Implementation of the INTERGROWTH-21st Project in Oman

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The Middle Eastern site in the INTERGROWTH-21st Project was Muscat, the capital city of the Sultanate of Oman, which lies on the southeast coast of the Arabian Peninsula. It borders the United Arab Emirates to the northwest, Saudi Arabia to the west and Yemen to the southwest.

For the provision of health care, Oman is divided into 11 regions (Figure 1). One of these, Muscat, the capital city, was selected to participate in the INTERGROWTH-21st Project, as a continuation of its role in MGRS. The city lies at sea level and has over 600 000 inhabitants. In 2003, 60% of the city’s population were Arabic-speaking Omanis, with the remainder being expatriates, most of whom were migrant workers from Bangladesh, Egypt, India, Jordan, Pakistan and the Philippines.

Muscat was chosen as the Middle East site for several reasons. First, the city is relatively affluent with a gross domestic product (GDP) of US$20,999 per capita (2006 data), a free healthcare system, and mean life expectancy of 75.3 years, thereby making it suitable for a prescriptive study of this nature. Second, early antenatal booking is the norm and the vast majority of the city’s births take place in hospital. Third, the capital attracts the country’s experts

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in antenatal and neonatal care. Finally, the Ministry of Health in Oman provided support and advocacy for the project. The research team at the Department of Family & Community Health has considerable experience in implementing large longitudinal studies and could therefore be relied upon to execute the protocol effectively.1

Preparatory activities

Hospital selection

There are three major maternity units in Muscat, each with a clearly defined catchment area. There are approximately 10 500 births per year in Muscat; of these, 55% take place in the Royal Hospital (RH), 41% in Khoula Hospital (KH), and just 2% in Quiryat Hospital.4 As RH and KH account for 96% of the births in Muscat, they were selected for the Newborn Cross-Sectional Study (NCSS), making the sample truly population-based (Figure 2). RH is more specialised, serving as a maternity unit for the Muscat region and as the main tertiary referral centre for the rest of the country; deliveries at RH are therefore typically medium to high risk. On the other hand, KH predominantly serves mothers who are at low risk of fetal growth impairment (Table 1) and it was therefore chosen as the main recruitment site for the Fetal Growth Longitudinal Study (FGLS).

Recruitment and training of personnel

Two national supervisors were recruited as research coordinators for the project, under the supervision of the local Principal Investigator (Figure 3). A data manager and two lead ultrasonographers were trained in Oxford at the centralised training sessions in April 2009.6,7 The lead anthropometrist completed the standardisation programme session in Nairobi, Kenya, as described elsewhere in this supplement.8 Each team leader then conducted similar training sessions with their respective local teams in Oman.

Organisational and advocacy activities

The Oman Research and Clinical Studies Committee approved the study in April 2009. The INTERGROWTH-21st protocol was translated into Arabic, but there was no need to translate the forms as the key members of the research team all spoke English fluently. Ministry of Health officials, including the Minister, were introduced to the project when the INTERGROWTH-21st Project Leader first visited Oman. Orientation activities at KH and Wattyah Polyclinic (an antenatal clinic serving KH) took place, and media coverage was also secured (Appendix S1).

Figure 1. Location of Muscat, Oman. H: hospital participating in the INTERGROWTH-21st Project; h: hospital not participating in the INTERGROWTH-21st Project.

Figure 2. Summary of population-based sampling strategy in Muscat, Oman.
Criteria used in MGRS.1 A country-specific indicator for low socio-economic status was developed, including socio-economic constraints. The women at low risk for factors known to affect fetal growth were selected from the general population served by these four healthcare facilities, 11 of which serve KH. Screening for FGLS took place at four such facilities, which were selected on the basis of: (1) the high socio-economic status of the population they served; (2) their high rates of early antenatal care booking (60–73%), and (3) their proximity to the Wattyah Polyclinic.

Women who met the study’s inclusion criteria were selected from the general population served by these four primary healthcare facilities. The screening criteria identified women at low risk for factors known to affect fetal growth and development, including socio-economic constraints. The country-specific indicator for low socio-economic status was <4 years of female education, which was adapted from the criteria used in MGRS.1

During the pilot phase, 42 women were screened in one week at Wattyah Polyclinic, of whom ten were found to be eligible, i.e. a potential recruitment rate of 24%. Major reasons for exclusion were maternal age, BMI and gestational age >14 weeks of gestation.

To encourage early booking for antenatal care, a number of advocacy campaigns were carried out with the help of health educators and community support groups. A variety of activities took place in health facilities and the community, including the production and distribution of health education leaflets in Arabic.

Recruitment for FGLS began in August 2009 (Figure 4). However, achieving the recruitment target of 25 women per month was a considerable challenge initially, partly because of the H1N1 influenza epidemic, which made mothers reluctant to come to the primary healthcare facilities. Once the epidemic was over and the population became familiar with the study (through an active media campaign), the recruitment rate increased considerably.

<table>
<thead>
<tr>
<th>Table 1. 2008 Muscat data</th>
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<tr>
<td>Indicator of population at low risk of fetal growth impairment</td>
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<tr>
<td>Low birthweight rate (%)</td>
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<tr>
<td>Perinatal mortality rate (per 1000 live births)</td>
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<tr>
<td>Mean birthweight (g)</td>
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<tr>
<td>Maternal secondary education (%)</td>
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<td>Altitude (m above sea level)</td>
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Follow-up logistics

Once an eligible woman was identified, gestational age was confirmed by measuring crown–rump length with a Philips HD-3 ultrasound machine (Philips Ultrasound, Bothell, WA, USA), according to the INTERGROWTH-21st protocol.9,10 Once a woman’s eligibility was confirmed, the research nurse explained the study to her in more detail and took written consent. Mothers were given information leaflets in Arabic that contained the answers to frequently asked questions and the contact details of the study teams.

Every 5 ± 1 weeks until delivery, fetal growth scans were performed at the Wattyah Polyclinic by the study’s trained ultrasonographer, using the Philips HD9 ultrasound machine, according to the INTERGROWTH-21st protocol.9 The same commercially available machine was used by ultrasonographers at all the INTERGROWTH-21st participating centres to ensure reliable measurements, facilitate technical support and data transfer, and ensure that a balance was struck between various criteria, e.g. cost, imaging quality, functionality.

Wherever possible, the research team recorded more than one contact number so that women could be contacted immediately if they failed to attend an appointment. Women were also given the flexibility of rescheduling appointments if necessary, as long as the new appointment was within the timeframe specified by the protocol.

Participants in FGLS were provided with a slightly different antenatal care package to that usually given to low-risk women attending primary healthcare facilities. This included each woman having a dedicated doctor so as to establish good relationships with the research team. Family members were made welcome at the scan visits, and women were given priority to shorten waiting times. Appointment slots at the clinic were reserved in blocks for women in FGLS and four rooms were allocated solely for study use. The research coordinator reviewed the appointment lists daily and made telephone calls to mothers a day before each appointment.

The research coordinator was also given a mobile telephone to which mothers could be contacted immediately if they failed to attend an appointment. The research coordinator then sent a text to the lead anthropometrist to ensure that measurements of the newborn were obtained within 12 hours of birth. All of these strategies served to ensure the smooth running of FGLS and to minimise loss to follow-up, even during the summer months when it is typical for many Omani women to travel to cooler climates.

Preterm follow-up logistics

The Preterm Postnatal Follow-up Study (PPFS) coordinator at KH was immediately alerted if a mother in FGLS delivered < 26 weeks or > 37 weeks of gestation. The coordinator

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arranged follow-up visits with the parents, according to the schedule in the study protocol. The phone numbers of both parents were recorded in case of missed appointments. An identification sticker with the study details and contact information for the research coordinator was also kept in the infant’s health record in case the infant was admitted or referred to another health facility.

Data entry and quality control
All completed forms were forwarded to the local study coordinating centre within 24 hours of being collected. All forms were then checked for missing or inaccurate values and queries were pursued with the field teams as necessary. Data were entered into the online database on a daily basis under the supervision of the data manager.
NCSS implementation

Preparatory activities
After the Directors General in charge of both hospitals participating in NCSS gave their formal approval, members of the central research team met with key people in the hospitals including the Heads of neonatology, obstetrics and gynecology, and nursing and midwifery to describe the study in detail. Any logistical problems were resolved with the local research team, with the support of the INTERGROWTH-21st Project Coordinating Unit.

The official policy of the Ministry of Health is to obtain weight, length and head circumference measurements for all newborns at birth; therefore, the majority of anthropometrists were already familiar with the measurement procedures. Most were recruited from the labour ward staff and trained to use the study equipment and follow the INTERGROWTH-21st anthropometry protocol.11

Data collection logistics
Data collection for NCSS began in March 2010 (Figure 4). As a result of the large number of deliveries in both hospitals (approximately 18 per day) and the fact that the average postnatal stay in hospital in Muscat is 24 hours, it was important to keep a constantly updated birth register to ensure that no baby was missed. To obtain the anthropometric measurements within 12 hours of birth, a rota system was adapted to ensure that at least two anthropometrists were available for the twice-daily measurement shifts. The consultant neonatologists assessed morbidity in particularly sick or preterm newborns to decide on their suitability for measurement.

Data entry and quality control activities
Anthropometric standardisation sessions were conducted at each hospital every 3 months to ensure that the measurement protocol was followed. Expert members of the INTERGROWTH-21st Anthropometry Group attended the first two sessions. Retrospective quality control was performed on a 10% sample of all NCSS data collection forms, as detailed elsewhere in this supplement.6 In addition, all forms were visually checked for missing and inconsistent values on a daily basis by the research coordinators at each hospital. The forms were also validated centrally and queries were raised with the data collection teams if necessary. Data were uploaded to the online database on a daily basis.

Lessons learned and conclusions
The implementation of the INTERGROWTH-21st Project in Oman was a challenging task. Several difficulties had to be overcome: recruitment of sufficient numbers of women at an early gestational age; timely measurement of newborns and completion of forms; handling of a large volume of data, and maintaining the motivation of staff throughout the long duration of the project. Moreover, the initiation of FGLS coincided with the H1N1 influenza epidemic, which made release of staff for full-time research more difficult. Careful planning and close monitoring of study progress, therefore, were crucial aspects in the successful implementation of the project. Many individuals and institutions collaborated effectively over a period of several years to ensure that recruitment targets were consistently met and that high standards of data quality were maintained.

Disclosure of interests
None.

Contribution to authorship
YAJ, 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 the 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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Acknowledgements
A full list of Members of the International Fetal and Newborn Growth Consortium for the 21st Century (INTERGROWTH-21st) and its Committees appears in the preliminary pages of this supplement.

Supporting Information
Additional Supporting Information may be found in the online version of this article:
Appendix S1. Media coverage.

References