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The Maternal and Newborn Health Registry Study of the Global Network for Women's and Children's Health Research

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Conflict of interest

The authors have no conflicts of interest.

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Abstract

Objective—To implement a vital statistics registry system to register pregnant women and document birth outcomes in the Global Network for Women's and Children's Health Research sites in Asia, Africa, and Latin America.

Methods—The Global Network sites began a prospective population-based pregnancy registry to identify all pregnant women and record pregnancy outcomes up to 42 days post-delivery in more than 100 defined low-resource geographic areas (clusters). Pregnant women were registered during pregnancy, with 42-day maternal and neonatal follow-up recorded—including care received during the pregnancy and postpartum periods. Recorded outcomes included stillbirth, neonatal mortality, and maternal mortality rates.

Results—In 2010, 72 848 pregnant women were enrolled and 6-week follow-up was obtained for 97.8%. Across sites, 40.7%, 24.8%, and 34.5% of births occurred in a hospital, health center, and home setting, respectively. The mean neonatal mortality rate was 23 per 1000 live births, ranging from 8.2 to 48.5 per 1000 live births. The mean stillbirth rate ranged from 13.7 to 54.4 per 1000 births.

Conclusion—The registry is an ongoing study to assess the impact of interventions and trends regarding pregnancy outcomes and measures of care to inform public health.

Keywords

Maternal mortality; Neonatal mortality; Perinatal mortality; Pregnancy; Registry; Stillbirth

1. Introduction

Annually, 380 000 maternal deaths, 3.3 million neonatal deaths, and 2.7 million stillbirths occur worldwide [1–3]. Maternal mortality ratios range from less than 5 per 100 000 in high-income countries to more than 700 per 100 000 births in some South Asian and Sub-Saharan African countries [4]. More than 98% of maternal deaths occur in low-resource countries; India alone has the highest number of maternal deaths, accounting for 22% of the total [5]. Neonatal death and stillbirth rates range from 3 per 1000 births in high-resource countries to 70 per 1000 in some Sub-Saharan African countries [6]. However, because many countries with high mortality rates also have weak healthcare systems with inadequate birth registries, they often lack precise rates and causes of mortality. Although improvements in vital registration coverage in some transitional countries (81 countries now have systems with high coverage) have been reported, the existing systems account for only 27% of the world's births [7]. Underreporting of births and deaths remains an important problem in many low-resource countries [8]. Many estimates of pregnancy outcome, and obstetric and neonatal care rely on hospital reports, household surveys, or less commonly statistical modeling [9].

Neonatal death and stillbirth rates are informed by how these outcomes are defined, which varies among countries. To differentiate stillbirth from miscarriage, the lower limit for stillbirths recommended by the World Health Organization (WHO) for international comparisons is 1000-g birth weight or 28 weeks of gestation, where gestational age is available [1,10–12]. Another consideration is whether a stillbirth is classified as prepartum or intrapartum, with the latter occurring around the time of delivery and generally being considered preventable [7–9,12–14]. Distinguishing between an intrapartum stillbirth and an early neonatal death may be challenging, especially for home births. The time of fetal and neonatal death has important implications for prevention and intervention programs.

Population-based birth data are critical to clinical trials and for programmatic prioritization to improve pregnancy outcomes.

The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Global Network for Women's and Children's Health Research (Global Network) was established in 2001 as a collaborative partnership of clinical researchers from South Asia, Africa, and Latin America working with investigators in the USA. The Global Network investigators conduct studies designed to test feasible, sustainable interventions to improve the outcome of women and children and to develop research capacity in resource-poor settings [10–13]. To address the paucity of population-based pregnancy data, the Global Network established a population-based vital registry system in 2009 to document stillbirth, neonatal mortality, and maternal mortality rates. In addition to tracking outcomes over time to understand mortality better in these areas and planning interventions, the data may ultimately inform public health policy.

2. Materials and methods

The present study was conducted under the auspices of the Global Network, which is a multi-country research network funded by the NICHD. Investigators from each site, the NICHD, and the Data Coordination Center (DCC) constitute the Maternal Newborn Health (MNH) Registry Study Committee, which oversees protocol design, study implementation, data analyses, and publications. Within each Global Network site, the registry is overseen by the senior investigator, the study coordinator, and his/her designee, who ensure overall completeness and data quality. Study sites in each country (Argentina, Guatemala, India [2 sites], Kenya, Pakistan, and Zambia) have established research infrastructure in 6–24 distinct geographic areas (clusters), appropriate for long-term registry data collection and ongoing Global Network research. Each cluster was selected with a target birth rate of 300–500 deliveries per year. Specifically, the clusters were generally formed based on the existing healthcare service delivery areas, as defined by the Ministry of Health in the participating countries. For example, the Primary Health Centers (PHCs) were the basis of the clusters in India. The PHCs typically serve a defined population and the births were estimated via the birth rates from the available Ministry of Health data. To oversee data collection, each study cluster employs designated Registry Administrators (RAs), who are well-respected healthcare providers within the community. The RAs—who work closely with the existing healthcare service providers within their communities and, in turn, enhance the healthcare delivery system—receive ongoing central training, including data form completion, data monitoring and editing, and quality improvement. The RAs monitor the pregnancies in the cluster, facilitated by local informants (e.g. village elders, birth attendants, and facility registries).

The appropriate Institutional Review Boards and Ethics Research Committees of the participating institutions, and the Ministries of Health of the respective countries approved the MNH Registry. Prior to initiation of the study, approval was sought from the participating communities through sensitization meetings. Individual informed consent for study participation is requested from each study participant. Study staff read to each potential participant an information page that has been translated into the local language to inform her of the study purpose. There are no monetary reimbursements to study participants and there is no remuneration to the communities participating in the study. A Data Monitoring Committee, appointed by the NICHD, oversees and reviews the registry at annual meetings.

All pregnant women who are permanent residents of the study cluster are enrolled and their outcomes collected, regardless of whether they deliver within the study cluster. In addition,

pregnant women who are not permanent residents but who deliver within the study cluster are enrolled. Birth attendants are sensitized to the study activities and requested to report all deliveries to the RAs, regardless of whether the delivery occurs at home or in a facility, or whether the birth is attended. Birth attendants or the mothers are provided clean delivery kits as an incentive for reporting birth outcomes to the RAs.

Complete registration of all eligible women and tracking of outcomes through to 42 days after delivery comprise the study goal. Monitoring visits and data quality checks are performed to maximize the quality of data capture for all births. Each site has established methods to ensure completeness of pregnancy outcome data for all births. At the onset, each site mapped all health facilities and birth attendants in each cluster. In addition to delivery kits provided to birth attendants as incentives to notify the study team of their deliveries, birth attendants are contacted by study staff routinely to document deliveries. For facility births, hospital logs are routinely reviewed for any otherwise unreported deliveries of women from a study cluster. The study team monitors cluster-level monthly data to assess trends over time. Site-specific, culturally appropriate strategies have been developed to supplement reporting. In several countries, cell phone reporting by local village elders and traditional birth attendants has been effective [15]. Several sites have developed unique systems for ensuring the completeness of the registry data—including annual household surveys to enumerate married women of reproductive age and to identify those likely to become pregnant in the ensuing year, and comparison of registry rates with alternate local data sources such as vital records, where available. The overall goal of the registry is to capture all outcomes of pregnant women residing in the cluster.

To quantify and assess the trends in pregnancy outcome in defined low-resource geographic areas, population-based statistics on fresh and macerated stillbirth rates, early (7-day) neonatal mortality rate, 28-day neonatal mortality rate, and 42-day maternal mortality rate are collected. Data are collected at 3 time-points for each eligible woman: registration as early as possible during the pregnancy; within 48 hours of delivery; and 42 days after birth. The RAs determine pregnant women's eligibility and, for consenting women, record the following: date of last menstrual period; estimated delivery date; age; level of schooling; parity; and status of last child. For all enrolled women, the RAs collect data on: prenatal care; birth preparedness; complications during pregnancy; and delivery information such as place, mode, provider and practices, neonatal birth weight, status of the mother and newborn following delivery, referrals, and treatment provided to the mother and newborn at the referral facility. Maternal and newborn status is assessed 42 days after birth. In addition, demographic and healthcare utilization data are collected for the mother and the fetus/neonate. For specific study planning, additional time-limited data collection is performed. The study is consistent with the WHO definitions, whenever possible. The primary reference guide for the study definitions is the *Integrated Management of Pregnancy and Childbirth. Pregnancy, Childbirth, Postpartum and Newborn Care: A Guide for Essential Practice* [16].

The RAs review the forms to identify individual or patterns of errors by birth attendants, and the supervisory staff conduct audits. In total, 5% of all data forms are rekeyed. Data are entered into password-protected data management systems, with data transfer from each data management computer to a server maintained at each site, thus creating a complete data repository. Data are transmitted from the site to the DCC weekly.

The accuracy of actual data collected is checked by chart review (random 5%) and internal computer verification. Monthly audits and incomplete data reports are reviewed by a team including the senior investigator and the country coordinator. Data editing and error resolution are performed monthly. In addition, a sample of selected participants is visited to confirm their data. The quality assurance activities are shared between the site and the DCC.

The site data management system is used to perform validity checks on data items as they are being entered. Validity checks such as completeness of required fields, range, skip, and consistency are performed at data entry and repeated on the database at the DCC, where additional checks (e.g. across-form consistency) are performed. Detailed reports of edit check failures are returned to the site and the issues (or confirmation of value outside the range) are then resolved. To maintain participant confidentiality, all data that leave the site are identified by coded number only. Clinical information will not be released without written permission from the participant, except when necessary for monitoring by the Ethics Committees, the NICHD, or other authorized regulatory authorities.

3. Results

The MNH Registry has been conducted in 7 study sites, each comprising 6–24 clusters (Table 1). While the projected birth rate for clusters was 300–500 per annum, the mean births per cluster in 2010 ranged from 479 in Argentina to 1095 in Belgaum, India. In 1 year, 72 848 women were enrolled in the registry. Across sites, 99.8% of all women identified gave consent and were enrolled; the follow-up rate at 6 weeks was 97.8% of the women enrolled.

Across Global Network sites, prenatal care rates ranged from 93.8% in Argentina to 99.9% in Nagpur, India (Table 2). In the 2 African sites, 1.6%–2.7% of births were attended by physicians, compared with 70.5% in Argentina. In Zambia and Kenya, respectively, 21.2% and 12.5% of births were unattended by a provider, whereas 0.2% and 0.7% were unattended in Guatemala and Argentina, respectively. In Argentina, 98.7% of births occurred in hospitals, compared with 64.9%–70.9% at Indian sites and 5.7% in Zambia. As an indicator of healthcare, the cesarean rate was 28.5% in Argentina, 15.4% in Nagpur, and 1.0% and 1.1% in the African sites. Neonatal resuscitation ranged from 2.5% in Guatemala to 10.7% in Pakistan (although only 36.4% of cases in Pakistan were with bag and mask). Bathing the baby immediately after birth ranged from 0.7% in Argentina to 50.1% in Guatemala. The rate of breastfeeding after birth was approximately 80% at all sites, except Pakistan (29.3%).

In terms of primary mortality outcomes, during 2009–2010, low birth weight deliveries (defined as live births <2500 g) ranged from 3.9% in Kenya to 20.8% in Pakistan. The early neonatal mortality rate (deaths occurring within 7 days of birth) ranged from 7.6 per 1000 live births in Argentina to 38.5 per 1000 in Pakistan. The overall mean neonatal mortality rate was 22.9 per 1000 live births, ranging from 8.2 in Argentina to 48.5 in Pakistan. The mean stillbirth rate was 33.1 per 1000 births, ranging from 13.7 in Argentina to 54.4 in Pakistan. The mean maternal death rate varied from 88 and 90 per 100 000 live births in Kenya and Argentina, respectively, to 239 per 100 000 in Pakistan (Table 3).

4. Discussion

The overwhelming majority of stillbirths, neonatal deaths, and maternal deaths occur in low-resource countries but vital registration systems in many of these countries are poor. There is general agreement that maternal and neonatal deaths are underreported and that the true burden of maternal and newborn mortality is higher than that reported in the literature [13,16,17].

One of the limitations is the difficulty quantifying the potential missed pregnancies. Overall, however, the birth rates reported were higher than projected, indicating that the surveillance for the study registry was more comprehensive than the available census data. In addition, assessment of very early outcomes (stillbirth, early neonatal death) also remains a particular challenge in geographic areas with a high proportion of deliveries conducted at home,

unattended by skilled birth attendants. However, the initial registry results indicate that it is feasible to implement a registry system and that specific strategies can improve the quality and completeness of the data collection. For example, the distribution of cell phones and scales to village elders may increase reporting, with rates stabilizing over time—as demonstrated in the Kenya site [15]. Some sites have faced challenges of tracking the outcomes of pregnant women who migrate in or out of the study clusters to the homes of their mothers at the time of delivery. To address these challenges, numerous systems have been developed and, through monitoring, a relatively stable enrollment rate has been achieved at the study clusters. With close oversight and community support, obtaining these outcomes is feasible.

Much of the care provided still varies widely across countries and geographic regions within the Global Network. For example, less than 10% of births in the African sites occur in a hospital setting. By contrast, nearly all births in Argentina take place in health facilities. In India, where significant efforts have been made to improve rates of facility births, nearly 15% of births still occur without a skilled provider available. Similarly, traditional birth attendants—who have limited skills—deliver a substantial proportion of births at all sites, with the exception of Argentina. When examining outcomes, the mean stillbirth and neonatal mortality rates across Global Network sites remain significantly higher (33 per 1000 and 23 per 1000, respectively) than the stillbirth and neonatal mortality rates reported by most high-income countries (less than 5 per 1000). Together, these results indicate that there is a substantial amount of work needed to reduce further the pregnancy-related mortality rates in low-income countries, across a variety of settings and healthcare conditions, with improvements in obstetric care a central component [18,19].

The Global Network registry was designed to collect accurate data on pregnancies and their outcomes. This is among the first international, multicenter, population-based registries of pregnancies to assess pregnancy outcomes, enabling the investigators to determine the impact of future interventions to improve maternal and newborn outcomes, monitor trends over time, and evaluate the changing patterns of perinatal care in low-income countries to inform health policy. Accurate and complete data remain essential for informing the best use of scarce resources to reduce maternal, fetal, and neonatal mortality rates.

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Synopsis

The Global Network registry provides population-based birth outcomes for low–middle-income countries. Neonatal mortality was 8.2–48.2 per 1000 live births; stillbirth rates were 13.7–54.4 per 1000 births.

Table 1 Global Network study sites: characteristics for 2010 ^a

	Argentina	Guatemala	Zambia	Kenya	Pakistan	Nagpur, India	Belgaum, India
Clusters	6	10	10	16	24	20	20
Annual births	2875	6119	7306	9100	14 779	10 761	21 908
Annual births by cluster	479 ± 88	612 ± 200	731 ± 434	569 ± 173	616 ± 193	538 ± 163	1095 ± 215
Enrolled	97.8	100.0	100.0	100.0	99.8	100.0	99.9
Follow-up at 42 days	97.9	99.6	99.9	99.9	99.0	99.2	99.9

^aValues are given as number, mean ± SD, or percentage.

Table 2

Healthcare provision 2009–2010 ^a

	Argentina	Guatemala	Zambia	Kenya	Pakistan	Nagpur, India	Belgaum, India
1 prenatal care visit	93.8	96.0	98.2	94.9	76.7	99.9	99.3
Provider							
Physician	70.5	27.9	2.7	1.6	22.7	53.4	56.5
Nurse/midwife	28.8	1.5	43.9	34.8	25.1	33.6	30.5
Traditional birth attendant	0.0	70.4	32.2	51.1	49.7	8.7	6.3
Family/unattended	0.7	0.2	21.2	12.5	2.5	4.3	6.7
Birth location							
Facility	98.7	26.0	5.7	9.5	24.3	60.2	61.5
Clinic	0.2	3.1	42.0	25.6	23.3	25.3	24.3
Home	1.1	70.9	52.2	64.9	52.3	14.6	14.1
Cesarean rate	28.5	11.4	1.0	1.1	6.6	15.4	8.7
Neonatal resuscitation	3.3	2.5	2.8	4.1	10.7	3.3	5.2
Bag and mask	89.1	79.6	72.2	27.8	36.4	76.0	91.4
Baby bathed	0.7	50.1	35.8	45.7	31.0	1.4	8.3
Baby breastfed	86.3	80.6	81.5	76.0	29.3	85.8	83.6

^aValues are given as percentage.

Table 3

Stillbirth rate and neonatal outcomes 2009–2010 ^a

	Argentina	Guatemala	Zambia	Kenya	Pakistan	Nagpur, India	Belgaum, India
Clusters	6	10	10	16	24	20	20
Births	5772	10 706	14 154	17 541	25 909	14 910	41 883
Low birth weight	6.3	12.6	7.2	3.9	20.8	19.4	16.2
Early neonatal mortality rate per 1000 live births	7.6 ± 2.6	18.3 ± 5.6	19.5 ± 6.9	11.8 ± 5.9	38.5 ± 10.7	19.6 ± 9.1	21.4 ± 5.4
Neonatal mortality rate per 1000 live births	8.2 ± 2.7	25.2 ± 6.9	22.7 ± 5.8	15.5 ± 7.3	48.5 ± 13.4	26.2 ± 9.9	26.2 ± 6.5
Stillbirth rate per 1000 births	13.7 ± 3.5	22.3 ± 8.7	26.9 ± 7.5	19.5 ± 7.2	54.4 ± 15.2	33.5 ± 10.5	30.3 ± 7.2
Fresh stillbirth	60.8	74.1	70.4	79.4	65.1	80.5	68.1
Maternal mortality rate per 100 000 live births	90 ± 148	95 ± 91	211 ± 132	88 ± 91	239 ± 137	126 ± 157	187 ± 85

^aValues are given as number, percentage, or mean ± SD.