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Contextual Challenges in the Implementation of the Alliance for Maternal and Newborn Health Improvement, Prospective Cohort Study, an Experience from Rural Pakistan

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Abstract

Introduction: Improving maternal and newborn survival needs robust data on patterns of morbidity and mortality from well-characterized cohorts. It is equally important for researchers to document and understand the contextual challenges of data collection and how they are addressed. **Methods:** This was a prospective cohort study implemented from December 2012 to August 2014 in Matiari, Pakistan. A total of 11,315 pregnancies were enrolled. Participants were approached at home for sequential data collection through the standard pretested structured questionnaires. Some indicators were sourced through health facility records. Information on field challenges gathered through field diaries and minutes of meetings with field staff. **Results:** Inaccurate reporting of last menstrual period (LMP) dates caused difficulties in the planning and completion of antenatal data collection visits at scheduled gestational weeks. We documented ultrasound reports wherever available, relied on quickening technique, and implemented a seasonal event calendar to help mothers' recall their LMP. Health system coordinators of public sector and private healthcare providers were individually approached for maximum data collection. But an unregulated private health system with poor record maintenance and health care providers' reluctance for cooperation posed a greater challenge in data collection. **Conclusions:** Within a broader understanding of the health systems and socio-cultural environment, temporal and spatial feasibility of data collection should be considered thoroughly at the early stages of study designing, planning, resource allocation, and implementation. Pre-defined regular and need-based meetings with each tier of data collection teams and study managers help to reinvigorate field execution plans and optimize both

quantity and quality of study data.

Keywords

Maternal and Newborn Health Research, Contextual Challenges, Data Collection, Field Implementation, Lessons Learnt

1. Introduction

Globally, each day an estimated 810 mothers die of preventable pregnancy and childbirth complications [1]. Immediate interventions are required to eliminate such avoidable maternal deaths [2]. In Pakistan, estimated more than half of maternal, newborn and child deaths occur due to preventable causes [3]. Pakistan ranked among the top countries where rates of stillbirths and child mortality are high [4] [5]. Introduction of evidence-based interventions can substantially avert these deaths [3]. Limited population and hospital-based data remain the biggest challenge to understand the causes of maternal mortalities in the countries where most deaths happen [6]. Given the paucity of data, Alliance for Maternal & Newborn Health Improvement (AMANHI) morbidity study was carried out in 11 sites of 8 countries of South Asia and sub-Sahara Africa (Pakistan, India, and Bangladesh from South Asia; and Ghana, Democratic Republic of Congo, Ghana, Kenya, Tanzania and Zambia in sub-Saharan Africa). World health organization (WHO) led this consortium. This was a population-based prospective cohort study. Study protocol and primary results are already published [7] [8]. The AMANHI study was built on ongoing neonatal health research studies [9]. See published protocol for further details [8].

Briefly, the AMANHI study aimed to generate evidence pertaining to maternal morbidities, health care seeking during and after the termination of pregnancy and their association with various maternal and newborn adverse outcomes.

It is important to note that, each community-based research has its own context-specific challenges and diverse realities. The process documentation of learned lessons during study implementation could substantially add to the planning of similar prospect work and in estimating the allocation of resources towards various field activities [10] [11] [12].

This paper is explicitly elaborating on the contextual challenges in the implementation processes of AMANHI study. We also systematically describe the way these challenges were addressed by the study teams. Findings may potentially assist researchers around the globe to carefully plan and adopt the appropriate strategies to successfully implement similar research work in comparable settings.

2. Methods

The AMANHI, a population-based prospective cohort study was implemented from December 2012 to August 2014. The overall goal of study was to produce

exclusive evidence to influence policy makers to improve maternal and neonatal health outcomes. The study was carried out in 10 union councils having the estimated 350,000 population of a rural District Matiari of Sindh, Pakistan.

Matiari is at the distance of about 200 kilometres to the north-east of Karachi. Of the estimated 0.8 million population, 80% live in around 1800 villages (District health system data 2020). The district typically represents the rural Pakistan [13]. Majority families rely on agricultural farming and livestock; women equally work in the fields with men.

Within the ANISA (parent) study, bi-monthly pregnancy surveillance was established over 10 union councils of District Matiari to identify and enrol the pregnant women [9]. Regardless of their participation in the ANISA study, those identified pregnant women were separately requested by field research staff to have their consent to participate in the AMANHI study. At the end, a total of 11,315 pregnancies were enrolled in the study. The enrolled pregnant women were followed up at their homes for data collection on morbidities and care-seeking patterns. Teams of female data collectors used centrally standardized questionnaires (across the sites) translated in local language. Three visits during the antenatal period (visit 1: 24 - 28 weeks, visit 2: 32 - 36 weeks and visit 3: 38+ weeks) and two during postpartum (visit 1: 0 - 6 days and visit 2: 42 - 60 days after delivery) were carried out. Active screening for pregnancy-induced hypertension, pre-eclampsia/eclampsia and postpartum haemorrhage were carried out during these visits. These involved recording of blood pressure and performing urine dipstick tests at all 5 visits. Some data were collected from the health care providers who assisted delivery and fewer indicators were extricated from health facility records. Data regarding field challenges were gathered from staff field diaries and from minutes of (weekly) meetings with field staff and supervisors at research filed offices.

2.1. Study Team

The study was built on ongoing existing neonatal research study (Aetiology of Neonatal Infections in South Asia (ANISA); hence field activities were conducted by the same staff employed for ANISA study. We deployed 10 teams (one/each union council) comprised of a team leader and 04 data collectors.

Data collectors had a minimum 12-year of education. Monitoring and supervision staff had master's degree with relevant research experience. Keeping in mind cultural sensitivities, majority of the data collectors were female. Acknowledging the cultural values which restricted the female mobility without male companion—we hired male team leaders. The male member apart from accompanying the female staff served to orient the male members of the community and household heads to the study objectives and facilitate consent to carry out data collection in the respective village.

2.2. Study Activities Flow Diagram

Figure 1 shows the flow of multiple data collection activities carried out at the

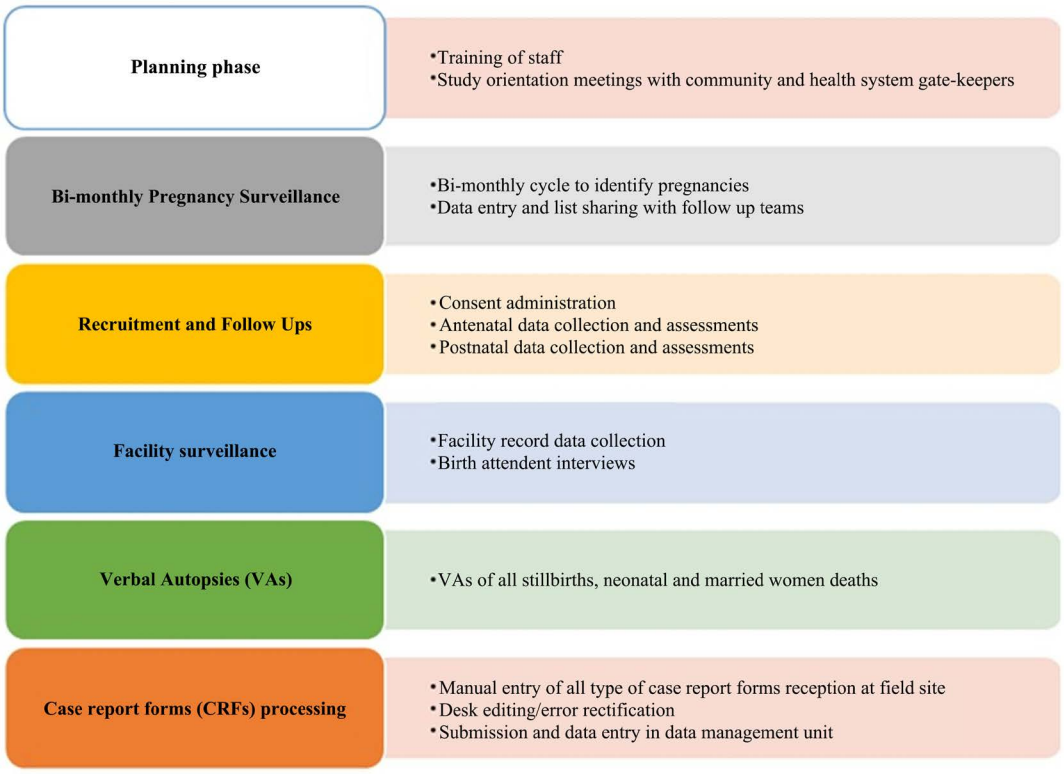

Figure 1. Flow diagram of study activities.

field site Matiari. Trainings of the staff were conducted by the faculty and laboratory staff from Aga Khan University as per requirement of data collection and assessments. Based on observations during field monitoring visits and desk review of data, we arranged monthly and quarterly refreshers for data collection teams.

3. Results

The mean age of the AMANHI study participants was 29.3 ± 5.3 years. Majority participants were between 20 - 35 years (85%), only <2 percent participants were adolescent (15 - 19 years). A greater proportion 81.5% was not formally educated. Occupationally >60% of participants was engaged in a kind of work that required them to be outside home (Table 1). This was one of the factors which had created troubles for data collection team to approach participants at home. Within Table 1, continuous variables are presented as mean and standard deviations while numbers and percentages are given for categorical variables.

Contextual Challenges in the Implementation of AMAHNI Data Collection Activities

Pregnancy confirmation and last menstruation dating

Reliability of pregnancy dating has several implications, include pregnancy care, [14] [15] screening of various pregnancy related condition and interpret the pregnancy outcomes [16] [17].

Table 1. Demographic and individual characteristics of participants.

Participants' Characteristics	N = 11315
Age in years	
Mean ± SD	29.3 ± 5.3
15 - 19	191 (1.7)
20 - 49	11,123 (98.3)
Don't Know	1 (0.0)
Education	
No formal education	9219 (81.5)
Primary	2096 (18.5)
Secondary and above	
Occupation	
Housewife	4216 (37.3)
Farming	2804 (24.8)
Daily Wages	2357 (20.8)
Self employed	1767 (15.6)
Govt/Pvt Job	162 (1.4)
Others	9 (0.1)
HH density	8.2 ± 5.2
Religion	
Muslim	9093 (80.4)
Hindu	2211 (19.5)
Christian	10 (0.1)
Don't Know/Missing	1 (0.0)
Main source of drinking water	
Improved sources	11,151 (98.6)
Unimproved sources	163 (1.4)
Don't Know/Missing	1 (0.0)
Type of toilet facility used by household	
Improved sanitation facility	7551 (66.7)
Unimproved sanitation facility	3763 (33.3)
Don't Know/Missing	1 (0.0)
Health related	
Gravidity	
Primigravida	1962 (17.3)
Multigravida	9346 (82.6)
Don't Know/Missing	7 (0.1)
Place of delivery	
Hospital	7645 (67.6)
Home	3656 (32.3)
Other	14 (0.1)

Within the participants of the AMANHI study, the cessation of the menstrual cycle was/is an indication of pregnancy for most women. Nausea and vomiting were believed to be confirmatory signs and symptoms of pregnancy. In many instances women with irregular menstrual cycles and those who did not experience added signs had no precise idea whether they were pregnant or not in the early weeks of pregnancy. During surveillance, such pregnancies were missed and identified at later stages. Subsequently, delayed identification of pregnancies led to unreliable LMP dates especially where an ultrasound report was not available, and we had to rely on pregnant women' recall. The pregnancy dating through recall of last menstrual cycle has not been accurately reported across various studies conducted in both developed and developing world [17] [18] [19] [20]. However, within the low and middle income countries researcher consider LMP as a reliable alternate where ultrasound dating is not available [16]. Considering its cost effectiveness World Health Organization (WHO) also adhered to rely on the LMP recall [21].

In the AMANHI study, accurate LMP was essential for the field teams to conduct three antenatal data collection visits within the scheduled gestational window period and document pregnancy outcomes precisely (such as preterm births and low birth weights). Moreover, we observed that majority of women had ultrasound in 3rd trimester, and this was done mainly with the intent to know the sex of the baby and possible mode of delivery. Few clinics did not provide a copy of the ultrasound report to families. Some women had lost or discard the reports. Collectively these issues challenged the field teams to record accurate LMP.

To overcome this issue, field teams probed further with the assistance of Islamic/moon calendar and local cultural events. The second strategy used by the team was on enquiring about the quickening or "first fetal movement", this information would also provide some insight of the current trimester and facilitated in the estimation of LMP [22]. In each antenatal visit, the LMP date was reconfirmation to identify any discrepancies. We revised the window period of each antenatal visit to capture maximum information. **Table 2** below described the extended the window periods of antenatal data collection visits.

This strategy improved the completion of data collection rate from (40% to 80%) for all three antenatal visits.

Absence of pregnant women at home because of agricultural chores

Majority of families of study area relied on agricultural farming; both male & female members of the family participate in agriculture work, especially in the seasons of cotton sowing, pickling and wheat harvesting (two main crops of study area). It was a major challenge that field team faced to find study participants at home during these crops' seasons. Study team had to made frequent visits to these households to complete interviews with pregnant women. We planned home visits at different times of the day to access all such cases, in few cases, where possible study team visited these women in the fields.

Table 2. Antenatal data collection window periods.

Visit number	Window period original Gestational Age in weeks	Window Period Revised Gestational Age in weeks
1	24 - 28	24 - 28 can be up to 31
2	32 - 36	32 - 36 can be up to 37
3	38+	38+

We provided team members' cell phone and office phone numbers to the enrolled families to call us whenever available at home.

Table 3 shows the trend of absence. The women involvement in agriculture and other occupations reduced and their availability for interview improved near term.

Delivering at parents' home: A widespread trend

We had to collect data from a mother within 0 - 6 days after birth as per protocol, but it was observed that many women went to their parents' homes for childbirth, which were located outside of the study area. Culturally in the event of first delivery majority women visit their parents' home for delivery. Usually, they move to their parents' home in the third trimester and return generally after 6 weeks of delivery. In a few published studies, data collection and assessments pertain to maternal and newborn health/care soon after delivery posed several socio-cultural, geographic, and demographic challenges. Improvised context specific strategies have been instrumental to achieve quality benchmarks [10] [11] [12].

To overcome this challenge, we designated two mobile birth surveillance teams to follow such cases in the study adjacent areas to collect data within 0-6 days of birth. This addition substantially increased targeted data collection within due window of time. Second, mothers were asked to share their planning of birthplace in advance—this also helped us to plan data collection visits accordingly. We had dedicated office-based operator to call families and receive notification of births. We shared our contact details with pregnant women families, volunteers from villages and health facilities to notify births. We reimbursed a mobile phone-card worth rupee 100 against a single birth notification if notified within 24 hours of birth.

Performing Urine Dipstick Test

Study teams also faced difficult to urine sample for dipstick test during few home visits. In such cases study teams had to reschedule a follow up visit on the next feasible day to perform the test. Study office-based operator was responsible to track these families for their availability at their homes to provide urine sample.

Facility Surveillance

Facility surveillance data around delivery, maternal and newborn health was supposed to be collected from hospital record. We faced multiple challenges in this activity.

Table 3. Absenteeism of participants at scheduled data collection visits.

Visit type	Antenatal visits						Postnatal			
Visit number	1		2		3		1		2	
	n	%	n	%	n	%	n	%	n	%
Temporarily absent	769	8.0	743	7.3	544	6.1	142	1.3	167	1.5

Logistic issues

We captured around 65% births at 60 different government and private hospitals, maternity centres and small clinics. These facilities were located within and outside the study areas and these facilities were situated around 40 to 50 KMs radius of the field office. This was quite hard for a single facility surveillance team to reach at all these facilities to acquire information.

We increased surveillance teams to reach maximum facilities. Wherever it was not possible for the study team to reach out facility—the families were accessed through phone and requested to bring hospital discharge records with them, so study staff could collect information about facility procedures and morbidities. Similar issues with birth surveillance have been reported in a few studies conducted in Pakistan and Bangladesh [10] [11] [12].

Poor record maintenance at facilities

The quality of record keeping for both mothers and newborn was poor in majority of facilities. In addition, the facilities administration was reluctant to allow study teams to provide access to facilities record. Once the mother/baby dyad was discharged, there was no structured method of archiving medical records, and it was impossible to collect in-depth information from medical records. Even if records were no unique identification available on medical records such as family name and addresses etc. Hence it became difficult to track these families at their home and we had to seek other source of reaching out to these families. Even in US, a committee on improving patient record observed the outdated patient record keeping patterns which were not able track the individual information. The committee suggested using different mode of technologies for automation and appropriate use of patients' record [23]. There have been multiple barriers to access health information reported in various settings [24] [25].

Thus, to handle with this issue, we developed a small one pager form containing information regarding home addresses with cell phone and details of care provided and morbidities, if occurred. The study teams encouraged health care providers to voluntarily participate in the study and filled this form for each delivery. The study teams visited facilities every month to collect these forms.

Unavailability of antenatal and postnatal cards with mothers

We had to collect some data from antenatal and postnatal cards from health facilities. According to district health system protocols, all public health facilities must provide these cards to every woman who sought care either during pregnancy or after pregnancy termination. Private facilities/health care providers (HCPs) had not issued such cards to women. Discharge summaries were also not availa-

ble in both public and private health facilities. However, we encouraged health care providers to provide discharged summary and antenatal/postnatal cards.

Health system coordination

It was easy for us to coordinate with the public sectors health facilities staff to establish strong liaison and collaboration through district health official letters.

Whereas it was difficult to seek cooperation of health care providers of private sector the study area, as they are working in isolation and there is no official governing body, formal regulation system or a focal point. Therefore, study staff had to create cordial liaison individually with private practitioners to encourage them to be part of the study for greater human interest.

Out of 60 different facilities, we were initially not allowed by a single facility to interview either with mother or health care provider and access the facility record. Later, after individual meetings with facility administrators, staff, and providers, we were able to establish liaison with majority health care facilities.

4. Conclusions

Within the general understanding of the health system layout and socio-cultural environment of study site, the temporal and spatial feasibility of data collection should mindfully be reviewed at the stage of study design and protocol development. The involvement of gatekeepers at the outset (those that directly or indirectly influence the collective decision-making of a village or household) of field activities may help in overcoming community challenges.

Like any other research activity, AMANHI a population-based study posed several contextual challenges corresponded to data collection and individual assessments. We observed that with many logistic eases, a study that builds on already ongoing research with its own set and nature of activities may potentially multiply challenges for the field data collection/implementation team.

Collectively, we understand that careful planning of study implementation at inception and regular meetings with all study staff could be useful to troubleshoot the challenges and implement the study with its full essence.

Strengths and Limitations of This Study

- The study findings provide robust contextual challenges that will benefit future implementation research.
- The findings provide insight on relevant cultural, spatial, temporal and health system factors that should be addressed at the conceptualization and planning phase.
- The paper highlights critical barriers and enablers in the data collection processes that are critical to generating plausible outcomes in any population-based study.
- The challenges that are alluded to in this paper are not numerically quantified. This may potentially lead to some degree of uncertainty on the magnitude of the problem.

- Lack of quantitative data may be a challenge for resource allocation in similar settings.

Declarations

Patient and Public Involvement

The public was not involved in the design of the research tools, but they were part of the study. The key findings had shared with community through their representatives as part of the dissemination plan at local level.

Ethics Approval

The study was approved by Ethical Review Committee of Aga Khan University, Pakistan, ID 2236-Ped-ERC-12.

Availability of Data and Materials

The datasets used for this article are available from the corresponding author on request.

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Authors' Contributions

SBS was the principal investigator of the study. SBS & SA had drafted the country specific adaptation of protocol. YW & SA contributed to multiple amendments, field SOPs development, trainings and implementation. AH, and IA developed data entry screens, assisted with the data management, cleaning and data analysis. YW produced initial draft of this manuscript. SA, SM, MAA, AH & SBS critically reviewed the manuscript. All authors reviewed and approved the manuscript.

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Conflicts of Interest

The authors declare that they have no financial or non-financial competing interests.

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List of Abbreviations

AMANHI: The Alliance for Maternal and Newborn Health Improvement; ANISA: Aetiology of Neonatal Infections in South Asia; CHW: Community Health Worker; HCP: Health Care Provider; KM: Kilo Meter; LMP: Last Menstrual Periods; VA: Verbal Autopsy; WHO: World Health Organization.