Implementation of the WHO Multicentre Growth Reference Study in India

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Abstract

The World Health Organization (WHO) Multicentre Growth Reference Study (MGRS) Asian site was New Delhi, India. Its sample was drawn from 58 affluent neighborhoods in South Delhi. This community was selected to facilitate the recruitment of children who had at least one parent with 17 or more years of education, a key factor associated with unconstrained child growth in this setting. A door-to-door survey was conducted to identify pregnant women whose newborns were subsequently screened for eligibility for the longitudinal study, and children aged 18 to 71 months for the cross-sectional component of the study. A total of 111,084 households were visited over an 18-month period. Newborns were screened at birth at 73 sites. The large number of birthing facilities used by this community, the geographically extensive study area, and difficulties in securing support of pediatricians and obstetricians for the feeding recommendations of the study were among the unique challenges faced by the implementation of the MGRS protocol at this site.

Key words: Anthropometry, breastfeeding, child health, child nutrition, growth, growth monitoring, growth references, India, infant feeding practices

Introduction

The World Health Organization (WHO) Multicentre Growth Reference Study (MGRS) Asian site was New Delhi, India. Its sample was drawn from a subpopulation of selected neighborhoods in South Delhi in which relatively large groups of affluent, educated individuals reside. Data from a previous survey showed that children in this community having at least one parent with at least 17 years of education experience unconstrained growth [1]. To select the required community-based subpopulation, all 133 residential neighborhoods in South Delhi were identified. After neighborhoods with institutional residential areas, hostels, or low-income group housing had been excluded, 95 neighborhoods remained. Of these, the 58 with the highest land valuations were included [2, 3]. The survey referenced also showed that 80% of births in this population occurred in 46 hospitals or nursing homes throughout South Delhi [1]. This characteristic presented unique challenges for the site, as described below in greater detail.

Planning phase

Study timeline and preparatory activities

The initiation and duration of key study phases are summarized in figure 1. Preparatory activities were initiated on January 1, 2000. The first child was enrolled on April 9, 2000, and the last on October 31, 2001. The study was completed at the end of 2003.

Among the principal preparatory activities designed to facilitate study initiation and community acceptance were the recruitment of dedicated personnel for the various study activities and public relations efforts. To conduct the survey, written permission was obtained from local associations to survey the 58 neighborhoods described above. In some neighborhoods, presentations were made to groups of residents to facilitate required approvals and the collaboration of the community.

Institutional ethical approvals were obtained from the Ethics Committee of the All India Institute of Medical Sciences.

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Members of the WHO Multicentre Growth Reference Study Group and Acknowledgments are listed at the end of the first paper in this supplement (pp. S13–S14).

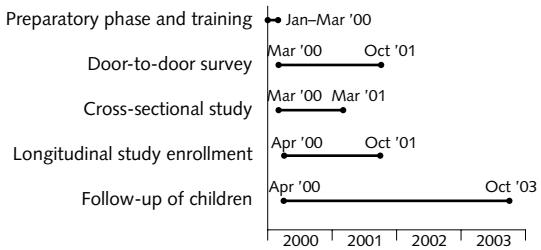

FIG. 1. Study timeline

Study teams

The survey team, coordinated by a physician, was composed of five workers who conducted the door-to-door survey described below, and three pairs of workers who completed the cross-sectional questionnaire and took anthropometric measurements of the recruited subjects. An eight-member team, working in pairs and supervised by another physician, conducted the longitudinal follow-up. The lactation counseling team was made up of five members supervised by the overall study coordinator. A six-member data management team was also recruited and supervised by the site's data manager. The overall study coordinator conducted quality control activities and provided overall supervision of the study.

All team coordinators were physicians with training in pediatrics; the overall coordinator was an obstetrician/gynecologist. The fieldworkers were postgraduates in nutrition or social sciences. Trained lactation counselors were not available in New Delhi at the time of initiation of the study. Postgraduates in nutrition with effective interpersonal skills were therefore recruited and, together with the coordinators and physicians of the study, completed a 40-hour WHO/UNICEF breastfeeding counseling training course [4].

Training and initial standardization

The members of the teams underwent training for various periods up to three months. The training sessions focused on applying questionnaires, the correct filling in of forms, and minimizing inter- and intraobserver variability of anthropometric and motor development measurements or observations through rigorous standardization exercises, as appropriate. Staff from the WHO Coordinating Centre and an international lead anthropometrist conducted the initial standardization session. The local team repeated standardization sessions every two months, and fieldworkers whose performance deviated from the MGRS protocol were retrained by the local lead anthropometrist. The international lead anthropometrist participated in the bimonthly sessions once a year and provided retraining as required [5].

The follow-up team members conducting the motor development assessments were trained by staff from the WHO Coordinating Centre following the motor development study protocol [6]. The site's data manager was especially trained by WHO staff to use the centrally prepared MGRS data management system described elsewhere in this supplement [7].

Public relations

Strong community and health professional education and communication efforts were major features of the study. These were conducted in early and subsequent phases, as needed. Public awareness of the study was enhanced by posters displayed in public places, such as shops, clubs, and meeting halls in the 58 neighborhoods from which the study sample was drawn. Other informational material was distributed to local neighborhood associations, and presentations of the goals and methods of the study were made to community officials and other leaders.

A meeting was organized for pediatricians, obstetricians, and administrators of the area's major hospitals. The goals and methods of the study were presented, with the principal aims of gaining acceptance of the infant feeding recommendations of the study and building a communication network for sustaining cooperation and adherence to recommended feeding guidelines throughout and after the conclusion of the study. The network also provided a means of keeping the community and its health professionals informed of the progress of the study.

The study investigators and/or physicians visited all 73 hospitals where pregnant women recruited through the survey (described below) intended to deliver. The number of hospitals and delivery facilities was substantially larger than expected from the survey done in this community [1]. Material that was specially designed to provide information about the goals and methods of the study was distributed to administrators, pediatricians, and obstetricians and reviewed with them by study personnel.

The media were also utilized in the preparatory and subsequent phases of the study. The study received coverage in a leading daily newspaper and on a popular television news program when the first child was enrolled.

Implementation of the longitudinal study

Overall strategy

A door-to-door survey was conducted in the 58 selected neighborhoods to identify pregnant women whose newborns were likely to be eligible for the longitudinal study. Children aged 18 to 71 months also were

identified by this survey for inclusion in the MGRS cross-sectional component.

All selected neighborhoods were listed alphabetically and given identification numbers (1 to 58). A computer-based random-number generator was used to determine the sequence in which neighborhoods would be surveyed. Serial numbers were assigned to the generated sequence, and the neighborhoods were surveyed in that order. All 58 neighborhoods were surveyed twice to identify 1,000 pregnant women, which was projected to be the necessary number for recruitment of the required sample size. Figure 2 summarizes the calculation of this estimate.

Exclusion criteria specific to the Indian site are shown in table 1. A total of at least 17 years of education for the mother or father was used as a criterion to select a subpopulation of infants with no constraints on physical growth, as validated in a prestudy survey conducted in the same subpopulation [1]. The morbidity criteria were selected through a consensus process among senior pediatricians of conditions most likely to affect physical growth and development significantly. The remaining exclusion criteria for individuals are described in the methodology paper included in this supplement [8].

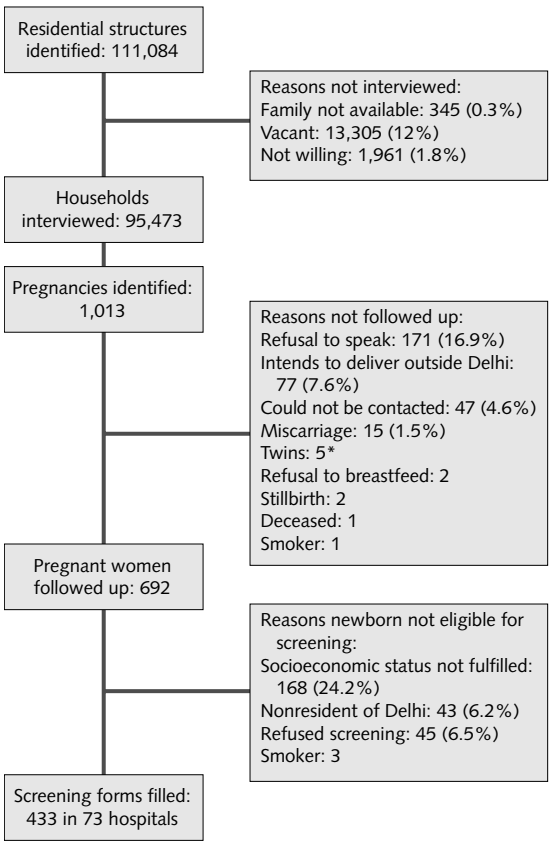

FIG. 2. Flow chart for identification of pregnancies

TABLE 1. Exclusion criteria specific to the Indian site

Perinatal morbidity such as severe birth asphyxia, congenital heart disease, congenital malformations, chromosomal anomalies, hormonal abnormalities, congenitally acquired infections (cytomegalovirus, toxoplasmosis, syphilis), nursery stay for more than 24 hours for morbidity
Not intending to breastfeed at all
Both parents have had less than 17 years of education

Informed consent was obtained from all pregnant women who were identified in the surveys and who agreed to participate in the study. Consenting women intending to deliver in New Delhi and fulfilling the socioeconomic eligibility criteria were revisited as appropriate at 10, 24, and 36 weeks of gestation. A study physician made the first visit, and subsequent visits were made by one of the study lactation counselors. Daily contact was maintained with all pregnant women after 36 weeks of gestation through telephone calls and/or home visits.

The intended place of delivery was ascertained at the first visit. The study coordinator contacted the hospital authorities and the subject's designated obstetrician and pediatrician. They were informed of the study and given documents relevant to its goals and methods, and permission was requested for a visit to their patients soon after delivery. The families were requested to inform the study coordinator or lactation counselor of the delivery as soon as possible. Mobile telephone numbers of study personnel were attached to the expectant mother's antenatal card to help families meet this request.

A lactation counselor visited the hospital soon after each delivery. A study physician and two members of the follow-up team visited after the initial visit of the lactation counselor. These teams were on 12-hour shifts to ensure contact with the mother as soon after delivery as possible. The follow-up team physician screened the child for eligibility and obtained oral informed consent from a parent for the infant's participation.

Follow-up logistics

The first visit of the follow-up team was scheduled for two weeks after delivery. The child was given a gift and rescreened for eligibility at this visit. This was necessary to identify "hidden refusals" or "hidden ineligibles," e.g., infants whose fathers did not support the mother's initial decision to participate or infants whose mothers used formula soon after delivery. Written informed consent was obtained at this visit, and a baby's participation diploma was given to the mothers. Anthropometric measurements were recorded on the diploma at each visit. Hidden refusals and ineligibles

were excluded. All refusals, subjects ineligible owing to breastfeeding intentions, and dropouts from the study were contacted at the child's first birthday for the 12-month study [8].

Home visits for obtaining anthropometric measurements and ascertaining feeding practices, intake of vitamin and mineral supplements, and morbidity were made according to the MGRS protocol [8]. Visits by the follow-up and lactation teams were conducted separately. If the mother inadvertently made concurrent appointments for both teams, the follow-up team waited outside the room until the lactation counselor completed her interview (fig. 3).

When the infants were four months of age, motor development assessments were initiated and repeated monthly in the first year and every two months in the second year until the child could walk independently [6].

Lactation support and complementary feeding

Several visits by the lactation counselors were made to boost the low rates of exclusive breastfeeding characteristic of this setting [1]. These included alternate-day visits during the first week after birth and weekly visits for the first four months. Visits were made every two weeks from four to six months, and monthly visits were made until the child's first birthday. The lactation counselors often interacted with grandmothers, because in this setting they often determine child feeding practices.

A week before the child reached the age of six months, the lactation counselor visited to provide guidance on complementary feeding. Each mother was given complementary feeding guidelines prepared by the investigators, a booklet containing nutritious and appetizing recipes, a plate and spoon, and a food calendar divided by months that permitted the caregivers to record foods consumed by the child. The complementary feeding guidelines developed by the investigators were finalized following feedback that was obtained from nutritionists and pediatricians of the major participating hospitals (table 2).

Implementation of the cross-sectional study

Children aged 18 to 71 months were selected for the cross-sectional study from the door-to-door survey conducted primarily to identify participants for the longitudinal study. Two members of the cross-sectional team visited children recruited to this study component. If a household had a pregnant woman and one or more eligible children aged 18 to 71 months, only the

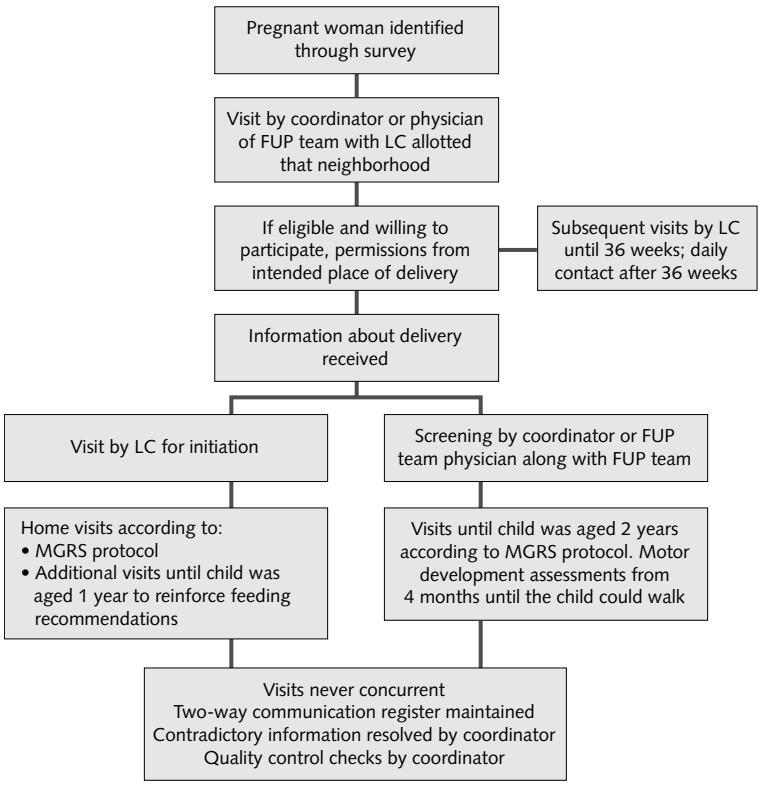

FIG. 3. Coordination between screening, follow-up (FUP) team, and lactation counselor (LC)

TABLE 2. Complementary feeding guidelines at the Indian site

Feeding practice	6–8 mo	9–11 mo	12–24 mo
Breastfeeding	Continue	Continue	Continue
Complementary foods			
Start	At 6 mo		
Quantity	280 kcal	450 kcal	750 kcal
Frequency (meals and snacks)	2–3	3–4	4–5
Consistency	Mashed, very soft	Soft	Finger foods, family diet
Food diversity	Give vitamin A–rich fruits and vegetables, meat, poultry, and fish. Use fortified foods such as iodized salt and iron-fortified flour		
Active feeding	Feed infants yourself, assist older children. Offer favorite foods if appetite is low. Talk to the child while feeding. Feed slowly and patiently. Minimize distractions. Feed from a separate bowl or plate		
Feeding during illness	Feed frequently and patiently. Give favorite foods. After recovery feed more often		
Hygiene and food handling	Wash your hands and the child's hands before feeding. Serve foods immediately after preparation. Use clean utensils to prepare and serve food. Do not use feeding bottles		
Other advice	Ensure immunization schedules are complete. Use oral rehydration therapy during diarrhea. Follow your pediatrician's recommendations for multivitamins and iron–folic acid supplements. Provide children with opportunities for exploration and autonomy		

pregnancy was followed up; if multiple eligible children 18 to 71 months were present in a household, only the youngest child in the family was included in the cross-sectional study component. The 1,490 children for the cross-sectional study were recruited successfully after surveying the first 51 neighborhoods.

Standardization, quality control, and data management activities

Standardization sessions

Anthropometric and motor development standardization sessions were conducted regularly for the relevant teams, as specified in the MGRS protocol [5, 6]. The anthropometry sessions were conducted every two months in one of the study clinics at an urban field site. Standardization sessions involving newborns were conducted at the All India Institute of Medical Sciences. The children assessed during the motor development standardization sessions were taken from among the participants in the longitudinal study.

Quality control activities

Quality control checks were performed on 10% of the follow-up and lactation visits. These were fixed for the Wednesday and Saturday of each week. On these days, the coordinator listed all follow-up and lactation visits that had been made since the last quality control check and randomly selected 10% of them for follow-up. Telephone calls were made to those selected. Information pertaining to morbidity, supplement intake, child feeding practices, maternal work, and the follow-up team's anthropometry technique and, if appropriate, lactation counseling was obtained from mothers. Feedback was obtained on the frequency and content of counselors' visits. Feedback also was obtained on any problems they faced as participants in the study. Information obtained in these quality checks was compared with information obtained by the teams. The study coordinator reviewed any inconsistencies with the relevant team.

Daily meetings were held by each of the study teams with their coordinators. Weekly review meetings were held with the project coinvestigators and each of the study teams. However, most queries and problems were resolved on a daily basis.

Data management

Data management activities followed procedures established by the centrally developed data management system [7]. The forms filled out by the different study teams were checked manually by the respective coordinators and forwarded to the data manager within 24 hours of collection. Double data entry and validation were completed within the subsequent 48 hours. The data were transmitted to the MGRS Coordinating Centre in Geneva on a monthly basis.

Conclusions

The implementation of the MGRS at the Indian site was a challenging task that required careful planning and

implementation. The large number of hospitals and other delivery sites used by this community precluded identifying potentially eligible infants soon after birth, as was done in all other MGRS sites. The requirement of the protocol that anthropometric measurements be obtained soon after birth made that approach impossible. Thus the door-to-door survey described above was necessary. This was particularly challenging. It meant obtaining permission to survey in each of the 58 neighborhoods and visiting 111,084 households over an 18-month period. The study area covered 116 km^2. This required overcoming serious practical constraints presented by gated communities and the work and social demands on the largely professional class of participants.

Another important challenge concerned securing the support of pediatricians and obstetricians and their endorsement of the feeding recommendations central to the MGRS protocol. Few physicians in this setting are convinced that withholding prelacteal feeds and exclusive breastfeeding for six months are relevant for families of high socioeconomic status. This barrier could not have been overcome without the public relations efforts initiated at the onset of the study and the strong international presence evident in all MGRS sites.

There were and are few well-trained lactation counselors in New Delhi. Thus the services of those trained for this study were in great demand. Although this was helpful in supporting recommended feeding practices, lactation counselors were often called upon to support both study participants and those not participating. Throughout the study, a lactation counselor was on call 24-hours a day, and a study vehicle remained with her so that visits could be made until late evening, if required. As a result of the MGRS implementation, lactation training workshops for nurses were organized at some of the major hospitals and the All India Institute of Medical Sciences on several occasions. In the end, it is gratifying that a great team effort helped overcome these multiple challenges and ensured data of high quality.

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