#### VISUAL ESTIMATION OF BLOOD LOSS

DURING CAESAREAN SECTION

A PROSPECTIVE REVIEW

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#### ABSTRACT

**BACKGROUND**: One of the major threats to women during childbirth is excessive bleeding. Visual estimation of blood loss has been known to be inaccurate and imprecise, may contribute to delay institution of adequate resuscitation. Our objectives are to compare the blood loss estimated between anaesthetists and obstetricians and assess their accuracy.

**METHODS**: A prospective study done in UMMC included 147 pregnant women who underwent lower segment caesarean section fulfilling inclusion criteria. Intraoperative blood loss was assessed by both the anaesthetist and obstetrician on duty via visual estimation. The preoperative and postoperative haemoglobin levels were obtained in order to calculate the amount of blood loss using a modified formula based on Gross.

**RESULTS**: There was no significant difference in terms of blood loss estimated by anaesthetists and obstetricians. Visual estimation by these 2 groups of healthcare providers was inaccurate based on interclass coefficient analysis and assessment via the Bland and Altman plot. However, the background and seniority of the assessing health care providers did not affect the accuracy of the estimation.

*CONCLUSION*: The visual estimation of blood loss between anaesthetists and obstetrician during LSCS was comparable, however the accuracy of this technique has low validity. Further education and simulation can be conducted to improve the quality of this technique.

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# LIST OF SYMBOLS AND ABBREVIATIONS

| ОТ   | - | operation theatre               |
|------|---|---------------------------------|
| LSCS | - | lower segment caesarean section |
| EBL  | - | estimated blood loss            |
| CBL  | - | calculated blood loss           |
| BMI  | - | body mass index                 |
| IQR  | - | interquartile range             |
| SD   | - | standard deviation              |
| SE   | - | standard error                  |
| CI   |   | confidence interval             |

#### **CHAPTER 1:**

#### INTRODUCTION

#### **1.1 Introduction**

Postpartum hemorrhage accounts for majority of maternal deaths internationally; especially in developing countries (1). This data is consistent in Malaysia for past few decades (2). Failure to recognize excessive blood loss during delivery leads to significant maternal morbidity and mortality.

The ability to estimate blood loss correctly in the setting of the perioperative by healthcare personnel plays a crucial role in determining the direction of healthcare interventions. Underestimation of blood loss can lead to delay in initiation of resuscitation with fluid and blood products and cause harmful effect towards patient hemodynamically. Overestimation can lead to wastage of blood products being transfused, risk of infection, costly and subject patient to additional risks (3).

The guide for blood transfusion during the perioperative period often rely on clinical estimation of blood loss as other methods of estimations either may not be practical or available at all the times (4). Visual estimation is made based on measuring the amount of suctioned blood loss collected into the drainage bottles, counting blood soaked swabs, drapes and pads used perioperatively. Other techniques to measure blood loss more objectively includes direct measurement, gravimetric, photometry and miscellaneous (5). However, visual estimation method has been demonstrated as inaccurate in repeated studies in comparing to other techniques.

Although visual estimation is the least accurate method compared to other techniques, it remains the main stream of practice because of its ease of use, fast, not labor-intensive or expensive (5, 6). Various prior researches also looked into blood loss

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estimation based upon practitioners from multiple specialties, which all been found to be neither precise nor accurate (7). There are limited researches done regarding the accuracy of estimating blood loss by anesthesia care providers (8). Some studies has shown that there were no difference in estimating blood loss accuracy in terms of clinical background (6).

#### **1.2 Objectives**

#### General Objective

To describe the blood loss during lower segment caesarean section by method of estimation and calculation technique.

## Specific Objectives

- To evaluate any difference in estimation of blood loss between anesthetist and obstetrician during lower segment caesarean section.
- To assess the accuracy of estimation of blood loss between anesthetist and obstetrician.

#### **CHAPTER 2:**

#### LITERATURE REVIEW

A clinical audit conducted by Khan et al in 2006 to evaluate the blood ordering practice, blood transfusion for Caesarean sections and to compare estimated blood loss between anesthetists and obstetricians. They found that 52% of estimation of blood loss by both matched within a 100ml of error. Accurate estimation of blood lost at the time of C- section delivery is important in transfusion practise. (9)

Larsson et al in 2006 has worked to validate estimation of blood loss after vaginal delivery and elective caesarean section. The result showed over-estimation of blood loss when compared to measured blood loss using alkaline hematin method. The correlation was moderate ( $r^2 = 0.55$ ) between estimated blood loss and measured blood loss which concluded estimation of blood loss is of low value and may lead to wrong conclusions. (10)

Bose et al in 2006 conducted a study to identify areas of greatest discrepancy between estimated blood loss and actual blood loss using clinical scenarios which were reproduced in the form of 12 OSCE style stations. The assessment were done between anesthetists, obstetricians, gynae nurses, midwives, theatre nurses and healthcare assistants. The result showed that significant underestimation in the volume of large floor spillage, large surgical swab capacity and massive PPH. However, anesthetists were the most accurate in estimating blood loss among the groups, with over-estimation of just 4%. (11)

A prospective, observational study done by Adkins et al in 2014 using clinical screnarios model, found that there was no difference in the mean error of blood loss

estimation based on provider training, gender, ethnicity, education or experience. The study also supported that visual estimation was most accurate with about 200cc of blood. There are no improvement in terms of accuracy of estimation blood loss with experience eventhough knowing the conventional volumes that surgical material holds. They have suggested for future study to be conducted with actual blood loss during surgical procedures, which are more relevant towards clinical practices. (8)

In 2008, a prospective study conducted by Stafford et al comparing visual estimation of blood loss versus calculated blood loss in which there were 231 cases recruited for caesarean section group. They found that calculated blood loss for more than 1000ml and 1500ml was significantly underestimated. (12)

Eipe et al in 2006 assessed the accuracy of clinically estimated blood loss with actual blood loss using calculation method. According to Blant and Altman method, clinical estimation is more inaccurate as average blood loss increases. There was also poor correlation between the estimated blood loss and actual blood loss. Hence, using clinical estimation alone to guide transfusion is inadequate. (4)

Calibrated vessel has shown to increase accuracy during visual estimation of blood loss in a study conducted by Wangwe et al in Tanzania 2005. Change in hematocrit also was shown to have high predictive values in detecting primary PPH. (13)

Al-Kadri et al in 2011 has proved again that health care providers were inaccurate and underestimating blood loss visually but such estimations were improved after education took place. The accuracy to estimate visually was not affected by participant's length of experience or clinical backgrounds ie nurses or physicians. (6)

A prospective study done by Ashburn et al in 2012 in Emergency medicine also supported poor estimations of blood loss by ED physicians which correlated well with other specialities, only 8% of estimates within 20% of actual amounts. However, there were no significant difference was found between resident and attending physician performance on estimation of blood loss. There were certain conditions highlighted in the article that might cause overestimation or underestimation ie in children whose total body blood volume is lower, in elderly or those taking medications which may change the physiological response to blood loss. (7)

#### CHAPTER 3:

## METHODOLOGY

#### 3.1 Study Setting

UMMC Ethics Committee approval was obtained prior to the conduct of this study. This study was conducted in Operating Theaters located at the Women and Childrens' Health Complex UMMC. About 100 cases per month of LSCS, including both emergency and elective operations. LSCS are conducted by anesthesiologist and obstetrician surgeons who comprises from Consultant, Senior Lecturer, and Trainees in both respective fields; aided by supportive staffs ie anesthetist nurses and scrub nurses.

#### 3.2 Study Design, Population & Duration

This is a prospective, observational study.

Patients were recruited between January 2016 and April 2016. All patients undergoing both elective or emergency LSCS were eligible to be included in this study. A total of 147 patients were recruited, age ranging from 21 to 43 years old, ASA 1 and 2. Patients who have received blood transfusion intra-operative or post-operative before post-operative hemoglobin sampling taken were excluded for the study. Patients who were enrolled into this study gave written consent. One patient was excluded from the study as she developed severe postpartum hemorrhage and was given blood transfusion prior to post-operative hemoglobin sampling. Five patients were excluded due to missing laboratory data.

#### 3.3 Study Protocol

Data was collected intraoperatively by anesthetist in charge of the case, which include patient demographic - patient RN, age, parity, weight, height, ASA status, preoperative hemoglobin level, operative profile – elective/emergency LSCS, indication, procedure (LSCS, + hysterectomy or + BTL), duration of surgery, type of anesthesia, estimation of blood loss (visual estimation) by anesthetist and obstetrician – which include their gender, position, years of experience, intra-op transfusion, hemoglobin level intra-op via ABG, post-operative info – post-op hemoglobin level, transfusion record post op. Visual estimation was made via measuring blood lost to suction bottles, counting blood soaked gauzes and abdominal packs, blood splashed and stained on drapes at operative field and spillage of blood on the floor.

Post operation hemoglobin level was taken between 6 - 24 hours from their operation. Pre and post hemoglobin levels were measured in Hematology laboratory UMMC using hematology analyzers XN-20 (Sysmex, Japan) with coefficient variant of < 5%.

The value for actual blood loss will be calculated based on the drop of hemoglobin preoperative to postoperative period multiplying with maternal blood volume. The following formula is used:

Calculated blood loss =  $\frac{\text{Pre Hb} - \text{Post Hb}}{\text{Mean Hb}} \times \text{Maternal blood volume (ml)}$ 

Where by

Mean Hb = (PreHb + Post Hb) /2

Maternal blood volume = (0.75 ([maternal height (inches) x 50] + [maternal weight (pounds) x 25])

In order to detect a difference of 94 mls between the estimation of blood loss by anesthetists and obstetricians with the power of 90%, a minimum sample size of 118 patients was decided to be included.

#### 3.4 Data Management and Analysis

Data collected were entered into Statistical Package for the Social Science (SPSS) program version 23. Descriptive analyses were carried out by calculating mean and standard deviation (SD) for continuous variables, and number and percentage for categorical variables. Because the data showed lack of symmetry, lack of normality and apparent heteroscedasticity, summary data were expressed as medians. The significance of difference between estimation of blood loss by anesthetists and obstetricians was found using Mann-Whitney test. A p value of < 0.05 was considered to be statistically significant. In order to assess the accuracy of blood loss between the anesthetists and obstetricians, Interclass Correlation Coefficient (ICC) was calculated. Bland and Altman plots were also generated for visual assessment of accuracy between these 2 groups with the calculated blood loss. Furthermore, factors that might affect visual blood loss estimation ie gender, position, seniority (years of experience) were taken into account and analyzed using Multivariate Linear Regression Analysis.

#### **CHAPTER 4:**

#### RESULTS

#### 4.1 Demographic data

A total of 147 patients were included in this study and met the inclusion and exclusion criteria. The mean age was  $32.1 \pm 4.2$ , with 78.9% consisted of ASA 1 patients, the rest being ASA 2. The median weight was reported as 70kg with interquartile range 17.2 however mean (SD) height was  $156.2 \pm 6.0$  cm. The median of BMI was 28.5 with IQR of 6.3. 30.6% of patients are primigravidae and 69.4% of patients are multigravidae. 70 cases (47.6%) were enrolled during elective LSCS while 77 cases (52.4%) were recruited during emergency setting.

Among all the patients, majority (80.3%) underwent LSCS with spinal anesthesia, 13 patients (8.8%) received combined spinal epidural (CSE) technique while patients who received epidural and general anesthesia were 8 cases (5.4%) each. Most patients (82.3%) LSCS was performed, while the remainder 17.7% had LSCS and BTL performed in the same setting. No case of hysterectomy was recorded in this study. The median operation time taken for the surgery was 45 mins with IQR of 25 mins. Pre operation hemoglobin level was documented as mean  $11.8 \pm 1.3$  g/dL meanwhile post operation hemoglobin level was recorded mean  $10.8 \pm 1.4$  g/dL. None of the patient received blood transfusion intra-operatively or postpartum in ward. The summary of the results are listed in Table 4.1.

| Demographic profile     | Mean $\pm 2$ SD | Median (IQR) |
|-------------------------|-----------------|--------------|
| Age                     | 32.1 ± 4.2      |              |
| Height (cm)             | $156.2 \pm 6.0$ |              |
| Weight (kg)             |                 | 70 (17.2)    |
| BMI                     |                 | 28.5 (6.3)   |
| Operative time (mins)   |                 | 45.0 (25.0)  |
| Pre-op Hb level (g/dL)  | 11.8 ± 1.3      | 107          |
| Post-op Hb level (g/dL) | 10.8 ± 1.4      | 0            |

Table 4.1: Demographic data of enrolled patients.



Figure 4.1: ASA status of enrolled patients.



Figure 4.2: Elective vs emergency status of LSCS



Figure 4.3: Gravidity of enrolled patients.



Figure 4.4: Type of surgery performed.



Figure 4.5: Type of anesthesia performed.

## 4.2 Comparison of EBL by Anesthetists and Obstetricians

Visual estimation of blood loss by both anesthetists and obstetricians were not normally distributed and therefore given as median (25-75% range). Overall the result of the visual estimation of blood loss during lower segment caesarean section by anesthetists and obstetricians are listed in the Table below with no statistically significant difference observed between these 2 groups.

Table 4.2: Comparison of visual estimated blood loss between anesthetists and

obstetrician.

|           | Anesthetists | Obstetricians | Z-statistic | <i>p</i> -value* |
|-----------|--------------|---------------|-------------|------------------|
|           | Median (IQR) | Median (IQR)  |             |                  |
| EBL (mls) | 400 (200)    | 400 (200)     | -0.647      | 0.518            |

\* Mann-Whitney test

The median calculated blood loss was 429.0 with IQR of 471.1mls.

#### 4.3 Accuracy of blood loss estimation

In order to assess the accuracy of estimation of blood loss done by the two groups of health care providers, we have employed 2 techniques. Firstly, the interclass correlation coefficient was calculated. The ICC in anesthetists group was measured to be only 0.203 while in obstetricians groups was 0.139; indicating poor correlation between the two methods and by the two groups of health care providers. Secondly, the agreement between two methods of clinical measurement was analyzed according to Bland and Altman methods. The difference between the measurements will reflect the accuracy of measurement. The mean difference between EBL and CBL in anesthetists group was 52.6 with SD 367.0 however the obstetricians group has a mean difference of 48.9 with SD 376.0. This indicates the true result of measured blood loss could vary hugely in view of large SD in difference of blood loss while applying visual estimation.



Figure 4.6: Bland & Altman plot. Mean difference between visual estimated and calculated blood loss by anesthetists is 52.6cc (SD 367.0cc). The difference could vary between -681 (-2 SD) and +786 ( +2 SD).



Figure 4.7: Bland & Altman plot. Mean difference between visual estimated and calculated blood loss by obstetrician is 48.9 cc (SD 376.0.0cc). The difference could vary between -703 (-2 SD) and +801 (+2 SD).

The position of the health care providers in both anesthetist and obstetrician group is displayed in the following figure.



Figure 4.8: Healthcare providers based on seniority.

# 4.4 Factors affecting estimation of blood loss

Results of multivariate regression analysis between two groups of health care providers are displayed in Table 4.3 and Table 4.4.

| Covariate           | В      | SE     | t     | 95% CI           | <i>p</i> -value |
|---------------------|--------|--------|-------|------------------|-----------------|
| Gender              | -44.50 | 65.90  | -0.68 | -174.79, 85.79   | 0.50            |
| Years of experience | -37.65 | 33.94  | -1.11 | -104.75, 29.45   | 0.27            |
| Consultant          | 860.73 | 914.99 | 0.94  | -948.13, 2669.60 | 0.35            |
| Specialist          | 328.73 | 202.44 | 1.62  | -71.48, 728.94   | 0.11            |
| Registrar           | -18.26 | 70.51  | -0.26 | -157.66, 121.14  | 0.80            |

# Table 4.3: Results of multivariate regression analysis for blood loss estimation by

anesthetists

# Table 4.4: Results of multivariate regression analysis for blood loss estimation by

obstetricians.

| Covariate           | В              | SE     | t     | 95% CI          | <i>p</i> -value |
|---------------------|----------------|--------|-------|-----------------|-----------------|
| Gender              | -3.01          | 68.60  | -0.04 | -138.63, 132.61 | 0.97            |
| Years of experience | -27.79         | 19.75  | -1.41 | -66.84, 11.26   | 0.16            |
| Consultant          | 730.29         | 298.20 | 2.50  | 140.78, 1319.81 | 0.02*           |
| Specialist          | No participant |        |       |                 |                 |
| Registrar           | 140.32         | 125.16 | 1.12  | -107.12, 387.75 | 0.27            |

Years of experience was defined as the number of years experience gained in the field of anesthesia or obstetric. No statistically significant in factors affecting visual blood loss estimation except the consultant obstetrician group has a p-value of 0.02.

#### **CHAPTER 5:**

#### DISCUSSION

Half a million of maternal deaths worldwide per year are reported by World Health Organizations and postpartum hemorrhage is one of the main reasons attributed. Poor clinical management and inadequate resuscitation has been found as the factors contributing to the death of mothers in Malaysia (2). It is pivotal to be able to estimate accurately the blood loss during delivery either vaginally or via caesarean section in order to institute adequate resuscitation with hemodynamic monitoring.

Visual estimation remain a technique of choice when it comes to gauge the blood loss despite multiple studies identified the limitations and inaccuracies of estimation (5). It was deemed to be easiest and most economical way to estimate blood loss. Other techniques include gravimetric methods and photometry method, with photometry method was described to be most precise but also most expensive and complex to use (5). Visual estimation is able to aid to identify blood loss peri-operative instantaneously and strategies to ameliorate blood loss can be instituted and resuscitation commenced simultaneously. The accurate measurement of blood loss is more relevant for research purposes.

Anesthetists and obstetricians were comparable with regards to visual estimation of blood loss during lower segment caesarean section based on our study findings. Similar study was carried out by Khan et al (9) however it showed that obstetricians estimated more blood loss visually as compared to the anesthetists. The significance of difference was not assessed in that study. Bose et al (11) was able to describe anesthetists as the most accurate estimators of blood loss with tendency to 'overestimate' blood loss in compensation to surgical underestimation in many cases due to the skills developed by anesthetist in routine for fluid management. Concurrently, Ashraf et al (14) proved that anesthetists were able to give closest estimate to blood loss assessed using the gold standard technique – swab weighing method. In UMMC, the Obstetric Department conducts regular postpartum hemorrhage courses which has improved the staff skills while attending hemorrhage emergencies, indirectly improving their visual estimation technique.

Research found that visual estimation showed inconsistencies regarding its accuracy. There was underestimation using this technique reported by Prasercharoensuk et al (15) and Duthie el al (16) however Razvi et al (17) found that visual estimation overestimate 20% greater blood loss in 57% of vaginal births. In the mean time, Dildy et al (3) concluded that blood loss was overestimated at low volumes but underestimated at high volumes. In the present study, although the mean difference calculated from anesthetist and obstetrician group was low (52.63 vs 48.89), but SD displayed was large to account for bigger error during application of visual estimation technique. It was also supported with the low ICC ratio calculated between this two groups, in which anesthetist group obtained ICC of 0.203 and obstetrician group which scored 0.139. Eipe et al (4) also showed that ICC between visual estimation and actual blood loss is at 0.34. Hence, the accuracy of visual estimation blood loss by anesthetist and obstetrician are deemed inaccurate. Although the accuracy is questionable from the finding above, the visual estimation technique remain the most popular and applicable method to quantify blood loss during operation or in daily hemorrhage-related cases as this method is cheap, simple to apply and real-time assessment can be done (18).

Traditionally, the knowledge of blood loss estimation was acquired bedside. There was no formal textbook teaching of clinical assessment of blood loss in various fields (3). Hence the experienced clinician has no sound foundation of making better estimations than the junior ones. In our study, there was no statistically difference based on the gender, position and seniority (years of experience) of the person who estimated the blood loss except in the consultant obstetrician group. Total cases estimated by the consultant obstetrician was only 3 and one of the consultant made a blood loss estimation with a huge discrepancy between estimated blood loss and calculated blood loss. This has contributed to the fact of statistically significant result when large difference of blood loss in a small sample size group. In general, this study finding is consistent with literature that reported no difference in accuracy of blood loss based on seniority and years of experience (8).

Calculation of blood loss using modification formula based on Gross (19) which was originally derived to calculate allowable blood loss. It predicted blood loss more accurately than linear formula and ease of use compared to the logarithm formula. It also takes into account of ongoing hemodilution occurring, assuming normovolemia was maintained. Most importantly, no blood transfusion was given that might interfere with the application of above formula. In order to calculate maternal blood volume, the application of above formula was based on the Stafford et al (12) study and currently the calculator for calculating blood loss was made available online.

Despite the imprecision of visual estimation of blood loss technique, studies has proved that accuracy can be improved with education via simulation (3, 6, 11). Simulation conducted using multiple stations, clinical scenarios based and different fixed amount of blood were being used to soak the surgical materials. Didactic session was conducted as educational intervention. Teaching has aid to reduce the error of blood loss estimation significantly for inexperienced as well as experienced clinicians. Moreover, Srilar et al (20) has shown that the effect of education was able to be retained up to 3 months. In UMMC, a pictorial representation of blood loss in different surgical materials and patient beds has been put on displayed in operating theater and labour rooms to allow ongoing recall and revision regarding proper estimation of blood loss. This reduction or error of blood loss estimation has strong potential to reduce hemorrhage related morbidity and mortality.

From our study, the mean visual estimated blood loss by anesthetists and obstetricians were 428.6 mls and 432.3 mls. Mean of calculated blood loss was 481.2 mls. The margin of difference between the 2 groups of health care providers to calculated blood loss ranged from 48 to 53 mls. This amount of difference although was considered as inaccurate statistically, however, it was not huge difference and does not possess clinical implication during patient management.

Several limitations of this study need considerations. Calculation technique does not appear to be the gold standard when assessing blood loss as the validity of this method has not been established. Some patients recruited into the study had pregnancy induced hypertension / pre-clampsia, hence received reduced volume loading during induction and affecting the hemoglobin level post-op. Heterogenicity in terms of amount of fluid replacement given during perioperative period by different anesthetists potentially affect the hematocrit and hemoglobin concentration post-operatively. Mixing of amniotic fluid into suction bottles might interfere with decision of clinician upon deciding the blood loss to be estimated.

## **CHAPTER 6:**

### CONCLUSION

In conclusion, no difference in visual estimation of blood loss between anesthetist and obstetrician was found during LSCS. Visual estimation has lack of accuracy when assessing blood loss perioperative. It is important to assess the ongoing clinical situation based on hemodynamic status in order to facilitate timely resuscitation. Simulation, education and evaluation of blood loss at various points during specific event may improve accuracy.

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#### APPENDIX A

#### MEDICAL ETHICS COMMITTEE UNIVERSITY MALAYA MEDICAL CENTRE

# PATIENT INFORMATION SHEET

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

Version No.: 1 Version Date: 21-9-15

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

1. Study Title:

Visual estimation of blood loss during Caesarean Section – A Prospective Review.

2. Introduction (Scientific basis of the study)

Visual estimation has been the commonest technique used perioperatively for assessment of blood loss. Accurate assessment of blood loss enable us to decide the need for blood transfusion and prevent wastage.

3. What is the purpose of this study?

This study is aim to describe the amount of blood loss during lower segment caesarean section and compare the estimating blood loss effort between anaesthesiologists and obstetricians.

4. What are the procedures to be carried out?

All that required from you is that twice blood taking for Full Blood Count before and after LSCS.

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

You will only be required to be available during your hospitalization period for LSCS procedure.

- 6. Who should not enter the study (exclusion criteria)?
  - a) If you are less than 18 years old
  - b) If you suffer from major medical condition which are life threatening ie symptomatic heart failure, renal failure, uncontrolled hypertension.
  - c) If you have been given blood transfusion perioperatively, you will be automatically excluded in the study.
- 7. How many patients/research subjects will be recruited into this study?

We are estimating to recruit 100-150 patients into this study.

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

The research data and relevant medical records only accessible by the research team members.

9. Will the records/data be kept confidential?

Yes.

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

To you as a subject: -None. However it will benefit the patients undergoing anaesthesia in the future.

To the investigator. -None. It will help the doctors to improve the estimating skill in the future. 11. What are the possible drawbacks (side effects, etc.)?

None. Similar anaesthesia technique will be carried out throughout the operatio.

12. What payments or reimbursement will research subjects receive?

No payment or reimbursement will be given.

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

Absolutely. Your decision to refuse will not affect your medical care.

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

Dr Carolyn Yim Chue Wai Dr Tan Wei Keang Tel: 016-3127465 Tel: 012-6655489

**BK-MIS-**

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### APPENDIX B

# CONSENT BY PATIENT FOR CLINICAL RESEARCH

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

Version No.: 1 Version Date: 21-9-2015

| I,<br>Identity Card No<br>(Name of Patient)   |
|---|
| of  |
| Title of Study: Visual estimation of blood loss during Caesarean Section – A Prospective Review   |
| the nature and purpose of which has been explained to me by<br>Dr   |
| and interpreted by  |
| 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<br>and complications (as per patient information sheet). After knowing and understanding all the possible<br>advantages and disadvantages of this clinical research, I voluntarily consent of my own free will to participate<br>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)<br>)<br>Identity Card No)<br>Signature  |
| (Witness for Signature of Patient)  |
| Designation)<br>I confirm that I have explained to the patient the nature and purpose of the above-mentioned clinical research.   |
| Date Signature  |
| CONSENT BY PATIENT R.N.<br>FOR Name<br>CLINICAL RESEARCH Sex<br>Age   |

# KEIZINAN OLEH PESAKIT UNTUK PENYELIDIKAN KLINIKAL

Sila letakkan Nombor Versi dan Tarikh Versi untuk dokumen ini:

Nombor Versi: 1 Tarikh Versi: 21-9-2015

| Saya,<br>No. Kad Pengenalan   |
|---|
| beralamat(Alamat)   |
| dengan ini bersetuju menyertai dalam penyelidikan klinikal (pengajian klinikal/pengajian soal-<br>selidik/percubaan ubat-ubatan) disebut berikut:   |
| TajukPenyelidikan:Visual estimation of blood loss duringCaesarean Section – A ProspectiveReviewyangmanasifatdantujuannyatelahditerangkankepadasayaolehDr(Nama & Jawatan Doktor)   |
| mengikut terjemahan<br>(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<br>(mengikut kertas maklumat pesakit). Selepas mengetahui dan memahami semua kemungkinan kebaikan<br>dan keburukan penyelidikan klinikal ini, saya merelakan/mengizinkan sendiri menyertai penyelidikan<br>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)<br>DI HADAPAN  |
| Nama)   |
| No. K/P) Tandatangan<br>) (Saksi untuk Tandatangan Pesakit)   |
| Jawatan)  |
| Saya sahkan bahawa saya telah menerangkan kepada pesakit sifat dan tujuan penyelidikan klinikal tersebut di atas.   |
| Tarikh:   |
| No. Pend.<br>KEIZINAN OLEH PESAKIT Nama<br>UNTUK Jantina<br>PENYELIDIKAN KLINIKAL Umur  |

APPENDIX D

| Visual Estimation of Blood Loss during   | LSCS   |  |  |  |
|--|--|--|--|--|
| Subject Number :   | patient's sticker<br>make sure include RN                          |  |  |  |
| Date of data collection:   | make sure include tit  |  |  |  |
| Patient Data   |  |  |  |  |
| Age: Weight:kg   | ASA: I II III  |  |  |  |
| Parity: GP Height:cm   | Pre-op Hb:g/dL   |  |  |  |
| GSH GXM, pir   | ts   |  |  |  |
| Operation Profile  |  |  |  |  |
| Elective Emergency   |  |  |  |  |
| Indication:  |  |  |  |  |
| Procedure: LSCS<br>LSCS + BTL<br>LSCS + Hysterectomy<br>Others:  | Type of anesthesia: SAB<br>CSE<br>GA                               |  |  |  |
| Duration of surgery:min  | K V  |  |  |  |
| Estimation of blood loss   |  |  |  |  |
| Anesthesiologist:  | Obstetrician:  |  |  |  |
| Name:  | Name:  |  |  |  |
| Gender: male female  | Gender: male female  |  |  |  |
| Position: Consultant<br>Specialist<br>Registrar<br>Medical officer   | Position: Consultant<br>Specialist<br>Registrar<br>Medical officer |  |  |  |
| Years of experience:yrs Years of experience:yrs  |  |  |  |  |
| Amount estimated: mls  | Amount estimated: mls  |  |  |  |
| Intraoperative transfusion:<br>If yes, any intraop Hb before transfusion?<br>Amount of packed cell transfused:<br>Yes,g/dL<br>No<br>No |  |  |  |  |
| Post op Record:  |  |  |  |  |
| Post-op Hb:g/dL  |  |  |  |  |
| Any transfusion given in ward:<br>If yes, is it before of after taken post-op Hb?  | Yes No<br>Before After   |  |  |  |
|  | Recorded by:   |  |  |  |