# Session 15: PMS sampling, tracking and quality of clinical data

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# PMS sample

- Facilities with the capacity to provide PAC (preferably those with enough cases to provide useful data over 28 days).

# PMS sample: Same sample as HFS

- In a smaller country or with extensive resources you can use the exact same sample as the HFS accounting for facilities that do not provide PAC in the weights.

# PMS sample: Different from HFS

- In a larger country of with more constrained resources you can take a sample of facilities from the HFS sample.
- Sampling frame- HFS universe
- You can stratify like in HFS- by province and level
- Similar to HFS we typically include all large facilities with most

Table 1. Universe and sample selection, by type of facility and survey, Zimbabwe 2016.

| | HFS Census [a] | | PMS Sample [b] | | MoHCC M&E [d] |
|---|---|---|---|---|---|
| Type of health facility | Response rate (%) | Facilities interviewed (No.) | Sample proportion from universe of facilities with PAC capacity (%) | Facilities interviewed (No.) [c] | Number of facilities |
| Primary health centers | 100% | 59 | 30% | 18 | 822 |
| District and mission hospitals | 100% | 89 | 52% | 47 | 3 |
| Provincial hospitals | 100% | 8 | 100% | 8 | |
| Central hospitals | 100% | 5 | 100% | 5 | |
| Private hospitals | 97% | 32 | 77% | 26 | |
| NGO | 100% | 34 | 68% | 23 | |
| **Total** | 99.6% | 227 | 56% | 127 | 825 |

# Revision: Calculating weights

- While creating the sample, it helps to create dummy weights to determine if there are enough cases per facility type, per region.
- For each facility type:

  Facility weight = #Universe / #Sample

- Computing the weight for each facility type in each region produces separate facility weights for each region.

# Tracking and quality of clinical data

# Staffing the study team

- Clinicians from within the facility
- External clinicians
- Research assistants
- Supervising clinician(s)- local, remote.

# What is the patient flow for PAC cases at your facility?

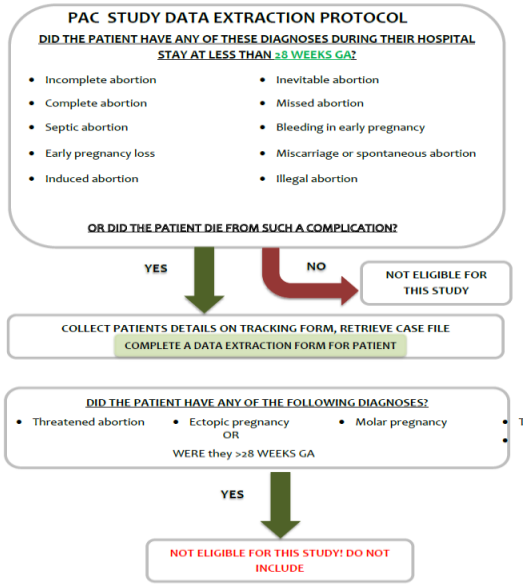
- OPD or EMERGENCY or A&E
  - How many?
- Wards
  - i.e. Female ward, Gynecology ward, Maternity ward, Female surgical ward, Pediatrics ward
- MVA ROOM or THEATRE or ICU
- Wards
  - The same ward or another ward?
- Family planning counselling clinic
- Discharge

# Reminding clinicians about inclusion criteria

Inclusion criteria:

1. Women admitted for abortion-related complications.

   Any hospitalizations resulting from (1)miscarriage/spontaneous or (2) induced abortion including (3) missed, (4) inevitable, (4) incomplete, (5) complete and (6) septic abortion whatever the abortion type (induced or spontaneous) and the severity (up to near-miss and death) at up to 28 weeks of gestation.



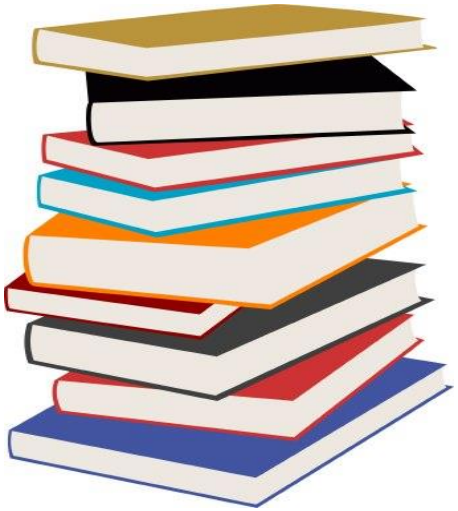
# What are the registers and record keeping procedures in your facility?

(1) How can we identify a patient who was admitted for PAC?

(2) Do all women receive case files?

(3) Where are patient case files stored in the facility and how can they be retrieved?

(4) Where will the study clinician keep patient files? Will copies be made?



# Tracking tools- routine patient registers

| No | Triage Register Patient Name | Patient file N° | Study N° | Time (Hr) of admission | Comments | Registre AMV | Remarques | Post Partum Register | Comments |
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# Tracking tools- Identifying what patient files have had data extracted

| No | Study ID | Patient file No. | Name | Date of admission | Copied (✓/X) | Filled in study file (✓/X) | | Comments |
|---|---|---|---|---|---|---|---|---|
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# Collecting objective clinical data

**Physical examinati**

**20) Vital signs:**

a. Temperature

b. Heart rate

c. Systolic blood pr

d. Diastolic blood p

e. Respiratory rate

**21) Appearance (C**

a. Normal .....

b. Pallor.....

c. Jaundice.....

**22) Mental status:**

a. Alert .....

b. Agitated .....

c. Lethargic .....

d. Comatose.....

**D. HEALTH FACILITY ADMISSION (ASSESSMENT AND OUTCOMES THROUGHOUT FACILITY STAY)**

**Questions 28-36, please indicate:**
1 = No
2 = Yes, at arrival or within 24 hours of stay
3 = Yes, after 24 hours of stay

→ **Severe Complications:**

**28) Severe Vaginal Bleeding** |__|

☐ *Heavy bright red vaginal bleeding (with or without clots),*

☐ *Pads, towels, or clothing blood-soaked within five minutes*

☐ *Pallor*

**29) Abdominal Syndrome** |__|

(Intra-abdominal injury suspicion)

☐ *Abdominal pain/cramping **AND** nausea/vomiting*

☐ *Shoulder pain*

☐ *Guarding/hard abdomen +/- distended/tense abdomen*

☐ *Rebound, Ileus (decreased/no bowels sounds, tenderness)*

**30) Uterine Infection** |__|

(endometritis or chorioamnionitis)

☐ *Chills, fevers, sweats*

☐ *Foul smelling vaginal discharge*

*+/-History of interference with pregnancy*

→ **Potentially life-threatening complications:**

**31) Severe hemorrhage** |__|

☐ *Blood loss estimated >1L*

Estimated blood loss……|__|__|__|__| ml

☐ *Blood loss with systolic BP <100 mmHg*

Lowest syst blood pressure (SBP)….|__|__|__| mmHg

☐ *Blood loss requiring 1 unit blood transfusion*

☐ *Blood loss with Hb < 4g/dL*

Lowest Hemoglobin level |__|__|.|__| g/dl

**32) Generalized peritonitis:** |__|

☐ *T°C>38,5°C*

Highest Temperature |__|__|.|__| °Celsius

***AND***

☐ *Abdominal guarding (contracture = hard abdomen like roc), rebound +/- ileus (decreased/no bowels sound, tenderness)*

**33a) Severe systemic infection:** |__|

☐ *T°C>38°C*

Highest Temperature |__|__|.|__| °Celsius

***AND***

☐ *Confirmed or suspected infection*

Type of infection: _____

***AND** at least one of the following signs:*

☐ *1) new/ worsened altered mentation*

☐ *2) respiratory rate ≥ 22/min*

Highest respiratory rate…… |__|__|__| per min

☐ *3) systolic blood pressure ≤ 100mm Hg*

Lowest syst blood pressure (SBP) |__|__|__| mmHg

**33b) Tetanus infection signs:** |__|

# Collecting objective clinical data

| CRF content | Completed |
|---|---|
| Eligibility Form | Yes ☐ No ☐ |
| A. History | Yes ☐ No ☐ |
| B. Health facility presentation – first assessment | Yes ☐ No ☐ |
| C. Laboratory findings | Yes ☐ No ☐ |
| D. Health facility admission (assessment and outcomes throughout facility stay) | Yes ☐ No ☐ |
| E. Eligibility to the quantitative and qualitative interview | Yes ☐ No ☐ |
| F. Management | Yes ☐ No ☐ |
| G. Outcomes | Yes ☐ No ☐ |

**Please check that the checklist on the cover page is completed**

DATA COLLECTION AND VERIFICATION:

**I confirm that the information collected in this form is complete and exact. I confirm that the completion process has been led in compliance with the study protocol.**

**Data collector name:** _____ **Signature:** _____ **Date:** ☐☐ / ☐☐☐ / ☐☐☐☐
(fulfilling the form)

**Data verifier name:** _____ **Signature:** _____ **Date:** ☐☐ / ☐☐☐ / ☐☐☐☐

# Additional information we will require

- Total number of obstetric and gynecological admissions for the duration of data collection
- Total number of deliveries and live births for the duration of data collection
- Total number of maternal deaths recorded within the hospital HMIS for the duration of data collection
- Number of women seen in facility with a diagnosis of abortion (except threatened abortion), who don't have a medical record (patient file).

# Linking the clinical and exit-interview questionnaires

- Clinicians and research assistants communicate regularly about eligible patients on admission daily/weekly
- PMS questionnaire completed by clinician when woman has recovered and is to be discharged alive and well OR if woman dies
- Clinician and research assistants keep in touch so that research assistants are aware when women will be discharged or have died
- Clinicians inform women who are admitted that another researcher will come by to ask questions about their health.
- Research assistants are easily accessible or they will miss cases who are unwilling to wait.

# Quality assurance summary points

- Tracking eligible women (clinicians and research assistants)
- Crosschecking the clinical data filled into forms (clinicians)
- Storing forms and handing them over to the study team (clinicians)
- Checking the completeness and coherence of forms (research assistants)
- Ensuring ID numbers for near-miss and exit questionnaires are linked (research assistants)
- Checking the clinical information provided (supervising clinician)
- Responding to questions and queries about data (clinicians)