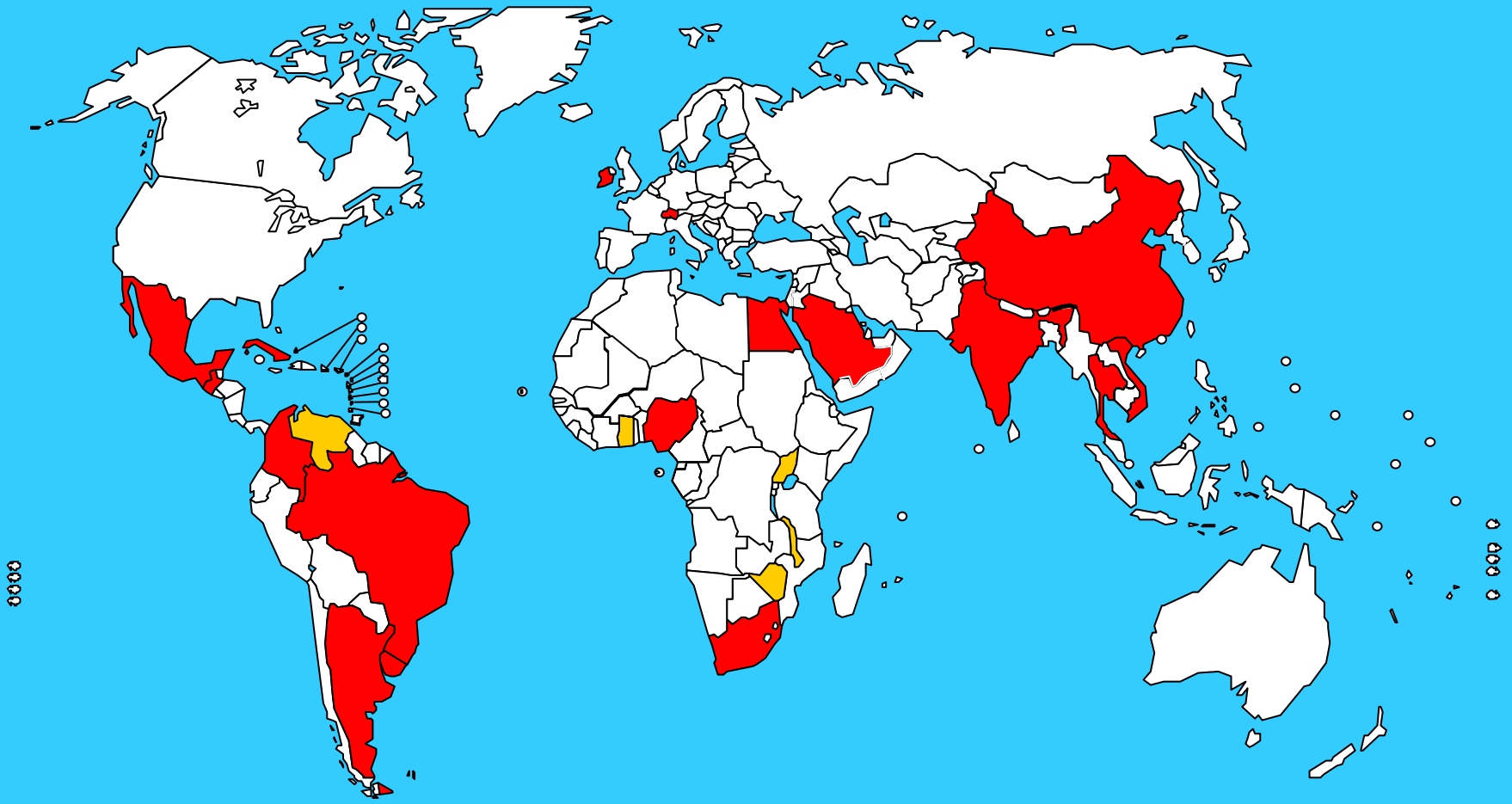
WHO Programme to Map Best Reproductive Health Practices

MATERNAL AND PERINATAL HEALTH RESEARCH

José Villar, Metin Gulmezoglu, Mario Merialdi, Gilda Piaggio, Ana Pilar Betran, Archana Shah, Carol Peters, Jane Pizot and Harriet Kabagenyi for the Maternal Health Research Group Network

WHO Maternal Health Research Network



WHO Programme to Map Best Reproductive Health Practices

Antenatal care

Postpartum haemorrhage

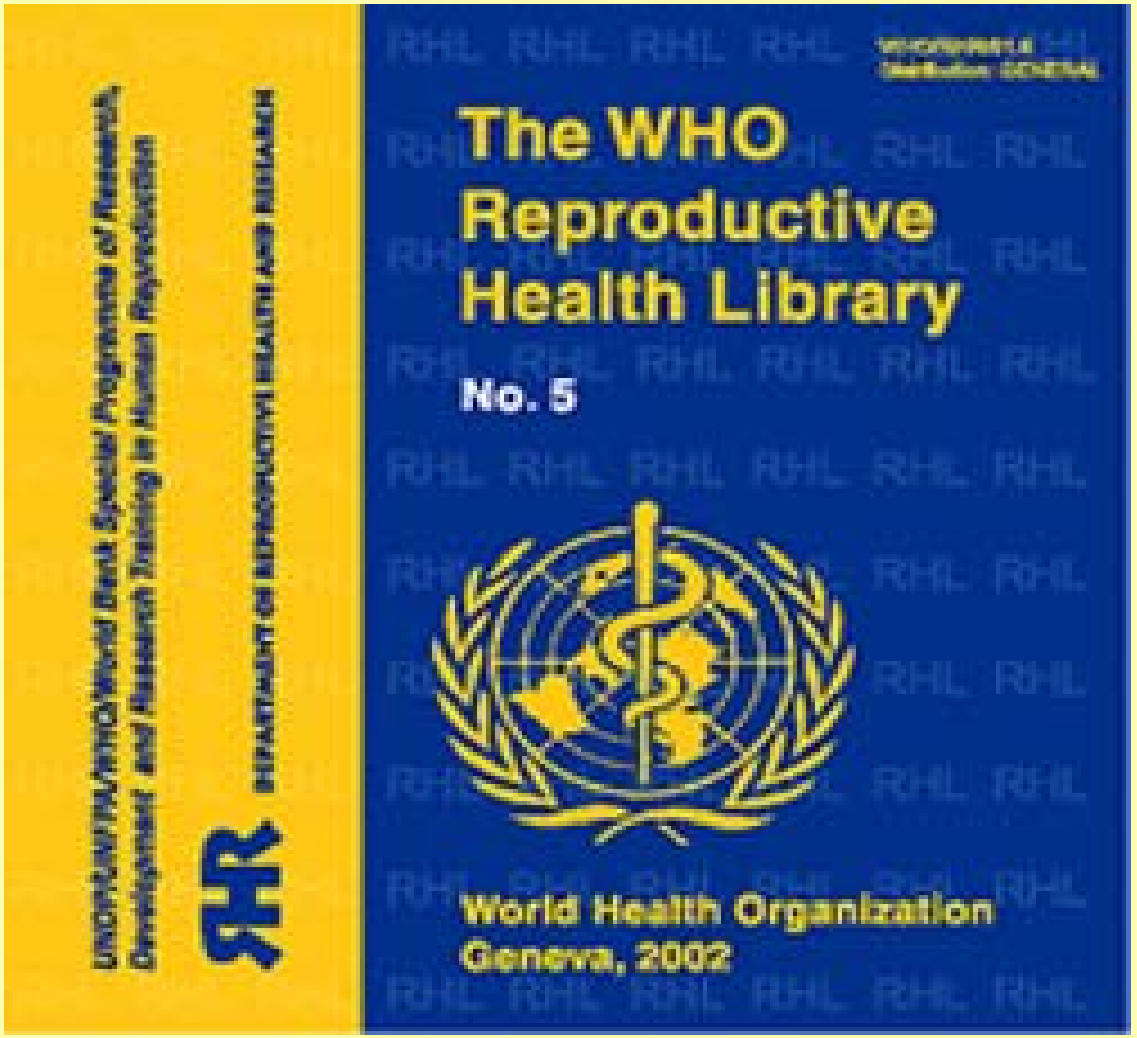
Infections

Maternal nutrition

Intrapartum care

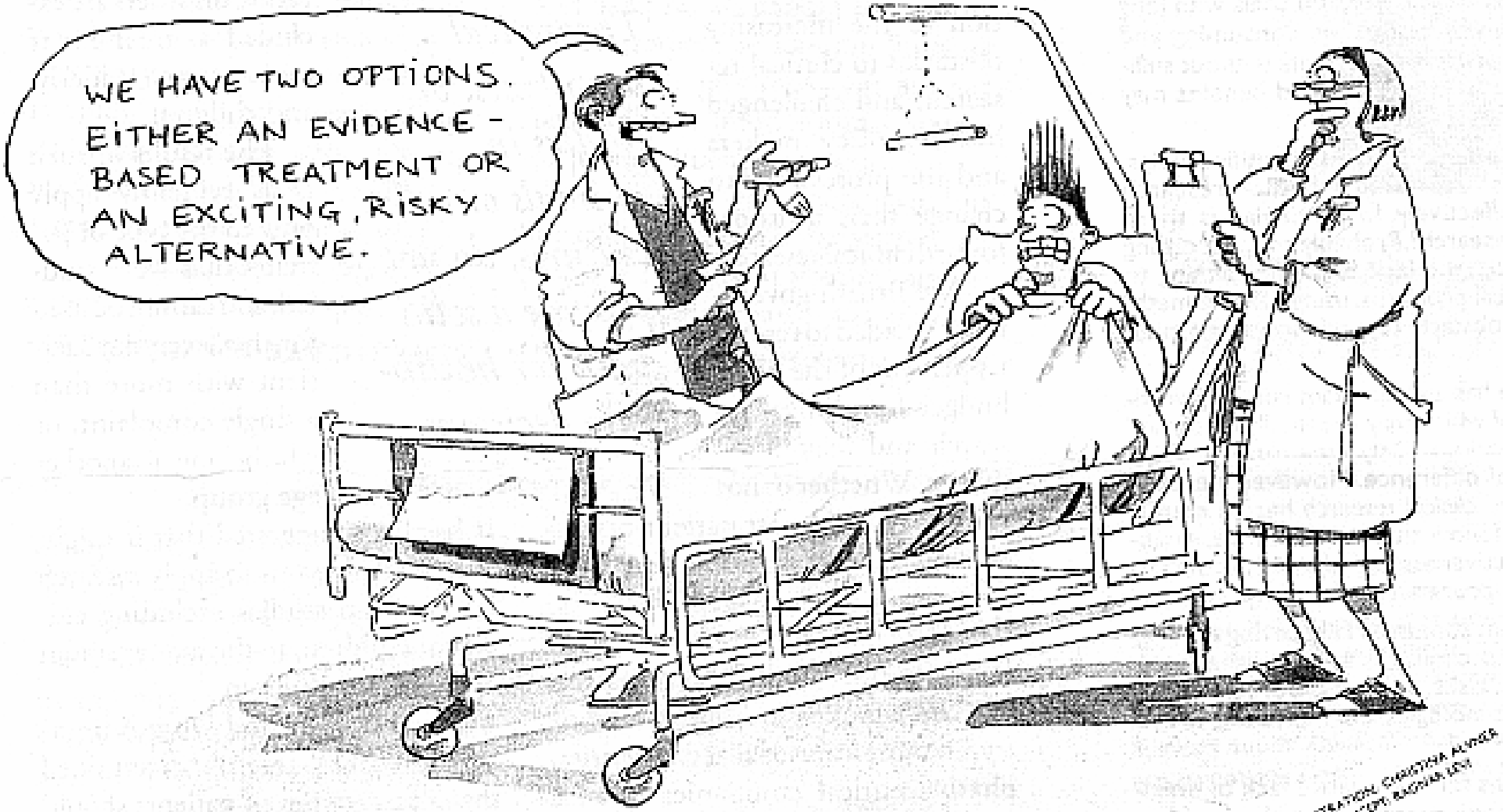
Pre-eclampsia/Eclampsia

Mapping the burden of maternal ill-health
Operations research
Research methodology
Capacity building


The WHO
Reproductive
Health Library
No. 5
World Health Organization
Geneva, 2002

PRINCIPLES

Faith Versus Facts



First, Do the Trials. Then, Do No Harm

By David Brown Sunday, August 4, 2002; Page B01,The Washington Post

The same evidence of efficacy and safety should be required for both drugs and non-drugs forms of care

The Case Of Antenatal Care

"By some curious chance, ANC has escaped the critical assessment to which most screening procedures have been subjected"

Cochrane, A. *Effectiveness and Efficiency, 1972*

"ANC should be….treated like any other medical activity and investigated by randomised controlled trials"

Cochrane, A. *Effectiveness and Efficiency, 1972*

The Lancet 19 May 2001; volume 357: 1551-1570

Articles

WHO antenatal care randomised trial for the evaluation of a new model of routine antenatal care

WHO systematic review of randomised controlled trials of routine antenatal care

Hypothesis

A New ANC Model based on components shown to improve maternal, perinatal and neonatal outcomes is as effective as the Standard ANC model with regard to:

- Low birth weight and maternal morbidity,
- is not more expensive and
- is acceptable by women and providers

- Trial design: cluster-randomised
- Unit of randomisation: ANC clinic

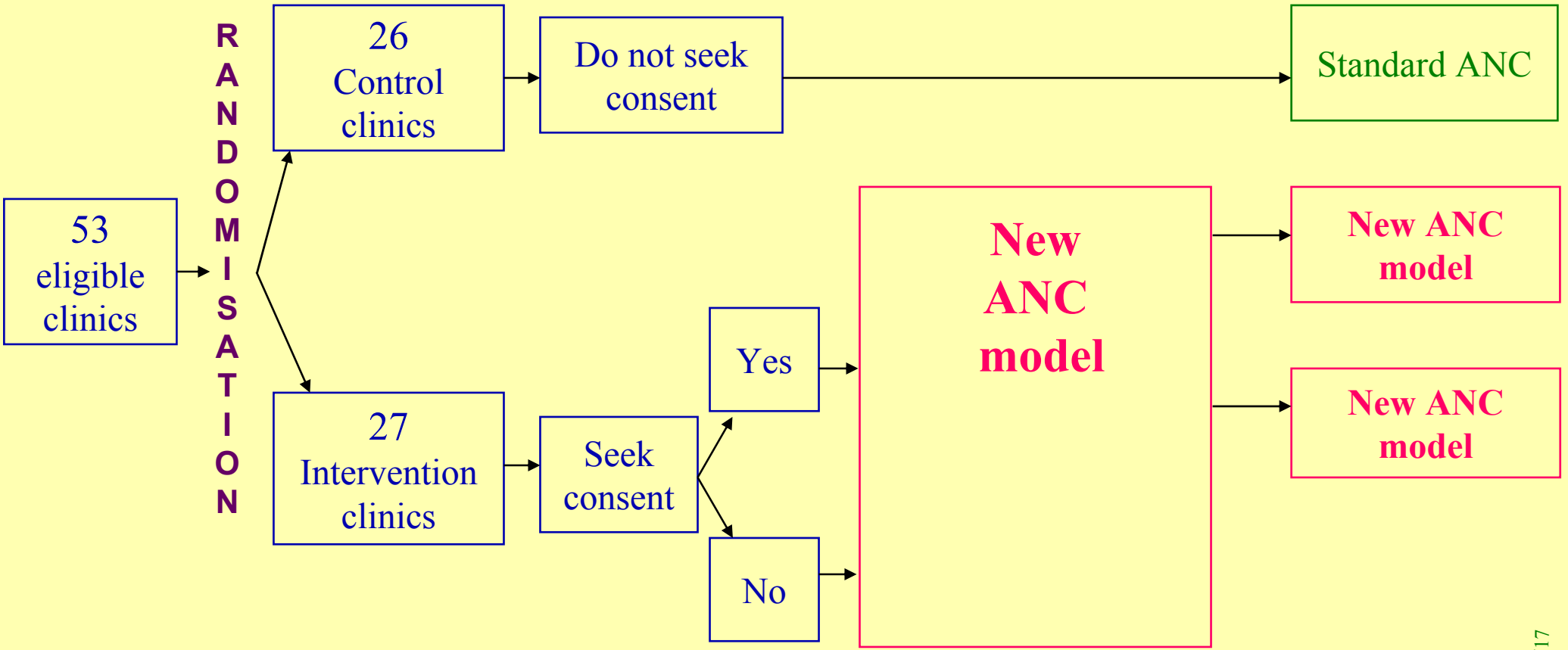
Sample size to detect a change in risk of LBW of 20% or more with 90 % power, two-sided alpha=5% test and average cluster size of 450 women:

19087 women

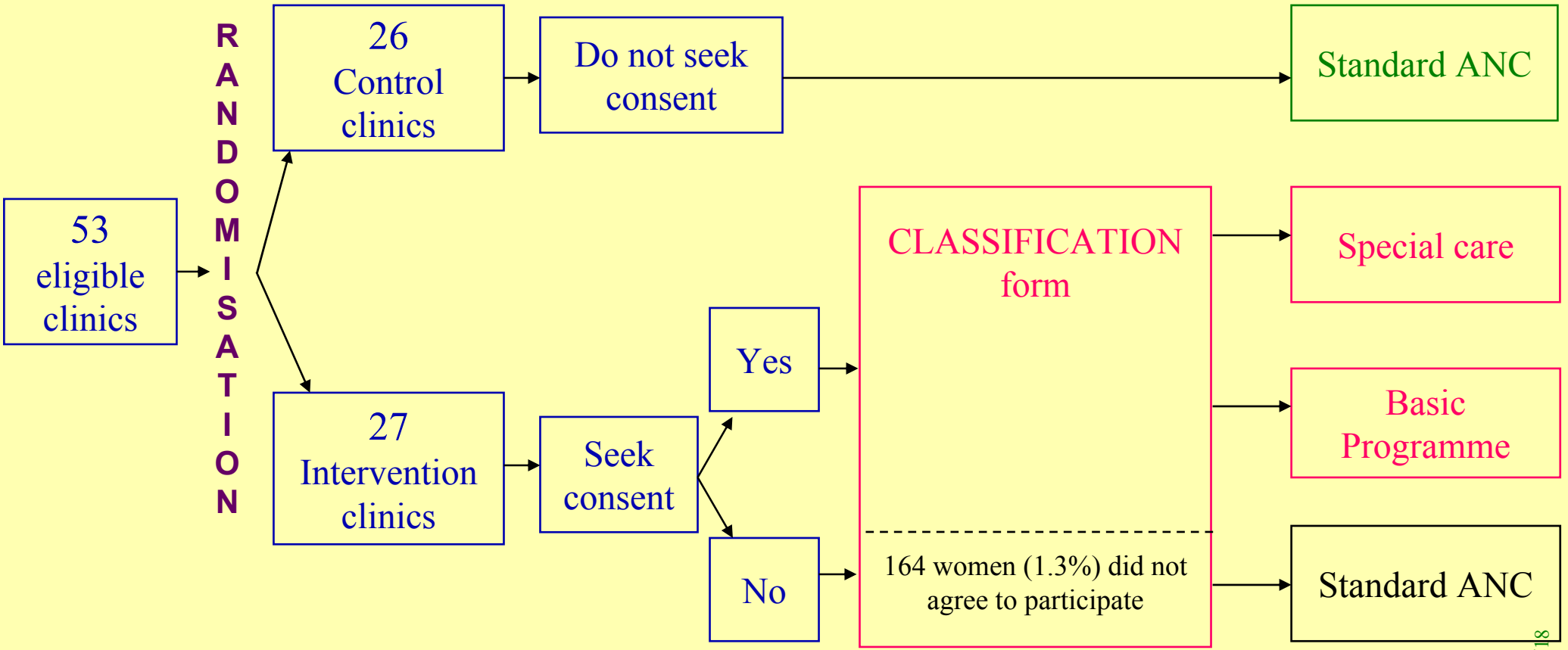
Study Population

All women initiating antenatal care after the date of the start of the trial, at each of the selected clinics, regardless of their gestational age, medical or obstetric characteristics, or previous care, were enrolled.

Study Design and Women's Flow Chart



Study Design and Women's Flow Chart



The New ANC Model

At the first ANC visit women were classified as to whether or not they required further assessment or any special care using the Classification Form

The Classification Form contained 18 questions on:

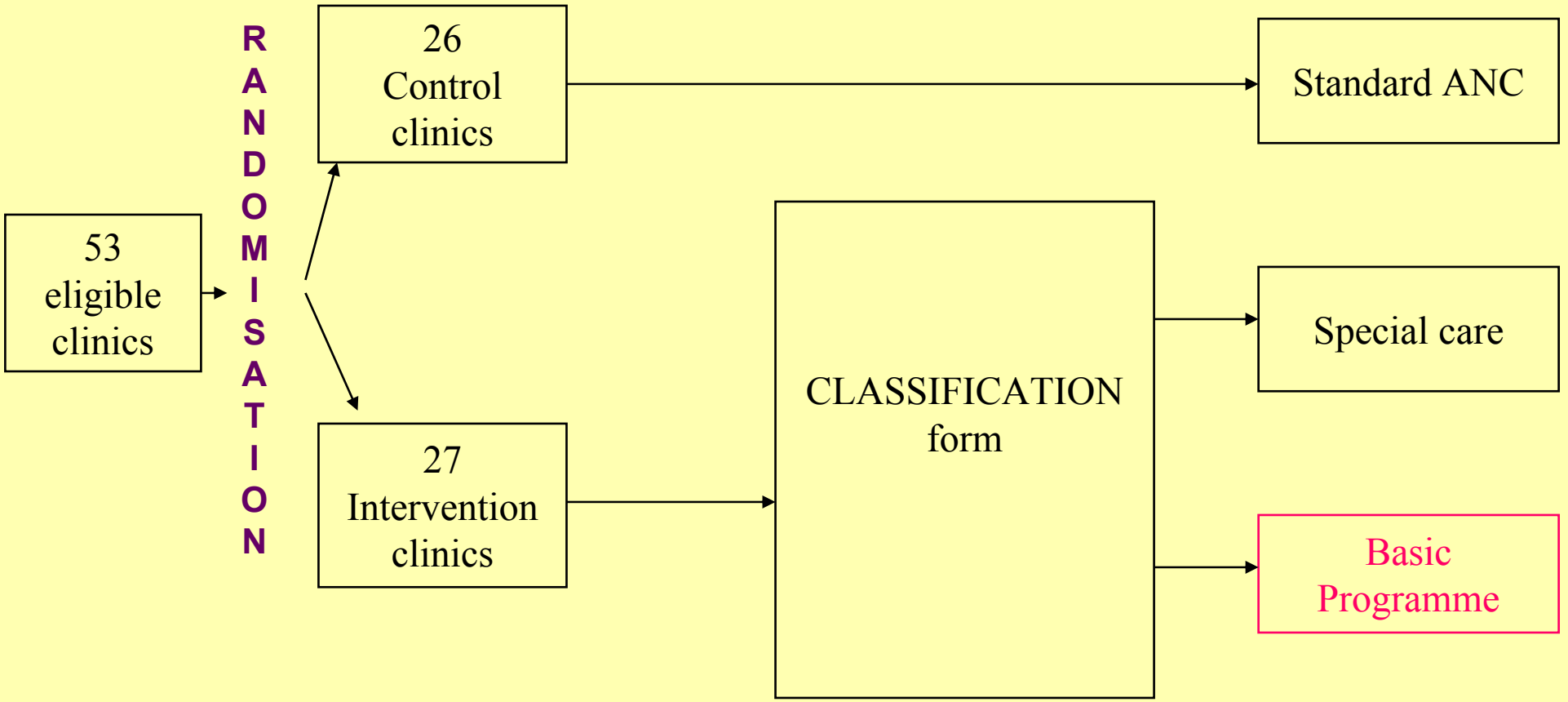
Obstetric history

Medical conditions

Current clinical and laboratory status

Women with all negative responses were considered not to require any further assessment or special care, and eligible for the Basic Programme.

Study Design and Women's Flow Chart



The **Basic Programme** consists of tests, clinical procedures and follow-up actions scientifically demonstrated to be effective in improving maternal and newborn outcomes

The number of visits in the **Basic Programme** is based on the need to perform activities proven to be effective rather than on an a priori fixed number of visits

The Basic Programme

First Visit (<12 weeks)

- Ob/gyn and clinical examination
- Weight/Height
- Blood Pressure
- Rapid syphilis test; treatment of STIs
- Urine test (multiple dipstick)
- Blood type and Rh
- Tetanus toxoid
- Fe/folic acid supplementation
- Recommendations and hot-line for emergencies

The Basic Programme

Second visit (26 weeks) and subsequent visits

- Obstetric exam
- Maternal weight
  (only women with low weight/height at first visit)
- Blood pressure and proteinuria
- Fe/folic acid supplementation
- Recommendations for emergencies

The Basic Programme

Third visit (32 weeks) add to second visit

- Repeat Syphilis test for high-risk populations
- Haemoglobin levels
- Tetanus toxoid (second dose)
- Instructions for delivery
- Recommendations for lactation/contraception

The Basic Programme

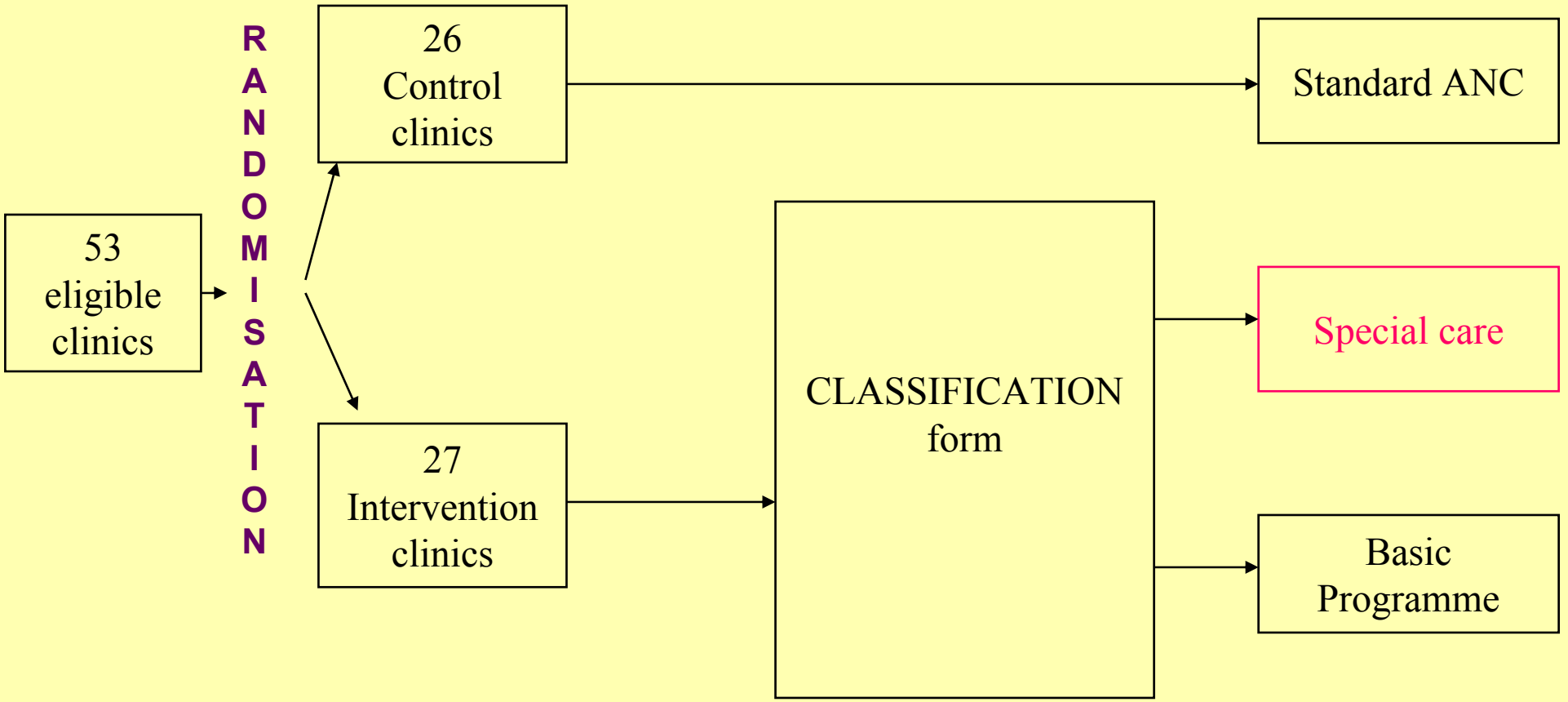
Fourth visit (38 weeks) add to second visit

- Detection of breech and referral for external version
- Instructions for delivery
- Recommendations for lactation/contraception

- Women initiating ANC after 12 weeks received all activities recommended for the previous visits up to the present gestational age.

- Activities relevant only to some populations (malaria, smoking, iodine, HIV, etc.) were to be added as needed.
- Congenital malformations screening
- Early gestational age determination

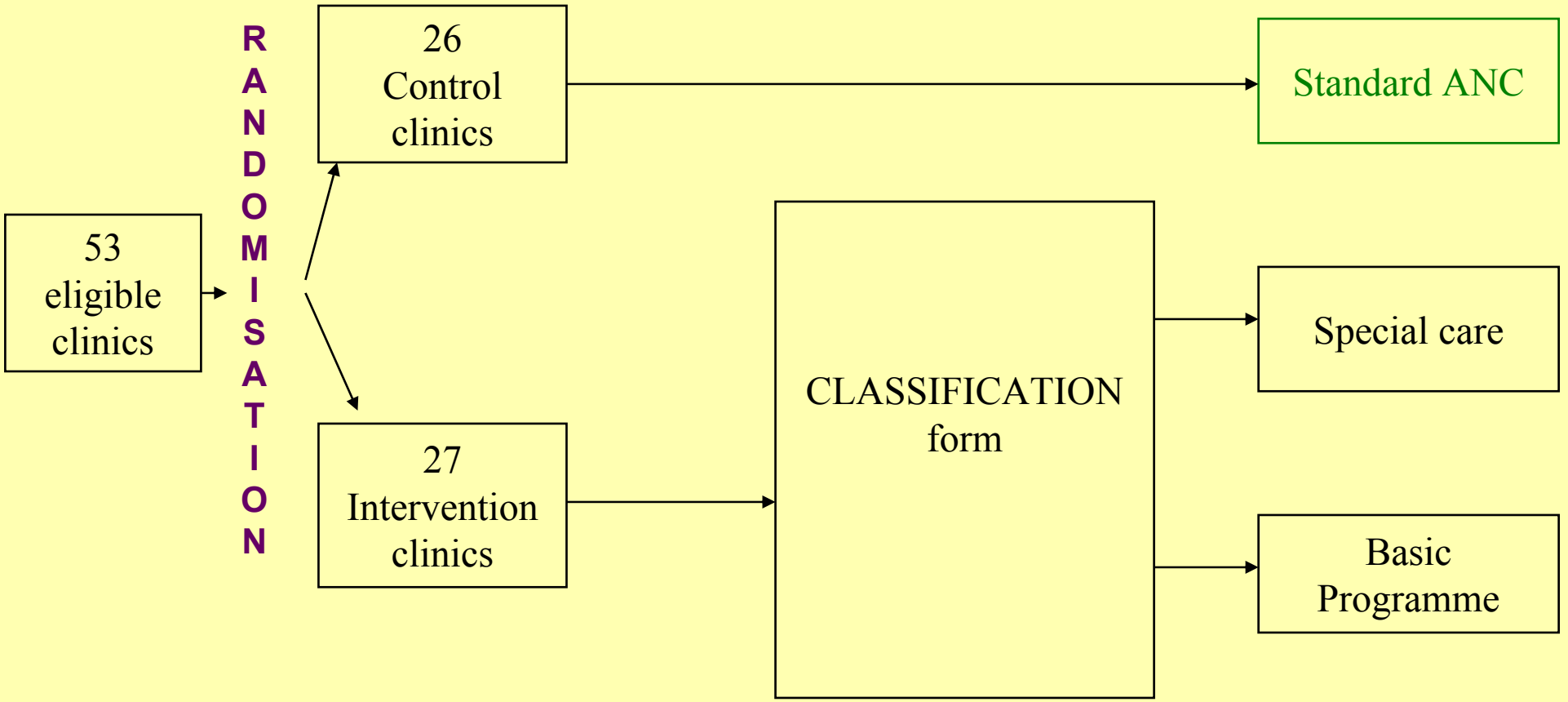
Study Design and Women's Flow Chart



Special Care

Women considered to require further assessment or special care received the protocols used in the study clinics for their condition

Study Design and Women's Flow Chart



Standard ANC

Control clinics followed guidelines formally recommended by the local health authorities based on the "traditional" Western ANC model.

Standard ANC

- Monthly visits during the first six months, one every two-three weeks the next two months and then every week until delivery

- Clinical activities, urinary tests, syphilis screening, haemoglobin and blood group typing were performed routinely

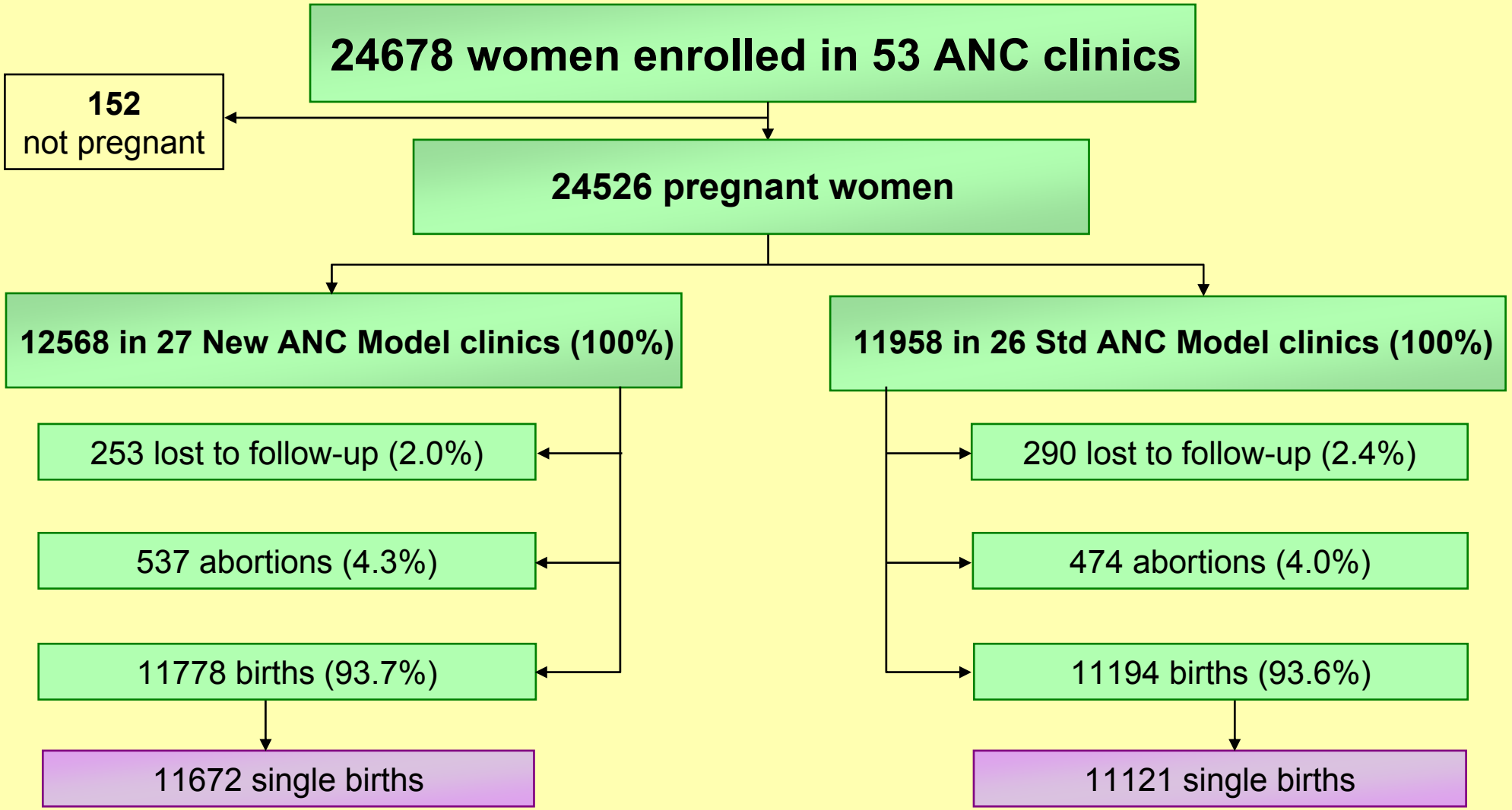
Standard ANC

Clinics in the Standard ANC Model had also available:

- Antenatal cardiotocograph
- Ultrasonographic scanning
- Bacterial culture in urine
- Glucose tolerance test
- High-risk clinic in the same building

Results

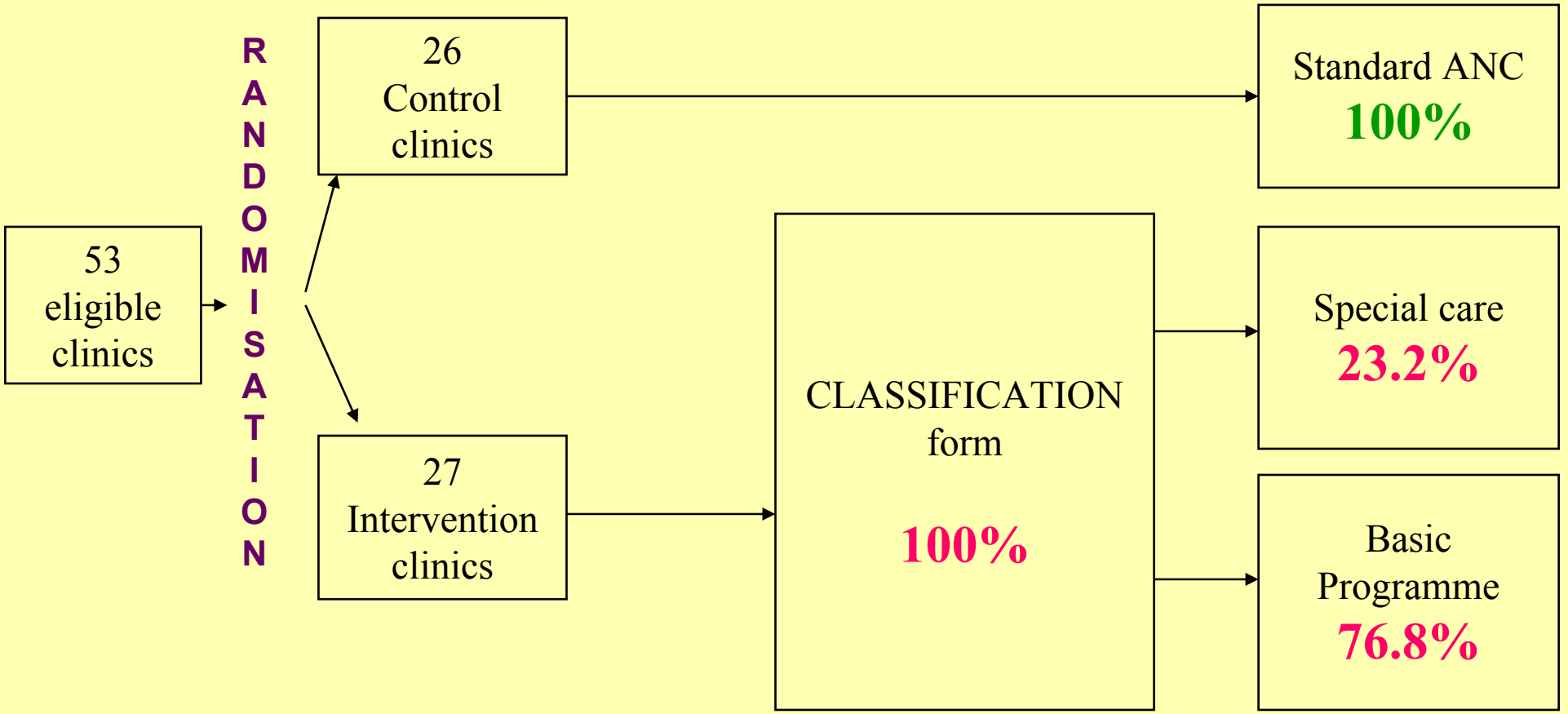
ANC Randomized Controlled Trial: Summary Profile



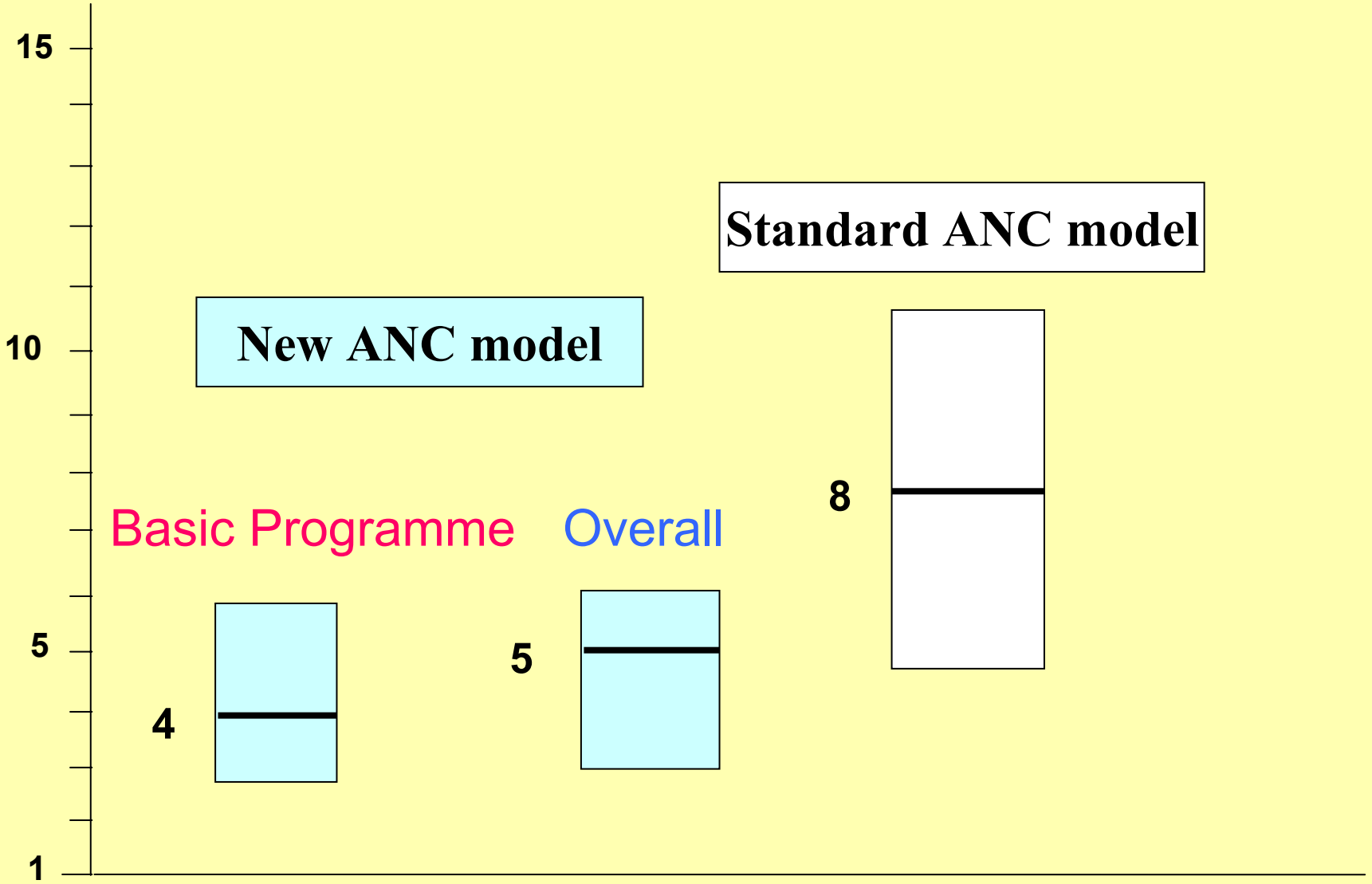
Baseline characteristics

- Clinic characteristics: location, new patients, resources
- Enrolled women: demographic, obstetric-gynecologic history, present pregnancy status
- Gestational age at entry to the trial:
  - New ANC Model: 16.5 ± 8.4 weeks
  - Standard ANC: 16.0 ± 8.0 weeks

Distribution of the study population



Number of Visits by ANC Model



Who was the principal provider of ANC?

(Percentages of women)

	New Model %	Standard Model %
Specialist in Obst.Gynecol	61.7	57.1
General practitioner	18.9	19.0
Midwife	19.1	18.8

The WHO ANC Randomised Controlled Trial
Primary outcomes

	ANC Model	Women N	(%)	Stratified OR	95% CI
Low birth weight (< 2500g)	New Standard	11534 11040	7.68 7.14	1.10	(0.95 to 1.27)
Preeclampsia/eclampsia	New Standard	11672 11121	1.69 1.38	1.22	(0.92 to 1.60)
Postpartum anaemia	New Standard	10720 10050	7.67 8.72	1.02	-
Treated urinary tract infection	New Standard	11672 11121	5.95 7.41	0.90	(0.56 to 1.45)

The WHO ANC Randomised Controlled Trial

Secondary outcomes

	New ANC Model N=11672 %	Standard ANC Model N=11121 %
Pregnancy-induced hypertension	3.4	5.0
Preeclampsia	1.6	1.3
Preeclampsia hospital admission	0.4	0.3
Eclampsia	0.07	0.08
Severe anaemia pregnancy	4.4	3.9
Hypertension with referral/treatment	2.3	3.9
Hypertension without referral/treatment	1.1	1.0
Vaginal bleeding 2nd trimester	0.8	0.5
Vaginal bleeding 3rd trimester	0.7	0.6
Any vaginal bleeding	3.2	2.2

The WHO ANC Randomised Controlled Trial

Secondary outcomes

	New ANC Model N=11672 %	Standard ANC Model N=11121 %
Syphilis postpartum	0.3	0.4
Postpartum hospital stay >= 7 days	3.3	3.4
Caesarean section	14.1	14.1
Assisted vaginal delivery	3.7	3.8
All breech presentation	3.5	3.0
Vaginal breech deliveries	0.5	0.4
Maternal death	0.06	0.05

The WHO ANC Randomised Controlled Trial

Secondary outcomes

	New ANC Model N=11534 %	Standard ANC Model N=11040 %
Small for dates	15.2	15.1
Preterm delivery (<37 weeks)	7.9	7.7
Very low birth weight (<1500g)	1.1	1.0
Medically indicated preterm delivery (<35 weeks)	0.7	0.7
Medically indicated preterm delivery (35-36 weeks)	0.6	0.7
PROM (<35 weeks)	0.7	0.6
PROM (35-36 weeks)	0.6	0.8
Apgar Score 1 minute < 7	3.5	3.2
Apgar Score 5 minutes < 5	0.2	0.2
Admission to neonatal intensive care > 2 days	5.4	6.4

The WHO ANC Randomised Controlled Trial

Secondary outcomes

	New ANC Model N=11672 %	Standard ANC Model N=11121 %
Fetal death	1.4	1.1
Neonatal Mort. (<1st day)	0.3	0.3
Neonatal Mort. (>1st-discharge)	0.4	0.4
Perinatal Mortality	2.0	1.7

The WHO ANC Randomised Controlled Trial

Stratified analysis according to baseline ANC visits:>=12 ANC visits

	New ANC Model	Standard ANC Model
	N=2852 (6 clinics) %	N=2721 (6 clinics) %
	(median ANC visits 6)	(median ANC visits 13)
LBW (<2500g)	7.2	6.7
Preeclampsia/eclampsia	2.0	1.6
Postpartum anaemia	9.4	10.3
Treated UTI	7.2	9.3

The WHO ANC Randomised Controlled Trial

Women's perception and satisfaction (%)

	New ANC Model N=790	Standard ANC Model N=748	Stratified Rate Difference (%) (95%CI)
Number of visits was right	77.6	87.2	-7.9(-16 to 0.2)
Happy with the spacing between visits	73.2	84.0	-8.3 (-16.8 to 0.3)
Happy with waiting time	81.9	82.1	0.7(-7.4 to 8.8)
Time with provider right	86.7	80.1	6.6(-0.5 to 13.7)

The WHO ANC Randomised Controlled Trial

Women's perception and satisfaction (%)

	New ANC Model N=790	Standard ANC Model N=748	Stratified Rate Difference (%) (95%CI)
ANC in this clinic			
Very satisfied	40.5	40.7	0.4 (-8.6 to 9.3)
Satisfied	58.5	57.6	-0.1 (-9.1 to 8.8)
Would you come back next pregnancy	96.7	94.7	1.4 (-2.2 to 4.9)
Would you recommend this clinic	97.4	95.0	1.6 (-1.4 to 4.7)

The WHO ANC Randomised Controlled Trial

Provider's perception

	New ANC Model N= 92 %		Standard ANC Model N=82 %	
Number of visits was right	68.5		64.6	
Time spent with women was right	85.9		69.5	
	Mean	SD	Mean	SD
Information provided (score 0-6)	5.6	0.9	5.2	1.3

WHO Antenatal Care Trial - Conclusions

- The New ANC Model is as effective as the Standard Model
- The New ANC Model is in general well accepted by women and providers, although some women will be concerned about the spacing between visits
- The New ANC Model costs less to women and services

Site	No. of clinics	No. of Women
Rosario City, Argentina	2 large	3461
	15 small	3642
Havana City, Cuba	12 small	6210
Jeddah City, Saudi Arabia	4 medium	1961
	8 small	2510
Khon Kaen Province, Thailand	2 large	1916
	6 medium	3300
	4 small	1526
Total:	**53 Clinics**	**24526**

Rate of severe postpartum anaemia (Hb < 90g/l)

Argentina

	New ANC Model % women	Standard ANC Model % women
Iron supplementation during pregnancy	85.5	20.6
Severe postpartum anaemia	8.8	13.3

Costs to providers and women

Mean difference of the average cost* per pregnancy

	New ANC Model minus Standard ANC Model
Providers' costs	
Cuba	-71.4 (-148.8 to 2.5)
Thailand	-38.9 (-46.3 to -30.9)
Women's costs	
Cuba	-68.0 (-144.0 to 7.7)
Thailand	-6.5 (-10.8 to -2.2)
Women's time in access to care	time / pregnancy (hours)
Cuba	-9.1 (-13.5 to -4.7)
Thailand	-14.9 (-18.0 to -11.8)

* US$ purchasing power parity

Reviews of Routine Antenatal Care

- Scientific basis for the content of ANC. Acta Obstet Gynecol Scand 1997; 76: 1 and 1997; 76: 15. Paediatric and Perinatal Epidemiology, 2001

- Systematic review of all trials evaluating ANC practices. Cochrane Library 2000 No. 3

- Systematic review of women's views about antenatal care.

Effectiveness of the content of Antenatal Care

To treat or prevent:

- IUGR — Obstet Gynecol Survey 1997; 52:139
- Pre-term birth — Obstet Gynecol Survey 1998; 53: 575
- Maternal morbidity — Int J Obstet Gynecol 1998; 63:231