Data monitoring

Case study: Neonatal Vitamin A supplementation studies

Sachiyo Yoshida

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Department of Reproductive Health and Research; Family and Community Health Cluster (WHO/RHR)

Overall objective of the data monitoring

- Monitoring and evaluation is a core function of WHO.
- Solid data - an underlying requirement for improvements and evidence-based decisions:
  - Guidance for research and development
  - Policy development at national and sub-national level to respond to MNH needs and related services
  - Realistic planning allowing for effective allocation and use of resources
  - Advocacy and information of general public

! Better monitoring -> Better data - Better decisions - Better health

Data monitoring

Case study: Neonatal Vitamin A supplementation studies

Outline of the presentation

- Flow of data
- Data quality checks
- Site specific data issues

A monthly circle of data monitoring in WHO

Monthly data transferred from the site to WHO

- All forms (e.g., PSF, SEF, BLF, PDF, IFF) & Audit trail
- Summary table/ flow chart
- Response to the query of preceding month

Process

- Data transfer via SharePoint or email
- Data stored in SQL server/stata
- Daily data backup in two external hard-drives
- Data monitored using STATA

Develop monthly report/**Run** Dummy DSMB analysis

Review report and make queries

Send feedback to the sites

Data transferred

Run data quality checks

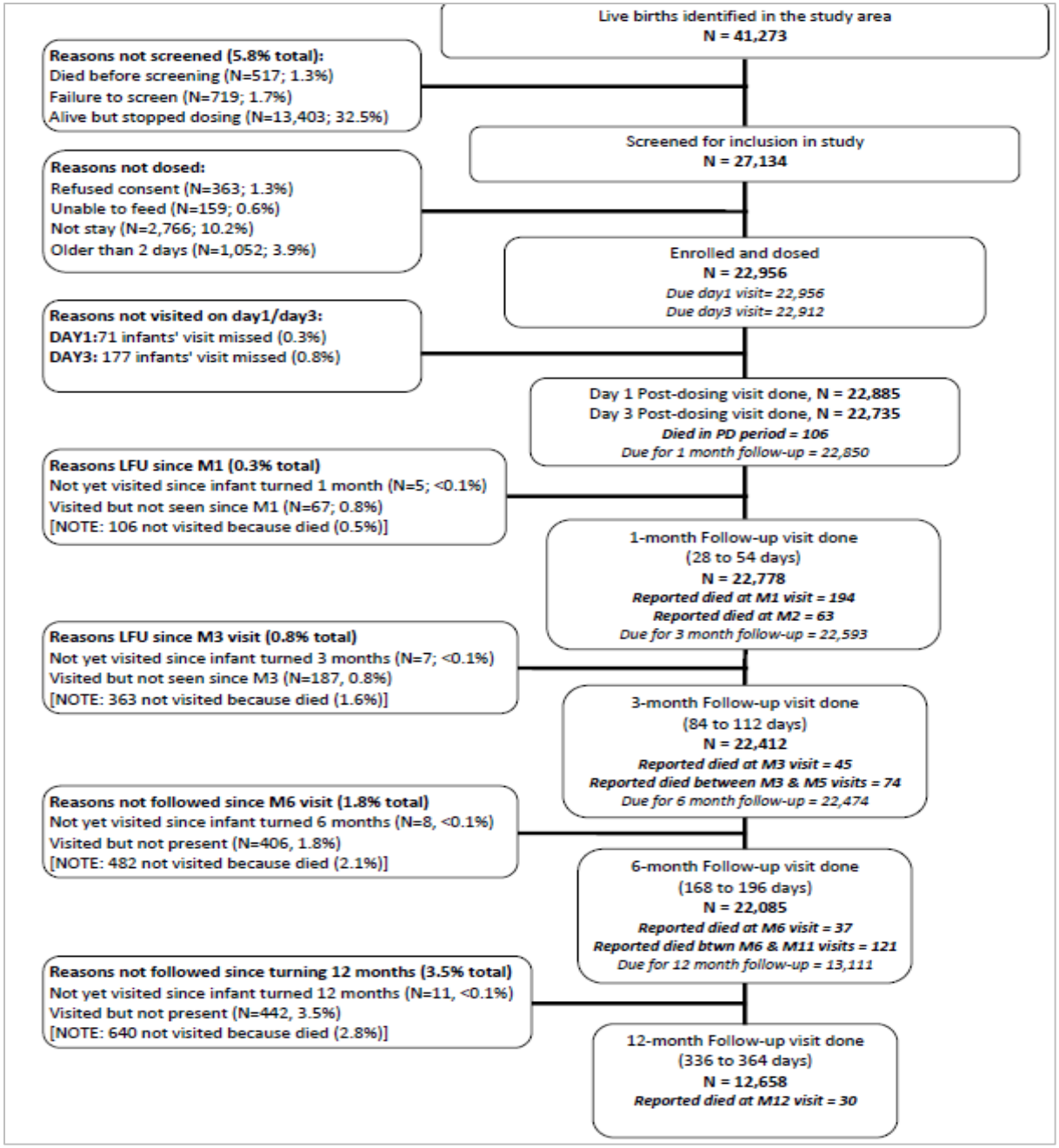
1 wk

2 wk

3 wk

4 wk

Data quality checks



Completeness and consistency

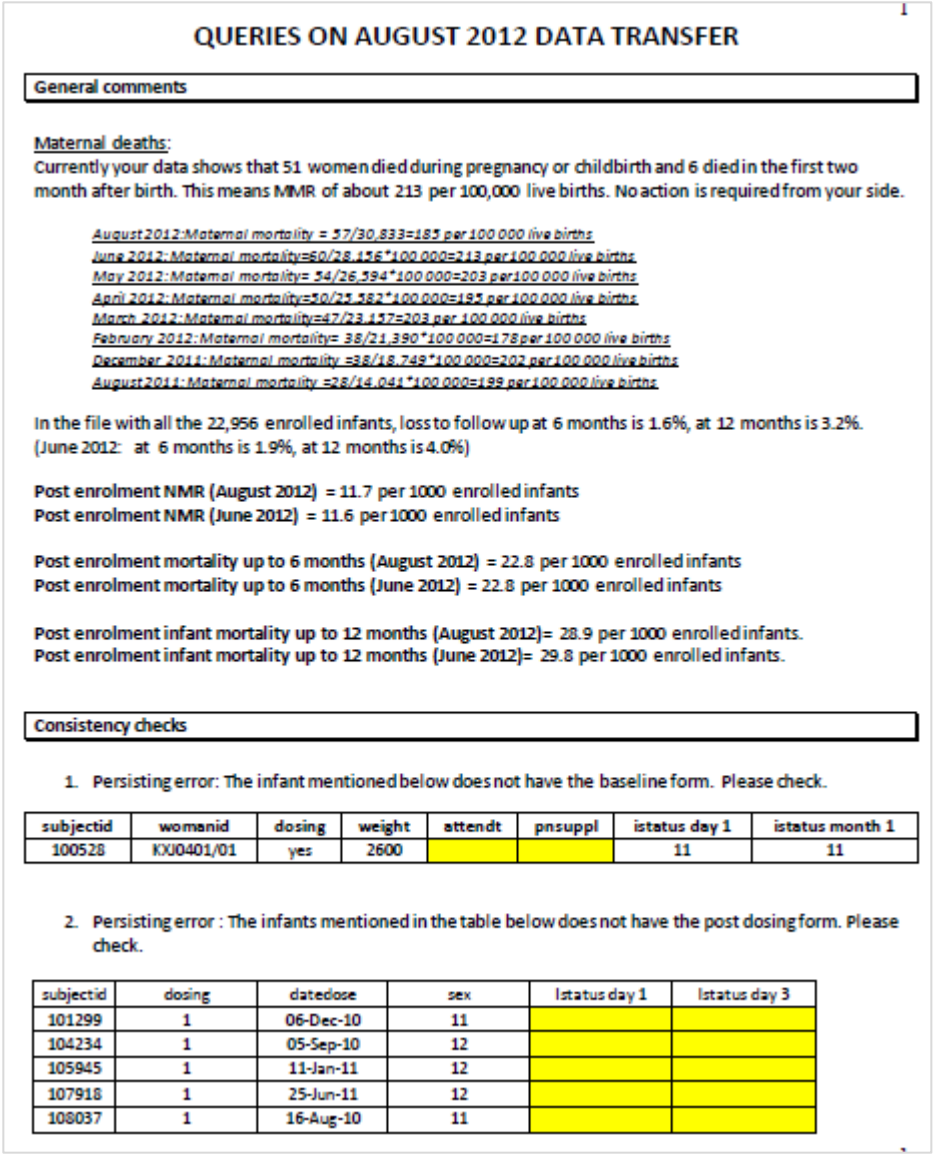
! Monitor overall flow of the study
->useful to capture the loss to follow up
-> Improve overall quality of the study

Data quality checks

monthly feedback on the quality of data

- Review the site's response on the query of previous month.
- Check if the potential errors has been fixed or not.
  - If yes, no more reporting
  - If no, keep reporting until they are fully fixed in the dataset.
- Based on above, develop queries and send them to the data manager in the sites.

! Provide monthly feedback on the quality/consistency -> gradually but constantly improve quality of data management.



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QUERIES ON AUGUST 2012 DATA TRANSFER

General comments

Maternal deaths:
Currently your data shows that 51 women died during pregnancy or childbirth and 6 died in the first two month after birth. This means MMR of about 213 per 100,000 live births. No action is required from your side.

August 2012: Maternal mortality = 57/30,833=185 per 100 000 live births
*June 2012: Maternal mortality=60/28,456*100 000=213 per 100 000 live births*
*May 2012: Maternal mortality= 54/26,594*100 000=203 per100 000 live births*
*April 2012: Maternal mortality=50/25,582*100 000=195 per 100 000 live births*
March 2012: Maternal mortality=47/23,157=203 per 100 000 live births
*February 2012: Maternal mortality= 38/21,390*100 000=178 per 100 000 live births*
*December 2011: Maternal mortality =38/18,749*100 000=202 per 100 000 live births*
*August 2011: Maternal mortality =28/14,041*100 000=199 per 100 000 live births*

In the file with all the 22,956 enrolled infants, loss to follow up at 6 months is 1.6%, at 12 months is 3.2%. (June 2012: at 6 months is 1.9%, at 12 months is 4.0%)

Post enrolment NMR (August 2012) = 11.7 per 1000 enrolled infants
Post enrolment NMR (June 2012) = 11.6 per 1000 enrolled infants

Post enrolment mortality up to 6 months (August 2012) = 22.8 per 1000 enrolled infants
Post enrolment mortality up to 6 months (June 2012) = 22.8 per 1000 enrolled infants

Post enrolment infant mortality up to 12 months (August 2012)= 28.9 per 1000 enrolled infants.
Post enrolment infant mortality up to 12 months (June 2012)= 29.8 per 1000 enrolled infants.

Consistency checks

1. Persisting error: The infant mentioned below does not have the baseline form. Please check.

subjectid	womanid	dosing	weight	attendt	pnsuppl	istatus day 1	istatus month 1
100528	KX00401/01	yes	2600			11	11

2. Persisting error : The infants mentioned in the table below does not have the post dosing form. Please check.

subjectid	dosing	datedose	sex	Istatus day 1	Istatus day 3
101299	1	06-Dec-10	11		
104234	1	05-Sep-10	12		
105945	1	11-Jan-11	12		
107918	1	25-Jun-11	12		
108037	1	16-Aug-10	11		

Data quality checks

- Do all enrolled infants meet the eligibility criteria?
- Are disease symptom accurately recorded in the post dosing form?
- Any duplication of infant id/womanid?
- Are all deaths accurately recorded in the post dosing form or in infant follow up form?
- Is the core set of variables present in the form?
- Is the data within the agreed range for each variable?
- Is there consistency between and across forms?

! Does the data tell you a story of a woman through pregnancy to birth and a story of a baby from birth to 12 months follow up.

Monthly monitoring of key outcomes

Adverse events within 3 days of dosing	Site A N (%)	Site B N (%)	Site C N (%)
Fever	1891 (9.5%)	435 (2.6%)	187 (4.6%)***
Vomiting	1093 (5.5%)	358 (2.2%)	19 (0.4%)***
Diarrhoea	1799 (9.0%)	130 (0.8%)	8 (0.2%)***
Not able to feed	220 (1.1%)	120 (0.7%)	18 (0.4%)***
Convulsion	28 (0.1%)	29 (0.2%)	0 (0%)***
Bulging fontanelle	98 (0.5%)	45 (0.3%)	13 (0.2%)
Death	91 (0.5%)	83 (0.5%)	72 (0.7%)

! The DSMB reviews severe adverse event (death) information every 3 months, and all the collected data every six months to determine if the study should be continued or stopped.

Site-specific data issues

	Very good	Not so good
Site A	• Data transfer is done in time • Summary table provided each month • Data are clean and make sense • Queries are addressed by the following month. • Deaths are accurately recorded in correct forms. • SAE forms are submitted in time.	None at the moment: data quality is excellent.
Site B	• Responses to queries provided in time. • Flow chart provided each month. • Deaths are accurately recorded in correct forms. • SAE forms submitted in time. •Prompt responses provided to our requests. •Duplication of subjectids resolved.	•Inconsistency in the date of immunization. •Minor out of range values.
Site C	• Bi-monthly data transfer done in time. • SAE forms submitted in time. • Age at dosing is early (Mean 14 hours). • Prompt responses provided to our requests.	•Information missing (date of birth 5%, weight 3%, time of dose 2%). •Screening form missing for 5% of infants. •Post dosing form missing for 7% of the infants. •Quite a number of inconsistencies still present. •Irregular submission of participant flow chart as well as responses to queries.

Conclusions

- Data monitoring is crucial not only in improving the data management but also in improving the overall quality of the study.
- Provision of monthly feedback to the study sites was extremely beneficial in improving the data quality.
- Constant communication with field operation team was useful in keeping up the data transfer mechanism on a monthly basis.