Informed consent
Surgical safety check list

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Informed consent: why?

• Why informed consent?
• Without consent, surgery = criminal assault
• Change from
  
  Surgeon knows best to patient should be part of the decision making process
• “Informed”
• “Consent”
Who?: Surgeon

- Should ideally be the surgeon
- As senior as possible
- Must either
  1. be capable of performing the procedure themselves; or
  2. have received specialist training in advising patients about the procedure

Who?: Patient

- Ideally the patient
- Children (<18 years): parents/guardians
- Competence
When?

• Process NOT an event
• Start at the first consultation
• Periodic discussion at all encounters
• Reinforce a day before surgery
• First time should not be on the day of surgery (= duress)
How?

• In a language that the patient understands
• Describe the procedure in simple, layman’s terms
• Mention the anesthesia
• Options (eg. aneurysm, AVM, VS)
• Risks and benefits of surgery
Risks

• ‘A patient may make an unbalanced judgement because he is deprived of adequate information. A patient may also make an unbalanced judgement if he is provided with too much information and is made aware of possibilities which he is not capable of assessing because of his lack of medical training, his prejudices or his personality.’ (per Lord Templeman in Sidaway (1985) 1AC 871 at 904, as cited by Lord Woolf in Pierce)
Risks: how much?

• All significant and irreversible risks
• Avoid too much and too little
• Any complication that is likely to occur in >1%; but death is mentioned in all neurosurgical operations
• Quote your complication rates not from literature
• A key point to remember is the doctor's responsibility to inform a patient of ‘a significant risk which would affect the judgement of a reasonable patient’ (i.e. cause the patient to decline surgery).
Document

- Document the discussion process (who and when)
- Consent form
- Signature of patient/relative
- Signature of doctor
- Signature of witness
- Date and time
Special scenarios

• Additional procedures due to un-expected findings
  Try and get consent if it is not an emergency
• In an emergency
  Document the emergency
  Try and get another surgeon’s agreement
CONSENT FORM FOR PATIENTS UNDERGOING PROCEDURES
IN NEUROSURGERY UNIT II

1) I __________________________________ son/daughter/ wife of __________________________________

aged ______ resident of door No. __________ Street __________________________

Village ______________ Town ______________ District _________________________

State, am the ______________ of ______________ CMCH No ______________ being under
the treatment in Neurosurgery unit II, Department of Neurological Sciences, Christian Medical College,
Vellore, 632004, Tamilnadu, India. I do hereby give consent to the performance of the following procedure
on ______________________ CMCH No. ______________

☐ ........................................ craniotomy and ........................................

☐ ........................................ laminectomy and ........................................

☐ Anterior cervical discectomy / corpectomy with bone graft
☐ Posterior fusion and bone graft
☐ Transoral .............................................................
☐ Endoscopic ..........................................................
☐ Shunt
☐ Stereotactic biopsy
☐ Stereotactic radiosurgery
☐ Tracheostomy
☐ Others (To be specified):

2) I declare that I am more than 18 years of age hence legally entitled for giving this consent.

3) Risks and potential benefits of the procedure have been explained by Dr. ______________
The alternative management are:

☐ Observation with periodic imaging ☐ Empirical treatment with medications
☐ Surgical resection ☐ Endovascular treatment
☐ Radiation therapy ☐ Chemotherapy
☐ Shunt ☐ Endoscopic third ventriculostomy
☐ Others (To be specified)
4) It has been explained to me / to my relative that the risks associated with the procedure include, but are not limited to:

- Death
- Loss of consciousness
- Memory impairment
- Visual loss
- Facial weakness
- Hearing loss
- Limb weakness
- Bleeding at the site of surgery
- CSF leak and infection
- Incomplete AVM obliteration
- Implant malfunction
- Others (To be specified)
- Seizures
- Speech/language impairment
- Double vision
- Facial numbness
- Difficulty in swallowing and speaking
- Imbalance while walking
- Headache and vomiting
- Urinary disturbances
- Re-operation

5) The above details have been explained to me in a language that I have understood and all of my questions have been answered.

6) I understand:
   a. that the procedure may not be done by the doctor who has seen me in the out-patient clinic or in the emergency department.
   b. However, the operation will only be done by a doctor/ team of doctors who are competent to perform the operation.

7) I understand that any information related to my illness now and at follow up will be kept confidential except for its publication in a scientific journal or presentation at a scientific forum, at which time my identity would be appropriately concealed.

8) I understand that any tissue that is removed from my body at the time of surgery may be stored for carrying out further tests in future and the results of these may be reported as a publication in a scientific journal or presentation at a scientific forum, at which time my identity would be appropriately concealed. I understand that I shall be informed of the results of such tests if it would have a direct bearing on the treatment of my disease at that time.

Signature ___________________________ Name ___________________________

Person's relationship with patient in case relative is signing consent:

Name of Doctor: ___________________________ Emp No: ______ Signature ______

Name of Witness: ___________________________ Emp No: ______ Signature ______

Date: ___________________________
Essential components

- Diagnosis/procedure
- Alternatives
- Anesthesia
- Possible complications
- Language understood by the patient
- Signature of patient/relative
- Signature of doctor with time and date
- Signature of witness
- Consent for use of tissue for research
Surgical safety checklist

• Why?
  
  Half of all surgical complications are avoidable
  
  Teamwork improves outcomes
  
  Communication helps in avoiding complications
A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population

**METHODS**

Between October 2007 and September 2008, eight hospitals in eight cities (Toronto, Canada; New Delhi, India; Amman, Jordan; Auckland, New Zealand; Manila, Philippines; Ifakara, Tanzania; London, England; and Seattle, WA) representing a variety of economic circumstances and diverse populations of patients participated in the World Health Organization’s Safe Surgery Saves Lives program. We prospectively collected data on clinical processes and outcomes from 3733 consecutively enrolled patients 16 years of age or older who were undergoing noncardiac surgery. We subsequently collected data on 3955 consecutively enrolled patients after the introduction of the Surgical Safety Checklist. The primary end point was the rate of complications, including death, during hospitalization within the first 30 days after the operation.

**RESULTS**

The rate of death was 1.5% before the checklist was introduced and declined to 0.8% afterward ($P=0.003$). Inpatient complications occurred in 11.0% of patients at baseline and in 7.0% after introduction of the checklist ($P<0.001$).
The Checklist Manifesto
A New York Times bestseller

How to Get Things Right

Atul Gawande
# Surgical Safety Checklist (First Edition)

## Before Induction of Anaesthesia

<table>
<thead>
<tr>
<th>SIGN IN</th>
</tr>
</thead>
<tbody>
<tr>
<td>- <strong>Patient has confirmed</strong></td>
</tr>
<tr>
<td>- Identity</td>
</tr>
<tr>
<td>- Site</td>
</tr>
<tr>
<td>- Procedure</td>
</tr>
<tr>
<td>- Consent</td>
</tr>
<tr>
<td>- Site marked/Not applicable</td>
</tr>
<tr>
<td>- Anaesthesia safety check completed</td>
</tr>
<tr>
<td>- Pulse oximeter on patient and functioning</td>
</tr>
</tbody>
</table>

**Does patient have a:**

- **Known allergy?**
  - No  
  - Yes
- **Difficult airway/aspiration risk?**
  - No  
  - Yes, and equipment/assistance available
- **Risk of ≥500mL blood loss (7mL/kg in children)?**
  - No  
  - Yes, and adequate intravenous access and fluids planned

## Before Skin Incision

<table>
<thead>
<tr>
<th>TIME OUT</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Confirm all team members have introduced themselves by name and role</td>
</tr>
<tr>
<td>- Surgeon, anaesthesia professional and nurse verbally confirm</td>
</tr>
<tr>
<td>- Patient</td>
</tr>
<tr>
<td>- Site</td>
</tr>
<tr>
<td>- Procedure</td>
</tr>
</tbody>
</table>

**Anticipated critical events**

- Surgeon reviews: What are the critical or unexpected steps, operative duration, anticipated blood loss?
- Anaesthesia team reviews: Are there any patient-specific concerns?
- Nursing team reviews: Has sterility (including indicator results) been confirmed? Are there equipment issues or any concerns?
- Has antibiotic prophylaxis been given within the last 60 minutes?
  - Yes  
  - Not applicable
- Is essential imaging displayed?
  - Yes  
  - Not applicable

## Before Patient Leaves Operating Room

**Sign out**

- Nurse verbally confirms with the team:
  - The name of the procedure recorded
  - That instrument, sponge and needle counts are correct (or not applicable)
  - How the specimen is labelled (including patient name)
  - Whether there are any equipment problems to be addressed
- Surgeon, anaesthesia professional and nurse review the key concerns for recovery and management of this patient

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*This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.*
<table>
<thead>
<tr>
<th>I. Before Intubation</th>
<th>II. Before Incision PAUSE</th>
<th>III. Before leaving OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Identity of patient (Hosp. No. and name) read from patient’s wrist tag matches with that on the image film or PACS</td>
<td>1. Antibiotic administered Yes/No&lt;br&gt;2. Anticonvulsant administered Yes/No/NA&lt;br&gt;3. Steroid / Mannitol administered Yes/No/NA</td>
<td>1. Hemodynamic events during surgery communicated to surgeon Yes/No/NA&lt;br&gt;2. Biopsy form filled Yes/No/NA&lt;br&gt;3. Specific instructions from anaesthetist regarding Airway Hemodynamic parameters</td>
</tr>
<tr>
<td>Yes/No</td>
<td></td>
<td>4. Operation billing done Yes/No&lt;br&gt;5. Anaesthesia billing done Yes/No&lt;br&gt;</td>
</tr>
<tr>
<td>2. Side of lesion on imaging and side of incision marked on patient match</td>
<td></td>
<td>Name, Signature and employment number of nurse reading out the checklist Name, Signature and employment number of surgeon performing the check</td>
</tr>
<tr>
<td>Yes/No</td>
<td></td>
<td>Name, Signature and employment number of nurse reading out the checklist Name, Signature and employment number of anaesthetist</td>
</tr>
<tr>
<td>3. Consent form has been signed</td>
<td></td>
<td>Name, Signature and employment number of nurse reading out the checklist Name, Signature and employment number of surgeon performing the check</td>
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<td>Yes/No</td>
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<td>4. Drug allergy, if any, has been communicated to anaesthetist Yes/No/NA</td>
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