor/Investigator

1. **Study Title:**

   A Survey on Patients' Postoperative Pain Experience

2. **Introduction (Scientific basis of the study)**

   Pain after surgery remains one of the major concern for patients. Inadequate pain relief after surgery not only affects patients physically and emotionally, it also impedes recovery and rehabilitation.

   Adequate pain control after surgery is essential for a pleasant postoperative experience as well as for recovery from the surgery.

   In UMMC, we have a dedicated team of doctors and nurses providing Acute Pain Service (APS) to postoperative patients.

3. **What is the purpose of this study?**

   This study is aimed at identifying factors that affects severity of pain, as well as to look at the level of satisfaction of patients with our pain service.

4. **What are the procedures to be carried out?**

   Subjects will be asked to complete a questionnaire on the first day after surgical operation.

5. How long will I be involved in this study?

The questionnaire will take up 5-10 minutes of your time.

6. Who should not enter the study (exclusion criteria)?

Subjects who are illiterate and those who are mentally challenged

7. How many patients/research subjects will be recruited into this study?

200

8. Who will have access to the subjects medical records or research data?

The data will be kept by the Principal Investigator. All data are private and confidential.

9. Will the records/data be kept confidential?

Yes

10. What will be the benefits of the study to the subject?

There will be no direct benefit to the study subject. However, your participation will enable us to have a better understanding of the patients' experience with pain and allow us to improve on our service.

11. What are the possible drawbacks (side effects, etc.)?

None

12. Is the investigatory product derived from a source that may be cultural sensitive, eg: bovine or porcine? (if applicable)

None

13. What payments or reimbursement will research subjects receive?

None

14. Can I refuse to take part in the study?

Yes. And your decision will not affect the current treatment given.

15. Who should I contact if I have additional questions during the course of the study?

Doctor's name: Dr Yeo King Hong **H/P no.: 0129503058**

BK-MIS-1116-E03

Appendix G: Ethics Committee Approval Letter

UNIVERSITY OF MALAYA MEDICAL CENTRE
MEDICAL ETHICS COMMITTEE
UNIVERSITY MALAYA MEDICAL CENTER
ADDRESS : LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA
TELEPHONE : 03-79493209/2251 FAXIMILE : 03-79492030

NAME OF ETHICS COMMITTEE/IRB Medical Ethics Committee, University Malaya Medical Center	MECID.NO: 20163-2229
ADDRESS : LEMBAH PANTAI, 59100 KUALA LUMPUR	
PROTOCOL.NO(if applicable) :	
TITLE: A Survey on Patients' Postoperative Pain Experience	
PRINCIPAL INVESTIGATOR : Dr Yeo King Hong	SPONSOR -

The following item [✓] have been received and reviewed in connection with the above study to conducted by the above investigator.

[✓] Application to Conduct Research Project(form)	Ver.No :	Ver.Date : 02-03-2016
[✓] Study Protocol	Ver.No :	Ver.Date :
[✓]	Ver.No :	Ver.Date :
[✓]	Ver.No :	Ver.Date :
[ ] Questionnaire	Ver.No :	Ver.Date :
[✓] Investigator's CV / GCP (Dr Yeo King Hong,RAMANI VIJAYAN SANNASI,)	Ver.No :	Ver.Date :
[ ] Insurance certificate	Ver.No :	Ver.Date :
[✓] Other Attachments		
1) Questionnaire BM	Ver.No : 1.01	Ver.Date : 01-03-2016
2) Questionnaire ENG	Ver.No : 1.01	Ver.Date : 01-03-2016
3) Data Collection Form	Ver.No : 1.01	Ver.Date : 01-03-2016

and the decision is [✓]

[✓] Approved

[ ] Rejected(reasons specified below or in accompanying letter)

Comments:

Questionnaire study

Investigator are required to:

1) *follow instructions, guidelines and requirements of the Medical Ethics Committee.*
2) *report any protocol deviations/violations to Medical Ethics Committee.*
3) *provide annual and closure report to the Medical Ethics Committee.*
4) *comply with International Conference on Harmonization – Guidelines for Good Clinical Practice (ICH-GCP) and Declaration of Helsinki.*
5) *obtain a permission from the Director of UMMC to start research that involves recruitment of UMMC patient.*
6) *ensure that if the research is sponsored, the usage of consumable items and laboratory tests from UMMC services are not charged in the patient's hospital bills but are borne by research grant.*
7) *note that he/she can appeal to the Chairman of MEC for studies that are rejected.*
8) *note that Medical Ethics Committee may audit the approved study.*
9) *ensure that the study does not take precedence over the safety of subjects.*

Date of approval : 11-03-2016

This is a computer generated letter. No signature required.