Nairobi Newborn Study Standard Operating Procedure 4.0 [SOP4.0]: Process of data entry from registers and records

Written by Georgina Murphy Version 1: 01.09.15

1. Purpose and scope

Standard Operating Procedures (SOPs) are required to assure quality, to reduce errors, and to standardise activities and tasks throughout the Nairobi Newborn Study.

2. Staffing, equipment, and resources

Data entry will be conducted by the data entry officers and overseen by the data entry supervisor. It is, therefore, these individuals' responsibility for following SOP4.0. A laptop programmed with the RedCap data entry tool, and with a power cable, is required for data entry. Data entry officers require access to the maternal admission register, newborn admission register, and newborn medical records relating to the period 1^{st} July $2014 - 30^{th}$ June 2015. They also require a space to work with an adequate power supply. Data officers are responsible for the upkeep and security of this work space, these records, and their equipment. The necessary paperwork required includes the enumeration list and the weeks and days sampling sheets.

3. Procedure

3.1. Orientation

- i. When you arrive at a facility, make contact with the manager listed on the facility list. Explain who you are. They will be expecting you.
- ii. Request to be shown the newborn and maternal registers and the newborn records for the previous year (1st July 2014 30th June 2015). Ask if the facility keeps a referral book. If so, ask if you could also have access to the referral book for this timeframe.
- iii. Ask to be shown to the most appropriate location for you to work from. This location should have a table, chair, power socket, and enough space for you to lay out and organise the registers and records.
- iv. The team supervisor should accompany data entry officers to the facility on the first day and remain at the facility for the first full day of data collection at each facility. The supervisor can therefore be available to answer any questions until data entry officers are comfortable with the new facility's records and procedures.

3.2. Newborn register

- i. Obtain the newborn register books for the preceding year (1st July 2014 30th June 2015).
- ii. Begin by tallying the total number of admissions between 1st July 2014 and 30th June 2015. In some cases the number of admissions will be summarised by month. In this case summate the number of monthly admissions during the sampling frame. Enter this number into the newborn enumeration list.
- iii. Beginning with the most recent date (30th June 2015), enter the relevant data from the register into RedCap tool for the newborn register in accordance with SOP4.2.
- iv. Proceed backwards in time, entering all admissions until 1st July 2014.

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3.3. Maternal register

- Obtain the maternal register books for the preceding year (1st July 2014 30th June 2015).
- ii. Tally the number of admissions between 1st July 2014 and 30th June 2015. In some cases the number of admissions will be summarised by month. In this case summate the number of monthly admissions during the sampling frame beginning with the most recent admission i.e. on or closest to 30th June 2015.
- iii. Where the total number of admissions is **510**¹ **or fewer** (scenario #1), enter all admissions for the study timeframe using the RedCap tool.
- iv. Where the total number of admissions is between **511 and 5,000²** (inclusive) (scenario #2), a random sample of weeks equating to at least 500 records should be entered. In this situation, refer to the 'weeks sampling' sheet. This sheet has a list of weeks in random order. Beginning at the top of the list, enter the admissions that correspond to the dates in the week. Move down through these weeks. When you have entered 500 records, RedCap will notify you to stop entering records.
- v. Where the total number of admissions is **above 5,000** (scenario #3), a random sample of days equating to at least 500 records should be entered. In this situation, refer to the 'days sampling' sheet. This sheet has a list of days in random order, beginning at the top of the list, enter the admissions that correspond to the dates. Move down through these dates. When you have entered 500 records, RedCap will notify you to stop entering records.

3.4. Newborn medical records

Prior to data entry of the newborn medical records the enumeration list must be complete. This list will contain the total number of admissions between 1st July 2014 and 30th June 2015 at each facility included in the study. These numbers are then used to produce sample sizes for each facility in order to obtain the same proportion of records from each facility and obtain a total number of 800 records across all facilities.

- i. Prior to arriving at the facility, ensure that you have the enumeration list for newborn medical records. This list will indicate the number of records you need to enter at the facility you are visiting.
- ii. Beginning with the medical records that indicate an admission date of 30th June 2015 (or the most recent date before 30th June 2015 for which an admission was made) and moving backwards through records according to admission date, enter information from the records into the newborn medical record RedCap tool on your computer (as describe in SOP4.3).
- iii. End data collection when you have entered the number of records indicated for data collection in the enumeration list for that facility.

3.5 Leaving a facility

 $^{^{1}}$ 510 is selected instead of 500 because if 51 weeks are taken instead of 52 for facilities over 500, we still need to ensure that a minimum of 500 facilities are entered. i.e. (annual admissions/52)*51 ≥ 500

² This threshold was chosen to ensure that no fewer than 5.2 weeks (10%) and no fewer than 36.5 days (10%) of oversampling would be done.

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- i. When data collection is complete, including re-entry of selected newborn medical records by the data entry supervisor, ensure that the registers and records are returned to their original places in their original order and condition, unless otherwise requested by senior staff at the facility.
- ii. Thank the relevant staff at the facility.

4. Related procedures and documents

- SOP 4.1: Data entry from maternal admission register
- SOP 4.2: Data entry from newborn admission register
- SOP 4.3: Data entry from newborn medical record

5. SOP-user signature log

By signing in the table below, I confirm I have red and am familiar with the SOP for accessing registers and records.

Name	Signature	Date