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Implementation of the INTERGROWTH-21st Project in Kenya

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The African site in the INTERGROWTH-21st Project was Parklands, a wealthy suburb of Nairobi, Kenya, with a largely middle-to-high socio-economic status population. There are three hospitals with obstetric units in Parklands, with approximately 4300 births per year. The Newborn Cross-Sectional Study (NCSS) sample was drawn from all three hospitals, covering 100% of births in this target population. The Fetal Growth Longitudinal Study (FGLS) sample was recruited from antenatal clinics serving these hospitals, using the eligibility criteria in the INTERGROWTH-21st protocol. Special activities to raise awareness of the study included securing media coverage and distributing leaflets in antenatal clinic waiting rooms. FGLS required women to be recruited in the first trimester; therefore, a major challenge at this study site was the high background frequency of first antenatal consultations in the second trimester. The problem was overcome by the study awareness campaign, as a result of which more women started attending antenatal care earlier in pregnancy.

Keywords Fetal growth, INTERGROWTH-21st, nutrition, standards.

Introduction

The International Fetal and Newborn Growth Consortium for the 21st Century (INTERGROWTH-21st) is a large-scale, population-based, multicentre project involving health institutions from eight geographically diverse countries, which aims to assess fetal, newborn and preterm growth under optimal conditions, in a manner similar to that adopted by the World Health Organization (WHO) Multicentre Growth Reference Study (MGRS).[1] The INTERGROWTH-21st Project has three major components, which were designed to create: (1) longitudinally derived, prescriptive, international, fetal growth standards using both clinical and ultrasound measures; (2) preterm, postnatal growth standards for those infants born at $\geq 26^{+0}$ but $< 37^{+0}$ weeks of gestation in the longitudinal cohort, and (3) birthweight-for-gestational-age standards derived from all newborns delivering at the study sites over an approximately 12 month period.[2]

The African site for the INTERGROWTH-21st Project was the Parklands suburb of Nairobi, Kenya (Figure 1). Kenya is located in the heart of East Africa, bordered by Tanzania, Uganda, Sudan, Ethiopia and Somalia. The country is bisected by the equator and is characterised by diverse topography; it has a population of 38.6 million based on a 2009 census.[3]

The Kenya Demographic and Health Survey is a nationally representative sample survey of women in the reproductive age group.[4] In 2008, it estimated that the total fertility rate for the country as a whole was 4.6, with a marked difference between urban (2.9) and rural (5.2) areas. The infant and under-five mortality rates are 52 and 74 per 1000 live births respectively.

Maternal health in the country is compromised by the burden of nutritional deficiency, malaria, HIV and limited access to maternity services, with only 44% of births occurring in the presence of skilled attendants. As a result, the
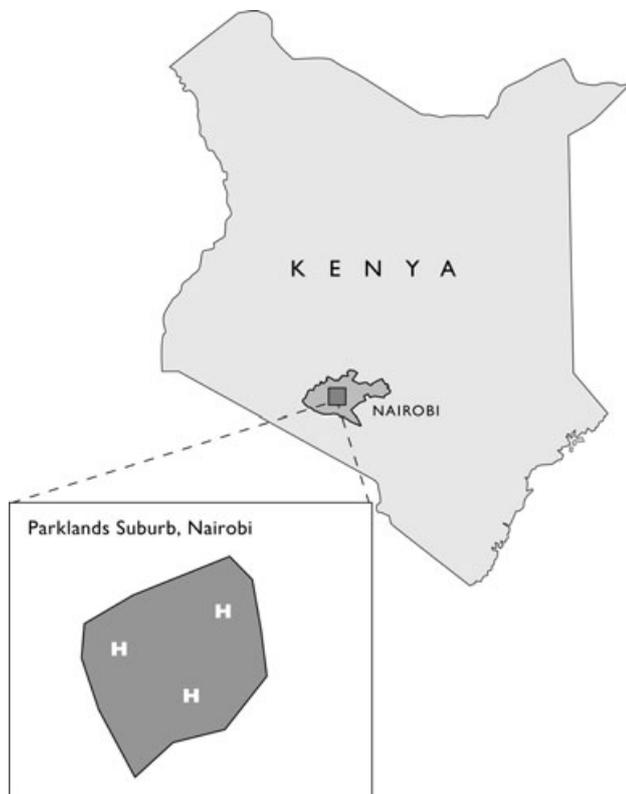
Figure 1. Location of Parklands suburb, Nairobi, Kenya, H: hospital participating in the INTERGROWTH-21st Project.

Table 1. Delivery information for Parklands' hospitals

Name of hospital	Approximate number of deliveries annually	Percentage of Parklands deliveries
Aga Khan University Hospital	2900	68
M.P. Shah Hospital	600	14
Avenue Hospital	780	18
Total	4280	100

Preparatory activities

Selection of health institutions

There are three hospitals in the Parklands suburb with obstetric units (delivery data are provided in Table 1). All three hospitals were selected to participate in the project: the Aga Khan University (AKUH), Social Service League MP Shah (MPSH) and Avenue (AH) Hospitals. All are private, not-for-profit institutions accessed predominantly by the middle and high socio-economic sectors. The local coordinating team was based at AKUH, where the study ultrasound machine and FGLS follow-up teams were also located. AKUH is a premier teaching and referral centre in East Africa and has residency programmes in all the main medical specialties. The majority of women recruited into FGLS attended the antenatal clinics serving AKUH. MPSH and AH primarily participated in the Newborn Cross-Sectional Study (NCSS), although they also provided a larger recruitment pool for FGLS. Together, these hospitals cover 100% of deliveries in Parklands. A summary of the population-based sampling strategy is shown in Figure 2.

An initial overview of the health status of pregnant women attending these hospitals was obtained from routinely collected data to confirm their low-risk characteristics, as required by the study protocol.[6] Selected indicators were the percentage of women with anaemia (haemoglobin <10 g/dl) at antenatal booking, the low-birthweight rate, and mean birthweight (Table 2).

Ethical approval was obtained from the nationally recognised Aga Khan University Research Ethics Committee in March 2009.

Recruitment and training of study personnel

The site research team was led by the local Principal and Co-investigators, based at AKUH. A project coordinator supervised a research midwife as well as a team of anthropometrists. Ultrasound scans were performed by three ultrasonographers: the leader attended the centralised workshop in Oxford in 2009 and trained her two colleagues

maternal mortality ratio remains high at 488 per 100 000 live births (95% confidence interval 333–643). The nutritional status of women varies considerably across the country: the prevalence of low (<18.5) body mass index ranges from 26% in the North Eastern Province to 3% in Nairobi. Conversely, obesity is starting to be a health problem in urban areas, especially in Nairobi where 11.2% of women have a body mass index ≥30.[4] HIV infection also remains a significant problem: Western Kenya is a major focus of the epidemic as are urban centres, e.g. Nairobi with a female prevalence of 10%.[5]

In the light of such adverse population and reproductive health indicators, identifying a suitable population for the Fetal Growth Longitudinal Study (FGLS) presented considerable challenges. The study inclusion criteria required participants to be drawn from a population at 'low risk of health, environmental or socio-economic constraints on fetal and newborn growth'.[6] In this context, the key considerations were low risks of malaria, malnutrition and maternal HIV infection. To meet these requirements, Parklands, a wealthy suburb of Nairobi (a non-malaria endemic area), mostly home to affluent Kenyan families, was selected to provide the study population.
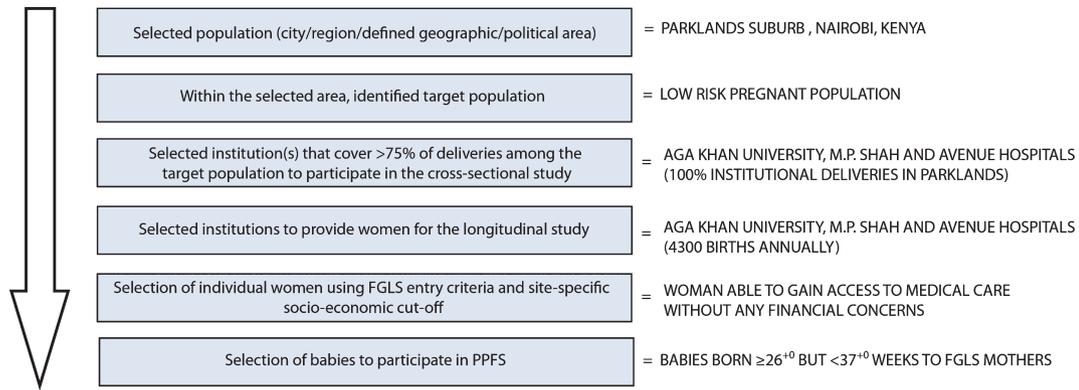
Figure 2. Summary of population-based sampling strategy in Parklands suburb, Nairobi, Kenya.

upon her return. Visiting members of the INTER-GROWTH-21st Ultrasound Unit carried out re-standardisation procedures in April 2010. A data manager was trained to enter data online at the data management workshop in Oxford, and was responsible for all case record form handling and electronic transfer of ultrasound data during the project. The nursing, midwifery and medical staff of the departments of Obstetrics & Gynaecology, Paediatrics and Radiology helped to recruit participants and troubleshoot clinical problems arising during the project.

Public relations

The INTERGROWTH-21st Principal Investigator and members of the Project Coordinating Unit visited AKUH before the studies commenced to brief the local team and stress the international significance of the research project. To raise awareness among doctors, midwives, pregnant women and the wider community, fliers, patient leaflets and posters were prepared and placed in all waiting areas and reception halls in the hospitals, and given to private doctors' offices. The need to generate high-quality information and communication lines arose because the participating women were under the care of various healthcare providers: private practitioners

Table 2. INTERGROWTH-21st protocol requirements

Indicator of population at low risk of fetal growth impairment	Value	Protocol requirement met
Low birthweight rate (%)	11	Yes
Perinatal mortality rate (per 1000 live births)	16.9	Yes
Mean birthweight (g)	3101	Yes
Maternal anaemia (haemoglobin <10 g/dl) at booking (%)	2	Yes
Altitude (m above sea level)	1680	Yes

(AKUH and MPSH), University faculty (AKUH) or hospital staff (MPSH and AH). Given the need to recruit women into FGLS in the first trimester, women in the population were encouraged to book their first antenatal clinic early in pregnancy so as to be eligible potentially for enrolment. Local journalists were briefed about the project and two features appeared in the local daily press.

FGLS implementation

Enrolment logistics

Routine maternity care for low-risk women in Parklands typically includes a schedule of visits at defined intervals with consultations and deliveries conducted by midwives, University or hospital medical staff, or private practitioners.

A pilot phase to test FGLS procedures was undertaken from February to May 2009, during which women attending the AKUH antenatal clinic were screened using the study's inclusion criteria. Potential participants identified at this stage were offered a dating scan to confirm their eligibility. The pilot phase clearly identified the need for the study awareness campaign because most women's first antenatal consultation occurred in the second trimester.

Recruitment for FGLS commenced in August 2009 (Figure 3). Women attending the antenatal clinics serving the three hospitals, who met the inclusion criteria, were invited to participate either by their private practitioner or hospital midwife, using the printed materials provided by the project team. The screening criteria identified all potentially eligible women at low risk for factors known to affect fetal growth, including socio-economic constraints. We used country-specific, socio-economic criteria and cut-off points to identify women at low risk of fetal growth restriction due to socio-economic constraints; women not meeting these criteria were considered not to be eligible for FGLS. In Nairobi, an ability to pay for medical care without financial barriers was chosen as a proxy for middle-to-high socio-economic status.
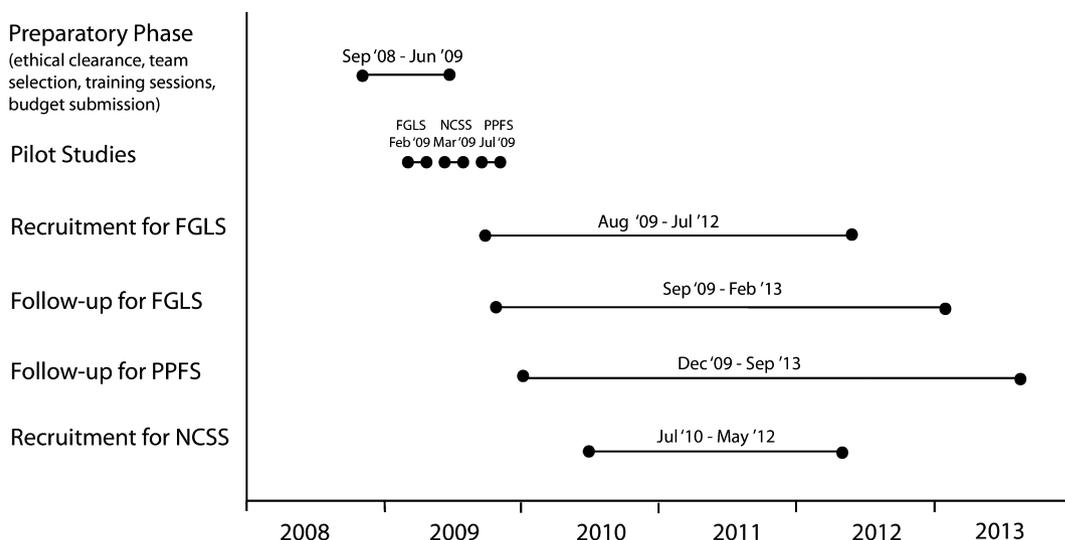
Figure 3. Project timeline in Kenya.

Those women who were potentially eligible at screening were invited for a dating ultrasound scan between 9^{+0} and 13^{+6} weeks of gestation (based on their menstrual dates). Gestational age was confirmed by measuring the crown–rump length using a Philips HD9 or IU22 (Philips Ultrasound, Bothell, WA, USA) or General Electric Logiq 9 (General Electric, New York, NY, USA). All subsequent fetal measurements were obtained using the Philips HD9 machine based on the INTERGROWTH-21st protocol.[7]

Potential participants who met all the inclusion criteria were asked to give written informed consent for enrolment. The interval between providing the initial information about the study at screening and confirming eligibility after the dating scan proved useful in giving women time to consult with partners and family members before giving informed consent. Some women attended their first antenatal visit as early as 6 weeks of gestation; however, maintaining their interest in the study until formal enrolment after the dating scan some weeks later was a challenge. Reflecting the make-up of the clientele of the hospitals, information materials and consent forms were provided in English, supported by verbal explanation in Kiswahili as required.

Follow-up logistics

Participants were provided with a follow-up appointment card at enrolment. Reminders of forthcoming appointments were given by telephone 2–3 days beforehand. At the AKUH clinic, follow-up appointments are also linked to an automated SMS reminder the day before the visit. Some difficulties were experienced linking clinic and scan appointments especially if they had to be changed at short notice, as most women were employed and they reported that it was hard to leave their workplace twice in the space of a few days.

Preterm follow-up logistics

All preterm babies ($\geq 26^{+0}$ but $<37^{+0}$ weeks) born to mothers in the FGLS cohort were enrolled into the Preterm Postnatal Follow-up Study (PPFS) according to the INTERGROWTH-21st protocol. This involved repeat visits to the hospital every 2 weeks for the first 8 weeks, and at intervals until the age of 2 years. This required a high level of commitment from the parents and was difficult to sustain in some cases, especially for late preterm babies with no medical problems. In these instances, home visits were carried out, but only if absolutely necessary.

NCSS implementation

After briefing the hospital staff, University faculty and private practitioners, all women delivering at the three hospitals were invited to participate in NCSS, for a 12-month period from July 2010 or until the target sample size of 7000 was reached (Figure 3).

Training and preparatory activities

In June–July 2009, the Kenya site hosted a training workshop in Nairobi for all the lead anthropometrists from the participating countries, which was led by international experts from the INTERGROWTH-21st Anthropometry Group. The workshop methodology is detailed elsewhere in this supplement.[8] Subsequent training and standardisation of methods for the Kenyan anthropometry team took place in April and July 2010, overseen by an expert from the Anthropometry Group. The local lead anthropometrist held training sessions for each hospital's anthropometrists in July and September 2010, following which the anthropometrists were given a training video. They also received feed-

back from both the local lead anthropometrist and experts from the Anthropometry Group.

Data collection

The anthropometry teams arranged rotas covering all hospitals to allow for data collection within 12 hours of birth. The teams introduced themselves to the parents on the postnatal wards. Written consent was obtained after providing information and a briefing about the aims of the study, which was considered desirable as many mothers had not previously heard about the study despite the best efforts of the local coordinating team. Data were collected from hospital records, supplemented by interviews with mothers where necessary.

It was difficult to obtain complete data on some NCSS participants: often missing were the first-trimester maternal weight and ultrasound details for women who had not received antenatal care within the hospitals. For women who had not booked with the hospital of delivery, limited information was obtainable from the records. Some women had to be visited more than once before data collection was complete because of clinical circumstances: for example, after a caesarean section or an adverse outcome such as a stillbirth. The results of investigations sometimes had to be requested from private practitioners who kept the patient records in their offices.

Conclusions and lessons learned

The INTERGROWTH-21st Project has been implemented at the Kenya site through the involvement and participation of the local medical fraternity, nurses and midwives, and most importantly the interest and commitment of the women and their families. Strengthening the involvement of partners and other family members in matters relating to pregnancy, birth and newborn care has been a benefit to the wider community and is consistent with international policies and strategies to overcome barriers related to gender and the prioritisation of the wellbeing of mothers and children.

Clinical care in the participating hospitals has been strengthened through involvement in the studies. The amount and content of information about pregnancy, childbirth and parenting that is shared with women during clinical encounters has steadily increased, leading to better informed mothers and families. The profile of new antenatal attendees has changed: more women are attending earlier in pregnancy, and benefiting more thereby from antenatal services. The INTERGROWTH-21st Neonatal Care Manual has also been made available in the neonatal unit for use by doctors not involved in the project.[9] This has helped to standardise care in the unit, even among the nursing staff.

In the wider community, there has traditionally been limited awareness of research and a perception that research is not relevant to individual wellbeing, as evidenced in the past by instances of withdrawal of consent late in pregnancy and lower than expected recruitment of eligible participants. In the institutional context of a new, research-oriented university the project has supported the model of clinical excellence in maternity care provided by staff linked with academic programmes.

Although challenges remain, such as the complex and diverse pattern of health service delivery in the country and region as a whole, the above factors and specific awareness-raising efforts have led to a steady increase in the readiness of women to participate in the study and maintain interest once enrolled.

Disclosure of interests

None.

Contribution to authorship

MC, WS, HEK and LCI wrote the manuscript and all authors read and approved the final version.

Details of ethics approval

The INTERGROWTH-21st Project was approved by Oxfordshire Research Ethics Committee 'C' (reference: 08/H0606/139), and the research ethics committees of the individual participating institutions and corresponding health authorities where the Project was implemented.

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