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Assessing Antenatal Care in Rural Zimbabwe

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Abstract
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Antenatal care has been associated with improved maternal and perinatal outcomes but there is no agreement on the most effective model in terms of content as well as the number and timing of visits. A cluster randomised controlled trial was conducted in a rural area of Zimbabwe to assess a 5-visit goal-oriented antenatal care model against standard care. In the same population was also determined the sensitivity of factors used for risk screening to predict pregnancy complications and the effectiveness of the referral system in managing women with identified risk markers or pregnancy complications.

Pregnancy records of 10 572 out of total 13 517 recruited women were available for analysis. The new model did not change the number of visits but resulted in better use of health care. The classical risk screening system had low predictive value and identified too large a risk group for referral. Nulliparous women had an increased risk for pregnancy complications whereas women with previous uncomplicated pregnancies were at low risk of complications even with high parity. Multiparous women with previous complications had an increased risk of complications but better utilisation of health care services for delivery reduced adverse perinatal outcomes. There was a functional referral system in Gutu and women complied with referral indications but efficiency of the system was reduced by failure of care providers to comply with referral recommendations.

Antenatal care can be improved in a rural setting through a focussed programme and the unpredictability of many pregnancy complications limits the value of antenatal risk screening. Until universal access to essential obstetric care facilities is attained in low resource settings, a critical re-examination of risk factors could avoid overburdening the referral system.

Keywords: antenatal, pregnancy complications, referral, risk factors, pregnancy outcome, rural, Zimbabwe

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To the women of Gutu and their African sisters
who endure overwhelming burdens to ensure survival of their clans

This thesis is a result of the longstanding collaboration in reproductive health research between Zimbabwe and Sweden.

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List of Publications

This thesis is based on the following papers, which will be referred to as Papers in the text by their Roman numerals.

I. Majoko F, Munjanja SP, Nyström L, Mason E, Lindmark G. Randomised controlled trial of two antenatal care models in rural Zimbabwe. Submitted

II. Majoko F, Nyström L, Munjanja S, Lindmark G. Usefulness of risk scoring at booking for antenatal care in predicting adverse pregnancy outcome in a rural African setting. J Obstetric Gynaecology 2002;22:604-9.

III. Majoko, F, Nyström L, Munjanja SP, Mason E, Lindmark G. Relation of parity to pregnancy outcome in a rural community in Zimbabwe. Afr J Reprod Health 2004;8:198-206.

IV. Majoko F, Nyström L, Munjanja SP, Mason E, Lindmark G. Does maternity care improve pregnancy outcomes in women with previous complications in Gutu district, Zimbabwe? Tropical Doctor, accepted for publication

V. Majoko F, Nyström L, Munjanja SP, Lindmark G. Effectiveness of referral system for antenatal and intrapartum problems in Gutu district, Zimbabwe. J Obstetric Gynaecology 2005;25:656-61.

Contents

Abbreviations

ANC	Antenatal care
BP	Blood pressure
CS	Caesarean section
CSO	Central Statistical Office
DHS	Demographic Health Survey
DMO	District Medical Officer
DNO	District Nursing Officer
GP	General practitioner
Hb	Haemoglobin
IUGR	Intra-uterine growth retardation
LBW	Low birthweight
MCH	Maternal and Child Health
MMR	Maternal mortality ratio
MoHCW	Ministry of Health and Child Welfare
OR	Odds ratio
PMD	Provincial Medical Director
PNMR	Perinatal mortality rate
RCOG	Royal College of Obstetricians and Gynaecologists
RGN	Registered general nurses
RHC	Rural health centre
RPR	Rapid plasma reagin
RR	Relative risk
SFH	Symphysis fundus height
SGA	Small for gestational age
UK	United Kingdom
UNICEF	United Nations Children's Emergency Fund
VVF	Vesico-vaginal fistula
WHO	World Health Organization

Introduction

Historical background of antenatal care

Antenatal care (ANC) refers to pregnancy related services provided between conception and delivery consisting of *monitoring the health status of women, providing information* to foster optimal health, good dietary habits and proper hygiene as well as *providing appropriate psychological and social support*. (Fink et al., 1992) (my emphasis)

There were no ANC structures in the 19th century as pregnancy was not considered as a medical phenomenon but rather a temporary alteration in function. Skilled attendant at delivery (nurse, midwife or doctor) became popular among the rich in mid-19th century but ANC was limited to advice on life style. In 1866 Glasgow Royal Maternity Hospital had an outpatient dispensing system offering free advice on diseases peculiar to women and children twice a week in the afternoon.

The idea of organised ANC is attributed to Ballantyne who in 1901 proposed a pro-maternity hospital. The initial interest was in prevention of foetal mortality but it was later realised that such care could reduce maternal and neonatal deaths (Alexander & Kotelchuck, 2001; Oakley, 1984). Prior to the start of outpatient antenatal clinics, nurses made home visits to women booked for hospital delivery to provide general advice and perform urinalysis. Pregnant women with complications were treated in the outpatient gynaecology clinics. The first antenatal outpatient clinic opened in Edinburgh in 1915 under Ferguson.

ANC was expected to obtain lower preterm delivery rate, a higher average birthweight and decreased neonatal mortality.

Organised ANC in Australia and the United States started around the same time as in the United Kingdom (UK). Wilson who had visited Edinburgh in 1908-09, started weekly outpatient ANC in 1910 in Adelaide, Australia (Oakley, 1984). In the United States, around 1901 nurses visited women in the Boston Lying-In Hospital and pregnant women had home visits by a nurse every 10 days but proper ANC clinics started in 1911.

The 1918 Maternity and Child Welfare Act in the UK enabled municipal authorities to fund maternity and child welfare work. The model of pregnancy at the time was that it should not be regarded as pathological but attention should be devoted to the prevention and treatment of minor departures from the normal. Later there was a shift from an emphasis on educating mothers to take care of themselves and their babies to an emphasis on the professional supervision of expectant mothers (Oakley, 1984).

The first government report devoted to maternal mortality was produced in 1924 by Janet Campbell, senior medical officer in the department dealing with maternity and child welfare in Ministry of Health and this initiated the first confidential inquiry into maternal deaths. Only thirteen percent of maternal deaths had received any clinical ANC and this was interpreted as an indication of an association between lack of ANC and maternal death. In a maternal deaths survey in 1930-32, primary avoidable factors were identified in almost half the cases and lack of ANC was among them. Expansion of ANC was considered the best remedy for Britain's poor record of maternal deaths. More and better ANC was recommended as a means of reducing mortality rates without any evidence about the exact contribution such care had made or could be expected to make to a reduction in mortality.

In 1929 a departmental committee on maternal mortality and morbidity issued a memorandum on the minimum standards in ANC with these stated aims:

- Predict difficult labour from examination in pregnancy.
- Detect and treat toxaemia.
- Diagnose, treat and prevent infection.
- Diagnose and treat venereal diseases.
- Ensure closest cooperation between clinic and all persons in charge of pregnancy care (MoH, 1929).

The ideal patient would attend first when 16 weeks pregnant. A full medical and obstetric history was taken, physical examination including urinalysis, blood pressure (BP) and external pelvic measurements were performed. The nurse-midwife would enquire about the patient's home conditions, advise on hygiene and arrange a home visit if necessary. Routine examinations were conducted in the clinic or in the patient's home at 24 and 28 weeks, then every 2 weeks until 36 weeks, and then weekly until delivery. Uterine height and abdominal girth were recorded at visits, foetal heart was listened to and urine was tested. Medical officer examinations were arranged at 32 and 36 weeks to detect presentation and engagement. No justification was offered in the memorandum for adoption of these guidelines.

In the UK the proportion of women receiving ANC rose to 40% in 1932 and 54% in 1937. In London, the average booking gestation was 24 weeks and the mean number of visits 6.5 in 1934-39. By 1948-50, the mean booking gestation had decreased to 19 weeks while the average number of visits increased to 9.

Routine procedures were incorporated into ANC as advances were made. Pre 1959, BP was recorded occasionally, there was no weighing or blood tests but urine was tested regularly. By 1959 weighing and BP were routine and haemoglobin was done 1 to 4 times. Examination included height of uterine fundus, position of foetus, level of presenting part and foetal heart and pelvic measurements.

Maternal height was recorded in 10% women in 1946-50 and in 100% in 1969-70 (Oakley, 1984). Ultrasound in pregnancy was started in Glasgow by Ian Donald in 1957. There was a growing list of obstetric indications for ultrasound, which extended to 20 items by 1970 and has continued to grow to the present day. At Queen Charlotte's Hospital in London 48% women received ultrasound in 1973, 62% in 1974 and 97% in 1978.

The risk concept in antenatal care

One of the major tasks of ANC is to screen a population of normal pregnant women in order to detect those at risk of disease, prevent, treat or manage complications of pregnancy which are asymptomatic such as pre-eclampsia. This screening is achieved through use of classical risk markers, which include obstetric history, parity, age, height and medical conditions. Success of risk screening depends on the ability of the care provider to predict or diagnose conditions correctly and then to treat or manage them successfully. There is an assumption that early and frequent attendance at antenatal clinics and thorough risk assessment will improve effectiveness. Risk assessment entails use of many different scoring systems according to which a pregnant woman is given a score on the basis of obstetric and medical history, present pregnancy conditions and social factors such as single and educational level. Medical history recorded at the booking visit is an important source of information on obstetric risk (Bergsjo & Villar, 1997; Chng et al., 1980).

Procedures routinely performed at antenatal visits in developing countries at the primary level include maternal weight measurement, BP measurement and abdominal palpation, screening for risk factors associated with the woman's medical, obstetrical and social history as well as those arising during the antenatal period. Most risk assessments classify a high percentage of women as at high risk (Lennox, 1984; McDonagh, 1996). Identification of

risk does not eliminate the possibility of adverse outcome as there may be no effective treatment e.g. for poor foetal growth (Coria-Soto et al., 1996). Also low risk does not mean pregnancy will be totally safe since risk screening has low predictive power. The risk screening system is not successful in correctly identifying women and babies who actually turn out to be at risk and in not identifying as at risk those who do not turn out to be. The low predictive power leads to many unnecessary referrals causing undue stress and cost to women and their families.

For risk screening to be effective, referral centres need to be available and referred women must receive the necessary care. In low resource settings often risk factors are identified and no further action is taken and this renders the exercise ineffective.

Planning for safe delivery is an important aspect of ANC, which enables the woman and her family to make arrangements for transportation in case of emergency and care of other children.

In developed countries with universal access to care, risk assessment is less important but in a rural area with poor communication and transportation systems, a form of risk assessment and recommending an appropriate level of care remains important.

Questioning antenatal care

Motivation for change in ANC programmes started in the early 1970s and has been driven by multiple groups with varied agendas. Sociologists in Aberdeen expressed their scepticism regarding the extent to which specific components of ANC as was practised did or could be of benefit or harm. They felt that ANC might not be as effective as it was often assumed to be and that it might be possible to look for its efficacy in some systematic way (Hall et al., 1985). They proposed research in order to determine the extent to which high risk cases were identified at first screening, which abnormal conditions of the mother or baby were detected by routine care and at which clinic visits they were detected, which problems occurred in spite of ANC and what use was made of specialist investigations. The retrospective study conducted by the group in Aberdeen (Hall et al., 1980) concluded that the benefits that might be achieved from routine ANC had been overestimated and that many problems arose despite routine ANC that could not have been detected or prevented by it. They felt that a more rational schedule of ANC could be devised by specifying the objective of each antenatal visit and by using data gained from the study and knowledge of natural history of pregnancy complications deciding when to aim for detection of each of them.

The schedule devised involved a reduction in the number of visits especially for normal multiparous women, a change in content with some visits where weighing and palpation were not performed, increased role of midwives and family doctors (GPs) in ANC and specification of main objectives of each visit. The suggested schedule was implemented in the Aberdeen ANC trial (Hall et al., 1985).

In the late 1970s, public interest in the management of pregnancy was triggered by interventions related to introduction of new technologies and procedures, such as foetal monitoring and induction of labour with prostaglandin. Health awareness and improved socio-economic situation in the consumer groups encouraged questions on the levels of interventions in pregnancy and their evidence base (Hall et al., 1985; Oakley, 1984).

Increasing health expenditure initiated an interest in economic cost effectiveness of health interventions including ANC by governments that finance most health services.

Initial doubts were expressed about the effectiveness of ANC during the 1930s but despite this the number of clinics and the proportion of expectant women attending them continued to rise. Acceptance of ANC was reinforced by the findings from the National Birth Surveys (1940-1970) of an inverse relationship between the number of visits and perinatal mortality rates (PNMR) (Hall et al., 1985; Young, 1992). These findings were widely interpreted as showing that the more ANC a woman had, the lower her risk of having a perinatal death. The importance of early and consistent attendance at antenatal clinics as a means of reducing the toll of perinatal mortality was stressed.

There is no agreement on the minimum procedures required to improve pregnancy outcomes and different models have similar outcomes (Blondel et al., 1985; McDuffie et al., 1996; Petrou et al., 2003). The scientific community has realised the need to implement only those interventions that are supported by evidence of effectiveness, that have an impact on pregnancy outcomes. There is lack of strong evidence that ANC as currently recommended is effective (content, frequency and timing of visits) (Carroli et al., 2001b; Fiscella, 1995) and therefore research is needed to establish optimum content and quality of ANC.

Earlier antenatal care trials

The schedule of antenatal visits that was recommended in 1929 changed little in over 50 years (Villar & Bergsjo, 1997). As women have complied

with recommendations and initiate ANC early the average number of visits has increased to between 10 and 15. Earlier trials addressed the quantity of ANC as reflected in the number of visits. The trial conducted in Aberdeen in 1975-8 showed that the number of visits in low risk women could be reduced without compromising pregnancy outcomes (Hall et al., 1985). In Britain the Royal College of Obstetricians and Gynaecologists recommended adoption of a reduced visits program in 1982 (RCOG, 1982). In the US in 1989 an expert panel also recommended a reduced visits ANC schedule (DHHS, 1989). Several other studies and expert panels confirmed that a reduced visits schedule was not associated with an increase in adverse outcomes and could be recommended for implementation (Binstock & Wolde-Tsadik, 1995; Gissler & Hemminki, 1994; Lindmark & Cnattingius, 1991; Sikorski et al., 1996).

An ANC trial conducted in Harare, Zimbabwe in 1989-91, compared standard care to a modified new model with 6-goal oriented visits in low risk women from an urban homogeneous population (Munjanja et al., 1996). ANC was provided by midwives, supported through weekly visits by medical officers who evaluated non-urgent referrals. The main outcomes assessed were the number of visits, referrals and obstetric interventions. Women receiving care under the new model had a reduced likelihood of antenatal referral, preterm delivery and referral for hypertensive disorders of pregnancy. There was no evidence that a reduced number of visits resulted in missed complications. A simultaneous effort to get women to book early for ANC was not successful.

A WHO coordinated study was conducted in four countries with the main objective to establish minimal levels of care for women at low risk through comparing less frequent or less intense care with standard care (Villar et al., 1998). Women were allocated a risk category using a risk classifying form with 18 items that included obstetric history, current pregnancy and general medical condition. Women in the new model who were classified low risk received basic ANC. Women classified high risk were not eligible for the basic care model but remained in the intervention group receiving care corresponding to risk factors. The primary maternal outcome was a morbidity indicator index whereas low birthweight (LBW) (<2500 g) was the primary foetal outcome (Donner et al., 1998). The study showed that for women without previous or current complications a program with reduction in the number of visits but with goal-oriented effective activities was not associated with increased risk to women or their babies (Villar et al., 2001a).

Main research issues in a rural African context

In the Harare ANC trial, the primary care clinics booked only low risk women while those with complicated pregnancies attended Harare Maternity Hospital where care was provided by specialist obstetricians. The city had a good ambulance service which enabled easy transfer to hospital of women with complications.

In Zimbabwe, as in many developing countries, there are major differences between urban and rural communities in access, availability, quality and utilisation of health facilities. Urban women are three times more likely to receive ANC from a doctor than rural women and to be advised about pregnancy complications (DHS, 2000). Failure to pay for treatment, distance to clinic and transport problems were more frequently reported in rural areas (DHS, 2000). Studies from other parts of Zimbabwe have highlighted poor quality of ANC services in rural areas (Kambarami, 2000; Kambarami et al., 1999; Kruip et al., 1994; Sikosana, 1994). Since there are significant differences in access, quality and availability of interventions between urban and rural areas in Zimbabwe, the results from the study in the urban area needed to be confirmed in a rural setting prior to implementation of the recommendations. A trial was therefore proposed for a rural setting to compare a more goal-oriented model with specified procedures to standard ANC. In the rural setting, low and high risk women attend the same clinics. Since access to obstetric facilities during emergencies is poor in rural areas special attention must be given to risk screening and planning for delivery.

Thesis objectives

The aim of this thesis is to assess a new ANC model with a specified number of visits and defined routines compared to standard care in a rural African setting. The material collected in the trial was also used to study the effectiveness of antenatal risk screening, the validity of the risk markers used in Zimbabwe and to assess the ability of the care providers in identifying women at risk as well as the effectiveness of the referral system in managing women identified as at risk.

Research objectives

- To compare a goal-oriented ANC model with specified number of visits and routines to standard care (Paper I).
- To determine the sensitivity of risk screening at booking in the prediction of pregnancy complications and adverse outcomes (Paper II).

- To determine the relation of parity to pregnancy complications (Paper III).
- To determine service utilisation by women with previous pregnancy complications and its effect on outcomes (Paper IV).
- To assess effectiveness of the referral system in managing women with pregnancy complications (Paper V).

Zimbabwe: facts and figures

After the gains experienced in the 1980s following independence, the health care system in Zimbabwe encountered problems in the 1990s as demands on the system grew and resources decreased. Between 1990-91 and 1993-94 government health expenditure declined by 34% (CSO, 1998). ANC coverage in 1997 was 88% compared to 95% in 1991 (MoHCW, 1998). Per capita health expenditure declined from US$ 22 in 1990 to US$ 11 in 1996 (CSO, 1996). The percentage of women with no education increased from 3.8% in 1994 to 6.0 in 1999 (DHS, 2000) and this has significant implications for maternal and child health (MCH). The government through the Ministry of Health and Child Welfare (MoHCW) is the main provider of health services, directly through hospitals and indirectly through grants to local authorities and other organisations that provide health care.

Half of Zimbabwe's population lives in communal farming area, 17% in large scale commercial farms, 3% in resettlement schemes and 30% in urban centres. There are rural-urban differences in the proportion of women with 4 or more antenatal visits, 38 vs. 59% (MoHCW, 1998).

Content of ANC varied with 42% of women informed about danger signs, BP recorded in 89%, urine sample tested in 80% and blood tested in 75% (DHS, 2000; WHO-UNICEF, 2003). Use of ANC is associated with use of skilled attendant at delivery, 57% of women with less than 4 visits compared to 79% of those with 4 or more visits were attended by a skilled person. When women with no visit were compared to those with 1 visit, 29% vs. 77% delivered with skilled attendant (WHO-UNICEF, 2003).

General information on Zimbabwe and Gutu district

	Zimbabwe	Gutu
Population	11.7 million	195 360 *
Crude birth rate (/1000)	32	30
Total fertility rate	4.0 ♣	
Rural / urban	70% / 30%	
Maternal mortality ratio	700 ♣	205 •
1985-2003 (reported)	1100 ♦	
2000 (adjusted)		
ANC coverage	93% ♣	96% ★
Skilled attendant at delivery	73% ♦	79% ★
Average booking gestation age		
(< 3 months)	28%	
(4-5 months)	43%	
Number of visits (≥4)	74% ♣	
PNMR (/1000)	40 ♥	34 •
Infant mortality rates (/1000)	53 ♠	
	65 ♣	
Rate of LBW (<2500 g)	7% ♣	
	♣ DHS 2000 ♦ WHO-UNICEF 2003 ♥ (WHO, 1996) ♠ (DHS, 1995)	* CSO 1994 • DMO 1995 ★ Nhindiri 1996

Health care system in Zimbabwe

The health system in Zimbabwe has four tiers intended to provide a chain of increasingly sophisticated curative care facilities (Hongoro et al., 1998). At the lowest level is the primary care centre providing preventive and basic curative care, staffed by registered general nurses (RGN), nurse-midwives and state certified or enrolled nurses. Eighty-five percent of Zimbabwe's population live within 8 km of health unit (CSO, 1989). District Hospitals form the second level of care. Each district has a designated district hospital, which is either a government institution or a church affiliated facility. At the third level are the Provincial Hospitals, which theoretically should have specialist doctors but have rarely been fully functional. The Central Teaching Hospitals make up the fourth level and there are only 4 such hospitals in the country.

In theory referrals should follow the hierarchy but the distribution of health facilities is such that the Central Teaching Hospitals act as district hospitals for the cities of Bulawayo and Harare.

Study area

Gutu is a district in Masvingo province in the south-eastern part of Zimbabwe (Figure 1). The administrative centre of Gutu district, Mupandawana was situated 225 km south east of Harare and 50 km north of Masvingo town (the provincial centre). Gutu was chosen as the ideal place to conduct the study because the utilisation of maternity services as well as status of health in women had been previously studied (Nhindiri et al., 1996; Nilses, 2000). Further, Gutu was sufficiently far from the major urban centres so the influence of practises in urban centres was minimal and therefore gave a true picture of a rural setting. The district was considered typical of rural areas in Zimbabwe with communal, small scale and commercial farmers in the same area. The population was 195 360 with 49% of the inhabitants younger than 15 years and 54% were females (CSO, 1994). The crude birth rate in 1994 was 30/1000 population with a PNMR of 34/1000 live births and maternal mortality ratio estimated at 205/100 000 live births (DMO, 1995). Gutu district had 25 health facilities comprising Gutu Mission Hospital, which was the designated district hospital, 6 rural hospitals and 18 rural health centres (RHC). Three of the rural hospitals were affiliated to the Roman Catholic Church and the other three were government institutions. Rural hospitals have up to 30 in-patient beds but no resident medical officer. The RHCs offer mainly out-patient services but have 4-6 beds for observing patients up to 24 hours, conduct normal births and have some postnatal beds. The basic staff for a RHC included two trained nurses, at least one with midwifery training, a nurse aide and general hand. As a result of limited manpower nurse aides often performed clinical duties such as conducting deliveries (Manungo et al., 1996). The facilities available at health centres differed, depending on who administered them i.e. government, district council or church-affiliated. The church-affiliated facilities were better staffed, had better supplies and usually had access to a vehicle that served as an ambulance. The district council-run health facilities had the minimal number of staff. The government-run facilities usually had access to an ambulance based at Gutu Rural Hospital, which was at the commercial centre of the district.

The practice was for mothers to book for ANC at the nearest health facility. The RHC had guidelines for referring patients to the district hospital. The utilisation of the RHCs for ANC was high with 96% of mothers attending at least once during the pregnancy but use of the health facilities for delivery was only 79% (Nhindiri et al., 1996).

The planning for the Gutu study started in 1991 but implementation was delayed due to a severe drought that affected Zimbabwe. It would have been impossible, and probably inhumane to embark on the study at a time when

the community was struggling to survive. This delay resulted in this trial occurring around the same time as the WHO coordinated multi-centre study.

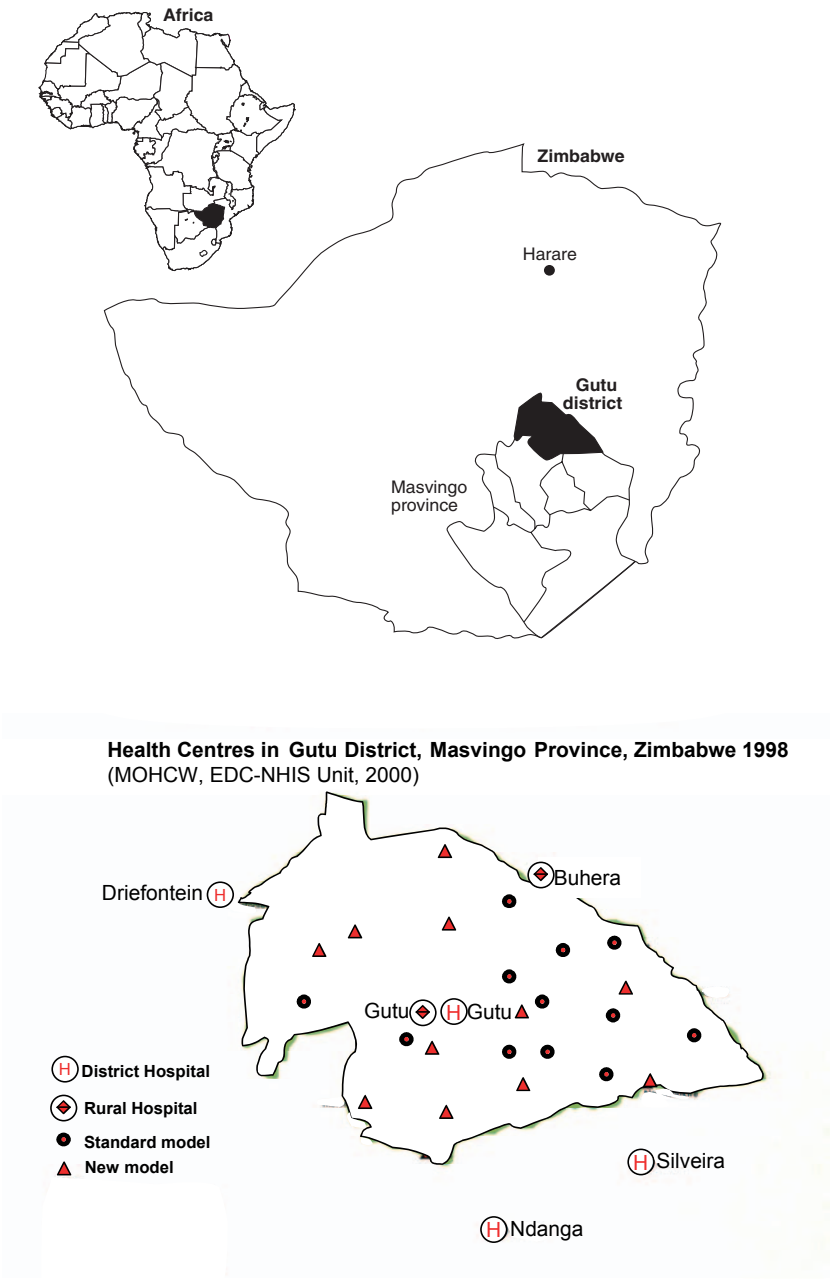

Figure 1. Study area

Methodology

Study design

The ideal study design to evaluate a health care intervention is the individual randomised controlled trial. Individual randomisation was not feasible for this study due to logistical problems. It would have been impossible to offer different types of care in the same clinic as staff would have found such a program more difficult to implement. Therefore a cluster design was used with the health centre as the unit of randomisation. Women received the care that was practised in the health centre they attended.

Ethical considerations

Health program research involves actors at several levels, decision makers, medical administrators and staff as well as clients. This trial protocol was developed in close collaboration with the MoHCW, as well as the Provincial and District medical administrators in Gutu. Staff in the participating clinics gave consent to participate. The decision for participation of a cluster is usually taken by a guardian and in Gutu this included the Provincial Medical Director (PMD), chiefs, headmen and village elders. The guardian acts in the best interest of the participants. Guardians may have potential conflict of interest and therefore safeguards such as ethics committee approval are desirable. The planning of the study and the development of the protocol was done in collaboration with the Masvingo PMD and discussed with the doctors working in the district hospital. Preparatory meetings were held with community and opinion leaders in the district's wards to discuss the study. At a final meeting at which all the wards of the district were represented, permission was granted for the study to proceed. Verbal consent was obtained from women for inclusion of their pregnancy records in the database. Women attending clinics that implemented the new model were informed about the study and the schedule of visits at the booking visit. Women were also informed that additional visits would be arranged if they felt the need to attend more frequently than the suggested schedule or if pregnancy complications developed. The Medical Research Council of Zimbabwe and the Medical Research Ethics Committee of Uppsala University approved the study.

The randomisation process

Of the 25 health facilities in Gutu district, two were excluded because of their function as referral centres (Gutu Mission Hospital and Gutu Rural Hospital) and their location at the commercial centre of the district made them more accessible. The remaining 23 health centres were then stratified according to whether or not they had radio/telecommunication facilities and or a waiting shelter for expectant mothers. The health centres in the strata were then randomly allocated to the new (n=11) or standard (n=12) model (Figure 2 and Table 1). The waiting shelter allows mothers who live far from the health centre to await labour within the grounds of the health centre. They are not in-patient and continue their activities independent of the health centre. Facilities for communicating with the district hospital (i.e. telephone, radio communications) were not available in all health centres. In stratifying health facilities we used availability of radio-telecommunication as this related to ease of communicating with the district hospital in the event of intrapartum referral. The availability of a maternity waiting shelter tended to increase the use of a health facility for delivery.

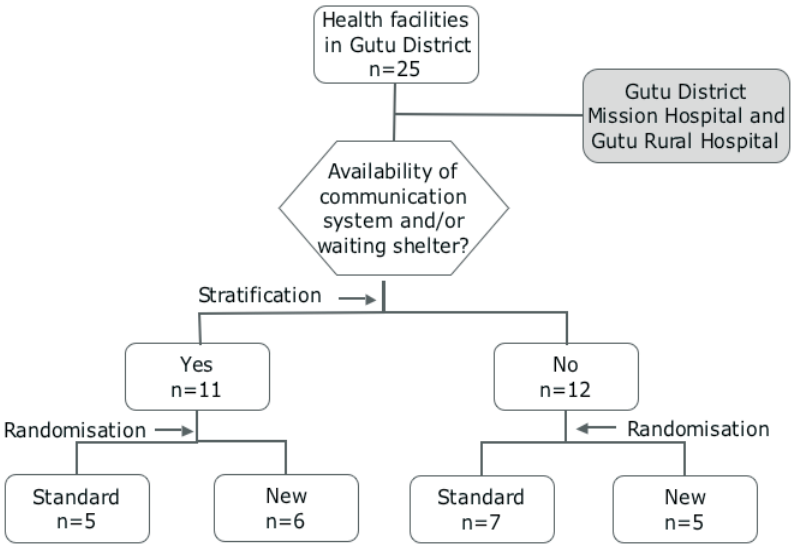

Figure 2. Stratification diagram

Table 1. Stratification of rural health centres to new and standard models

Rural health centre	Model randomised to
Stratum 1. Availability of telephone and waiting shelter	
Mukaro	New
Mutema	New
Serima	New
Soti Source	New
Chinyika	Standard
Chingombe	Standard
Mutero	Standard
Zvavahera	Standard
Stratum 2. Availability of radio communication	
Denhere	New
Nemashakwe	New
Chiwore	Standard
Stratum 3. Neither radio-telecommunications nor waiting shelter	
Chitando	New
Dewure	New
Majada	New
Matizha	New
Mazuru	New
Cheshuro	Standard
Magombedze	Standard
Munyikwa	Standard
Nyazvidzi	Standard
Tirizi	Standard
Zinhata	Standard
Gutu South (Mushaviri)	Standard

Interventions

In the standard model clinics, the ANC schedule of visits and routines continued as in the past while in the new model clinics, a five-visit programme with specified procedures was introduced (Table 2).

Table 2. New model for the intervention clinics

Visit number	Gestation age (weeks)	Goal	Procedures*
1	<20 (ideal)	Risk assessment Health education Delivery plan	Haemoglobin RPR Tetanus Urinalysis
2	24-28	Exclude multiple pregnancy Check for PIH***	Urinalysis**
3	32-34	Exclude anaemia Check foetal growth Review delivery plans	Haemoglobin Urinalysis**
4	36-38	Check foetal growth Exclude abnormal presentation Discuss labour	Urinalysis**
5	40-41	Check foetal wellbeing Referral for post-term at 42 weeks	Urinalysis**

* Blood pressure and SFH were measured at each visit

** If BP ≥140/90

*** Pregnancy induced hypertension

The standard model followed the traditional schedule with a visit every:

- 4 weeks from booking until 28 weeks
- 2 weeks between 28 and 36 weeks
- a weekly visit from 36 weeks until delivery

Blood pressure, body weight and urinalysis were measured at each visit while haemoglobin and rapid plasma reagin (RPR) were tested only at the first visit.

Referral criteria

The criteria for antenatal referral to the district hospital were modified in the new model with the result that most referrals were to be made in the third trimester (Table 3).

Table 3. Referral criteria for the new model

Indication	Referral recommendation
Hypertension in pregnancy	When detected
Antepartum haemorrhage	When detected
Medical condition	When detected
Anaemia	Only if haemoglobin <70 g/L after treatment with iron and folic acid tablets
Abnormal lie or presentation	After 36 weeks
Previous CS or instrumental delivery	After 36 weeks
Primigravidae	At 38 weeks
Short stature (<150cm)	No referral if previous vaginal delivery

In the standard clinics the national referral recommendations from MoHCW were implemented. This consisted of a long list of risk factors for referral at the booking and subsequent visits. There were recommendations for early antenatal referral in women whose risk of complication was labour and delivery related e.g. previous CS. The list of referral recommendations is provided in Table 4.

In Figure 3 the timing of activities in the trial is shown. Women were recruited over a period of thirty-three months. Recruitment into the trial started in January 1995 and continued until October 1997. The last enrolled woman had delivered by June 1998. Women who had not returned the pregnancy record were identified from the clinic registers and then followed-up through home visits to establish pregnancy outcomes. A final workshop was held at which experiences of nurse-midwives with ANC were explored as part of another study (Mathole et al., 2004).

Table 4. Referral criteria implemented in the standard model.

Criteria for referral at first visit	**Criteria for referral at first and subsequent visits**
Age (<16 or >35)	Anaemia (<100 g/L)
Parity (0 or >6)	Antepartum haemorrhage (APH)
Height (<150cm)	Abnormal lie or presentation after 36 weeks
History of medical condition	Albuminuria with high BP
Asthma	Early rupture of membranes
Blood pressure (>140/90)	Eclampsia
Diabetes mellitus	Elevated BP (>140/90)
Epilepsy	Glycosuria
Heart disease	Pregnancy more than 42weeks
Mental illness	Reduced foetal movements or absent foetal heart
Renal disease	Severe weight loss
Tuberculosis	Uterus too large or too small for dates
Obstetric history	
Caesarean section (CS)	
Eclampsia	
Forceps or vacuum extraction	
Myomectomy or tubal surgery	
Postpartum haemorrhage	
Preterm delivery	
Puerperal infection	
Retained placenta or manual removal of placenta	
Ruptured uterus	
Stillbirth or neonatal death	
Third degree tear	
Vesico-vaginal fistula (VVF)	

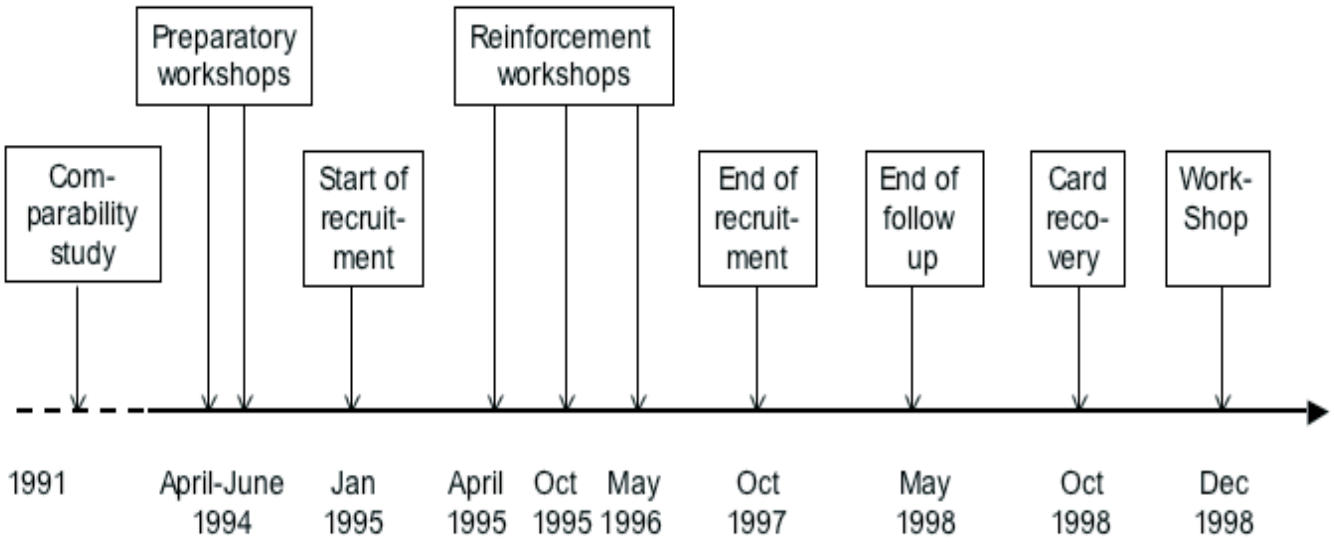

Figure 3. Time schedule

Antenatal care activities/procedures and their justification

Essential procedures in ANC should be based on effectiveness in preventing specified adverse outcomes. The new model excluded routine weighing and urinalysis after the first visit. There is no evidence to support routine urinalysis at all visits when there is normal BP in asymptomatic women (Carroli et al., 2001a; Carroli et al., 2001b; Gribble et al., 1995). Serial recording of maternal weight has not been proven to be beneficial in predicting poor foetal growth or pre-eclampsia and may increase anxiety (Carroli et al., 2001a; Carroli et al., 2001b; Dawes & Grudzinskas, 1991).

Preparatory work

Before introduction of the new ANC model, it was necessary to train the staff in the clinics about the new model. Workshops were arranged so that all staff from the health centres could attend at least one workshop. The background to the study was given and the new model was introduced. The pregnancy record (antenatal card), which had been designed for the study was discussed and comments were noted for improvements. A new register was also designed and introduced into all clinics in the district. This was to ensure that uniform information was collected by all clinics. Clinics had always kept a register of their maternity work but there was a wide variation on what information was collected from clinic to clinic. A procedure manual was also designed which described the various procedures in the antenatal clinic. The procedure manual for the standard model clinics did not contain a description of measuring the fundal height (SFH) since this procedure was not practised in these clinics. Posters of the timing and procedures for each visit in the new model were provided for the consulting rooms.

Field work

The team in the field included a midwife who was based in the district and a driver. The midwife visited each health centre at least once a month and dealt with the problems on the round. She checked on how the procedures were performed and gave some demonstrations on correct procedures. She had a back-up supply of equipment to ensure that all health centres had their equipment requirements met. She worked in close collaboration with the district nursing officer (DNO) and the MCH team. The midwife in the field was also responsible for collecting the cards after delivery so that information could be transcribed onto the data entry form.

Each RHC was visited regularly by one of the medical practitioners involved with the project. There was a checklist completed at each visit, which included an assessment of how procedures were performed and compliance with the protocol. Where problems were identified more supportive visits were arranged.

Reinforcement workshops were arranged six months after project commencement and problems were discussed. The clinics in the standard model also had workshops for updating staff on ANC. Both arms of the trial had a similar number of workshops.

Data handling

The antenatal cards were collected after the postnatal clinic for patients who delivered in the RHC and a copy was made upon discharge for women who delivered in the district hospital. The information from the antenatal card was then transcribed onto a data entry form and computerised using Epi Info 6. The accuracy of data entry was checked by a double entry of randomly selected records (~5%).

Statistical methods

With a mean cluster size of 500 women, an intra-cluster coefficient of 0.05, an α of 0.05, 6900 women in 14 clusters needed to be recruited in each group to obtain a power (1-β) of 80% to detect a 10% decrease in the proportion of women making 5 or fewer visits.

Statistical analyses were by intention to treat and accounted for the within-clinic correlation. An equivalence trial efficacy analysis was done comparing the two models using the standard model as a reference. Rate difference and odds ratio with 95% confidence intervals were calculated adjusted for the cluster randomisation. The software Epi Info, SPSS and ACLUSTER were used for statistical analysis. A p-value <0.05 was considered to indicate a significant difference. If the 95% confidence interval excluded unity, the difference was considered significant.

Results

Although the study was conducted as a single process, the results are presented in three themes (Table 5). The first addresses the implementation of the new model based on five planned visits for women with uncomplicated pregnancies (Paper I). The second examines the activity of screening for risk factors. This concentrates on the classical risk factors in common use, their predictive value and outcomes in women with identified risk factors (Papers II-IV). This leads to the final section dealing with the referral system for women with identified risk factors. The effectiveness of the referral system in management of women with historical risk factors and those developing complications in pregnancy is assessed (Paper V).

Table 5. Themes of results

Specific aim	How assessed	Paper
Implement goal-oriented 5 visit model	Health facility utilisation • Number of visits • Institutional deliveries Detection of complications	I
Risk factor identification and validity of risk factors	Sensitivity of risk factors in predicting adverse pregnancy outcome. Pregnancy outcomes among women with complications.	II-IV
Assess referral system	Compliance of women and care providers with referral indications. Pregnancy outcomes among women with complications.	V

Patient flow

During 33 months of recruitment 13 517 women booked for ANC in the 23 study clinics (Figure 4). We estimate that the study clinics catered for 90 percent of pregnancies in the district. Pregnancy records were retrieved from 10 572 women (78%) and outcomes were known in a further 2651 women

(20%) but in two percent of women we could not obtain information on maternal and foetal outcomes.

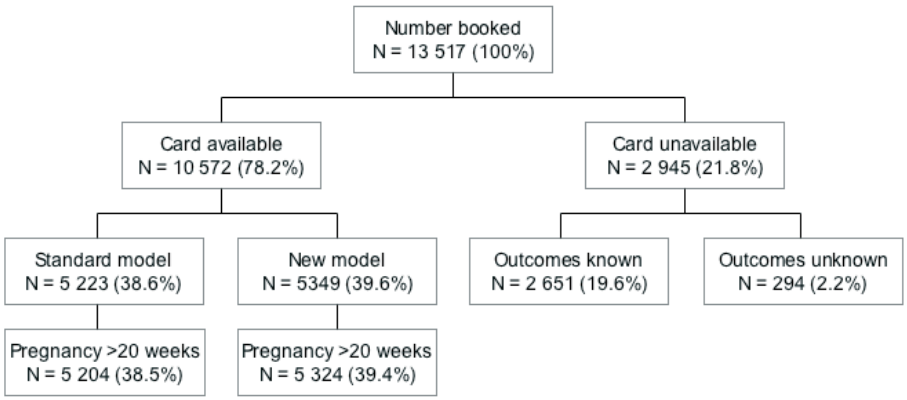

Figure 4. Patient flow chart

The recruitment and card retrieval from individual clinics is shown in Table 6. There was no difference in dropout rates between the models. The number of cases contributed by the clusters ranged from 170 to 1291, with a median of 400 for standard and 421 for the new model.

Table 6. Total number of women recruited for each clinic and proportion (%) of retrieved cards

Standard model			**New model**		
	Number of women			Number of women	
Cluster number	Total	Card retrieved (%)	Cluster number	Total	Card retrieved (%)
1	456	396 (87)	1	251	251 (100)
2	490	315 (64)	2	413	373 (90)
3	1282	906 (71)	3	1291	1049 (81)
4	236	236 (100)	4	421	355 (84)
5	1090	832 (76)	5	1073	778 (73)
6	543	482 (89)	6	1046	728 (70)
7	932	724 (78)	7	712	463 (61)
8	170	170 (100)	8	219	219 (100)
9	344	289 (84)	9	419	294 (70)
10	593	509 (86)	10	505	410 (81)
11	170	170 (100)	11	547	429 (78)
12	314	194 (62)			
	6620	5223 (79)		6897	5349 (78)

Table 7. Maternal characteristics at booking in the standard and new models for women with retrieved pregnancy records

Characteristic	Standard model (n=5223)		New model (n=5349)	
	Ratio	%	Ratio	%
Age (years)				
≤19	815/5193	15.7	898/5311	16.9
≥35	742/5193	14.3	714/5311	13.4
Parity				
0	1618/5222	31.0	1734/5346	32.4
≥6	389/5222	7.4	388/5346	7.3
Gestational age at booking (weeks)				
≤20	2122/5028	42.2	2235/5229	42.7
≥29	843/5028	16.8	931/5229	16.8
Previous pregnancy complications (multiparous women only)				
Stillbirth	123/3604	3.4	125/3613	3.5
Preterm birth	115/3604	3.2	130/3613	3.6
Neonatal death	119/3604	3.3	123/3613	3.4
CS	174/3604	4.8	153/3613	4.2
Any complication	539/3604	15.0	531/3613	14.7

There was no difference in maternal characteristics at baseline (Table 7). Fifteen percent of multiparous women had experienced a complication in a previous pregnancy.

Adherence to new model

How strictly the changes in the program were implemented was assessed through the performance of recommended visits (Table 8) and new procedures such as symphysis fundus height (SFH) measurement. SFH measurement was performed on 84% of the women during 77% of visits. Only 67% of SFH measurements were plotted on the growth chart in the woman's pregnancy record. The prevalence of SFH measurement was around 85% in visits 1 to 3 but decreased to 76%, 61% and 45% in visit 4, 5, and 6 respectively. Six percent (273/4488) of SFH measurements at the booking visit were larger than expected for gestation. Only 21% (57/273) of these women were referred as suspected multiple pregnancies, out of which 32 (56%) were confirmed. SFH measurement was no better than obstetric palpation in diagnosis of multiple pregnancies. The proportion of twin pregnancies

Table 8. Antenatal procedures and utilisation of health facilities in the two models. Odds ratio (OR) and 95% confidence intervals (CI) crude and adjusted for the cluster design.

Characteristic	Standard model	New model	OR	95% CI	
				Crude	Adjusted
Number of visits ≤5	3561/5182	4106/5327	1.5	1.4-1.7	1.1-2.2
Antenatal procedures					
Syphilis testing	4214/5223	4697/5349	1.7	1.6-1.9	0.97-3.1
Haemoglobin check	4052/5223	4782/5349	2.4	2.2-2.7	1.00-5.7
Blood pressure check	5181/5223	5323/5349			
Place of delivery					
Home or in transit	1248/5137	964/5261	0.70	0.64-0.77	0.40-1.2
Health centre	1986/5137	2660/5261	1.7	1.6-1.9	0.88-3.0
District hospital	1782/5137	1499/5261	0.75	0.69-0.81	0.49-1.2
Other hospital	72/5144	95/5265			
Referrals					
Antepartum	1558/5223	1531/5349	0.94	0.87-1.03	0.62-1.4
Intrapartum	406/5136	283/5261	0.66	0.56-0.78	0.44-0.98
Postpartum	29/5129	45/5257	1.5	0.93-2.5	0.53-4.3

correctly identified was 42% (34/82) in the standard and 43% (32/75) in the new model.

In the new model exclusion of abnormal presentation at the fourth visit (36-38 weeks) was one of the goals. There was no difference in the proportion of correct antenatal diagnosis of breech presentation in the two models, 54% (39/72) vs. 62% (40/64) in the standard and new models respectively.

The proportion of women with fewer than 6 visits in the new model was slightly higher but a box-plot of number of visits by clinic and model (Figure 5) showed a homogenous pattern. The box-plot also illustrates the wide individual variations in the number of visits with a tendency towards reduced

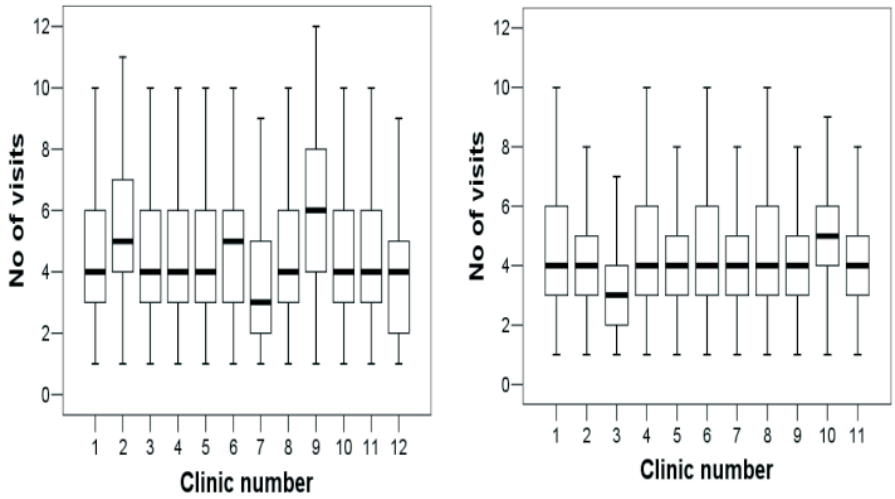

Figure 5. Box plots for number of visits in each clinic in the new and standard models showing median and ranges

number of excess visits in the new model (box-plot on the right). In the new model 9 out of 11 and in the standard 8 out of 12 clinics (box-plot on the left) had a median of four visits resulting in a median number of visits in both arms of four. The likelihood of making five or fewer visits was significantly higher in the new model, OR 1.5 [adjusted 95% CI 1.1-2.2].

There was a decrease in home births in the new model although the difference was not statistically significant after adjusting for the cluster design. However, the proportion of women who needed emergency transfer during labour in the new model was reduced by 34% (OR 0.66; 95% CI 0.44-0.98). This confirms that planning for delivery enables women to attend the appropriate level of care.

The rate of detection of hypertensive episodes was higher in the standard model (100/1000 vs. 92/1000) but there was no excessive occurrence of eclampsia in the new model suggesting that there were no significant episodes of hypertension missed. On the contrary, eclampsia occurred more frequently in the standard model (2.3/1000 vs. 0.6/1000) (Table 9). Operative delivery also occurred more frequently in the standard model (46/1000 vs. 36/1000). This can be partly explained by the higher utilisation of the district hospital for delivery in the standard model. Intervention rates tend to be higher in hospitals even among low risk women. There were no excess perinatal deaths in the new model indicating that the increased use of RHC for delivery was probably among low risk women.

Table 9. Number and rate per 1000 of pregnancy complications and outcomes by model of ANC

Characteristic	Standard model		New model	
	Ratio	Rate/1 000	Ratio	Rate/1000
Maternal complications				
Hypertensive disorders	522/5204	100	492/5324	92.4
Eclampsia	12/5126	2.3	3/5238	0.6
Antepartum bleeding	12/5126	2.3	9/5239	1.7
Operative delivery	233/5118	45.5	190/5232	36.3
Postpartum haemorrhage	34/5123	6.6	34/5238	6.5
Maternal deaths*	2/6620	0.30	4/6897	0.58
Foetal-neonatal				
Preterm delivery (<37 weeks)	588/4930	119	599/5058	118
Birthweight <2500 g	227/3833	59.2	267/4280	62.4
Birthweight <1500 g	22/3834	5.7	25/4280	5.8
Foetal and neonatal mortality				
Stillbirth	69/5105	13.5	63/5242	12.0
Stillbirth ≤36 weeks	27	5.3	36	6.9
Stillbirth >36 weeks	37	7.2	24	4.6
Early neonatal death	15/5105	2.9	19/5242	3.6
Late neonatal death	35/3941	8.9	49/4173	11.7
Perinatal death	119/5105	23.3	131/5242	25.0

*Total booking in each group used as denominator.

The number of maternal deaths was 2 in standard and 4 in new model. In two deaths (one in each group) there was insufficient information to attribute a cause as the maternal record was unavailable. The second woman in the standard model died from postpartum haemorrhage following a home birth at 36 weeks. In the new model one woman died from puerperal sepsis associated with HIV infection after a preterm delivery in a RHC. Two women died after home births, one from postpartum haemorrhage and the other from puerperal sepsis. The maternal deaths could not be attributable to any factors related to the ANC received.

Risk factors and screening for complications

At the booking visit women were allocated a risk category based on characteristics at baseline and obstetric history. There was no difference by mater-

nal risk factors (young/old age, nulliparity/grand multiparity, and previous pregnancy complications) Using these risk factors at booking, 55% of women in both models were classified in the high risk category. The majority of women (39%) were classified high risk for parity reasons (nulliparity or grand multiparity) and 15% because of obstetric historical factors (Table 10).

Table 10. Prevalence (%) of classical risk markers at booking by intervention group

Risk marker		Standard model (n=5223)	New model (n=5349)
Age	≤16	88 (1.7%)	99 (1.9%)
	≥35	742 (14.3%)	714 (13.4%)
Parity	0	1618 (31.0%)	1734 (32.4%)
	≥6	389 (7.4%)	388 (7.3%)
Medical condition		78 (1.5%)	46 (0.9%)
Obstetric history (parous women only)		(n=3604)	(n=3613)
Antepartum haemorrhage		25 (0.7%)	29 (0.8%)
Hypertensive disorders		53 (1.5%)	51 (1.4%)
Preterm delivery		115 (3.2%)	130 (3.6%)
Stillbirth		123 (3.4%)	125 (3.5%)
Neonatal death		119 (3.3%)	123 (3.4%)
Postpartum haemorrhage		88 (2.4%)	83 (2.3%)
CS		174 (4.8%)	153 (4.2%)
Any		539 (15.0%)	531 (14.7%)

Pregnancy complications developed in 20% women classified low risk at booking and in 30% (389+1353/5824) of women classified high risk. The sensitivity of the risk allocation system was 64% (Figure 6).

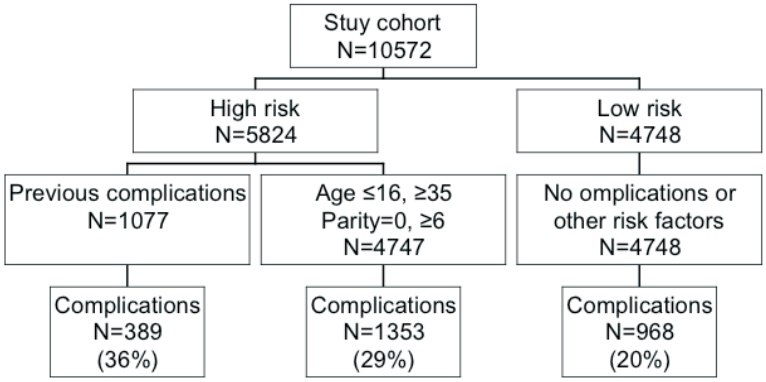

Figure 6. Study cohort

Parity

The relation of parity to complications and pregnancy outcome among women in Gutu was also assessed since the majority of women were classified in the high risk group because of nulliparity or grand multiparity.

Compared to women with one previous birth (parity=1), nulliparous women had an increased risk of hypertensive disorders, operative delivery and LBW (<2500 g) (Figure 7). Risk of pregnancy complications was stable from the second to the sixth pregnancy (parity 1 to 5). Women of high parity (≥6) had an increased risk of hypertensive disorders but this was an effect of age and was not significant after stratification by age (see Table 5 in Paper III). High parity women had fewer labour and delivery complications.

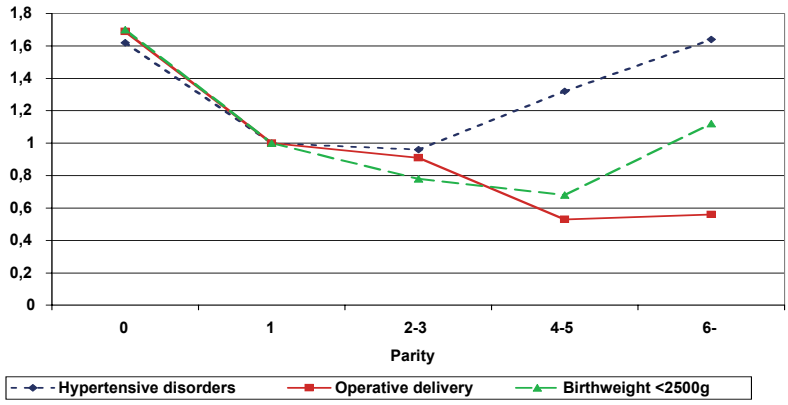

Figure 7. Odds ratios (OR) for specified complications by parity using primiparous women (parity =1) as referents.

When multiparous women were stratified by previous pregnancy complications, there was no difference in risk of complication between low (parity 2-5) and high parity women without previous complications (Figure 8 a-c).

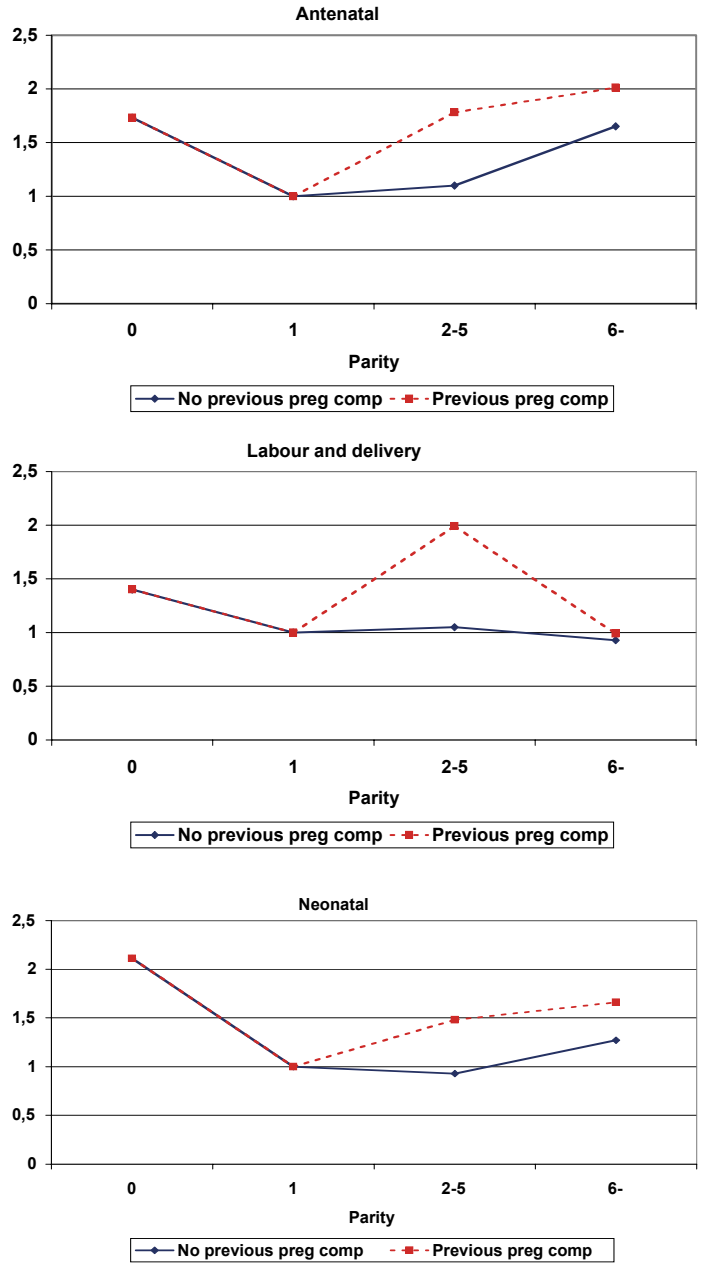

Figure 8 a-c. Odds ratio for antenatal, labour and delivery, and neonatal complications by parity and previous complications.

Obstetric history

The effect of previous pregnancy complications on pregnancy outcome was evaluated. Women who had experienced complications in a previous pregnancy were classified as high risk and were compared to women with previous uncomplicated pregnancies (low risk).

Women with previous complications had good utilisation of services with reduced likelihood of booking for ANC later than 28 weeks gestation (RR 0.78; 95% CI 0.67-0.90), fewer than 6 antenatal visits (RR 0.86; 95% CI 0.83-0.90) and home delivery (RR 0.50; 95% CI 0.45-0.57) (Table 11). Only 48% of women considered high risk gave birth in hospital while 33% gave birth at RHC and 19% at home.

Pregnancy complications developed in 21% (1295/6140) low risk and 36% (389/1077) high risk women ($p<0.001$). Among high risk women there was an increased risk for hypertensive disorders (RR 1.6; 95% CI 1.3-1.9), primary CS (RR 2.2; 95% CI 1.2-4.2), and LBW (<2500 g) (RR 2.0; 95% CI 1.5-2.6).

There was increased risk for perinatal death in high risk women, which did not reach statistical significance (RR 1.6; 95% CI 0.98-2.5). Perinatal mortality was higher for high risk women who gave birth at home, 47/1000 vs. 19/1000 in low risk women (RR 2.5; 95% CI 1.2-5.1).

The risk for any pregnancy complications was increased in women with previous complications (RR 1.7; 95% CI 1.6-1.9). There was a high recurrence risk for hypertensive disorders of pregnancy, preterm delivery and CS.

As complications developed in 21% of low risk women and in 36% of high risk women, the sensitivity of previous complications in predicting further complicated pregnancies was only 23%.

Table 11. Utilisation of services, pregnancy complications and neonatal outcome in low and high risk women. Relative risk (RR) with 95% confidence intervals (CI) with low risk as referents.

Characteristic	**Low risk***	**High risk#**	**RR**	**95% CI**
Number of women	6140	1077		
Late booking (>28 weeks)	1053	149	0.78	(0.67-0.90)
Less than 6 ANC visits	4811	728	0.86	(0.83-0.90)
Place of delivery				
Hospital	1091	503	1	
RHC	3492	359	0.55	(0.50-0.59)
Home	1486	206	0.50	(0.45-0.57)
Antenatal complications	489	135	1.6	(1.3-1.9)
Hypertensive disorders	476	130	1.6	(1.3-1.9)
Antepartum haemorrhage	45	20	2.5	(1.5-4.3)
Labour delivery complications	747	260	2.0	(1.8- 2.3)
Preterm delivery	677	140	1.2	(1.0-1.4)
Primary CS	45	12	2.2	(1.2-4.2)
Postpartum haemorrhage	36	13	2.1	(1.1-3.9)
Neonatal complications	249	80	1.8	(1.4-2.3)
LBW (<2500 g)	188	67	2.0	(1.5; 2.6)
Perinatal death	81	22	1.6	(0.98; 2.5)

Low risk* multiparous women with no previous complications
High risk# multiparous women with previous pregnancy complications

Referral system

There were 3094 women (29%) referred to the district hospital prior to onset of labour and 694 during labour (13% of women who attended the RHC in labour). Parity (nulliparity and grand multiparity) was the most frequent referral indication accounting for 59% of antenatal and 50% of intrapartum referrals. Fifty-eight percent (401/694) of intrapartum referrals were for risk factors that were identifiable prior to the onset of labour. Thirty percent (947/3094) of women with antenatal referral did not comply with referral advice and failed to attend the district hospital for assessment. Women frequently presented to the hospital without RHC referral either because of perceived risk or logistical problems of accessing the RHC (n=993). Among the 993 self-referrals, 320 (32%) had a risk factor that had not been acted upon by the nurse-midwife. Women with medical problems and those presenting with antepartum haemorrhage had the highest likelihood for referral

(Table 12). Apart from referral for high parity (≥6), the majority of women followed referral advice with compliance ranging between 70% and 91%.

Table 12. Nurse-midwife and women's compliance with selected antenatal referral indications

		Referred		Complied	
Referral indication	No. eligible	No.	%	No.	%
Parity					
Nulliparity	3352	1432	43	1008	70
Multiparity (≥6)	777	406	52	207	51
Medical condition	124	111	90	88	79
Past obstetric history	1077	443	41	328	74
Previous Caesarean	327	201	62	167	83
Blood pressure >140/90	1014	487	48	383	79
Antepartum haemorrhage	50	44	88	40	91
Malpresentation	---	118	---	97	82
Suspected multiple pregnancy	---	116	---	91	78

Among women not referred in the antenatal period (women with no risk factors or risk factors not acted upon) the risk of perinatal death was elevated for women referred intrapartum when compared to the group with RHC delivery (RR 3.4; 95% CI 1.7-6.8) (Table 13). In all subgroups, home births had a significantly elevated risk of perinatal death. Women with a historical risk factor who were not referred had a higher risk of perinatal death, (RR 2.4; 95% CI 0.88-6.4) when compared to those referred in the antenatal period. The risk of perinatal death was also elevated among self-referred women, (RR 2.6; 95% CI 1.5-4.5).

Nurse-midwives' compliance with recommendations for referral was poor since only 41% of women with historical obstetric risk factors were referred, although women with previous CS delivery were more often referred (61%). Women with a medical condition and those presenting with antepartum haemorrhage had the highest referral rates. Among women with no identified risk factors who gave birth at RHC, perinatal mortality was low (7.7/1000).

Table 13. Risk of perinatal death according to referral group with place of delivery and by booking risk. Relative risk (RR) with 95% confidence intervals (CI).

	No. women	Perinatal deaths			
Category		No.	Rate/1000	RR	95% CI
No antenatal referral (n=7488)					
RHC delivery	4277	33	7.7	1	
Intrapartum referral to hospital	385	10	26.0	3.4	1.7-6.8
Self-referral to hospital	993	20	20.1	2.6	1.5-4.5
Home delivery	1822	44	24.1	3.1	2.0-4.9
Antenatal referral (n=3094)					
Hospital delivery	1856	26	14.0	1	
Intrapartum referral to hospital	309	7	22.7	1.6	0.71-3.7
RHC delivery	495	9	18.2	1.3	0.61-2.8
Home delivery	434	14	32.3	2.3	1.2-4.4
Historical risk allocation (Low: n=6140; High: n=1077)					
Low risk multiparous*	3193	18	5.6	1	
High risk, antenatal referral	443	5	11.3	2.0	0.75-5.4
High risk, no antenatal referral	634	17	26.8	4.8	2.5-9.2
High risk, intrapartum referral	94	3	31.9	5.7	1.7-19

*Women with no antenatal or intrapartum referral who delivered at RHC

Discussion

Summary statement

This trial was conducted in a rural African setting where women booked late, staff had a number of other responsibilities, transport both to the primary clinic and to higher level of care was often difficult and resources were limited to care for complications at the primary level. The new ANC model was constructed to provide effective ANC in 5 planned visits for women with uncomplicated pregnancies in this setting. Some aspects of the new model such as planning for delivery were incorporated into practice but new procedures e.g. SFH measurement were performed less often than expected.

Study limitations

The study had limitations arising from problems encountered during fieldwork and the loss to follow-up of twenty-two percent of women. However, outcome of pregnancy was established for 98% of women.

The reasons for failure to retrieve the pregnancy record included migration and inability to make contact with the woman after delivery, especially following home births. There was no difference in characteristics at baseline between women with retrieved cards and the loss to follow-up group. The pregnancy outcomes among women with retrieved records and those, in whom only outcomes were established through home visits but without the pregnancy records, were similar. However, loss to follow-up could be higher among women with an adverse outcome who because of this do not come back for postnatal care. The loss to follow-up in our study is within the reported range from similar studies of 16 to 30% (Carroli et al., 2001b) and is lower than in other reports (Jelley & Madeley, 1983; Mahomed et al., 2000).

In an effort to increase card retrieval, village community workers were encouraged to follow up all recently delivered mothers in their villages and check on whether they still had the pregnancy records. The district MCH team was requested to enquire about the pregnancy records of recently delivered mothers during immunisation clinics and to ask for it, if it had not yet been collected.

The effect of contamination as a result of women moving between clinics and also from staff movements is difficult to estimate. Women often moved between clinics implementing the new and standard models especially towards the end of the pregnancy. This was mainly due to the cultural practice of a woman in her first pregnancy returning to be with her mother at delivery and partly due to the geographical distribution of the maternity waiting shelters and telecommunication facilities. Women who gave birth in health facilities out of the district often had the pregnancy record retained with their hospital notes and record filing systems in most hospitals were poor thus making it impossible to retrieve such records.

Due to staff shortages, it was unavoidable that staff would move between clinics offering the two care models. Such movement was necessitated by leave, staff re-training or family reasons. Efforts were made to minimise movement from the new to standard model clinics since the introduction of the new protocol into standard clinics could lead to contamination. Also new staff coming into the district and allocated to new model clinics could have applied the standard model since they were familiar with it. Staff that had missed the initial training exercise was introduced to the new model but there is individual variation on how quickly change is adopted. Contamination dilutes the demonstrated effect leading to finding no effect when one actually exists (type 2 error) (Elley et al., 2004). Inflation of sample size may deal with contamination but in Gutu as the trial was confined to one district there was a limit to the sample size achievable in a reasonable time. It is recognised that, due to their nature ANC trials are prone to contamination, protocol deviation and co-interventions (Carroli et al., 2001b).

Some of the clinics in the new model did not comply fully with the visit schedule in the protocol during the early part of the project. This slowly improved as the staff gained confidence in the new protocol. Resistance to a reduced number of antenatal visits is not unique to this low resource setting, and is also reported from several trials conducted in developed countries.

Rationale of changing antenatal care programmes

Doubts regarding the effectiveness of ANC date to the 1930s but acceptance of ANC was supported by findings from National Birth Surveys that suggested a dose-response effect between the number of ANC visits and improved neonatal outcomes (Fink et al., 1992; Hall et al., 1985). Observational studies suggest ANC is beneficial in that women with no ANC have poor pregnancy outcomes compared to women with some ANC and those with inadequate care have poorer outcomes compared to women with adequate care (Delvaux & Buekens, 1999; Fink et al., 1992; Gissler & Hem-

minki, 1994; Villar et al., 1993). However belief in the effectiveness of ANC has not been matched by strong scientific evidence and clinical trials of interventions to prevent preterm birth show current ANC approaches to be ineffective (Alexander & Kotelchuck, 2001; Rosenberg et al., 2004). There is however evidence to show that ANC is effective in prevention and treatment of infections and anaemia, detection of malpresentation and detection and management of hypertensive disorders (Gerein et al., 2003).

The standard schedule of antenatal visits evolved and activities have been added without scientific evaluation (Villar et al., 2001b; Villar et al., 1993). Concern about hypertensive disorders shaped the content of ANC such as serial BP readings and urine tests for proteinuria and played a role in establishing the timing and frequency of visits (Alexander & Kotelchuck, 2001). There are some commonly performed procedures, which are of unknown value as well as others which are unrelated to outcome. Recent attempts to improve ANC have focused on implementing only those activities that make a difference in pregnancy outcomes (Lindmark & Cnattingius, 1991; Villar & Bergsjo, 1997; Villar et al., 1993). A need for systematic research into relative effectiveness of each of the many diverse components of ANC using outcomes that can be modified by provided services has been highlighted (Alexander & Kotelchuck, 2001; Lindmark, 1992). Evidence is needed on whether a programme of ANC that emphasises essential elements of care shown to improve selected pregnancy outcomes is as effective as traditional "western" care in preventing maternal and foetal morbidity (Villar et al., 2001a).

Design choices/study methodology

An RCT is necessary for evaluation of effect of ANC on pregnancy outcome to control for patient selection likely to occur in observational studies (Donner et al., 1998; Reading et al., 2000). Although cluster randomisation design decreases the power of the study compared to individual randomisation it is often used in health services research when individual randomisation is impractical (Donner et al., 1998; Reading et al., 2000). Several ANC trials have used this methodology (Hall et al., 1985; Munjanja et al., 1996; Villar et al., 2001a). Cluster randomisation can be done with a smaller sample size in the individual clusters but needs a large number of clusters to be efficient thus the total sample size required is larger than for an individual randomisation trial (Kerry & Bland, 1998; Reading et al., 2000). The power of the Gutu trial could have been increased by using two adjacent districts, one to implement the new model, and the other to continue standard care. This would have increased the number of clusters and therefore the power. This could also have reduced contamination by women in the two models

attending the same clinics, as exchange of information between staff from different districts is limited. However, it is likely that this would have had significant cost implications.

Statistical matters

As individuals within a cluster tend to be more similar, the standard statistical tests that assume independence cannot be used because of the risk of bias with increased chances of finding a significant result when one does not exist (type 1 error) (Bland, 2004; Donner et al., 1998; Elley et al., 2004). There is also a potential for clusters with higher number of cases to bias results, but with stratification there was even distribution of large clinics in the two models in this study. Until recently many cluster randomised trials were reported without adjusting for the design (Bland, 2004).

Assessing implementation of the model

Assessing change as a result of an intervention is often a difficult process (Eccles et al., 2003). An assessment model needs to incorporate secular trends of change unrelated to the intervention. An RCT is the gold standard for evaluating healthcare interventions as it ensures that confounders are distributed evenly across groups (Eccles et al., 2003; Elley et al., 2004). The relation of ANC to pregnancy outcome can be confounded by factors such as patient characteristics, accessibility of health facility and quality of care (Berg, 1995).

Schedule

The new model was based on performing specified procedures in 5 planned visits in normal pregnancies. A median number of visits around 5 would indicate implementation of the visits schedule. The likelihood of reducing the number of visits in a rural area was low due to late initiation of care and was not the primary aim of the study. In addition, since this was an unselected population, at risk women would have more visits and thereby raise the mean number of visits. Antenatal programmes aimed at implementing a reduced visits schedule have been directed at low risk women (Hall et al., 1985; Munjanja et al., 1996; Villar et al., 2001a). The convergence of the median number of visits confirms that the standard model was not being implemented as recommended due to late booking. In the new model, women booking before 20 weeks expected 5 visits and this occurred in 42%

(945/2236) whereas women booking after 28 weeks expected a maximum of 4 visits and this proportion was 77% (714/931). If the standard model was correctly implemented, women booking by 20 weeks were expected to have 10 visits and those booking at 28 weeks would make 8 visits. The respective proportions for these women in Gutu were 6% (148/2304) and 2% (18/835). Our results show improved timing of visits in the new model. In a study performed during the same time in Gutu among women booked directly with the Gutu Mission Hospital the mean number of antenatal visits was 6.1 with 73% of women having ≥5 visits (Van den Heuvel et al., 1999). Non-adherence to schedules by both women and professionals leading to convergence of mean number of visits has been reported in similar trials (Sikorski et al., 1996).

Content

Basic components of ANC include early and continuing risk assessment, health promotion and medical/psychological interventions. There was no significant difference in the frequency of performance of antenatal procedures such as serology for syphilis and haemoglobin check although there was a trend towards improved performance in the new model. There was a reduction in detection of episodes of hypertension in the new model similar to previous reports (Berglund & Lindmark, 1998; Munjanja et al., 1996; Villar et al., 2001a).

Abdominal examination in pregnant women includes measuring of fundal height, listening to foetal heart sounds and manual palpation to assess the position of the fetus. In the new model measurement of fundal height was introduced, but the procedure was performed infrequently and little action was taken for abnormal results. Fundal height is often recommended as a cheap and effective way of monitoring foetal growth but this does not seem to be true in settings where appropriate follow-up is not easily available.

Developing a delivery plan is an important aspect of ANC and all women should be knowledgeable about signs and symptoms of pregnancy complications especially those occurring intrapartum (Berg, 1995; Villar et al., 1993). In the new model the woman was helped to plan for delivery from the first visit and encouraged to use an appropriate level facility according to her risk status. There was a reduction in home births and emergency transfers in labour in the new model indicating an effect of this delivery planning.

Success of reduced visits programmes

It is the content of an antenatal visit rather than quantity of visits that promotes healthy outcomes and counting the number of visits is misleading because the number is determined by several factors including gestational age at initiation of care, frequency recommended by the provider, presence of complications, need for hospitalisation, women's compliance and gestational age at delivery (Fiscella, 1995; Petrou et al., 2003). Use of relative number of visits may be a better indicator of amount of care (Gissler & Hemminki, 1994).

Assessments of scientific evidence for ANC practice standards have not been accompanied by progressive change in ANC content or practice (Alexander & Kotelchuck, 2001). It is often difficult to abandon ineffective and costly treatment once it has been implemented (Porter & MacIntyre, 1984; Villar et al., 2001b). ANC programmes recommending a reduction in number of visits have been poorly implemented due to resistance by care providers. In Britain the recommendation by the RCOG working party in 1982 that the number of visits in low risk women should be reduced was hardly implemented and neither was the United States expert panel guidance of 1989 (DHHS, 1989; RCOG, 1982). In Norway a recommendation for a reduced visits programme was issued in 1985 but the number of visits remains higher than recommended, indicating that care providers do not comply with guidelines to reduce visits in low risk women (Backe, 2001). In a survey among practising midwives 71% agreed they could give effective ANC using a reduced frequency schedule but few used it in practice (Walker et al., 2002). Doubts have been expressed by midwives regarding reduced frequency of visits (Berglund & Lindmark, 1998; Sanders et al., 1999). There has been concern that a reduction in the number of visits could have adverse psychological effects on women if they feel they are not being properly cared for (Sanders et al., 1999; Jewell et al., 2000). Initially worries were expressed about safety of a reduced visits schedule, including increased morbidity from hypertensive disorders especially eclampsia if the traditional schedule of ANC was changed (Hall et al., 1985; Sikorski et al., 1996). Also in our study there was no increase in the rate of undiagnosed conditions in the new model. Several trials have shown that for women without previous or current complications a reduction in the number of visits including goal-oriented effective activities is not associated with increased risk to women or their babies (Hall et al., 1985; Munjanja et al., 1996; Sikorski et al., 1996; Villar et al., 2001a). Detrimental effects of over-utilisation of care include unnecessary medical interventions (Backe, 2001).

Quality of care

The key issue in changing ANC practices is not reducing the number of visits but implementing only those activities proven to be effective (Villar & Bergsjo, 1997). As is common in a developing country setting the quality of care in Gutu was poor (Prual et al., 2000; Urassa et al., 2002). Problems were often detected with little result in interventions as reflected in failure to act when abnormal BP or SFH was noted.

Antenatal clinic visits should only take place if an objective can be specified with reasonable expectations of being met. ANC also provides opportunity for women at high risk to receive family planning counselling and parenting education (Fiscella, 1995).

Risk factor screening

ANC programmes attempt to screen the entire pregnant population, and provide surveillance and treatment to individual women or groups of women according to level of need. It is hoped that through a series of health examinations with predefined content, health personnel will detect conditions in the mother or foetus which may threaten pregnancy and its outcome and that if the condition is treated or monitored outcome will be better. The risk approach attempts to allocate existing resources according to a formal risk scoring system that reflects need rather than access or demand. In most low resource settings the demand for obstetric beds outstrips supply and therefore beds are filled on basis of medical or obstetric indications. The effectiveness of a risk scoring system is measured by its ability to discriminate between women at high or low risk. Most risk scoring systems have poor positive predictive values and inadequate sensitivity. Risk prediction wrongly identifies many women as being at risk who go on to have normal delivery and also wrongly identifies as low risk many women who develop complications, offering them a false sense of security and probably contributing to them presenting late for care. Only 10-30% of women allocated to the high risk group experience the adverse outcome for which they are predicted to be at risk by the scoring system (Carroli et al., 2001a).

The factors used for risk screening as recommended by Zimbabwe MoHCW were adapted from risk markers used by WHO (Rooney, 1992). In Gutu the proportion of women classified as high risk at booking was 55% comparable to reports from other low resource settings (de Groot et al., 1993; Lennox, 1984; Mahomed et al., 2000; Prual et al., 2000). Risk status changes during pregnancy when complications occur and up to 30% of nulliparous women considered low risk at booking changed into the high risk group. This pro-

portion was 14% among multiparous women (Tucker et al., 1994). This demonstrates the need for continuous evaluation of risk during pregnancy and responding appropriately. In Gutu 24% of low risk women developed complications, a rate that is similar to other reports (Kulmala et al., 2000; Tucker et al., 1994).

Parity as marker of risk

Parity has been used as a risk marker with nulliparous and grand multiparous women classified as at higher risk for pregnancy complications. Nulliparous women are considered to be at risk for pregnancy induced hypertension and fetopelvic disproportion leading to operative delivery, whereas high parity women are considered at risk of complications associated with previous pregnancy problems and age related medical disorders such as diabetes and hypertension. Risk markers such as maternal age and medical condition may be present at booking in 12 to 36% of nulliparous women (Petrou et al., 2003; Tucker et al., 1994). In Gutu 39% of women classified as high risk had parity as a reason, which is similar to other reports from the region (Jelley & Madeley, 1983; Kruip et al., 1994; Prual et al., 2000). Parity influences utilisation of services with women in the first pregnancy more likely to initiate care earlier than multiparous women and to have a higher number of visits (Glei et al., 2003; Hemminki & Gissler, 1993; Jansone et al., 2001). High parity women have a higher likelihood of home birth than nulliparous women (Bloom et al., 1999; Pang et al., 2002). In Gutu home birth was associated with increased risk of adverse neonatal and maternal outcomes as previously reported (Etuk et al., 2000; Pang et al., 2002).

The results of this trial confirm that the first pregnancy is associated with a higher rate of complications and need for operative intervention when compared to second and subsequent pregnancies. Increasing parity does not appear to have an independent effect on rate of complications, independent of age or previous pregnancy complications. In women with previous uncomplicated pregnancies increasing parity is not associated with increased risk of adverse events. Women of high parity, however, tend to be older and already have age related medical conditions such as hypertension. Any increase in complications, above the rates of low parity women, appears to be a result of the underlying medical conditions and not parity *per se*. Our findings also suggest that multiparous women with uncomplicated previous pregnancies can be safely managed in the health centre. Such a policy would decongest the district hospital and possibly increase institutional delivery by high parity women if they were encouraged to use local facilities.

Obstetric historical factors

Women with previous pregnancy complications made good use of health services resulting in booking earlier, higher number of visits and reduced number of home births. This observation was similar to previous reports that showed previous pregnancy complications to increase likelihood of hospital delivery (Glei et al., 2003; Hemminki & Gissler, 1993; Kulmala et al., 2000; Van den Heuvel et al., 1999). Women with previous uncomplicated pregnancies may be less motivated and feel no need for early booking (Myer & Harrison, 2003).

Similar to previous reports, we found that women with previous complications had an increased risk for complications (Greenwood et al., 1994; Kulmala et al., 2000; Lennox, 1984; Robson et al., 2001). Unlike in previous reports there were no excess perinatal deaths among women with previous complications who gave birth in a health facility (Weiner et al., 2003). We considered the increased risk of complications without excess perinatal mortality in the high risk group an indirect indicator of the effectiveness of the care provided.

Our results did not confirm that a history of preterm birth was a powerful risk factor for preterm birth as previously reported (Umeora et al., 2004). There was a low recurrence ratio for most complications, which also reduces the predictive value of historical obstetric factors.

Effectiveness of risk screening

Providers tend to forget or not recognise how ineffective much of routine ANC is and mothers are led to believe that early and regular attendance for routine care can and will prevent complications and that all or most complications are predictable and avoidable. The ineffectiveness of ANC to predict, diagnose or treat complications of pregnancy is a consequence of the nature of the complications rather than of poor care and the pooling of heterogeneous outcomes further reduces the predictive value of specific risk markers. The unpredictability of many pregnancy complications makes the provision of high quality essential obstetric care facilities for immediate care of women who develop complications the most efficient action.

Referral practices

Epidemiological studies show that a skilled attendant at delivery has an important role in the reduction of poor pregnancy outcomes. The goal of uni-

versal access for all women to give birth with a skilled attendant is not achievable in the majority of developing countries in the foreseeable future due to lack of capacity and poor access to facilities. Women with risk factors traditionally considered at higher risk of childbirth complications are identified and encouraged to give birth in hospital. Identification of risk markers and the action taken relies on the care provider's competence and motivation. For ANC to reduce morbidity good quality care must be available, women must use services, a functioning referral system must exist and be used. Satisfactory treatment must be provided for women to seek ANC.

In Gutu there was a referral system in place and the referral hospital appeared to be effective in implementing interventions. The rates of antenatal and intrapartum referral in Gutu of 29% and 13% respectively are comparable to those in previous reports (Acheson et al., 1990; Hall et al., 1985; Kowalewski et al., 2000; Kruip et al., 1994; Leeman & Leeman, 2002). In Tanzania two thirds of women used the referral level because of a general consideration of safety, not because of specific risk factors or health problems. There was a gap between professionally defined need and actual use of obstetric care (Kowalewski et al., 2000).

Compliance with referral recommendations

Success of the risk approach depends on the predictive value of risk factors and women's compliance with referral. There is evidence of frequent failure to elicit important information on risk factors especially those based on past obstetric and medical history and failure to take appropriate action when high risk history is elicited (Carroli et al., 2001a; Prual et al., 2000). Risk factors were missed or not acted upon in 32% of women in Gutu. Studies from the region show low compliance with referral recommendations among women and their care providers with rates of compliance for both as low as 25% (Dujardin et al., 1995; Jahn et al., 1998; Jelley & Madeley, 1983; Kowalewski et al., 2000; Kruip et al., 1994).

Sometimes women with risk factors may be referred but do not act on the advice because they consider the referral indications trivial. We found that women referred for parity related reasons who had not experienced previous complications tended to ignore referral advice. Women evaluate advice and act according to their judgement. Women's perception of risk may be different from the medical definition of risk therefore ANC providers need to know people's perceptions of risks of pregnancy and how to promote benefits of professional care (Gerein et al., 2003; Glei et al., 2003; Kowalewski et al., 2000; Mathole et al., 2004). There is a need to convince women about the need for more supervision, not just to instruct them. The reasons for re-

ferral must make sense to them. Women accept hospital care for previous CS, antepartum haemorrhage, malpresentation, and medical problems. In Gutu women with previously complicated pregnancy complied with advice for referral, whereas women without previous complications did not consider high parity a reason for concern.

Compliance rates also varied according to risk factor. It may be appropriate to place emphasis on the risk factors that are best accepted. Risk factor such as nulliparity or grand multiparity may be too frequent resulting in too many women being referred thereby decreasing acceptability of the referral indication by women. Rare risk factors such as medical condition yielded highest compliance rates. Highest compliance is for a risk factor perceived by women to endanger their own life. Women's compliance with referral advice is closely related to geographic accessibility and women's perception of danger to herself (Dujardin et al., 1995). Compliance with referral advice is also related to previous experience of services or perception of quality, and worry about costs. If referral services have a reputation for poor services, women will not comply with referral advice (Berg, 1995). Good relations between the clinic and hospital are important for facilitating referrals. Patient compliance with referral was high in Gutu similar to that reported in Harare (Munjanja et al., 1996). Accessibility of health services is considered a critical determinant of health care choice in developing world where an inverse relationship exits between the proximity of the clinic and use of medical care during pregnancy (Myer & Harrison, 2003). Barriers other than physical access are sometimes responsible for failure to comply with referral advice (Kowalewski et al., 2000).

Care providers involved in risk scoring tasks must be trained and motivated to implement the system. Lack of motivation of midwives and difficult relationships between midwives and pregnant women diminishes the effectiveness of antenatal consultations. Discussion is needed among health care providers, pregnant women and health authorities to improve relationships and quality of maternal care (Mathole et al., 2005).

There is a need to re-examine the risk factors and re-define cut-off points in order not to overburden referral centres (Mahomed et al., 2000). If all women with risk markers in Gutu had been referred, the district hospital would not have been able to cope. Overloading referral centres risks diverting attention of health personnel away from complicated pregnancies.

Recently emphasis has been on ensuring that women understand why they need a skilled attendant for delivery and how they are able to access obstetric care in emergencies (Gerein et al., 2003). Identification of women with increased risk does not always lead to required action and often health work-

ers fail to recognise importance of risk. Facilities may be inadequate or inaccessible and women may be unconvinced of need to use them or of their effectiveness. Improving services for all women is the best approach (Carroli et al., 2001a).

Conclusions

In this thesis an assessment of ANC in a rural setting is presented. This was a pragmatic trial assessing how ANC was delivered in practice and the feasibility of introducing change into clinical practice by a modified schedule of visits and new procedures such as SFH measurement. Pragmatic studies test whether an intervention is likely to be effective in routine practice by comparing a new procedure against current regimens and all allocated subjects are analysed in the allocated group irrespective of whether they received intervention or not. This trial shows successful incorporation into clinical practice of care aspects that providers were comfortable with. This has been the experience from similar trials. An important effect of the new model was better delivery planning which increased appropriate utilisation of RHC, reduced emergency intrapartum transfer and home births.

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