

nd EDITION

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Patient Safety Unit, Medical Care Quality Section, Medical Development Division, Ministry of Health Malaysia

In collaboration with

Safe Surgery Saves Lives Steering Committee, Ministry of Health Malaysia 2018



SAFE SURGERY SAVES LIVES PROGRAMME



Patient Safety Unit, Medical Care Quality Section, Medical Development Division, Ministry of Health Malaysia

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2ND EDITION GUIDELINES ON MOH SAFE SURGERY SAVES LIVES PROGRAMME

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Foreword by THE DIRECTOR-GENERAL

OF HEALTH MALAYSIA

According to the World Health Organization, avoidable surgical complications account for a large proportion of preventable medical injuries and deaths globally. Although knowledge of surgical safety has improved tremendously, adverse events involving surgery still occur. Surgical safety is now being recognized as a global public health issue. Hence, in 2007, the World Health Organization established the "Safe Surgery Saves Lives" Programme as the 2nd Global Patient Safety Challenge, whereby Surgical Safety Checklist was introduced.

I am proud to share that Malaysia is one of the pioneer countries that have implemented this programme since 2009 and has produced our very own "Safe Surgery Checklist", based on the WHO Checklist. In 2013, the "Safe Surgery Saves Lives" Programme has been incorporated into our Malaysian Patient Safety Goals with the target of having 'zero wrong side/site surgery' and 'zero unintended retained foreign body'. Since then, awareness on the importance of surgical safety has increased amongst our healthcare staff.

Studies around the globe have shown that the use of Surgical Safety Checklist can significantly reduce the incidence of wrong surgery. Nevertheless, the use of checklist alone will not prevent error. In fact, this needs to be coupled with the implementation of "just culture", "safety thinking", safe practice, system improvement, good team work and effective communication. The leadership of surgeons and anaesthetists is integral to the success of this Safe Surgery Saves Lives Programme.

This Second Edition of the Ministry of Health Malaysia Safe Surgery Saves Lives Guidelines has been produced to provide more detailed knowledge of the various aspect of surgical safety which were not included in the First Edition of the guidelines. I have been informed that the Checklist has also been updated based on invaluable feedback from the endusers. It is my sincere hope that this commendable effort will further enhance the safety of our surgical service in Malaysia. This is crucial in transforming our healthcare organisations towards becoming High Reliability Organisations.

I would like to thank and congratulate each and everyone involved in the production of this new Guidelines spearheaded by the Ministry of Health, Safe Surgery Steering Committee in collaboration with the Patient Safety Unit of the Medical Care Quality Section, Medical Development Division, MoH. May our passion, commitment and efforts in striving to improve patient safety in this country grow from strength to strength. As it has once been said "If you want to go fast, go alone; if you want to go far, go together".

Datuk Dr. Noor Hisham Abdullah Director General of Health Malaysia and Chairman of Patient Safety Council Malaysia

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INTRODUCTION

Adverse event in surgery is an important issue globally in which many are preventable. In order to reduce the number of preventable surgical death and complication across the world, Surgical Safety Checklist was introduced by the World Health Organization (WHO) in 2008 as a tool to improve surgical safety. This checklist is used to check critical points before, during and after surgery. The ultimate goal of the checklist is to ensure that operating team consistently adhere to a number of critical safety steps and hence minimize avoidable risks that can be harmful to patients undergoing surgery.

This Safe Surgery Programme is the Second Global Patient Safety Challenge initiated by the World Health Organisation in 2008. Malaysia was represented by The President of College of Surgeons, Malaysia during the launching of this programme on the 25th June 2008 in Washington DC.

In Malaysia, this programme acts as a catalyst to system improvement in surgery. It started with the establishment of `Safe Surgery Saves Lives' (SSSL) Steering Committee in 2008. This programme was endorsed by Patient Safety Council Malaysia on the 24th Oct 2009 and was launched officially in Malaysia on the 15th November 2009 in Langkawi with the theme 'Safer Surgery through Better Communication'. Commencing from 1st January 2010, the SSSL programmes was implemented in all Ministry of Health Hospitals performing surgery. The journey of SSSL is illustrated in Diagram.

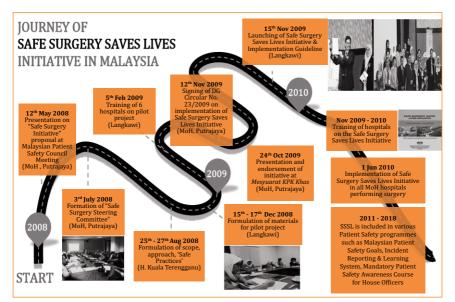
"Director General of Health Malaysia Circular No 23/2009: Implementation of Patient Safety Programme - Safe Surgery Saves Live" dated 12 Nov 2009 has stated clearly the need to implement this programme in all hospitals starting from 1st January 2010. The details of implementation is described in the 1st Edition of "Safe Surgery Saves Lives Programme - Implementation Guidelines", Nov 2009.



This main objectives of this programme are to improve surgical safety and prevent surgical adverse events by two main strategies:

- 1) Improving communication and team work to ensure safer surgery.
- 2) The use of "Surgical Safety Checklist" to improve the standards of surgical safety.

In 2013, Safe Surgery Saves Lives programme was included as part of Malaysian Patient Safety Goals. The target of this goals is to have "zero" wrong side/site surgery and "zero" unintended retained foreign body.



THE JOURNEY OF SSSL PROGRAMME IN THE MINISTRY OF HEALTH MALAYSIA



SURGEONS LEADERSHIP IN SAFE SURGERY SAVES LIVES PROGRAMME

In order for Safe Surgery Programme to be implemented effectively, a good team work involving multidisciplinary staff is required. Hence, good leadership is essential to drive, motivate and empower the team members in ensuring surgical safety and provides safer care. Surgeons need to demonstrate leadership skills and create safety culture.

According to A Guide to Best Practice - Surgical Leadership produced by The Royal College of Surgeons, England 2014; good surgical leaders have these criteria:

- act with integrity
- are honest, open and consistent
- are accessible
- are open to challenge and feedback
- are decisive
- are self aware and mindful of their impact on others
- recognise their own responses to stress.

The Guide also mentioned that good leaders:

- minimise status and power differences
- ensure they are accessible
- encourage learning
- actively engage to create a shared sense of teamwork that increases collaborative behaviours
- instil a sense of responsibility in each person for the well-being of the team
- encourage feedback, challenge and input
- create a culture of safety by surfacing and mitigating issues that might cause harm to the patient
- promote a positive working environment through good teamwork.

Based on the feedback received from staff regarding implementation of Safe Surgery Saves Lives Programme in Malaysia, surgeons leadership need to be further improved. Although the process of "ticking the Safe Surgery Checklist" may be conducted by the nursing staff, surgeons need to be involved in the process of "checking", ensure each process is "checked" prior to the "tick" and involve all team members (surgeons, anaesthetists, nurses etc). The surgeons also need to lead and drive this Safe Surgery Saves Lives Programme as well as educating and motivating other team members to be part of this programme.



2ND EDITION OF SAFE SURGERY SAVE LIVES GUIDELINES

The First Edition of the guideline introduced the concept of Surgical Safety and the use of Safe Surgery Checklist as a tool to ensure safe practice during surgery. It also contain key messages on this programme.

This Second Edition of the guideline provide updates on the new version of Safe Surgery Checklist and give further details on ways to improve surgical safety and other matters related to safe surgery such as ethics, consent, communication and guide on handling unexpected incidents.

The main objectives of this Safe Surgery Saves Lives Programme is to improve surgical safety and reduced preventable harm during surgery.

VERSION 2.0 OF SAFE SURGERY @ PERI-OPERATIVE CHECKLIST

This checklist consists of four components:

- 'Pre-Transfer Checklist'
- 'Operating Team Checklist'
- 'Swab Count Form'
- 'Post-Operative Transfer Checklist'

This checklist is based on WHO Surgical Safety Checklist and incorporate various MOH existing checklists related to peri-operative care.

Safe Surgery Checklist Version 2.0 is an enhancement from previous version. This new version is based on the feedback received from the implementers. Among the improvement include:

- Use of two patient identifiers
- Detailing and rewording of statement in the checklist to ensure easy and better understanding among staff using the checklist

ORGANISATIONAL STRUCTURE IN SAFE SURGERY SAVES LIVES PROGRAMME

a) National Level

Safe Surgery Steering Committee is responsible to spear head the Safe Surgery programme at national level. The committee needs to develop relevant policy and guidelines to facilitate the implementation of this programme. The committee is also required to drive, lead, champion and monitor this programme nationally. It comprises of surgeons, anaesthetists, public health physician, OT nurses. Patient Safety Unit, Medical Care Quality Section, Medical Development Division, Ministry of Health Malaysia acts as the Technical Coordinator of this Steering Committee.

b) State Level

Safe Surgery State Committee is responsible to drive, lead and champion Safe Surgery programme at the state level. It comprises of surgeons, anaesthetists and OT nurses. Department in charge of Patient Safety in the State Health Department acts as the secretariat of this committee.

c) Hospital Level

Safe Surgery Hospital Committee is responsible to drive, lead, monitor, and discuss issues/challenges in order to improve Safe Surgery programme in hospital. It comprises of surgeons, anaesthetists and OT nurses. Department in charge of Patient Safety in the hospital acts as the secretariat of this committee.

ROLES OF SAFE SURGERY SAVES LIVES COMMITTEE

ROLES OF SAFE SURGERY STEERING COMMITTEE AT NATIONAL LEVEL

- 1. To spear head and to drive the Safe Surgery Saves Lives Programme throughout the country.
- 2. To plan the way forward of SSSL programme in a more comprehensive and holistic manner at national level.
- 3. To develop policy and guidelines on SSSL programme to be used by the country.
- 4. To promote, educate and disseminate information on safe surgery and SSSL Programme nation wide.
- 5. To monitor, evaluate the implementation and effectiveness of SSSL programme at national level.
- 6. To further strengthen and enhance implementation of SSSL at National level.
- 7. To share and learn from patient safety incidents related to surgery.
- 8. To encourage innovative improvement of surgical safety.

ROLES OF SAFE SURGERY STATE COMMITTEE

- 1. To identify suitable Safe Surgery champions or potential champions in the relevant state to be members of the Safe Surgery State Committee or involved in the Safe Surgery activities at state level.
- 2. To lead and to drive the Safe Surgery Saves Lives Programme throughout the state.
- 3. To plan the way forward of SSSL programme in the state.
- 4. To promote and disseminate information on safe surgery and SSSL Programme throughout the state.
- 5. To monitor, evaluate the implementation and effectiveness of SSSL programme in the state.
- 6. To further strengthen and enhance implementation of SSSL programme in the state.
- 7. To give feedback to the National Safe Surgery Steering Committee regarding issues and challenges faced in order to improve the SSSL programme.
- 8. To share and learn from patient safety incidents related to surgery.
- 9. To assist hospitals in improving the implementation of SSSL programme.



ROLES OF SAFE SURGERY HOSPITAL COMMITTEE

- 1. To identify suitable Safe Surgery champions or potential champions in the hospital to be members of the Safe Surgery Hospital Committee or involved in the Safe Surgery activities in the hospital.
- 2. To lead and to drive the Safe Surgery Saves Lives Programme in the hospital.
- 3. To plan the way forward of SSSL programme in the hospital.
- 4. To promote and disseminate information on safe surgery and SSSL Programme throughout the hospital.
- 5. To monitor, evaluate the implementation and effectiveness of SSSL programme in the hospital.
- 6. To further strengthen and enhance implementation of SSSL in the state.
- 7. To give feedback to the State Safe Surgery Committee and National Safe Surgery Steering Committee regarding issues and challenges faced in order to improve the SSSL programme.
- 8. To share and learn from patient safety incidents related to surgery.
- 9. To encourage innovative improvement of surgical safety.

Suggested Organisational Structure of Safe Surgery Committee in Hospital

- Effective committee is essential in driving this initiative. Hence, identification of suitable staff is important.
- It is recommended that members should be selected from "Safe Surgery champions" or "potential champions" in the hospital.
- Suggested composition of the committee:
 - o Chairman (Surgical)
 - o Vice Chairman (Surgical / Anaesthesia)
 - o Secretariate-Department in charge of Patient Safety in Hospital
 - o Committee Members
 - o Head/representatives of surgical-based disciplines and anaesthesiologist.
 - o Representatives from OT matron/sister
 - o Representatives from ward matron/sister
 - o Others deem necessary
- Hospital Director needs to be updated regularly by the Chairman of the SSSL Committee. For instance regarding the matters discussed in the meeting, proposed activities and resources needed.

OPERATING THEATRE ETIQUETTE

(Do's nd Don'ts in The Operating Room)

Etiquette is described as personal conduct or behaviour evaluated by an accepted standard of appropriateness for a social or professional setting.

The operating theatre etiquette may vary by region and culture.

The following are important etiquette to be addressed:

• Personal Protective Equipment (PPE):

- PPE is essential during surgery to protect the staff as well as the patient.
- Wear clean PPE in operating theatre (OT).
- Surgical mask must be worn once the set of surgical instruments are opened.
- If the surgery might predispose the staff to 'splashing hazard' such as blood and body fluid, eye protection is crucial.
- Once scrubbed, maintain sterility.
 - If you are standing away from the operating field, clasp your hands together at the level of your chest.
 - If you are standing at the OT table place your hands flat in the sterile area.

• For new healthcare personnel:

- Introduce yourself to operation theatre manager/nursing sister, the surgeons, the anaesthetist and clearly display your identification badge.
- Obtain surgeon permission before scrubbing or observing the surgery.
- If you are scrubbing for the case, know your patient well and the procedure.

• General matters:

- Avoid wearing bracelet, ring or fake nails (*kuku palsu*) especially when you want to scrub.
- Avoid unnecessary traffic in operating room (OR) when surgery is ongoing.
- Surgeons or assistants should never take instruments from the instrument trolley/tray. Ask for the instrument and wait for it to be passed to you.
- Blades and sharps are passed via a tray to prevent sharps injury.
- Remember to return all instruments once you have finished using them.
- Avoid unnecessary talk. Respond clearly with "yes" or "no".
- Answering phone calls during surgery should be kept to a minimum and not at all if possible.
- Thank the team members before exiting a surgery.

USING THE CHECKLIST

It is the responsibility of the Surgical Team leader conducting the procedure to participate and ensure the use of this checklist.

It is the responsibility of the Checklist Coordinator to ensure that the checklist is completed.

It is mandatory to use the checklist regardless of situation (i.e. elective or emergency surgery).

This Safe Surgery Saves Lives Checklistis called 'Ministry of Health Peri-Operative Checklist'. It is a 4-page form and consists of:

Page 1: Pre-operative checklistPage 2: Operating team checklistPage 3: Swab and instrument count formPage 4: Pre-discharge check

Note:

For MULTIDISIPLINARY/MULTIPROCEDURE SURGERIESevery team/procedure should have their OWN FORM.

The second page (i.e Operating Team Checklist) is a modification of the 'WHO Surgical Safety Checklist'.



PAGE 1: PRE-OPERATIVE CHECKLIST

This checklistis used before sending the patient to the theatre and at the Reception Area of the OT.

- The 'Patient Profile' section is filled in the ward by the ward nurse before sending the patient to the Operating Theatre (OT). Ensure the patient is identified using two(2)- identifiers. For example using any two of these identifiers- patient's name, MRN, I.C. number, passport no., birth date.
- The 'Pre-Transfer Check' section:
 - o The `**Ward**' column is filled up by the ward nurse before sending the patient to OT.
 - o The **`OT**' column is filled by the OT nurse at the OT Reception area.
- The lower section of the form, `INFORMATION ON OPERATING ROOM/ SURGEON / TIME OF SURGERY' need to be filled up in the Operating Room (OR) by the Circulating Nurse.

PAGE 2: OPERATING TEAM CHECKLIST

- This is the checklist adapted from 'WHO Surgical Safety Checklist'.
- It is used in the Operating Room before starting until the completion of surgery.
- The Checklist Coordinator is usually the Circulating Nurse. It can also be other members of the team if agreed by the team.
- Although the process of "ticking the Safe Surgery Checklist" may be conducted by the nursing staff, surgeons need to be involved in the process of "checking", ensure each process is "checked" prior to the "tick" and involve all team members (surgeons, anaesthetists, nurses etc).
- The culture of "ticking" the checklist without "checking" is prohibited/not allowed.



THE `SIGN-IN'

This is done before Induction of Anaesthesia

It is the responsibility of the anaesthetist to check and verify the items in this section except in procedures performed under local anaesthesia in which the local anaesthesia is given by surgeon.

THE `TIME-OUT'

- This section is done in the presence of the surgeon, scrub nurse and anaesthetist. **This must be done before skin incision**.
- If the surgery involved multiple teams, each team must conduct their time out before the start of their respective surgery.
- Relevant imaging studies should be displayed by the surgical team members where applicable.
- "White Board".

The white board in the operating room shall be written by a member of the surgical team before the start of surgery. This board is used to display information about the current operation. This includes – **the name of the patient, diagnosis, surgical procedure and names of the operating team members**. Other information may include **antibiotic requirement, tourniquet time, implant size and other special needs or reminders**.

INTRA-OPERATIVE COMMUNICATION

This is an **additional section** that encourages communication between team members during the surgery. It has 4 components.

i) CHECK-IN

• The surgeon, after having completed the cleaning and draping process, **communicates** with the anaesthetist and scrub nurse to determine their **readiness to commence surgery**. Only when both have indicated so, should the surgeon initiate the skin incision.



ii) PERIODIC UPDATES

- For procedures exceeding 1 hour, it is a good practice to communicate the situation among the members of the operating team. This should be done at regular intervals or whenever necessary.
- The surgeon should inform the anaesthetist of the progress of the surgery. Similarly, the anaesthetist should update the surgeon about the patient's clinical condition.

iii) SHOUT-OUT

- This refers to the act of vocalising clearly to the appropriate team members about certain intra-operative events in order to obtain undivided attention of a specific team member to the event.
- An example is when a pack is inserted into the abdominal cavity, the surgeon should `shout-out' "ONE PACK IN!" The scrub nurse takes note of it and repeats the `shout-out' to the circulating nurse. The same is done when the pack is removed from the cavity. The surgeon should ' shoutout' "ONE PACK OUT!"
- This does not replace the system of tags placed at the end of packs or other forms of reminders already in place.
- Other events that require `shout-outs' are:-
 - When instruments, gauzes have fallen off the operating field on to the floor.
 - When there is critical equipment malfunction, eg. "diathermy not working!"
 - When there is excessive bleeding, the surgeon should `shout-out' to the anaesthetist so that he is aware of the situation. This will enable him to prepare for the worst.
 - When the patient condition turns unstable, the anaesthetist should 'shout-out' the situation to the surgeon. The surgeon may want to pause or review his actions.

CAUTION: The patient who is NOT UNDER GENERAL ANAESTHESIA IS AWARE of all the `shouting'.



iv) PRE-CLOSURE DISCLOSURE

- The surgeon informs members of the operating team at the completion of the surgery prior to the wound closure.
- This will enable the anesthetist to plan for reversal.
- The scrub nurse can commence swab and instrument count. She will inform the surgeon after this is done.
- This is also the appropriate time to call the next case to the OT or the next team to procede in the situation of combined surgery.

THE `SIGN-OUT'

- This is also called 'debriefing'.
- The surgeon summarises the operative findings and procedure. He will verify the specimen(s) and relevant tests(s) to be conducted and how it should be labelled.
- The anaesthetist highlights post operative anaesthetic plan for patient if applicable.
- The operating team will discuss any specific post-operative instructions.
- Any instrument problems or major issue(s) to be addressed.
- "Inform The Relatives"
 - In long procedure or critically ill-patient, surgeon and anaesthetist should update relatives regarding the progress of the surgery.
 - For instance how this is done depends on the local OT set-up and the public expectation.
 - In some instances, operative specimens are also shown to the relatives. This usually enhances communication.



PAGE 3: SWAB AND INSTRUMENT COUNT FORM

- If the surgery involves more than one operating teams or sites on the same patient, each should have its own swab count forms.
- Any issues or incidents in the Operating Room should be recorded in the "Incidents/Instrument Malfunctions" section of this form. For example, blunt scissors, diathermy malfunction or unsatisfactory temperature/humidity in the OR.
- If more than two scrub nurses scrub for the same case, just add the name after the first scrub nurse following a slash (/). The time that the 2nd nurse joined the team must be documented above the name. The same applies to the circulating nurse.

PAGE 4: PRE-DISCHARGE CHECK

This is done by the Ward Nurse, together with the Recovery Room Nurse before the patient leaves the OT.

*The completed Peri-Operative Checklist Form must be kept in the patient's case notes.

PERI-OPERATIVE CHECKLIST

SAFE SURGERY SAVES LIVES PERI-OPERATIVE CHECK LIST

| PRE OPE | RATIVE CHEC | KLIST | | | |
|----------------------------|-------------------------|-------|---------------|-------|--|
| Name | | I/ | C Passport No | | |
| Age | Sex | Race | Hospital Reg. | No | |
| Unit | | Ward | We | light | |
| Diagnosis (as p | er OT list) | | | | |
| Planned Operation / Pro | cedure (as per consent) | | | | |

PRIMARY TEAM CHECKLIST

| Operation / Procedure (as per conse | nt) | | | |
|-------------------------------------|------|--------------|--|--|
| Checked By (Ward Staff) | Date | (DD/MM/YYYY) | Contact person & HP no. (next of kin) | |

B. PRE-TRANSFER CHECK

(Is done by the ward nurse before sending patient to OT and at Reception Area in OT by the OT Reception Nurse) Mark (\checkmark) where check has been performed

| No. | | | |
|-----|--|----|-----------|
| 1. | Patient's Name /unknown Patient's ID (use two identifiers) | | |
| 2. | Consent for : Surgery Anaesthesia Transfusion Photos Re-check procedure with : Consent form patient OT list | | |
| 3. | Check side of operation LEFT RIGHT NA | | |
| 4. | Site of operation marked ? YES NO NA | | |
| 5. | Last meal : date(dd/mm/yyyy) timeH (24 hour format) | | (specify) |
| 6. | Check for dentures, jewellery, contact lenses, implant/ foreign body etc. (for person incharge of removing the item(s), to write their name and quantity of item in the remarks) | | |
| 7. | Allergies ? | | (specify) |
| 8. | Availability of implant / prosthesis ? | 0 | |
| 9. | Premedication (drug,dose,route and time given) | | |
| 10. | Blood or Blood product availability (write what is available) | | |
| 11. | □ Case Notes □ Relevent Old Notes □ Other Document(s) (To specify other document(s) and type of imaging studies in the remarks) | | |
| 12. | Imaging study | | |
| 13. | B/P: / mmHg Pulse rate : bpm Temperature :*C | | |
| | ed over by Ward Nurse Received by OT Nurse (Sign & Stamp) | se | |
| | nportant issues to be highlighted been corrected or rectified) | | |

(Written in OR by Checklist Coordinator)

| Operating Room No. | Temperature | Humidity | |
|-----------------------|-------------|----------|--|
| Anaesthetist(s) | | | |
| Surgeon(s) | | | |
| Checklist Coordinator | | | |



PAGE 2 of 4 - SSSL POCL VER.2.0

OPERATING TEAM CHECKLIST

BEFORE INDUCTION OF ANAESTHESIA

| Confirmed patient's | | | |
|--|------------|------------|--|
| Name | LILO | DIG | |
| Planned procedure | | | |
| Site/side | | | |
| Consent | | | |
| Op site marked | DYES | □NO | |
| GA machine checked? | DYES | □NO | |
| Pulse oximeter turned | | □NO | |
| on and functioning? | | | |
| Patient has allergy? If yes, please specify | VES | □NO | |
| | TYES | | |
| Difficult airway / aspiration risk? | LITES | LINU | |
| Any GXM/GSH? | | □NO | |
| Adequate IV access? | □YES | □NO | |
| Suction apparatus checked & functioning | VES | □NO | |
| OT Table checked & functioning | | □NO | |

BEFORE SKIN INCISION

| TIME OUT (By Surgeon, Anaesthetist & Scrub Nurse) | | | |
|---|-------------|--|--|
| 'WHITE BOARD' written | | | |
| Introduce team members | | | |
| Confirmed patient's Name Planned procedure Site/side Consent | □YES □NO | | |
| Antibiotic prophylaxis given within the last 60 minutes? | | | |
| Essential imaging displayed? | | | |
| Briefing by Surgeon: Incision, critical steps, estimated duration and blood loss | | | |
| Anaesthesia review: Any patient-specific concern? | | | |
| Scrub nurse review: Instrument/ implant available. Equipment (diathermy, suction) ready | | | |

PRIMARY TEAM CHECKLIST

CHECK IN

| Surgeon inform anaesthetist & scrub nurse of his/her intention to start |
|---|
|---|

DURING PROCEDURE

| INTRA-OPERATIVE COMMUN (By Surgeon, Anaesthetist & Scr | |
|---|----------|
| PERIODIC UPDATES | DYES DNO |
| SHOUT - OUT | DYES DNO |
| PRE-CLOSURE DISCLOSURE | |

BEFORE SURGEON LEAVES OPERATING ROOM

| SIGN OUT/Debriefing (By Surgeon / Checklist Coordina | tor Nurse) |
|--|------------|
| The final procedure, findings and post-op orders | |
| Final instrument & swab count was done | |
| Specimen(s) to be labelled | |
| Any incidents or issues to be addressed? | |
| Any special post op instructions by anaesthetist or surgeon? | |
| Inform relative(s) If no, why? | |

ISSUES/ INCIDENTS OCCURRED (IF ANY)

Checklist Coordinator (name, signature & stamp)

AUDITING PURPOSE ONLY

| Sign In= | /10 | Sign Out = | /6 |
|------------|-----|------------|-----|
| Time Out = | /8 | | |
| Check In = | /1 | | |
| IntraOp = | /3 | TOTAL = | /28 |

SAFE SURGERY SAVES LIVES PERI-OPERATIVE CHECK LIST

PAGE 3 of 4 - SSSL POCL VER.2.0

2nd coun Final count Gauzes Abdominal packs Blades Atraumatic Needles Loose Needles Diathermy cleaner Actual operation(s)/ procedure(s) done Specimen(s) sent Name of 1st Scrub Nurse Time start Time End Signature Name of 2nd Scrub Nurse Time start Time End Name of Circulating Nurse Time start Time End Name of Surgeon & MMC No. **Time start** Time End

SWAB & INSTRUMENT COUNT FORM

PLANNED SURGICAL PROCEDURE DATE / TIME START SET & INSTRUMENTS DATE / TIME END (Use 24 hour format of time,e.g. 2315H) Contact of time,e.g. 2315H)

BASIC SET USED IN PROCEDURE

SUPPLEMENTARY SET USED IN PROCEDURE

PRIMARY TEAM CHECKLIST

SAFE SURGERY SAVES LIVES PERI-OPERATIVE CHECK LIST



RIMARY TEAM CHECKLIST

PRE-DISCHARGE CHECK

(Is done by the Ward Nurse in the presence of the Recovery Nurse before the patient leaves the OT)

| | | | от | Ward | Remarks |
|-----|------------------------------------|--|----------|--------|--------------------------|
| 1. | Patient's Nam | | | | |
| 2. | Consciousness | s level: Drowsy | | | |
| 3. | Inform Vital S score | igns (BP , PR , SpO2) & pain | | | |
| 4. | Check operati | ve site / dressing | | | |
| 5. | Check drains, | tubes, urinary catheter | | | |
| 6. | Check IV lines | and infusions | | | |
| 7. | Blood used an | id unused | | | |
| 8. | Specimens (cr | ulture(s) etc.) | | | |
| 9. | Other Docu GA form (To specify ot) | Relevent Old Notes ment(s) Operative Notes her document(s) and type of es in the remarks) | | | |
| 10. | Imaging Stud | | | | |
| 11. | Check post-op | perative pain relief order | | | |
| 12. | Others, e.g. : | amputated parts , placenta etc. | | | |
| 13. | Arterial Line (| should be removed if not needed) | | | |
| 14. | PCA pump or | epidural checked | | | |
| 15. | | | | | |
| 16. | | | | | |
| 17. | | | | | |
| от | Nurse | (Name, sign | ature & | stamp) | |
| Wa | rd Nurse | (Name, signa | ture & : | stamp) | |
| | te | (DD/MM/YYYY) Ti | me | | E 24 HOUR FORMAT OF TIME |

'SAFER SURGERY THROUGH BETTER COMMUNICATION'

Safe Surgery Saves Lives Programme

Safe Surgery Saves Lives Steering Committee & Patient Safety Unit Medical Care Quality Section Medical Development Division Ministry of Health, Malaysia



| Kinaly rejer to th | e primary team check | aise for com | piece informatio | in on the checklist | |
|------------------------------|-----------------------|--------------|------------------|--|--|
| PRE OPER | ATIVE CHEC | KLIST | | | |
| Name of Departr | nent | | | | |
| A. PATIENT P | ROFILE | | | | |
| Name | | | I/C Pas | sport No | |
| Age | Sex | Ra | ce | Hospital Reg. No | |
| Unit | | Wa | ard | Weight | |
| Diagnosis (as per | OT list) | | | | |
| Planned Operation / Proce | dure (as per consent) | | | | |
| Checked By (Ward Staff) | | Date | (DD/MM/YYYY) | Contact person & HP no. (Next of kin) | |

(has been corrected or rectified)

c. INFORMATION ON OPERATING ROOM / SURGEON / TIME OF SURGERY (Written in OR by Checklist Coordinator)

| Operating Room No. | Temperature | Humidity | | |
|-------------------------|-------------|---------------------------------|----|---------|
| Anaesthetist(s) | | | | |
| Surgeon(s) | | | | |
| Checklist Coordinator | | Time Start Surgery/Procedure | 35 | H (24H) |
| OPERATING TEAM CHECKING | ST | Time Complete Surgery/Procedure | | H (24H) |

BEFORE SKIN INCISION

DURING PROCEDURE

| ATT 100000 | |
|------------|--------|
| | |
| | |
| | |
| OYES (| ∃NO |
| | |
| | |
| | |
| | |
| | DYES (|

| INTRA-OPERATIVE COMMUNIC (By Surgeon, Anaesthetist & Scrut | |
|---|----------|
| PERIODIC UPDATES | TYES NO |
| SHOUT - OUT | |
| PRE-CLOSURE DISCLOSURE | DYES DNO |

BEFORE SURGEON LEAVES OPERATING ROOM

| SIGN OUT/Debriefing (By Surgeon / Checklist Coordinator N | lurse) |
|---|----------|
| The final name of the procedure, findings and post-op orders | DYES DNO |
| Final instrument & swab count was done | DYES DNO |
| Specimen to be labelled | |
| Any incidents or issues to be addressed? If yes, please specify below | |
| Any special post op instructions by anaesthetist or surgeon? | |
| INFORM THE RELATIVE | |

SAFE SURGERY SAVES LIVES PERI-OPERATIVE CHECK LIST



SWAB & INSTRUMENT COUNT FORM

PLANNED
SURGICAL PROCEDURE

1" TEAM

2" TEAM

2" TEAM

Cure 7 TIME START

Use 24 hour format of time,e.g. 2315H

Cure 24 hour format of

| Items | Initial count | Additional | Extra count | Additional | 2nd count | Additional | Final count |
|-----------------------|---------------|------------|----------------|------------|--------------|------------|-------------|
| Gauzes | | | | | | | |
| Abdominal packs | | | - | | | | |
| Blades | | | | | | | |
| Atraumatic Needles | | | | | | | |
| Loose Needles | | | | | | | |
| Diathermy cleaner | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

Specimen(s) sent

| Name of 1st Scrub Nurse | Time start | Time End | Signature |
|---------------------------|------------|----------|-----------|
| | | | |
| Name of 2nd Scrub Nurse | Time start | Time End | |
| | | | |
| Name of Circulating Nurse | Time start | Time End | |
| | | | |
| Name of Surgeon & MMC No. | Time start | Time End | 1.1 |
| | | | 1 |

PERI-OPERATIVE CHECKLIST SUMIMARY (Who to Do What, Where & When)

| WHEN | Before sending the case to OT | On arrival in OT | On arrival in OR | Before the Surgeon enters | Before Induction | During Procedure | After Closure | Before starting, before and after closure | Before patient leaves OT |
|------------------------------|----------------------------------|-----------------------------|--------------------------------------|------------------------------------|-------------------------------|------------------------------------|-------------------------------|---|------------------------------|
| WHO "WRITES" ON THE LIST? | Ward Staff Nurse | OT Reception Nurse | Circulating Nurse | Circulating Nurse | Circulating Nurse | Circulating Nurse | Circulating Nurse | Circulating Nurse | Ward Staff Nurse |
| IN THE PRESENCE OF | 1 | Ward Staff Nurse | - | Anaesthetic Assistant | Scrub Nurse / Anaesthetist | Scrub Nurse | Scrub Nurse / Anaesthetist | Surgeon / Circulating Nurse | Recovery Room Nurse |
| WHO "СНЕСКЅ"? | Ward Staff Nurse | OT Reception Nurse | Circulating Nurse | Anaesthetist/ Circulating Nurse | Surgeon | Surgeon / Anaesthetist | Surgeon | Scrub Nurse | Ward Staff Nurse |
| LOCATION (WHERE) | Ward | Reception Area in OT | Operating Room | Operating Room | Operating Room | Operating Room | Operating Room | Operating Room | Reception Area in OT |
| PROCESS (WHAT) | Pre-op Check (Pg1) | Pre-transfer Check (Pg1) | Information on OR & Surgery (Pg1) | Sign In (Pg2) | Time Out (Pg2) | Intra-op Communication (Pg2) | Sign Out (Pg2) | Swab & Instrument Count (Pg3) | Pre-discharge Check (Pg4) |
| STEPS | 1 | 2 | ß | 4 | ы | Q | 7 | Ø | σ |



TIME-OUT BEFORE PROCEDURE/SURGERY (VERBAL)

Before any procedure/surgery the team involved should perform VERBAL timeout to ensure correct procedure(s) is (are) performed on the correct patient.

Read Out Loud (Circulating Nurse/Operating Team Member)

| Date | : |
|---------------------|--|
| Patients Name | : Confirm (Surgeon)(Anaest) (Patient-GA Nurse to Respond) |
| Diagnosis | : Confirm (Surgeon) |
| Procedure/surgery | (: Confirm/Modify (Surgeon) |
| Site/side of surger | 'y : Confirm/Modify (Surgeon) |
| Name of Team Me | mbers : Respond (Each Member) |
| Consent : | Confirm (Surgeon)(Anaest) |
| Antibiotics given? | Respond (Anaest) |
| Surgeon Briefing | : (Incision, duration, blood loss, special steps/positioning) (Surgeon & Anaest) |
| Anaesthetist Read | y? : Check & Confirm (Anaest) |
| Scrub Nurse, All eo | quipments Ready? : Check & Confirm (SN&CN) |
| Check-In : Can we | start now? (Surg) : Respond (Anaes), (SN) |



PRE-OPERATIVE PATIENT VISIT

This is usually done on the day before elective surgery or on the day of surgery for emergency and day-care surgery.

BENEFITS OF PRE-OPERATIVE VISIT

- Allows the operating surgeon and anesthetist to know the patient and vice versa. This will help to reduce the patient's anxiety.
- Gives the surgeon an opportunity to do a final check on the pre-operative diagnosis and plan accordingly.
- Ensure the necessary equipment, instrument or implant is available.

DURING THE VISIT

- Introduce yourself and get to know the patient and relatives.
- Review diagnosis and the surgical plan. Communicate this with the patient. This may include risks, complications and subsequent post-operative care.
- Invite questions from the patient or relatives.
- Any change(s) to the surgical plan, either cancellation, postponement or modification should be conveyed to the patient.
- Any change of plan should be conveyed to the rest of the operating team.
- Marking of the operating site (where applicable) may be performed during this visit.

POST-OPERATIVE PATIENT VISIT

WHAT?

• Doctor assessing patient's condition following the surgery.

WHY?

- To assess patient's condition immediately after the surgery including vital signs, pain score and specific assessment if necessary e.g. neurovascular status.
- To explain to patient and family members regarding operative finding(s) and post-operative plan e.g. rehabilitation/physiotherapy.
- To detect any anaesthetic and post-operative complications.
- To check and ensure post-operative anaesthetic orders are carried out.
- To refer to appropriate discipline if indicated, such as acute pain service team for pain management.
- To ensure specific post-operative orders are understood and being carried out e.g. post vascular injury anticoagulant regime, abduction pillow, DVT prophylaxis etc.

WHEN?

• Preferably within 12 hours post operation and also when required.

WHERE?

• In the operation theatre recovery bay, ward or intensive care unit.

WHO?

• Preferably by the surgeon/medical officer and/or the anaesthetist/medical officer.

SURGICAL SITE MARKING

WHAT?

When a surgery involves a specific 'side' (left or right) or 'level' (as in spine surgery), the side/site is marked with indelible ink. This helps in ensuring the precise side/site to be operated on and prevent error from happening.

- Identify the site and/or side to be operated.
- Examples of procedure(s) that requires site/side marking:
 - o Brain
 - o Spine level for spine pathology
 - o Specific digit, limb or lesion
 - o Dual/multiple surgical sites
 - o Stoma site

WHY?

• To avoid wrong site (area) or side (right or left) of surgery.

WHO TO MARK?

• The operating surgeon or assistant with the participation of the patient/guardian.

WHEN?

• During pre-op visit or anytime before the patient is sent to OT.

HOW?

- After confirming the diagnosis.
- Use indelible, permanent black/blue marker pen.
- The mark is to be written on the skin.
- The mark is to be an arrow, (X) or (O) on or distal/proximal to the designated site and side.

Examples.:

- On the right thigh for the right hip
- On the right forehead/neck/shoulder for the right eye
- On the right neck for the right ear

WHERE?

• The site and/or side of the operative procedure where applicable.

SAFE USE OF TOURNIQUET IN SURGERY

WHAT?

A tourniquet is a mechanical device commonly used in surgery of the extremities to restrict blood flow in order to obtain a "bloodless" field. Staff involved in the use of tourniquet must know the potential risks to the patient.

WHY?

To avoid complications related to tourniquet.

WHEN?

For all procedures requiring the use of tourniquet in surgery.

WHERE?

In the operating theatre.

WHO IS USING?

The operating surgeon or assistant.

HOW?

As per standard operational procedure on the usage of tourniquet.

Note:

- Ensure correct indication, correct site, appropriate cuff size and pressure, proper padding and be aware of the tourniquet time.
- The area of skin over the thigh or arm should be checked for any signs of complication.

SAFE USE OF ELECTROSURGICAL UNIT (ESU)

WHAT?

ESU refers to the tool that apply electrical current to biological tissues as means to cut, coagulate, desiccates, or fulgurate tissues. Examples of ESU are diathermy, harmonic scalpel and ultrasonic dissectors.

WHY?

To assist in surgery.

WHEN?

During surgery.

WHO IS USING?

The operating surgeon or assistant.

SAFETY PRECAUTIONS WHEN USING DIATHERMY

- To ensure the correct mode of diathermy (i.e monopolar, bipolar) is used to avoid serious burn example airway burn by monopolar diathermy or interruption of medical device(s) such as pacemaker.
- 2. Place the pad on a clean, dry skin surface over or under a large muscle mass area, as close as to the operative site.
- 3. The dispersive electrode should not be placed on skin over a metal implant, such as a hip prosthesis and direct contact with any metal surface because current could be diverted to the implant and generate excessive heat.
- 4. Keep the electrosurgical pencil/probe in its holster when not in use to prevent direct skin burns or injury by its sharp tip.

Note:

We must follow strictly the standard operating procedure for the usage of other ESU e.g. laser surgery, harmonic scalpel and ultrasonic dissectors.



DOING SWAB, SHARP AND INSTRUMENT COUNTS

OBJECTIVES

- To prevent unintended retention of sponges, sharps and instruments in the body during surgery.
- To ensure accurate and complete documentation of sponges, sharps and instruments used during surgery.

THE COUNT

WHO?

The counting process is conducted by a Scrub Nurse and the Circulating Nurse.

WHAT?

There are three types of "count".

- 1) Pre-operative (initial count)
 - Sponges, sharps and instrument are counted before operation commenced.
 - Documentation of "initial count" is written at the "Swab & Instrument Count Form" by the circulating nurse.
- 2) Intra-operative count
 - Sponges, sharps and instrument are counted before closure of cavity within cavity and before closure of peritoneum.
 - Should be done intra-operatively and Surgeon must be informed.
 - The Scrub Nurse and Circulating Nurse must perform intra-operative count of sponges, sharps and instruments correctly before closure of cavity within cavity and closure of peritoneum.
 - Any item which is dropped at anytime during surgery, should be picked up by the Circulating Nurse. The Scrub Nurse must be notified regarding this incident. This must also be "shouted out". This item must be placed at the appropriate area, away from the sterile field but not out of the theatre environment.
 - Any supplementary pack, instrument or sponges added intraoperatively must be counted as well.
 - Documentation of "intra-operative count" is written at the "Swab & Instrument Count Form" by the circulating nurse.

- - 3) Post-operative count (final count)
 - Sponges, sharps and instrument are counted before skin closure.
 - Following the completion of the final count, the Scrub Nurse and Circulating Nurse must inform the Surgeon that the final count or postoperative count of sponges, sharps and instruments is correct. The Surgeon should verbally acknowledge this.
 - Documentation of "post-operative count" (final count) is written at the "Swab & Instrument Count Form" by the circulating nurse.

HOW?

- It should be done audibly and viewed concurrently.
- If the sponges are inadequate/incorrect it must be removed and open a new pack.
- If the instruments in the set are incomplete, it should be documented and either changed with a new set or add in supplementary item(s).

WHEN SCRUB NURSE CHANGED

(At The Time of Permanent Relief Involving Either The Scrub Nurse or The Circulating Nurse)

If the Scrub Nurse needs to be replaced, a full Surgical count must be undertaken and their names in the "Swab & Instrument Count Form" must be documented.

MANAGING COUNT DISCREPANCY

1. In the event of count discrepancy the surgeon must be notified. It is the responsibility of the surgical team to manage the situation.

2. Dismissing/accepting an incorrect count by the perioperative team is not accepted.

- 3. If the patient's condition permits, the procedure needs to be stopped temporarily.
- 4. The wound shall not be closed until the situation is resolved.
- 5. A recount and thorough search of the surgical field and surrounding area need to be conducted.



- 6. If the item is not found, an intraoperative X-Ray/Image intensifier should be done.
- 7. The surgeon may perform an exploration of operative field.
- 8. If the count is still incorrect and after extensive search, consensus decision among team members must be reached before the surgical wound is closed.
- 9. All steps taken should be documented in the patient's record. This record must be signed by the scrub nurse and the operating surgeon.
- 10. Make an incident report.
- 11. Conduct investigation to find out the contributing factors and the root cause.
- 12. Take necessary actions to prevent recurrence of incident.
- 13. Notify the Head of Department/Hospital Director.
- 14. Inform the patient.

DEEP SURGICAL WOUND/CAVITY PACKING

WHO DECIDES?:

Operating surgeon.

WHY?:

- Secure heamostasis.
- Prevent collection of blood, pus, serous etc.
- Deliver local antiseptic (when the pack is soaked with antiseptic).
- Prevent premature wound closure.
- Promote wound healing.

HOW?

- Use raytex gauze/abdominal pack/roller gauze.
- Use appropriate size gauze for packing.
- Number of gauze used depends on the size of the cavity.
- Ensure the end of the packed gauze is easily visible and remain outside when packing the open wounds.
- Reconfirm with the scrub nurse and the circulating nurse the number of packed gauze used before the outer dressing is applied.
- Document clearly the number of packed gauze in the Safe Surgery Checklist form and also in the operative notes.

DON'T:

- Use non raytex sponges.
- Pack without the knowledge of the scrub nurse and circulator.
- Cut gauzes/sponges.



PROPHYLACTIC ANTIBIOTICS

The appropriate use of prophylactic antibiotics is an important strategy in the prevention of surgical site infection.

AIM:

• To achieve serum and tissue drug levels that exceed the minimal inhibitory concentrations (MIC) for the organisms likely to be encountered during the operation.

WHEN?

- The procedure is associated with high risk of infection (eg, colon resection); or
- Consequences of infection are unusually severe (eg, total joint replacements)

or

• Catastrophic risk (neurosurgery, cardiac surgery) even in clean elective surgery.

WHAT TO USE (CHOICE)?

• Antibiotics with longer half-life should generally be chosen.

TIMING:

- Administered preoperatively **as close to the time of the surgery** (usually within one hour of surgery); before induction of anesthesia in most situations or before inflation of tourniquet applied for related procedure.
- The `Time-Out' portion of the checklistserves as a timely reminder.

ROUTE:

• Generally intravenous (IV).

RE-DOSING:

- Advisable for procedures exceeding 3 hours. This must be verified during the intra-operative communication.
- In the event of major intraoperative blood loss in adults (>1,500 ml)/ children (25ml/kg); additional dosage of prophylactic antibiotic should be considered after fluid replacement.



DURATION:

• Generally, single dose or not more than 24 hours postoperative administration of preventive systemic antibiotics beyond 24 hours has not been demonstrated to reduce the risk of surgical site infection.

IMPORTANT NOTE:

- Preventive systemic antibiotics should not be used to prevent nosocomial infection.
- Systemic preventive antibiotics is only of value in the prevention of infections at the surgical site and not for subsequent nosocomial events.
- Proper surgical technique and gentle tissue handling rather than systemic antibiotics is the most important measure in preventing surgical site infection.

Notes:

Refer to Ministry of Health Malaysia National Antibiotic Guidelines 2014 for choices of antibiotics to be used

EFFECTIVE COMMUNICATION IN SAFE SURGERY

Effective communication is essential in ensuring safer surgery.

Three areas on communication need to be emphaised:

- 1. Understanding of patients and relatives about the surgery.
- 2. Effective communication between operating team members.
- 3. Rapport between operating team members and patients.

1) Understanding of patients and relatives about the surgery

Informed consent for surgery involves giving appropriate information about the surgery to the patient. This can be done at the time of booking in the clinic, when the patient first agreed for the proposed surgery. Ideally, the explanation about the surgery should be done by the surgeon who will conduct the surgery. If this is not possible, a senior member of the team should do the explanation.

Nowadays, the anaesthetist too have taken steps to explain to patients about the process of anaesthesia at the Pre-Anaesthetic Clinic.

Another opportunity for the surgeon to get to know the patient better is after he is admitted to hospital for the surgery. It is important for the surgeon to meet the patient prior to the surgery. In a situation where the relatives are present, they may also have questions to ask the doctor regarding the planned operation.

A surgeon should make pre-operative visit a ritual. During this visit, the surgeon:

- Will be able to know the patient present condition.
- Can make any changes to the planned procedure, if necessary.
- Will be able to counsel the patient about post-operative care.
- Can answer any questions, the patient or relatives may have.
- Can mark the operative site (where applicable).

The most common question asked by relatives during pre-operative visit is "What time is the surgery tomorrow?"

Pre-operative visits do reduce anxiety in patients undergoing surgery.



Post-operatively, the surgeon should visit the patient within 24 hours after the surgery. During this visit he can:

- Inform the patient about the surgical findings.
- Review patient condition and plan the post-operative management (eg. Resume oral intake or removal of sutures).

The most common question asked by relatives during post-operative visit is "When can the patient go home?"

2) Effective communication between operating team members

Members of the operating team refers to those in the operating room at the time of surgery. Basic key personnels are the:

- Surgeon and his assistant(s)
- Anaesthetist and his assistant(s)
- Scrub nurse and circulating nurse
- Attendant

Before the start of surgery, all these individuals need to be on the same page. They should be aware of what procedure will be carried out and the role they need to play. In the majority of cases, the diagnosis and the planned operative procedure is familiar to the team members. However, this must not be taken for granted. The surgeon must ensure that the procedure to be carried out is understood by all, especially if there are possible variations in technique or positioning.

The surgeon must take the lead to know the members of the operating team. The `**white board**' serves as a good reference. If any special equipment or anaesthesia technique is required, this should be communicated before the commencement of anaesthesia.

`**Time out**' serves as the final check of readiness before the start of surgery. As a matter of courtesy, the surgeon should seek the 'green light' from the anaesthetist and the scrub nurse before making the first incision. This is the `**check-in**'.



Intraoperatively, the anaesthetist, the surgeon and the scrub nurse must freely communicate critical information such as 'two packs-in', 'diathermy not working' and 'patient barking'. This is important, so that the the respective team members can respond appropriately in order to ensure smooth running of the surgery.

Before leaving the Operating Room, the surgeon should thank the team members after the debriefing.

3) Rapport between patient and operating team

In order to improve the rapport between the patient and the operating team, the patient should at the minimial know who is the surgeon conducting the surgery. This is important since the other members of the operating team may not be constant.

The surgeon may delegate one of his assistants as a contact person representing the surgical team. This contact should be made available until the patient is discharged from follow-up.

MANAGING ADVERSE EVENTS

WHAT?

According to World Health Organization 2009, Conceptual Framework for the International Classification for Patient Safety Version 1.1, **adverse** event is defined as an injury that was caused by medical management or complication instead of the underlying disease and that resulted in prolonged hospitalization or disability at the time of discharge from medical care or both.

For instance post-operative complications, wrong side/site surgery, unintended retained foreign body.

*Some may use the terminology 'adverse event' quite loosely and perceive that 'any outcome which is worse than expected (by patients or relatives)' can be considered as 'adverse events', in this context.

WHY?

Adverse events was caused by medical management or complication instead of the underlying disease. Appropriate response to adverse events can alleviate anxiety, prevent anger and possible litigation. Appropriate and effective communication is the key in managing adverse events.

WHO?

Staff who are at the scene of the event are required to institute necessary management /treatment immediately. If the incident involved severe outcome, death of patient or potentially medico-legal, the event need to be managed further by the Head of Department and the Hospital Director.

WHEN?

The response to the "adverse event" must be as prompt as possible.

HOW?

Incident Reporting need to be submitted following the event.

The Head of Department and the Hospital Director must be informed immediately.

He or she, then gathers all the facts relating to the event from direct sources.



A meeting or 'family conference' need to be arranged with the affected patient and relevant relatives. The purpose is to :

- Convey the news of the event and facts related to it
- Apologise and empathise

Continue managing the case with higher level of care (eg. If it is surgical complication or patient safety incidents such as wrong surgery or retained foreign body), the level of care should be specialist-led.

The affected patient/relatives should be given 'a person in-charge' contact number to facilitate communication between hospital and patient/relatives.

Investigation such as Root Cause Analysis, to find the root cause and the contributing factors of the incident should be conducted by the Root Cause Analysis team of the hospital. Staff involved in managing the case should not be part of the investigating team. They can only be the individuals giving information on the incident.

An investigation report with effective risk reduction strategies and action plan need to be produced and discussed with the Safe Surgery Saves Lives Committee. In the the case of Patient Safety Incident leading to severe harm or death of patient, the case need to be discussed during Patient Safety Committee Meeting at hospital level.

Any 'system issues' should be rectified to prevent similar incidents from happening.

For Patient Safety Incident leading to severe harm or death of patient, the RCA Report also need to be submitted to Patient Safety Unit, Medical Care Quality Section, Medical Development Division, Ministry of Health Malaysia. (*Please refer to Guidelines on Implementation - Incident Reporting & Learning System 2.0 for Ministry of Health Malaysia Hospitals. Available at Patient Safety Council Malaysia website*).

*Patient Safety Incident – an event or circumstances which could have resulted or did result in unnecessary harm to patient. An incident can be reportable circumstances, near miss, no harm incident or harmful incident (adverse event).

SSSL CHECKLIST AUDIT

WHAT?

This audit is intended to monitor the compliance to the use of Safe Surgery Checklist in hospitals.

WHY?

Findings from the audit will be used to identify issues, challenges of implementation and improve implementation of the SSSL Programme further.

WHO?

The audit will be coordinated by the Safe Surgery Saves Lives Committee in hospital. A specific sub-committee for audit can be established to assist in conducting the audit.

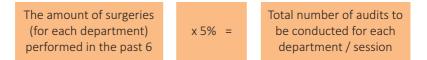
WHEN?

Data will be collected retrospectively for surgeries conducted within a period of 6 month (i.e biannual audit).

HOW?

Sample Size

5% of the number of operations performed for each Surgical Related Departments. The amount to be audited is based on the following formula:



If the number of surgeries performed is less than 10 , all cases performed by the Department should be included.

Audit Forms & database for analysis

The audit form and database is downloadable at the official Patient Safety Council Malaysia Portal www.patientsafety.moh.gov.my/v2.

• Preparation and presentation of SSSL Checklist Audit report

The findings of the audit should be discussed with and presented to the Safe Surgery Saves Lives committee chairman and committee members.

GUIDE ON TAKING CONSENT

WHAT?

Informed consent is the process by which the treating health care provider discloses appropriate information to a competent patient so that the patient may make a voluntary choice to accept or refuse treatment.

WHY?

Important part of medical ethics and the international human rights law.

WHO?

- For consent to be valid, it must be voluntary and informed, and the person consenting must have the capacity to make the decision.
- Voluntary the decision to either consent or not to consent to treatment must be made by the person themselves, and must not be influenced by pressure from medical staff, friends or family.
- Capacity the person must be capable of giving consent, which means they understand the information given to them and they can use it to make an informed decision.
- Consent should be given by the healthcare professional directly responsible for the patient's current treatment.

WHEN?

Should be obtained in advance prior to the procedure.

HOW?

Informed – the person must be given all of the information in terms of what the treatment involves, including the benefits and risks, whether there are reasonable alternative treatments, and what will happen if treatment does not proceed.

Patients should have their consent taken in advance, so they have time to obtain information about the procedure and ask questions.





WORLD HEALTH ORGANIZATION - 10 OBJECTIVES FOR SAFE SURGERY

- 1. The team will operate on the correct patient at the correct site.
- 2. The team will use methods known to prevent harm from anaesthetic administration, while protecting the patient from pain.
- 3. The team will recognize and effectively prepare for life-threatening loss of airway or respiratory function.
- 4. The team will recognize and effectively prepare for risk of high blood loss.
- 5. The team will avoid inducing any allergic or adverse drug reaction known to be a significant risk for the patient.
- 6. The team will consistently use methods known to minimize risk of surgical site infection.
- 7. The team will prevent inadvertent retention of instruments or sponges in surgical wounds.
- 8. The team will secure and accurately identify all surgical specimens.
- 9. The team will effectively communicate and exchange critical patient information for the safe conduct of the operation.
- 10. Hospitals and public health systems will establish routine surveillance of surgical capacity, volume, and results.

Reference

Selected bibliography supporting the ten essential objectives for safe surgery http://www.who.int/patientsafety/safesurgery/knowledge_base/bibliography/en /index.html

Apendix 2



HOSPITAL

KEIZINAN PEMBEDAHAN/PROSEDUR

PER/CONSENT/2016

| Saya, | beralamat |
|--------------------------------------|---|
| | _dengan ini bersetuju dan memberi keizinan untuk: |
| * (A) menjalani pembedahan/prosedur | |
| * (B) menyerahkan *anak/jagaan saya, | , No. KP/ID |
| untuk menjalani pembedahan/prosedur | |
| | |

di bawah (jenis anestesia) *anestesia umum/setempat/lain-lain _____yang maklumat/tatacara, tujuan dan risikonya telah diterangkan kepada saya oleh Dr. ______ melalui penterjemah (jika ada) ______. Saya mengaku bahawa saya faham akan penerangan yang diberikan dengan sepenuhnya dan saya juga faham sebab, akibat dan risiko pembedahan/prosedur berkenaan.

Saya juga bersetuju dan memberi keizinan untuk sebarang pembedahan/prosedur tambahan atau alternatif sebagaimana yang didapati perlu semasa pembedahan/prosedur tersebut di atas dan pemberian anestesia umum, setempat atau lain-lain bagi tujuan ini.

Tidak ada jaminan yang telah diberi kepada saya bahawa pembedahan/prosedur/rawatan bius itu akan dijalankan oleh mana-mana pengamal tertentu.

| | Peringatan: |
|---|---|
| Ditandatangani : (*Pesakit/Ibu/Bapa/Penjaga) Hubungan/Tali Persaudaraan: No. KP/ID : Tarikh : | Jika seseorang itu memberi keizinan sebagai seorang penjaga, hendaklah hubungan/tali persaudaraannya dijelaskan di bawah tandatangannya. Saksi boleh terdiri dari pengamal berdaftar/jururawat yang tidak terlibat secara langsung dengan rawatan dan tiada hubungan/tali persaudaraan dengan pesakit atau pengamal yang meminta keizinan. |
| Saksi: | |
| Tandatangan : | Penterjemah (jika ada): |
| Nama : | Tandatangan : |
| No. KP/ID : | No. KP/ID : |
| Jawatan : | Tarikh : |

Saya mengakui bahawa saya telah menerangkan maklumat/tatacara, tujuan dan risiko pembedahan/prosedur ini kepada *pesakit/ibu/bapa/penjaga.

_____ Bahasa yang digunakan :_____

| Ditandatanga | |
|--------------|---------------------------------|
| | (Pengamal *Perubatan/Pergigian) |
| No. MPM | : |
| Tarikh | : |
| Cap Jawatan | : |

Peringatan: Sebarang pindaan kepada borang ini hendaklah dibuat sebelum penerangan diberi dan borang dikemukakan untuk ditandatangani.

*Potong yang tidak berkenaan

Tarikh



| Nama Pesakit | | - | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | | |
|--------------|---|---|-------|---|---|---|---|---|---|---|---|---|------|---|---|---|---|---|---|---|---|
| No. MRN | : | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | | _ | _ | _ | _ |
| No. KP/ID | : | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ |
| Jantina | : | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ |
| Tarikh | | | | | | | _ | | | | | | ng - | - | • | | | | | | |

| Lampiran A: | Penjelasan tentang pembedahan/prosedur | · |
|-------------|--|---|
| | | |

Maklumat/Tatacara:

| - | | | - | | | - | - | - | - | | - | - | - | - | - | | - | | | - | | | • | | | | - | | | - |
|---|------|-------|---|------|------|-------|---|---|---|------|---|---|---|---|---|------|---------|---|------|---|------|------|---|------|------|------|---|------|------|-------|
| - | | | _ | | | | | - | | | | | - | | | | | | | - | | | | | | | - | | | - |
| _ | | | - | | | | _ | _ | | | | - | _ | - | _ | | · _ | | | - | | | | | | | - | | | - |
| _ | | - | _ | | | | - | - | | | | - | - | - | | | | | | _ | | | | | | | - | | | - |
| _ | | - | _ | | | | _ | _ | | | | | _ | _ | | | | _ | | _ | | | - | | | | - | | | - |

Tujuan:

| | | _ | | | | | - | | |
|------|------|---|------|------|------|------|-------|------|------|------|------|------|------|------|------|------|------|--|
| | | _ | | | | | - | | |
| | | _ | | | | | _ | | |

Risiko:

| 2. | |
|----|--|
| 3. | |
| 4. | |
| 5. | |
| | |

Nota penjelasan tambahan yang diberi (jika ada) bertajuk: ______

Tandatangan *Pesakit/Ibu/Bapa/Penjaga:

Peringatan:

Keizinan Pembedahan/Prosedur dan Lampiran A hendaklah ditandatangani oleh individu yang sama.

*Potong yang tidak berkenaan



CONSENT FOR OPERATION/PROCEDURE

PER/CONSENT/2016

| l,(| of (address) |
|--|--|
| . 3 | hereby agree and consent |
| Station Aller | |
| *(A) to undergo the operation(s)/procedure(s) of | |
| *(B) to the submission of my *child/ward, | , IC/ID No |
| to undergo the operation(s)/procedure(s) of | |
| under (type of anaesthesia) *general/local/other(s) | |
| the nature, purpose and potential risk(s) of which has | ave been explained to me by Dr |
| through interpretation by (if any) | I fully understand the explanation given |
| and also understand the reasons, consequences and | risks of the operation/procedure. |

I also agree and consent to any additional or alternative operative measures/procedures as may be found necessary during the course of the above mentioned operation(s)/procedure(s) and to the administration of general, local or other anaesthesia for any of these purposes.

No guarantee has been given to me that the operation/procedure/anaesthetic care will be performed by any particular practitioner.

| Signed | : (*Patient/Parent/Guardian) |
|--------|---------------------------------|
| | p: |

Witness:

| Signature | : |
|-----------|----|
| Name | : |
| IC/ID No. | : |
| | n: |
| Date | : |

Note:

 If the person gives his/her consent as a guardian, his/her relationship with the patient should be stated below his/her signature.

 The witness may be another practitioner or a nurse who is not directly involved in the management of the patient nor related to the patient or the practitioner taking consent.

Interpreter (if any):

| Signature | : |
|-----------|-------|
| IC/ID No. | : |
| | : |
| Language | used: |

I confirm that I have explained the nature, purpose and potential risk(s) of this operation(s)/ procedure(s) to the *patient/parent/guardian.

| Signed | : |
|--------|-------------------------------|
| | (*Medical/Dental Practitioner |
| MMC/MD | CNo.: |
| Date | : |
| Stamp | : |

Note:

Any amendments to the form are to be made before the explanation is given and the form is submitted for signature.

*Delete as appropriate



| Name of patien | t: | - | | | | | | _ | _ | _ | | | _ | _ | _ | | _ | _ | _ | _ | _ |
|----------------|----|---|---|---|---|---|---|---|---|---|---|---|----------|---|---|---|---|---|---|---|---|
| MRN No. | : | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ |
| IC/ID No. | : | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ |
| Gender | : | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | <u>.</u> | _ | _ | _ | _ | _ | _ | _ | _ |
| Date | : | _ | _ | | _ | _ | _ | _ | _ | | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ |

Attachment A: Explanation of operation/procedure

Nature:

| - | | | | - | - | _ | | | | | - | | | | | | | | | | | | - | | - | | - | | |
|---|------|------|------|---|---|---|------|------|------|------|-------|---|---|---|-------|------|------|-------|---|------|-------|------|---|------|-------|------|---|------|--|
| - | | | | - | _ | _ | | | | | - | | - | | - | | | | - | | - | | - | | | | - | | |
| _ | | | | - | _ | _ | | | | | - | - | - | | | | | • | | | - | | - | | - | | | | |
| _ | | | | _ | _ | _ | | | | | _ | - | _ | - | | | | | | | - | | - | | _ | | - | | |
| _ | | | | _ | _ | _ | | | | | _ | | - | | | | | | - | | _ | | - | | | | - | | |

Purpose:

| - | | - | - | | _ | | - | _ | | _ | | - | | | | | | _ |
|-------|------|-------|---|------|-------|------|---|---|------|-------|------|-------|------|------|------|------|------|------|------|-----|------|------|------|---|
| - | | | | | - | | | - | | - | | - | | • - | | | | - |
| _ | | _ | _ | | _ | | | _ | | _ | | | | | | | | | | | | | | |

Risk(s):

| 1. | |
|----|--|
| 2. | |
| | |
| 4. | |
| 5. | |

| Title of additional explanatory note/information sheet provided (if any): |
|---|
| |

Signature of *Patient/Parent/Guardian:

Note:

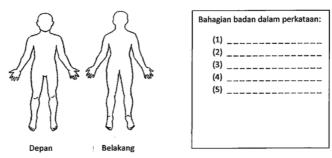
Consent for operation/procedure and Attachment A must be signed by the same person.

*Delete as appropriate

Apendix 3

| | e seconda - 🔊 | |
|--------------|--------------------------------------|----------------|
| | HOSPITAL | |
| | BORANG KEIZINAN FOTOGRAFI/MULTIMEDIA | PER/PHOTO/2016 |
| Nama pesakit | : | |
| No. KP/ID | • | |
| MRN | : | |

Ditandakan dalam gambarajah di bawah, bahagian badan yang akan dirakam imejnya (jika berkenaan):



Saya, *pesakit sendiri/ibu/bapa/penjaga/suami/isteri/saudara kepada pesakit yang namanya tertera di atas, dengan ini bersetuju dan memberi keizinan untuk *fotografi/rakaman multimedia diambil ke atas *saya/pesakit, seperti yang ditandakan di atas, bagi tujuan diagnosa, perawatan, pembelajaran, akademik dan penyelidikan sahaja. Rakaman ini tidak akan diterbitkan bagi tujuan komersial atau peribadi. Walau bagaimanapun, saya bersetuju dan memberi kebenaran untuk rakaman ini digunakan bagi promosi kesihatan atau pembelajaran. Saya difahamkan bahawa kerahsiaan dan kehormatan diri *saya/pesakit akan dilindungi sebaik mungkin.

| | | <u>Penterjemah (</u> | <u>iika ada):</u> |
|---------------|------------------------|----------------------|-------------------|
| Tandatangan * | pesakit/pemberi izin : | Tandatangan | : |
| Nama pemberi | izin : | Nama | : |
| Hubungan den | gan pesakit: | No. KP/ID | : |
| No. KP/ID pem | beri izin: | Tarikh | |
| Tarikh | : | Bahasa yang di | gunakan: |
| Pemohon: | | Saksi: | |
| Tandatangan | : | Tandatangan | : |
| Nama | : | Nama | : |
| Jawatan | : | Jawatan | : |
| No. KP/ID | : | No. KP/ID | : |
| Tarikh | : | Tarikh | : |

*Potong yang tidak berkenaan

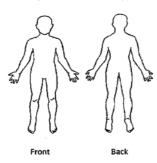
m/s 1/1



PHOTOGRAPHY/MULTIMEDIA CONSENT FORM

| Name of patient | : |
|-----------------|---|
| IC/ID No. | : |
| MRN | : |

Indicated in the diagram below, is the area(s) which is/are to be photographed/recorded (if applicable):



| Part(s) | of the body in words: |
|---------|-----------------------|
| (1) | |
| (2) | |
| (3) | |
| (4) | |
| (5) | |
| | |
| | |
| | |
| | |
| | |

PER/PHOTO/2016

I, *parent/guardian/spouse/relative of the above named, consent to the *photography/multimedia recording, as indicated above, of *myself/the said patient, to be used only for diagnostic, treatment, teaching, academic and research purposes. The record is not for commercial or personal publication. However, I agree and give my consent for this record to be used for health promotion or teaching. I have been explained and understand that *my/the patient's identity and modesty will be protected as far as possible.

| Signature of *patient/person consenting: | | | | | | | | |
|--|---|-----|--|--|--|--|--|--|
| Name of person consenting | : | Na | | | | | | |
| Relationship | : | IC/ | | | | | | |
| IC/ID No. of person consenting | : | Dat | | | | | | |
| Date | · | Lar | | | | | | |
| | | | | | | | | |

Requesting person:

| Signature | : |
|-------------|---|
| Name | : |
| Designation | : |
| IC/ID No. | : |
| Date | : |

Translator (if any):

| Signature | : |
|---------------|----|
| Name | ·: |
| C/ID No. | : |
| Date | · |
| Language used | : |

Witness:

| Signature | : |
|-------------|---|
| Name | : |
| Designation | : |
| IC/ID No. | : |
| Date | : |
| | |

*Delete as appropriate

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Apendix 4



HOSPITAL

SURAT AKUAN TIDAK SETUJU RAWATAN/PROSEDUR PER/REFUSE/2016

Saya, _____No. KP/ID ______ adalah *pesakit sendiri/ibu/bapa/suami/isteri/anak/penjaga/saudara kepada pesakit, ______No. KP/ID ______, tidak bersetuju menerima rawatan/prosedur _______ ke atas *saya/pesakit. Saya mengakui bahawa saya telah dimaklumkan dengan terperinci mengenai rawatan/prosedur tersebut termasuklah keperluan dan kebaikannya.

Saya juga telah dimaklumkan dan memahami risiko-risiko yang boleh dihadapi jika rawatan/ prosedur ini tidak dilakukan.

Saya mengaku bahawa keputusan ini adalah di atas kerelaan diri saya sendiri. Saya akan bertanggungjawab sepenuhnya ke atas sebarang kemungkinan akibat tindakan saya ini.

Saya mengakujanji tidak akan mengambil sebarang tindakan undang-undang terhadap pihak hospital atau mana-mana pihak lain yang berkenaan sekiranya berlaku sebarang perkara yang tidak diingini akibat daripada keputusan saya ini.

| Tandatangan | : | Tandatangan pe | enterjemah: |
|-----------------|--|-----------------|-------------|
| (*Pesakit/ibu/b | apa/suami/isteri/onak/penjaga/saudara, | (jika ada) | |
| nyatakan hubung | an:) | Nama Penterje | mah: |
| Alamat | | No. KP/ID | : |
| | | Tarikh | : |
| No. Telefon | : | Bahasa yang dig | gunakan: |
| Tarikh | : | | |

| Tandatangan D | oktor : | Tandatangan | saksi : |
|---------------|-----------|-------------|---------|
| Nama Doktor | : | Nama saksi | : |
| No. MPM | : | No. KP/ID | : |
| Tarikh | : | Jawatan | : |
| Cap Jawatan | : | Tarikh | : |

*Potong yang tidak berkenaan

m/s 1/1



HOSPITAL

TESTIMONIAL LETTER OF REFUSAL OF TREATMENT/PROCEDURE PER/REFUSE/2016

| l, | IC/ID No, |
|---------------------------------|---|
| *patient/parent/spouse/son/dat | ghter/guardian/relative of the patient |
| IC/ID No | refuse the treatment/procedure of |
| for *me/the patient. I have bee | n given detailed explanation of the treatment/procedure including the |
| purpose and benefit(s). | |

I have also been explained and understand the possible risk(s) if the treatment/procedure is not performed.

I confess that this decision was made on my own free will. I shall be fully responsible for any possible consequence(s) arising from this action.

I affirm that I will not take any legal action upon the hospital or any other relevant parties should there be any unfortunate outcome resulting from this decision.

| Signature | : | Signature of trai | nslator: |
|--------------------|---|-------------------|----------|
| (*Potient/Porent/ | 'Spouse/Son/Daughter/Guardian/Relative, | (if any) | |
| state relationship | :) | Name of transla | tor: |
| Address | : | IC/ID No. | : |
| | ~~~~~ | Date | : |
| Tel. No. | : | Language used | : |
| Date | | | |

| Signature of Doctor: | Signature of witness: |
|----------------------|-----------------------|
| Name of Doctor: | Name of witness: |
| MMC/MDC No.: | IC/ID No. : |
| Date : | Designation : |
| Stamp : | Date : |
| | |

*Delete as appropriate

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Patient Safety Unit, Medical Care Quality Section, Medical Development Division, Ministry of Health Malaysia

In collaboration with

Safe Surgery Saves Lives Steering Committee, Ministry of Health Malaysia 2018

