

Implementation of the WHO Multicentre Growth Reference Study in Norway

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Abstract

The World Health Organization (WHO) Multicentre Growth Reference Study (MGRS) European site was Oslo, Norway. Oslo has a high breastfeeding rate. Ninety-nine percent of mothers initiate breastfeeding soon after delivery, and 80% continue for at least six months. There is no evidence that socioeconomic conditions constrain growth. As in other sites, the study had two components, longitudinal and cross-sectional. Recruitment for the longitudinal component was conducted in three hospitals that account for most births in Oslo. Approximately 850 subjects were screened in one year by using a systematic allocation scheme to recruit a sample of about 300. Recruitment for the cross-sectional component was based on a systematic interval sampling scheme prepared by the National Registry. More than 4,000 subjects were screened to achieve the required sample size. One of the major challenges of the study was to achieve an acceptable participation rate; great efforts were made to motivate pregnant women via the health care system and the media.

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

Introduction

The World Health Organization (WHO) Multicentre Growth Reference Study (MGRS) European site was Oslo, Norway. The population of Oslo is about 500,000, and there are approximately 7,700 births annually [1]. The city has a high breastfeeding rate. Ninety-nine percent of women initiate breastfeeding soon after delivery, and 80% continue breastfeeding for at least six months [2]. Oslo's infant mortality rate was 3.2 per 1,000 live births in 1998 [3], and there is no evidence that socioeconomic status constrains growth in early childhood [4]. The city has an excellent breastfeeding support system and a population characterized by low geographic mobility, and it is at sea level.

As in all other sites, this study had two components, longitudinal and cross-sectional. The longitudinal component followed children from birth through 24 months. The cross-sectional component studied children aged 18 to 71 months. The sample for the longitudinal component was drawn from three hospitals that account for more than 95% of the city's births: Ullevaal, Rikshospitalet, and Aker. All three are designated as Baby-Friendly Hospitals by WHO/ UNICEF [5]. Less than 1% of women deliver their infants at home [6].

Planning phase

Study timeline and preparatory activities

Planning for the study began in September 1998, when a coordination center was established at the National Breastfeeding Centre in Rikshospitalet University Hospital. The timeline for the major phases of the study is summarized in figure 1.

The study was presented to the directors of the three participating hospitals, their physicians-in-chief and head midwives, and other maternity ward staff. Health personnel working in antenatal care or child health clinics were informed through meetings and written material of the goals and procedures of the

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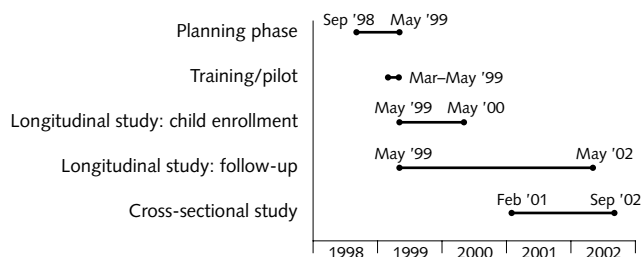


FIG. 1. Study timeline

study and their respective roles in supporting the successful implementation and completion of the study. Almost 100% of parents take their children to Oslo's public child health clinics during the children's first years of life. Cooperation agreements were therefore developed with child health clinics, and the research team sent letters outlining study procedures to the respective clinics as children from their catchment areas were enrolled.

Announcements in journals for health personnel and in the city's newspapers were used to recruit staff for the various positions in the study. Since the response was high, personnel with the best qualifications were recruited.

Institutional approvals were obtained from Rikshospitalet, Ullevaal, and Aker hospitals, the Regional Ethics Committee for Medical Research, the Data Inspectorate, and the Norwegian Board of Health.

Study teams

The study team consisted of two principal investigators who were physicians, one project coordinator, one supervisor, five lactation counselors who had been trained as midwives or public health nurses, eight follow-up interviewers who were nurses' aides (specially trained to work with children), a data manager and two data clerks, one quality control staff member, and a study secretary.

Training and initial standardization

The training phase lasted two months. Extensive practical anthropometric training with children of relevant ages followed a review of the underlying physiology of physical measurements and growth. The measurement techniques of the screening and follow-up teams were standardized against the measurements of one of the two WHO lead anthropometrists [7]. All candidates met the standardization criteria.

The follow-up team was trained in interview techniques and dietary assessment methods. The lactation team went through an extended training program on lactation counseling. All members of the lactation team became International Board Certified Lactation Consultants during the study period.

Adaptation of study materials and procedures

The study materials were translated and adapted to local conditions. The questionnaires reflected exact translations of the master English version, with a few site-specific variables (e.g., indicators of socioeconomic status and site-specific complementary foods) added as required in the master Manual of Operations [8].

Child rearing practices and encouragement by training could influence the acquisition of motor development milestones [9]. As a general practice, Norwegian parents are advised by the child health clinics not to push the baby to sit in an upright position, but to wait for the child to do this spontaneously. Hands-and-knees crawling is considered an important milestone that children should not skip. If it does not occur within a certain period, parents are advised to actively stimulate its development [10]. These practices were not contradicted by the study team when implementing the motor development study protocol [11].

Public relations activities

Achieving a high rate of participation was considered a challenge, because this community generally does not accept efforts of this type easily. Thus the assistance of the National Nutrition Council in the development and implementation of a public relations plan was particularly valuable.

Health personnel working in antenatal care were requested to display posters specially made for the study and to distribute informational leaflets to pregnant women to prepare them for a possible screening interview. All child health clinics were also sent posters introducing the study to the public.

A launching ceremony was organized with the Director-General of WHO, Dr. Gro Harlem Brundtland, as the main speaker. The event was given extensive media coverage. A proactive press strategy resulted in the publication of several articles in the main newspapers during the data collection period.

The children participating in the longitudinal study received small gifts at enrollment and on their first two birthdays, and those who completed the study were entered in a drawing in which the five winners would each receive US\$280. Every year a picnic for all participants was arranged in Oslo's main park to express the gratitude of the MGRS team and provide motivation for continued participation. Newsletters relating the progress of the study were also distributed to participants. The main factors motivating the parents to participate were probably the study team's professionalism and the global importance of the study. Both of these aspects were incorporated into all public relations activities.

Implementation of the longitudinal study

Sampling strategy

The screened population was selected to represent all children born in Oslo from May 1999 to May 2000. The recruitment rate at each hospital was related to the percentage of births each hospital was expected to contribute to the city's annual deliveries. An even seasonal distribution was achieved in all hospitals by frequent, regular visits to each by the study team.

Although most selection criteria were common to all sites [8], exclusion on the basis of morbidity was site-specific (table 1). In Norway the pediatric practice is not to measure the length of breech-delivered infants, because of concerns related to the risk of hip dislocation. Therefore, breech-delivered newborns were excluded at screening. Since there is no evidence for constrained growth among economically less privileged groups in Norway, socioeconomic status was not a criterion for eligibility. Regarding intention to breastfeed, no questions were asked regarding the intended duration of breastfeeding, because the rates of initiation are high, the duration is generally six months or longer,

TABLE 1. Exclusion criteria for morbidity at the Norwegian site

Criteria for assessing newborns
Serious birth asphyxia (hypoxic ischemic encephalopathy [HIE] level 2 or 3)
Seizures
Lack of muscle tone indicating possible neurological diseases
Hydrocephalus or cerebral hemorrhage
Serious infections, sepsis, meningitis, or encephalitis
Impaired respiratory function (definition: is in need of mechanical ventilation or increased oxygen requirements for more than 72 hours)
Congenital cardiovascular conditions (not atrial septal defect [ASD] or persistent ductus arteriosus [PDA])
Congenital abnormalities
Symptoms indicating chromosome abnormalities, Down syndrome, Turner syndrome, and others
Signs of having suffered from intrauterine infection
Criteria for assessing children between 18 and 71 months
Malignant disease, past or present
Chronic anemia
Chronic cardiac disease that influences daily activities
Chronic lung disease that influences daily activities
Chronic gastrointestinal, liver, or renal disease
Endocrine disorders
Chronic neurological disease that influences daily activity
Chronic mental disease that influences daily activity
Chronic systemic disease
Malformations that clearly influence daily activities and/or interfere with anthropometric measurements
Other chronic diseases that clearly influence normal daily activities

and the duration is often related to factors other than a mother's motivation to breastfeed.

Screening was carried out only on weekdays. This was not expected to result in a biased sample. Data from the 1997 Medical Birth Registry of Norway showed that 14.6% of children born at Oslo hospitals were delivered by cesarean section; 5.4% were planned cesarean sections, performed on weekdays [6]. Screening on weekdays alone thus implied a slight overrepresentation (by 2.2 percentage points) of elective cesarean section deliveries in the sampling frame. However, any bias introduced by this scheme had little if any relevance to expected child growth, so extending screening to include weekends was not considered further.

Screening and enrollment of children

The longitudinal component required that 300 infants be enrolled [8]. Thus, based on the number of days available for screening in one year, six children were to be enrolled weekly. The available data related to the different exclusion criteria and the anticipated enrollment rate indicated that 43% of those screened would be enrolled successfully. Therefore, to enroll six children per week, 14 screening interviews were needed per week. The sampling fraction recruited from each hospital was determined by dividing the estimated number of children born during a five-day week (see above) by the 14 screening interviews needed. The first child screened was the first born after 8 am on the index recruitment day. Thereafter, sampling was performed by systematic allocation (every fourth birth). If a designated screening interview could not be carried out because of a language barrier or serious illness, the next mother on the chronological list was interviewed as a replacement. A total of about 850 mothers were screened during a 12-month period. Written informed consent was obtained from all mothers participating in the study.

Follow-up logistics

Follow-up was carried out as outlined in the MGRS protocol [8]. The first home visit was scheduled at two weeks postpartum, during which baseline data were collected and eligibility and consent were reassessed. Mothers who indicated that they smoked or were already giving formula to their infants on a regular basis were considered "hidden ineligible" and excluded from further participation, in accordance with the MGRS protocol. Mothers who initially agreed to participate but were no longer interested by day 14 were considered "hidden refusals." Hidden ineligibles and refusals, as well as children who dropped out of the study before the age of 12 months, were contacted a few weeks before the child's first birthday for participation in the 12-month study [8]. The procedure was to call

at least five times at different times of the day over a two-week period. If no contact was achieved by then, the family was defined as "not traceable."

The motor development assessments [11] were initiated in April 2000, about 10 months after screening was initiated, which meant that the initial milestones could not be assessed for some infants.

Lactation support and complementary feeding

A combined screening and lactation team was established. Soon after enrollment, the lactation counselors helped newly delivered mothers in the maternity ward with the initiation of breastfeeding. The same consultant followed the mother–infant pair until the child's first birthday to provide frequent and individual lactation support. The mothers were contacted by telephone and lactation was assessed the day following discharge from the hospital, usually two to four days postpartum. Close follow-up of breastfeeding problems was offered from their onset. In addition to four scheduled home visits at weeks 1 and 2 and months 3 and 6, lactation counselors kept in contact with mothers by telephone at least once per month. Mothers having breastfeeding problems received extra support until the problems were resolved. A hotline for emergency support was available seven days a week from 8 am to 8 pm.

The mothers were advised to introduce complementary foods to their infants by six months. The infant nutrition guidelines developed by the Norwegian National Nutrition Council [12] were followed (table 2). The council's feeding guidelines are based on Norway's dietary patterns, which include cereals and potatoes as important staples. Cod liver oil is recommended from the age of four weeks as a vitamin D and essential polyunsaturated fatty acid supplement. In addition to the prevention of vitamin D deficiency, sufficient iron intake is a concern. Iron-fortified porridge is recommended most commonly to ensure that the infant's iron needs are met. Water rather than sweetened beverages is recommended, since consumption of the latter tends to replace more nutrient-dense diets.

Implementation of the cross-sectional study

Sampling strategy

The number of children aged 18 to 71 months living in Oslo during the implementation of the cross-sectional component of the study was estimated to be 28,000 [1]. From this population, 1,260 children were to be selected for the cross-sectional study. The sampling was done in cooperation with Statistics Norway [13]. All persons living on a permanent basis in Norway are registered in the National Registry. Information

TABLE 2. Complementary feeding guidelines at the Norwegian site

<p>From the age of four weeks, 10 µg of vitamin D is recommended, preferably through cod liver oil</p> <p>If the baby needs a supplement to breastmilk, iron-fortified infant formula is recommended for the first 12 months</p> <p>Complementary foods should be gradually introduced from the age of four to six months, while the baby is still breastfed, giving small amounts of only one type of food for some days so that possible reactions can be detected. This recommendation was revised in 2002, and exclusive breastfeeding for the first six months of life is now recommended</p> <p>Introduction of complementary foods may start with pureed potatoes, vegetables, fruits, and/or porridge</p> <p>After the introductory phase, pureed fish and meat, together with the staple potato and vegetables (dinner) should be introduced</p> <p>Do not add salt to baby food</p> <p>Iron-fortified baby cereals are a good source of iron. Two meals per day will ensure an adequate intake. If the child receives other good sources of iron such as dinner with meat, one may also use home-prepared porridges based on oatmeal, for example</p> <p>If the child has a history of food allergy, eggs, fish, and peas should not be introduced until the child is one year old</p> <p>Offer the child water instead of squash</p> <p>From the age of one year, children should receive the family food without too much salt</p>
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on each registrant includes an identity number and the name and address of the mother and father. The registry is updated every third week. By combining files from the National Registry and the Medical Birth Registry, it was possible to select only children both born and living in Oslo, to eliminate twins, and to select only one child per family. Based on population characteristics and experience from the longitudinal study, a participation rate of 31% was anticipated. According to the experience of Statistics Norway, it was necessary to increase the sample size by about 20% to allow for factors such as families not responding to telephone solicitations. A total of 5,185 children were sampled for the screening interview.

The sample to be screened was selected by a systematic interval sampling scheme. All children in the targeted age groups were sorted according to age and their home's postal code. A random entry point of sampling was selected, and then sampling was carried out at a fixed interval. This method results in a randomly selected, representative sample of designated age cohorts and provides a representative geographic distribution.

The sampling was divided into four periods to enable better focus on specified age groups. This method provided the most up-to-date lists possible and included fewer families who had left Oslo.

Screening, enrollment, and survey logistics

A letter explaining the goals and procedures of the study was sent to mothers of potentially eligible children one to two weeks before a projected screening interview. These letters were followed by telephone calls. Mothers were called at least five times at different times of the day over a two-week period. If no contact was achieved after the fifth attempt, the family was defined as "not traceable." Appointments for the cross-sectional survey interview and measurements were made with subjects who were eligible and willing to participate. Most visits occurred in the evenings in the subjects' homes to accommodate parents working outside the home.

Standardization, quality control, and data management activities

All quality control procedures outlined in the MGRS protocol were implemented [8]. Every questionnaire was checked, and irregularities were resolved in consultation with the appropriate interviewer. Ten percent of mothers (randomly selected) were called by telephone to review previous responses to interview questions, validate that visits were done, and assess the content of the visits.

Data management procedures were implemented by using the MGRS data management system, and the data management procedures of the study, described elsewhere in this supplement [14], were adhered to. The interviewers were given an overview of the data management system and brief hands-on experience with data entry. This provided a more complete understanding of the data management procedures

and emphasized the importance of completing questionnaires accurately.

Conclusions

The MGRS was a demanding study, and several major challenges had to be overcome to bring it to a successful completion in Norway. Chief among these in the longitudinal component of the study was the need to maintain a high level of momentum for continued participation in 21 follow-up visits over a two-year period. Because both parents of most young families work outside the home, maintaining commitment over a two-year period was a major achievement for the families and the study team. The behavioral and technical skills of the follow-up team were crucial to achieving high rates of continued participation, and more than 85% of the enrolled sample completed the 21 visits. The main reason for dropping out was the family's leaving Oslo.

The bimonthly (every two months) anthropometric standardization sessions were also a very demanding aspect of the longitudinal component of the study. Nonetheless, their necessity was also evident [7]. The difficulties presented by these sessions are clear from the fact that a 40% overrecruitment rate was necessary to ensure that a sufficient number of parents and children participated in any single session. Most children appeared to find the sessions stressful.

Despite these and other challenges, parents and staff sustained their participation because of the important role that growth standards play in developing and developed countries. Most participants viewed their participation as meeting a larger public service responsibility to Norway's and the world's children.

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