Implementation of Standard Operating Procedures/ Checklists
(With reference to Comprehensive Emergency Obstetric Care)

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Standard Operating Procedure

• Definition
  – A Standard Operating Procedure (SOP) is a set of written instructions that document a routine or repetitive activity followed by an organisation
  – The development and use of SOPs are an integral part of a successful quality system
  – It provides individuals with the information to perform a job properly
  – It facilitates consistency in the quality and integrity of a product or end-result
Standard Operating Procedure

• Purpose
  – SOPs detail the regularly recurring work process
  – They facilitate consistency in performance
  – SOPs are intended to be specific to the organisation
  – It assists an organisation to maintain
    • Their quality control
    • Quality assurance process
  – It ensures compliance with government regulations
Standard Operating Procedure

• Benefits
  – Minimizes variation
  – Promotes quality
  – Consistent implementation of a process and procedure
  – Permanent and temporary changes in personnel do not affect implementation of operation
  – Can be used as a personnel training programme
  – Minimizes opportunities for miscommunication
  – Can address safety concern
Standard Operating Procedure

• **Writing style**
  – To be written in a step-by-step, easy-to-read format
  – Information provided should be unambiguous and not complicated
  – The active voice and present tense should be used
  – The term “you” should not be used but implied
  – The document should not be wordy, redundant or overly lengthy
  – Information should be conveyed clearly and explicitly to remove any doubt as to what is required
  – Adopt the style followed in your organisation, e.g., font size, line spacing, margins
SOP Process

• SOP Preparation
  – The organisation should have a procedure in place for determining what procedures or processes need to be documented
  – These SOPs should then be written by individuals
    • Knowledgeable with the activity
    • Familiar with the organisation’s internal structure
SOP Process ......

- A team approach can be followed
  - In multi-tasked processes
    - Where experience of a number of individuals are critical
  - This facilitates “buy-in” from potential users of the SOP
- **SOP should be written in sufficient detail**
  - This facilitates individuals with limited experience with the procedure to implement it when unsupervised
  - Experience requirement for performing an activity should be noted in the section on personnel qualifications
SOP Review and Approval

• SOPs should be reviewed (that is validated) by one or more individuals with appropriate training and experience with the process
  – It is preferable that the draft SOPs are actually tested by individuals other than the original writer before the SOPs are finalised

• The finalised SOPs should be approved as described in the organisation’s Quality Management Plan
  – Generally the immediate supervisor and the organisation’s quality officer review and approve each SOP

• Signature approval indicates that an SOP has been both reviewed and approved by management
Frequency of Revisions and Reviews

• SOPs need to remain current to be useful
  – Whenever procedures are changed SOPs should be updated and re-approved

• SOPs should also be systematically reviewed on a periodic basis, e.g., every 1-2 years
  – This is to ensure that policies and procedures remain current and appropriate
  – This review may even determine whether SOPs are at all needed
  – The frequency of review should be indicated in the organisation’s Quality Management Plan
SOPs in CEmONC Facilities

- SOPs for CEmONC facilities can be two types:
  - Clinical SOPs
  - Supportive SOPs

- Examples of Clinical SOPs can be developed for:
  - Active Management of Third Stage of Labour
  - Cesarean Section
SOPs in CEmONC Facilities

- Blood Transfusion
- Manual Removal of Placenta
- Assisted Vaginal Delivery
  - Forceps delivery
  - Vacuum delivery
Examples of Administrative / support services SOPs:
- Admission and registration procedure
- Payment of remuneration to ASHA workers
- Maintenance of equipment of Operation Theatre / Labour Room
- Maintenance of Blood Bank Refrigerator
- Sterilization of Equipment/Quality Control of sterilization
- Inventory management of drugs and consumables
- Housekeeping/cleaning and disinfection procedures in OT/LR
- Biomedical Waste Management
- Hand Hygiene
SOP Creation, Implementation and Revision
Identify requirement for new SOP

SOP Preparation/Updating

Review & Approval

Yes.

Determine & conduct necessary training

Distribution & Control
- Secure storage of master
- Distribution of controlled copies
- Recall and destruction of previous superseded controlled copies
- Superseding of masters

Distribution & Control

SOP in Use (Effective)

Requires Updating?

Yes.

Regular Review (e.g., 2 yearly)

No.

Possible reasons
- SOP not clear
- Better way
- Change to process
- Format Change
Standard SOP Template
Title:

Document ID: XXX
Version: <insert version>
Author: <insert name>
Author Signature: ________________ Date: <insert date>
Effective Date: <insert date>
Review Before: <insert date>
Site/institution name: <insert Site/institution name>
Reviewed and Approved by: <insert name> <insert title/position>
Signature: ________________ Date: <insert date>
Principal Investigator: <insert name>
Signature: ________________ Date: <insert date>

1. AIM
2. SCOPE
3. APPLICABILITY
4. PROCEDURE
   1. Subheading
   2. Subheading
5. GLOSSARY
6. REFERENCES
7. APPENDICES
   1. Appendix 1: Appendix title
   2. Appendix: Document Tracking Form
   3. Appendix (Last): Appendix Change Log
Implementation

• It is important to realise that developing useful and effective SOPs require time and commitment from all management and employee levels.

• After development:
  – Educate employee about the new SOP
  – Control procedural drift
    • Ensure that SOP is followed consistently over time
  – Establish an evaluation and review system
    • To be certain that over time all the steps of an SOP are still correct and appropriate for the procedure
Checklists
Checklists

• A checklist is an algorithmic listing actions to be performed in a given clinical setting
• The goal is to ensure that no step is forgotten
• It is a simple intervention
  – It has a sound theoretical basis in human factor engineering
  – It plays major role in some of the most significant success in the patient safety movement
Checklists

• There are two types of tasks:
  – Involving schematic behaviour
  – Involving attentional behaviour

• Tasks involving schematic behaviour are performed reflexively, as if in auto-pilot mode

• Tasks involving attentional behaviour requires active planning and problem solving
Checklists .......

- Patterns of error in these two types of behaviour are different
- Failures of schematic behaviour are called *slips*  
  - These occur due to lapses in concentration, distractions, or fatigue
- Failures of attentional behaviour are termed *mistakes*  
  - These are caused by lack of experience or insufficient training
Checklists ......

- In health care as in other industries most errors are caused by slips rather than mistakes.
- Checklists represent a simple method to reduce risk of slips:
  - List of steps to be followed needs to be standardized.
  - It is expected that every step will be followed for every patient.
  - Then the checklists shall have potential to greatly reduce errors due to slips.
Checklists

• Controversies
  – Checklists are remarkably useful tool in improving safety
    • Care needs to be taken not to overemphasize their importance
      – They cannot solve every patient safety problem
Checklists

- Successful implementation of a checklist requires
  - Extensive preparatory work to maximize safety culture in the unit where it will be used
  - Engagement of leadership in rolling out and emphasizing the importance of checklist

- Only certain types of errors can be prevented by checklists
  - Errors in clinical tasks that need primarily attentional behaviour require solutions focused on training, supervision and decision support rather than standardizing behaviour
Safety Checklists in Emergency Obstetric Care

• Well-designed protocols can serve as convenient reminders of best practices

• Similarly, low-tech physical checklists can be kept at nursing station and in labour and delivery rooms
  – They serve as reminders of best practices during obstetric emergencies
  – Example:
    • Having a laminated set of easy-to-read protocols for:
Safety Checklists in Emergency Obstetric Care

- Post-partum haemorrhage, Eclampsia, Maternal collapse, Shoulder dystocia etc

• Can allow a charge nurse to
  • check to make sure all proper procedures are being performed by the team actually administering the care to a patient in crisis

• This way nothing important is overlooked
Safe Birthing Checklist
# Safe Birthing Checklist

**Check 1**

### On Admission

Instructions: 1. Put the tick ☑ in appropriate box  
2. Follow the information given on right side for reference

**Does Mother need referral?**
- No
- Yes, organized

Refer to FRU if any of following danger signs are present and state reason on transfer note:
- Vaginal bleeding
- High fever
- Severe headache and blurred vision
- Convulsions
- Severe abdominal pain
- History of heart disease or other major illnesses
- Difficulty in breathing

**Paragrath started?**
- No, will start at ≥ 4 cm
- Yes

Start when cervix ≥ 4 cm
- Every 30 min plot contractions, FHS, and maternal pulse
- Every 4 hours: plot temperature, blood pressure, and cervical dilation in cm (cervix diseases ≥ 1 cm/hr)

**Does Mother need: Antibiotics?**
- No
- Yes, given

Give antibiotics to Mother if:
- Mother's temperature > 38¹⁄₂°C (>100.4°F)
- Foul-smelling Vaginal discharge
- Rupture of membranes >12 hrs without labor or >1.8 hrs with labour
- Labor > 24 hrs on obstructed labor
- Rupture of membranes <37 wks gestation

**Magnesium sulfate?**
- No
- Yes, given

Give first dose and then refer immediately to FRU if Mother has:
- If diastolic BP is ≥ 110 mm Hg and 3+ proteinuria
- Convulsions

**What is HIV status of Mother?**
- Positive
- Negative
- Status unknown, HIV test advised

If Mother is HIV positive:
- Give Nevirapine
- If not available, refer the patient immediately after birth

**Are soap, water and gloves available?**
- No
- Yes, I will wash hands and wear gloves for each vaginal exam

**Presence of Birth companion at birth encouraged.**
- Confirmed that Mother or companion will call for help during labour if needed

Call for help if any of
- Bleeding
- Severe abdominal pain
- Difficulty in breathing
- Severe headache and blurred vision
- Urge to push
- Cannot empty bladder frequently
### Check 2 Just Before Pushing (or Before Caesarean)

#### Does Mother need:

**Antibiotics?**
- [ ] No
- [X] Yes, given

**Magnesium sulfate?**
- [ ] No
- [X] Yes, given

Give antibiotics to Mother if any of:
- Mother’s temperature > 38°C (>100.4°F)
- Foul-smelling vaginal discharge
- Rupture of membranes >18 hrs with labor
- Labor > 24 hrs on obstructed labor now
- Cesarean section

Give first dose and then refer immediately to FRU if Mother has:
- If diastolic BP is ≥ 110 mm Hg and 3+ proteinuria
- Convulsions

#### Confirm essential supplies are at bedside:

**For Mother**
- [ ] Gloves
- [ ] Soap and clean water
- [ ] Oxytocin 10 units in syringe
- [ ] Pads for Mother

Prepare to care for Mother immediately after birth
1. Confirm single baby only (not multiple birth)
2. Give Oxytocin IM within 1 minute
3. Massage uterus other placenta is delivered
4. Confirm uterus is contracted

**For Baby**
- [ ] Clean towel
- [ ] Sterile scissors/blade to cut cord
- [ ] Cord ligature
- [ ] Mucus extractor
- [ ] Bag-and-mask

Prepare to care for Baby immediately after birth
1. Keep the baby dry and warm, give IM or IV
2. If not breathing: stimulate and clear airway
3. If still not breathing:
   - a. Clamp and cut the cord
   - b. Ventilate with bag-and-mask
   - c. Shout for help (Pediatrician/LMO/DDSP) trained service provide.

- [ ] Assistant identified and ready to help at birth if needed.
<table>
<thead>
<tr>
<th><strong>Check 3</strong></th>
<th><strong>Soon After birth (within 1 hour)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Is Mother bleeding abnormally?</strong></td>
<td><strong>If bleeding &gt; 500ml, or 1 pad soaked in &lt; 5 min:</strong></td>
</tr>
<tr>
<td>□ No</td>
<td>○ Massage uterus</td>
</tr>
<tr>
<td>□ Yes, shout for help</td>
<td>○ Start I/V fluids</td>
</tr>
<tr>
<td></td>
<td>○ Treat cause</td>
</tr>
<tr>
<td></td>
<td>○ If placenta delivered or completely, retained: give IM or I/V Oxytocin, stabilize, and refer to FRU</td>
</tr>
<tr>
<td></td>
<td>○ If placenta is incomplete: remove if any visible pieces, and refer immediately to FRU</td>
</tr>
<tr>
<td><strong>Does Mother need:</strong></td>
<td><strong>Give antibiotics to Mother if manual removal of placenta performed, or if Mother's temperature ≥ 38°C (&gt; 100.4°F) and any of:</strong></td>
</tr>
<tr>
<td><strong>Antibiotics?</strong></td>
<td>○ Chills</td>
</tr>
<tr>
<td>□ No</td>
<td>○ Foul-smelling Vaginal discharge</td>
</tr>
<tr>
<td>□ Yes, given</td>
<td><strong>Give first dose and then refer immediately to FRU, if Mother has:</strong></td>
</tr>
<tr>
<td></td>
<td>○ If diastolic BP is ≥ 110 mm Hg and 3 + proteinuria</td>
</tr>
<tr>
<td></td>
<td>○ Convulsions</td>
</tr>
<tr>
<td><strong>Magnesium sulfate?</strong></td>
<td><strong>Give Baby antibiotics if antibiotics were given to Mother, or if Baby has any of:</strong></td>
</tr>
<tr>
<td>□ No</td>
<td>○ Breathing too fast (&gt;60/min) or too slow (&lt;30/min)</td>
</tr>
<tr>
<td>□ Yes, given</td>
<td>○ Chest in-drawing, grunting, or convulsions</td>
</tr>
<tr>
<td></td>
<td>○ Looks sick (lethargic or irritable)</td>
</tr>
<tr>
<td></td>
<td>○ Too cold (Baby's temp &lt;35°C and not rising after warming) or too hot (Baby's temp &gt;35°C)</td>
</tr>
<tr>
<td><strong>Does Baby need:</strong></td>
<td><strong>Refer Baby to FRU if:</strong></td>
</tr>
<tr>
<td><strong>Antibiotics?</strong></td>
<td>○ Any of the above (antibiotics indications)</td>
</tr>
<tr>
<td>□ No</td>
<td>○ Baby looks yellow, pale or bluish</td>
</tr>
<tr>
<td>□ Yes, given</td>
<td><strong>Arrange special care/monitoring for Baby if any of:</strong></td>
</tr>
<tr>
<td></td>
<td>○ Preterm</td>
</tr>
<tr>
<td></td>
<td>○ Birth weight &lt;2500 gms</td>
</tr>
<tr>
<td></td>
<td>○ Needs antibiotics</td>
</tr>
<tr>
<td><strong>Referral?</strong></td>
<td><strong>If mother is HIV + . Follow local guidelines for baby</strong></td>
</tr>
<tr>
<td>□ No</td>
<td>(prophylaxis to be started within 12 hours after birth)</td>
</tr>
<tr>
<td>□ Yes, organized</td>
<td><strong>Special Care and monitoring?</strong></td>
</tr>
<tr>
<td></td>
<td>○ Yes, organized</td>
</tr>
<tr>
<td></td>
<td>□ No</td>
</tr>
<tr>
<td></td>
<td>□ Yes, given</td>
</tr>
<tr>
<td></td>
<td>□ Yes, given</td>
</tr>
<tr>
<td>□ Started breastfeeding and skin-to-skin contact (if Mother and Baby are well). Importance of colostrum feeding explained.</td>
<td></td>
</tr>
<tr>
<td>□ Danger signs explained and confirmed that Mother/companion will call for help if danger signs appear. (Refer to &quot;Danger Signs&quot; given under check 4).</td>
<td></td>
</tr>
</tbody>
</table>
Difficulties/Challenges in Implementation

• Doctors and other Health Care Workers want to give their best for their patients

• They are almost always well trained, hard working, highly motivated individuals

• Even then error occasionally occurs because:
  – Medicine has become highly complex
  – Physicians and nurses are human beings and may not perform perfectly all the time, with every patient
Difficulties/Challenges in Implementation

- The system in which they work are imperfectly designed
- Due to resource constraints, they are called upon to care for as many patients as possible in limited period of time

• Doctors often work in ‘silos’
  - Do not want their bastion to be penetrated or their actions influenced by any externally imposed directives
  - Ownership often lacks
There is a tremendous amount of variability from one patient to the other

- The generalized ‘cook book’ solutions given by SOPs/Checklists are resisted

Therefore, the SOPs should be developed with active participation of the doctors

Enough flexibility should be incorporated in the SOPs
Thank you