Implementation of Standard Operating Procedures/Checklists

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**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
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
  – Blood Transfusion
  – Manual Removal of Placenta
  – Assisted Vaginal Delivery
  • Forceps delivery
  • Vacuum delivery
SOPs in CEmONC Facilities

- 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
Standard SOP Template
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
- There are two types of tasks:
  - Involving schematic behaviour
  - Involving attentional behaviour
- Tasks involving schematic behaviour are performed reflexively, as if in autopilot 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
- 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
• 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
  – 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:
      - 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
## Annexure 12 | Safe Birthing Checklist:

### Safe Birthing Checklist

<table>
<thead>
<tr>
<th>Check 1</th>
<th>On Admission</th>
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#### Instructions:
1. Put the tick ☑ in appropriate box.
2. Follow the information given on the right side for reference.

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

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

### Refer to FRU if any of the 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

### 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)

### Give antibiotics to Mother if:
- Mother's temperature > 38°C (>100.4°F)
- Foul-smelling Vaginal discharge
- Rupture of membranes > 12 hrs without labor or >18 hrs with labour
- Labor > 24 hrs on obstructed labor
- Rupture of membranes < 37 wks gestation

### 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**

### 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
- Ugo to push
- Cannot empty bladder frequently
Check 2

Just Before Pushing (or Before Caesarean)

Does Mother need:
Antibiotics?
- No
- 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

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

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 I/V
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.
# Check 3

**Soon After birth (within 1 hour)**

## Is Mother bleeding abnormally?
- **No**
- **Yes, shout for help**

If bleeding > 500ml, or 1 pad soaked in <5 min:
- Massage uterus
- Start I/V fluids
- Treat cause
- If placenta delivered or completely retained, give IM or I/V Oxytocin, stabilize, and refer to FRU
- If placenta is incomplete, remove any visible pieces, and refer immediately to FRU

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

Give antibiotics to Mother if manual removal of placenta performed, or if Mother's temperature ≥ 38°C (>100.4°F) and any of:
- Chills
- Foul-smelling Vaginal discharge

**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

## Does Baby need:
**Antibiotics?**
- **No**
- **Yes, given**

Give Baby antibiotics if antibiotics were given to Mother, or if Baby has any of:
- Breathing too fast (>60/min) or too slow (<30/min)
- Chest in-drawing, grunting, or convulsions
- Looks sick (lethargic or irritable)
- Too cold (Baby's temp <35°C and not rising after warming) or too hot (Baby's temp>35°C)

### Referral?
- **No**
- **Yes, organized**

Refer Baby to FRU if:
- Any of the above (antibiotics indications)
- Baby looks yellow, pale or bluish

### Special Care and monitoring?
- **No**
- **Yes, organized**

Arrange special care/monitoring for Baby if any of:
- Preterm
- Birth weight <2500 gms
- Required
- Resuscitation
- Needs antibiotics

### Nevirapine?
- **No**
- **Yes, given**

If mother is HIV +, follow local guidelines for baby (prophylaxis to be started within 12 hours after birth)

- **Started breastfeeding and skin-to-skin contact (if Mother and Baby are well). Importance of colostrum feeding explained.**
- **Danger signs explained and confirmed that Mother/companion will call for help if danger signs appear. (Refer to “Danger Signs” given under check 4).**
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
  – 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
Difficulties/Challenges in Implementation

• 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