'Birth to Ten' — pilot studies to test the feasibility of a birth cohort study investigating the effects of urbanisation in South Africa

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Summary

'Birth to Ten' is a birth cohort study currently being conducted in the Johannesburg-Soweto area. This paper describes the various pilot studies that were undertaken to investigate the feasibility of a cohort study in an urban area. These studies were designed to determine the monthly birth rate, the timing, frequency and duration of maternal antenatal visits, the timing and frequency of visits to well-baby clinics and the accuracy and reliability of routinely collected growth data. In addition, a birth data collection form was tested to ascertain the appropriateness of its use in clinics within the study area.

S Afr Med J 1991; **79**: 449-454.

'Birth to Ten' (BT10) is a longitudinal birth cohort study being conducted in the metropolitan area of Johannesburg and Soweto, South Africa.[1] The study arose from concern over the rate of urbanisation in South Africa[2] and its implications for the health and well-being of urban children.[3] The overall aim is to determine the biological, environmental, economic and psychological factors that are associated with the survival, health, well-being, growth and development of children living in an urban environment.

While cross-sectional analytical studies are often useful to identify problems, larger follow-up studies (such as birth cohort studies) are critical when attempting to quantify and identify the impact of several factors on health. For that reason, a birth cohort study was planned for South Africa. A number of birth cohort studies have been carried out in developed countries[4-7] but conditions in South Africa differ from these countries in a number of important respects.

The policy of apartheid has created a fragmented health, education and housing structure to the detriment of the majority of the black population. Thus health, education and housing profiles differ significantly between different 'population groups' in South Africa. Fifty-six per cent of the South African population is urbanised, compared with more than 76% in developed countries. As the white population in South Africa is already predominantly urbanised, increased urbanisation in South Africa is restricted to the black population and, at a rate of 3,5%, will lead to an increase in black urban dwellers from 6,5 million in 1985 to over 20 million by the year 2000.[2] Thus sociopolitically and demographically South Africa presents a situation similar to countries in Latin-America. This *status quo* is, however, in a state of change brought about by major political changes in 1989 and 1990. The emergence of a post-apartheid, non-racial, democratic 'new South Africa' within the next 10 years is in process and the health services require empirical information on the factors affecting child health to make that transition one which will benefit the previously disadvantaged. The rationale and methods for the BT10 study have been reviewed in detail, highlighting the choice of the Johannesburg-Soweto urban area as a suitable venue for a birth cohort study.[8]

The Johannesburg-Soweto urban area is serviced by a number of health authorities. Curative, antenatal and delivery services are provided by the provincial health authority and the private sector. Preventive child health services, consisting mainly of growth monitoring and immunisation, are provided by local health authorities: Johannesburg City Health servicing Johannesburg, the so-called 'coloured' townships and part of Lenasia; Soweto City Health servicing Soweto, the Diepmeadow health authority servicing Diepkloof and Meadowlands, and peri-urban services servicing that part of Lenasia not serviced by Johannesburg City Health. This fragmentation of health services creates particular logistical challenges for the BT10 study.

The success of a prospective birth cohort study is dependent on an initial sample size large enough, and representative of the population, to (*i*) reflect a sufficient range of exposures, (*ii*) allow for generalisability of findings, and (*iii*) provide sufficient subjects who have stayed in the study throughout the period of investigation, a group known as the core sample.

The collection of the initial sample depends on obtaining consent from prospective mothers prior to delivery and thus on the feasibility of making contact with pregnant women during the antenatal period. In addition, the timing and frequency of antenatal consultations determine the amount of information that may be collected relating to the pregnancy; the earlier the contact the more extensive the information.

It is obvious that in the context of a birth cohort study the initial sample size is dependent on the birth rate and the length of the collection period. The maintenance of a statistically viable core sample is dependent on the predicted attrition rate over time.

Statistical viability relates to the minimum number of subjects that will provide an acceptable statistical error, or standard error, in the outcome variable at the end of the study period. Thus it is intimately related to the expected attrition rate. The acceptable statistical error does not necessarily relate to the measure of central tendency — the mean, median or mode.

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Because in a study of this type one is usually concerned with the limits of normality and thus the identification of the abnormal subject, it is related to the error of the chosen cut-off point. For example, if one wishes to identify children who are nutritionally stunted and thus below the 3rd centile of height for age, then the greater the sample size the smaller the standard error of the 3rd centile. Thus the chance of classifying a normal child as abnormal, or vice versa, is decreased with increasing sample size. Sample sizes greater than 200 per age and sex, however, give increasingly smaller gains in precision and create greater logistical problems. Thus, while the largest possible sample size is required, this need must be balanced against logistical difficulties and likely attrition rate over the course of the study.

In order to determine the feasibility of a longitudinal birth cohort study within the designated study area a number of pilot studies were required to elucidate the following information:

1. The monthly birth rate in the Johannesburg-Soweto metropolitan area.
2. The timing and frequency of antenatal visits by prospective mothers.
3. The frequency and timing of visits to well-baby clinics.
4. The availability of delivery data and the accuracy and reliability of routinely collected growth data.
5. In addition to the above questions it was thought desirable to create and test a form relating to birth data for use in the various delivery centres. This included testing the logistics of data collection and collection of cord blood.

In this paper we report on the methods and results of this series of pilot studies.

TABLE I. SAMPLING FROM THE DIFFERENT CLINICS AND HOSPITALS

Clinic/hospital	Average number of births per month*	Sample from each clinic/hospital
TPA clinics		
Senaone	126	38
Zola	117	35
Chiawelo	101	32
Tladi	97	31
Diepkloof	94	30
Koos Beukes	61	17
Meadowlands	37	29
TPA hospitals		
Baragwanath	1 104	101
Coronation	304	91
Johannesburg	115	34
J. G. Strijdom	70	21
South Rand	40	11
		470†
Private hospitals‡		
Parklane	123	44
Marymount	88	33
Florence	111	41
Sandton	24	10
Morningside	16	5
Lenmed	52	16
		149
	2 680	619

* Data based on births from 1 Aug to 30 Oct 1987.
† Total number included in retrospective study on antenatal clinic attendances.
‡ Only births to mothers resident in Johannesburg/Soweto were included. Sampling was done proportionately by population group.

Methods

Notifications of birth are routinely sent, by the hospital in which the births take place, to the local area health authority where they are used to compile statistics on the number of births within the area. This data source thus represents births that have taken place in hospitals and delivery centres, both provincial and private, in the local authority area, including home births attended by registered midwives. Home births attended by non-registered personnel are not included in this database. About 0,54% of births were thought to have occurred in this latter category in Johannesburg in 1987 - 1988. A comparable figure for Soweto is not available.

This birth register was used to survey the number of births occurring per month within the study period during the course of a single year.

To investigate the maternal use of antenatal health services and attendance at postnatal well-baby clinics all singleton births that took place in June 1987 were selected from the birth registers. From these a random sample, proportional to the number of births from each delivery centre, was selected (Table I). A subgroup of the mothers of these children was retrospectively traced to hospital records to assess the frequency, timing and duration of antenatal care, if any. This subgroup included only those mothers who had delivered in provincial hospitals and clinics. Mothers who had delivered in private hospitals were excluded because such mothers would be required to consult a gynaecologist during the antenatal period. There is little or no access to private care when a mother already in labour presents for the first time. Finally, access to private records is difficult and time-consuming. It was therefore concluded that all private deliveries included antenatal care.

For the purpose of this study antenatal care was not defined on the basis of clinical considerations but on the potential of field workers having access to the pregnant woman and was therefore defined as at least one visit to an antenatal clinic.

In the study area immunisation is conducted at well-baby clinics at which the babies are weighed and vaccinations are given; diphtheria, tetanus, pertussis and polio vaccination at 3, 4½ and 6 months and measles immunisation at 9 months. BCG vaccination is given at birth in the delivery centres. The area covered by the Diepmeadow council was not included in this pilot study. In the follow-up study all births, both provincial and private, were included. The presence of a record of vaccination on the child's clinic record represented a contact between the health service and the child. It also inferred that the child was still present within the study area, thus permitting potential contact with the child and his/her family or caregivers.

The results of this pilot study would also provide valuable information to the local health services. Meetings were therefore arranged with health visitors from the health authorities to present immunisation rates and to introduce the BT10 study to the health authorities.

Records of births at provincial delivery centres were collected to determine the availability of delivery data, growth data from records were also investigated. The accuracy and reliability of routinely collected growth data within the study area is complicated by the fragmentation of the health services and the consequent lack of standardisation of equipment and measurement techniques. The BT10 study would be required to use routinely collected growth data to decrease costs and minimise inconvenience to the mothers involved in the study by allowing them to attend their local clinic. However, the need for standardisation necessitated a study of the current status of measurement equipment and techniques.

Forty-eight clinics were visited, 10 under the control of Soweto City Health, 2 under the control of the Diepmeadow health authority and 36 under the control of Johannesburg City Health. The type and mass range of each scale was noted and measurement techniques were either observed in busy clinics or demonstrated by the sister in charge of each clinic visited outside peak times. During all visits the BT10 study was described to the health personnel.

A delivery data form was created and tested in the delivery centres to determine if the staff employed by the delivery centre could accurately and reliably complete the form. Two delivery centres were chosen for this study — Baragwanath Hospital and a typical satellite clinic. Baragwanath Hospital is the major referral centre for Soweto and is the busiest delivery centre within the study area. Midwife-assisted deliveries take place in the satellite clinic. All women in labour admitted to these centres within the 4-day study period were enrolled. Verbal consent was a prerequisite and, after delivery, data from the bedletters was transcribed onto a computer-compatible data form. In addition, cord blood was collected after each delivery and transported to a laboratory where it would form part of a blood bank. To obtain feedback on the acceptability of the data collection system an evaluation form was completed anonymously by the delivery centre staff.

Prior to the initiation of the delivery data collection study all delivery centre staff were invited to meetings, in their normal working time, during which the aim and logistics of the BT10 study were explained and the pilot study was described in detail. Input from these staff was used to modify the pilot study design. Following the pilot study the results were distributed to participating staff.

Results

Monthly birth rate

An average of 2 680 children were born each month within the study area during the specified period of time. The pilot study sample consisted of 619 singleton births of which 470 occurred in provincial delivery centres and 149 in private centres. The 470 births in provincial centres were used to assess the use of antenatal services (see Table I).

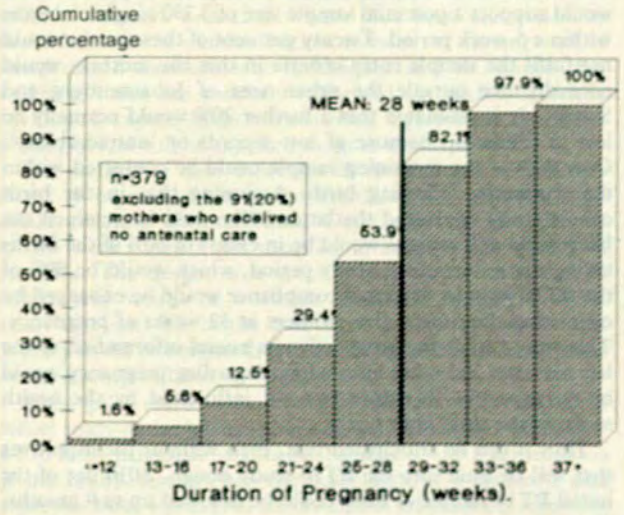

Fig. 1. Duration of pregnancy at first antenatal clinic visit (cumulative %).

Use of antenatal services

Eighty per cent of the 470 mothers received antenatal care. The mean duration of pregnancy for women presenting for antenatal care was 28 weeks. Forty per cent of the women attending ANCs had done so by 30 weeks and 82% by 32 weeks (Fig. 1). The average number of ANC visits was five and 89% of women were seen at least twice prior to delivery.

Visits to well-baby clinics

The data collected from immunisation record cards are presented in Fig. 2. Follow-up of the 19,2% that could not be traced revealed that 67% of these babies could be traced by active follow-up and home visits. Records of clinic attendance were therefore available for 394 of the 619 original subjects. Of these, 350 children (88,8%) presented for all three of the diphtheria, pertussis, tetanus and polio vaccinations, i.e. they visited the well-baby clinics until the age of 6 months (Table II). Three hundred and twenty-seven (83%) received a measles vaccination and thus visited the clinics at 9 months of age. It is assumed that for the purpose of follow-up all the vaccinations occurred on time.

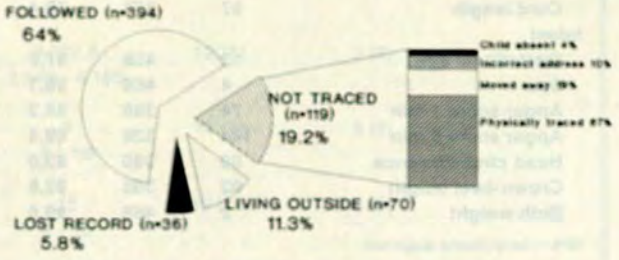

Fig. 2. Follow-up of children using routinely collected health service data.

TABLE II. IMMUNISATION STATUS OF CHILDREN TRACED IN WELL-BABY CLINICS (*N* = 394)

Immunisation		No.	%
DWT	**Nil**	9	2,3
	One	18	4,6
	Two	18	4,6
	Three	349	88,6
Polio	**Nil**	9	2,3
	One	18	4,6
	Two	17	4,3
	Three	350	88,8
BCG	**Nil**	8	2,3
	One	386	97,7
Measles	**Nil**	67	17,0
	One	327	83,0
Fully immunised*		327	83,0

* Fully immunised defined as 3 DWT, 3 polio, 1 BCG and 1 measles immunisations. DWT = diphtheria, whooping cough, tetanus.

Delivery data and growth monitoring

Table III presents the data available from delivery records. Data were missing in 0,9% to 23,6% of the 21 items studied. Approximately 20% of data were missing for eight of the categories: medication during pregnancy, history of antepartum

haemorrhage, rupture of membranes, cervical dilatation, cord length, Apgar score at 5 minutes, head circumference and crown-heel length.

TABLE III. DATA AVAILABLE FROM TPA HOSPITAL/CLINIC RECORDS

	No. missing	Available No.	Available %
Syphilis serology (RPR)	21	449	95,5
Rh factor	14	456	97,0
Medication during pregnancy	86	384	71,7
History of antepartum haemorrhage	106	364	77,5
Rupture of membranes	94	376	80,0
Examination on admission			
Blood pressure	53	417	88,7
Fundal height	56	414	88,1
Presentation	53	417	88,7
Cervical dilatation	111	359	76,4
Delivery			
Presentation	44	426	90,6
Placenta mass	37	433	92,1
Cord length	97	373	79,4
Infant			
Gestational age	12	458	97,5
Sex	4	466	99,1
Apgar score 1 min	74	396	84,3
Apgar score 5 min	144	326	69,4
Head circumference	80	390	83,0
Crown-heel length	82	388	82,6
Birth weight	2	468	99,6

RPR = rapid plasma reagin test.

Nine different scale types were found in the three health authorities studied (Table IV). There were differences in equipment both within and between the health authorities. Similarly there was a difference in the measuring tapes used to determine supine length; either a standard tape measure or a Pedobaby was used. Diepmeadow services had no measuring tapes. Equipment and techniques to measure head circumference were only available in Johannesburg health authority clinics.

There was a lack of standardisation in the techniques employed to obtain the growth measurements. This is of little consequence if the child visits the same measurer on each occasion but makes comparison between clinics difficult.

Collection of delivery data

Thirty-seven births (16%) in the hospital were not recorded while all births in the clinic were (Table V). Investigation revealed that the majority of women who had elective caesarean sections were missed as they entered the labour ward through a different route. Following this discovery only 7 births (3%) were missed, representing an acceptable loss. Information on estimated length of gestation, if the liquor was meconium-stained and the method of resuscitation, if any, required by the newborn after birth was missing in more than 10% of cases. Other unreliable information related to the length of time that membranes were ruptured prior to delivery. This lack of reliability appeared to be due to the way in which the information was requested on the data form.

TABLE IV. TYPE OF EQUIPMENT USED IN THE LOCAL AUTHORITY CLINICS FOR WEIGHT, HEIGHT AND HEAD CIRCUMFERENCE MEASUREMENT

Scale type	No. of clinics having this scale	Health authority
Weight		
Stathmore-Lindell	6	Soweto
AB (Sweden)	14	Johannesburg
	2	Lenasia
Detecto-Doctors Scale	4	Soweto
	1	Johannesburg
	1	Diepmeadow
SECA (German)	4	Soweto
	10	Johannesburg
Salter	1	J G Strydom
Tanita (Japanese)	2	Soweto
	7	Johannesburg
	1	Diepmeadow
Weylux (Supreme)	3	Johannesburg
Westa (bathroom scale)	1	Johannesburg
Masskot	1	Lenasia
Hanson (bathroom scale)	1	Lenasia
	5	Johannesburg
Length		
Std tape (1,5 m)	10	Soweto
	32	Johannesburg
	0	Diepmeadow
	2	Lenasia
Pedobaby (or Pedometer)	5	Soweto
	11	Johannesburg
	0	Diepmeadow
	0	Lenasia
Head circumference		
Wyeth — plastic tape	0	Soweto
	14	Johannesburg
	0	Diepmeadow
	0	Lenasia

Discussion

The results of these pilot studies indicate that the birth rate would support a potential sample size of 3 350 singleton births within a 6-week period. Twenty per cent of these births would not fulfil the sample entry criteria in that the mothers would normally live outside the urban area of Johannesburg and Soweto. It is estimated that a further 20% would normally be lost to follow-up because of lost records or 'untraceability'. Over 80% of the remaining sample could be contacted within the 9 months following birth. Assuming that in the birth cohort study envisaged the latter 20% would be retained the likely yield at 9 months would be in excess of 60% of the births taking place during the study period, which would be 80% of the BT10 sample. Maternal compliance would be enhanced by contacting the prospective mothers at 32 weeks of pregnancy. This would limit the prospective antenatal information to the last trimester and other information regarding pregnancy would be retrospective in nature but not influenced by the health status of the child after birth.

Thus it can be anticipated that, even without the incentives that will be built into the BT10 study design, 2 010 out of the initial BT10 sample of 2 680 could be followed up to 9 months. This sample size is thought to be statistically acceptable for analysis of the majority of routine outcome variables and allows for generalisability of findings to Johannesburg-Soweto

TABLE V. DESCRIPTIVE STATISTICS OF BIRTH DATA FROM BARAGWANATH HOSPITAL ($N = 195$) AND ITS SATELLITE CLINIC ($N = 39$) OVER THE 4 DAYS STUDIED

			Missing data	
	Hospital	Clinic	Hospital No. (%)	Clinic No. (%)
No. of deliveries/day				
Range	24 - 43	4 - 11		
Age (yrs)				
Mean	26	24	2 (1)	0
Range	14 - 48	17 - 31		
Parity				
Range	0 - 8	0 - 3	5 (3)	0
Gestational age by abdominal palpation				
Range (wks)	24 - 43	36 - 40	32 (16)	14 (36)
Meconium-stained liquor				
Frequency	21	4	66 (34)	1 (3)
%	16	10		
Baby alive				
Frequency	194	39	2 (1)	0
%	99,5	100		
Baby born before arrival at clinic				
Frequency	14	0	8 (4)	3 (8)
%	7,4			
Birth weight				
Mean (g)	3 046,6	3 207,8	12 (6)	3 (8)
Range	1 600 - 4 190	2 540 - 4 160		
Apgar scores 1 min				
Mode	9	9	12 (6)	2 (5)
Range	0 - 10	8 - 10		
Apgar score 10 min				
Mode	10	10	35 (18)	2 (5)
Range	6 - 10	9 - 10		
Resuscitated				
Frequency	15	1	155 (79)	10 (26)
%	7,7			

and other similar urban areas. The characteristics of those leaving the study during the first 7 months would be investigated as part of the external validity testing.

Routinely collected growth data pose major problems in terms of comparability between, and at times within, clinics. A series of contacts with clinics have thus been undertaken to stress the need for standardisation, to train the nursing staff in standardised measurement techniques and to ensure that weighing scales are properly calibrated. In addition, locally developed supine-length measuring equipment has been developed and will be supplied to those clinics in need.

The method of data collection in the delivery centres was found to be acceptable to the health service personnel and would generate adequate data. Deficiencies in the planned system were isolated and modifed to improve the quality of the data. The design of a specific data form, such that all information would be available from the bedletter, would mean that data on births that were missed at the time of delivery could be collected retrospectively, although cord blood would not be available.

These pilot studies demonstrated that a longitudinal birth cohort study in the Johannesburg-Soweto urban area is feasible. BT10 faces particular challenges because of the fragmentation of the health services but the acceptance of a standard data collection form would provide invaluable information regarding the monitoring of health and the planning of health services.

The repeated description of the study to health personnel was thought to be of major value; it increased the interest of nurses in the study from the outset and allowed them to contribute to the study design, thus increasing a sense of commitment to the study. Reporting of the results of the pilot studies also generated interest and created a sense of practical participation by health personnel.

There is little doubt that this form of contact is an important research-principle and is likely to increase the effectiveness of this birth cohort study. An early commitment by health personnel to the aims and objectives of the study and a sense of participation in the investigation is thought to be essential in the future planning of longitudinal studies.

We would like to thank the following for their input: Dr Derek Yach, Centre for Epidemiological Research in Southern Africa of the South African Medical Research Council, the late Dr Woody Matsie, City Health Department, Soweto, and Professor H. Hurwitz, City Health Department, Johannesburg. In addition we would like to thank the Centre for Epidemiological Research in Southern Africa for financial assistance.

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