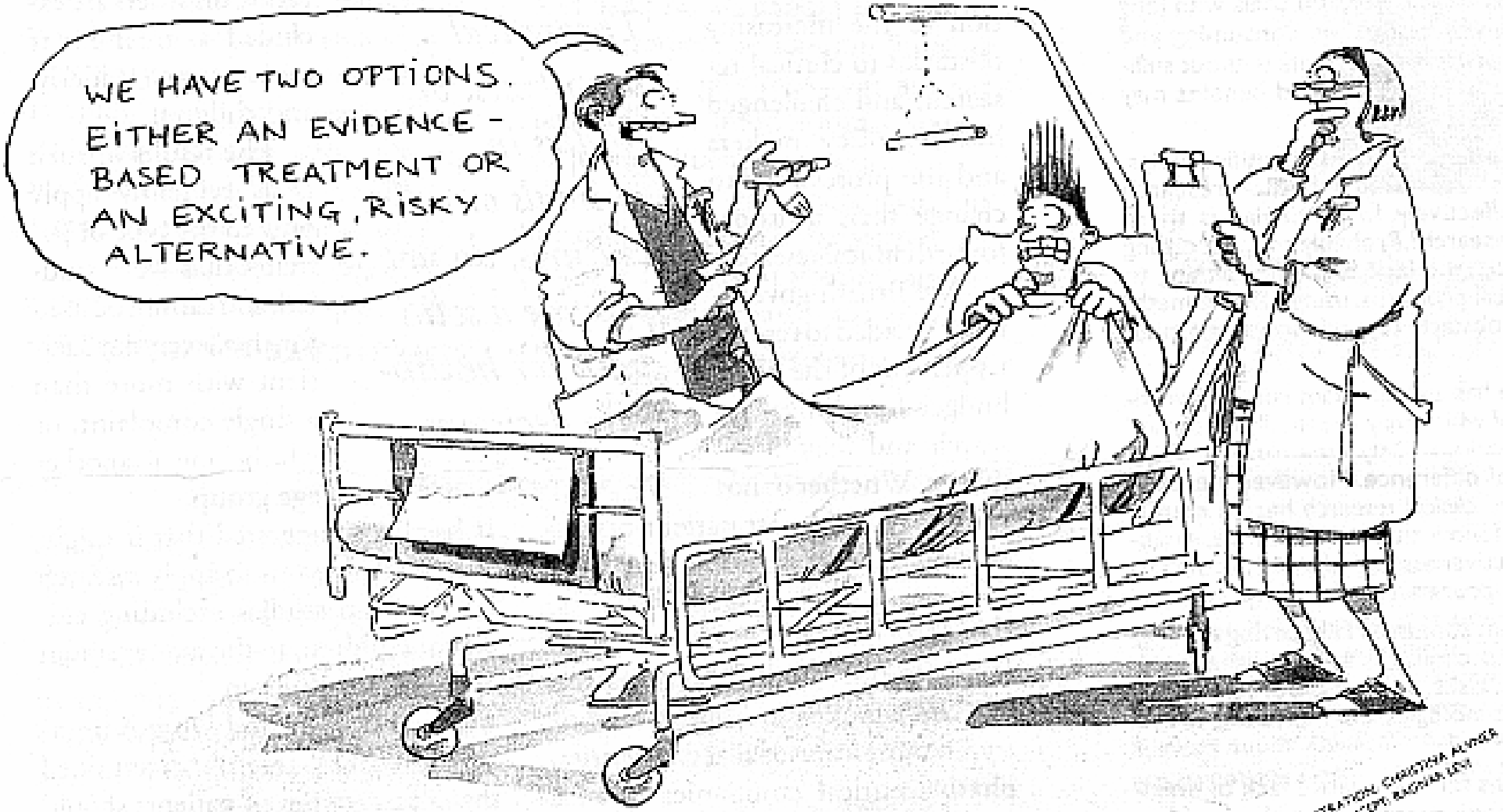
EVIDENCE BASED ANTENATAL CARE

Mario Merialdi

Training in Research in Reproductive Health
Geneva 2005

Faith Versus Facts



"What matters in health care is identifying and using interventions that have been shown by strong research evidence to achieve the best outcomes within available resources for everyone."

Fletcher R, Lancet 1999

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

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

Cochrane, A. *Effectiveness and Efficiency, 1972*

"…the emotive atmosphere should be removed an the subject 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

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

José Villar, Hassan Ba'aqeel, Gilda Piaggio,
Pisake Lumbiganon, José Miguel Belizán, Ubaldo Farnot,
Yagob Al-Mazrou, Guillermo Carroli, Alain Pinol,
Allan Donner, Ana Langer, Gustavo Nigenda,
Miranda Mugford, Julia Fox-Rushby, Guy Hutton,
Per Bergsjø, Leiv Bakketeig and Heinz Berendes†

Review of the literature

- Scientific bases for the content of routine antenatal care. Acta Obstet Gynecol Scand 1997; 76: 1 and 1997; 76: 15. Paediatric and Perinatal Epidemiology, 2001

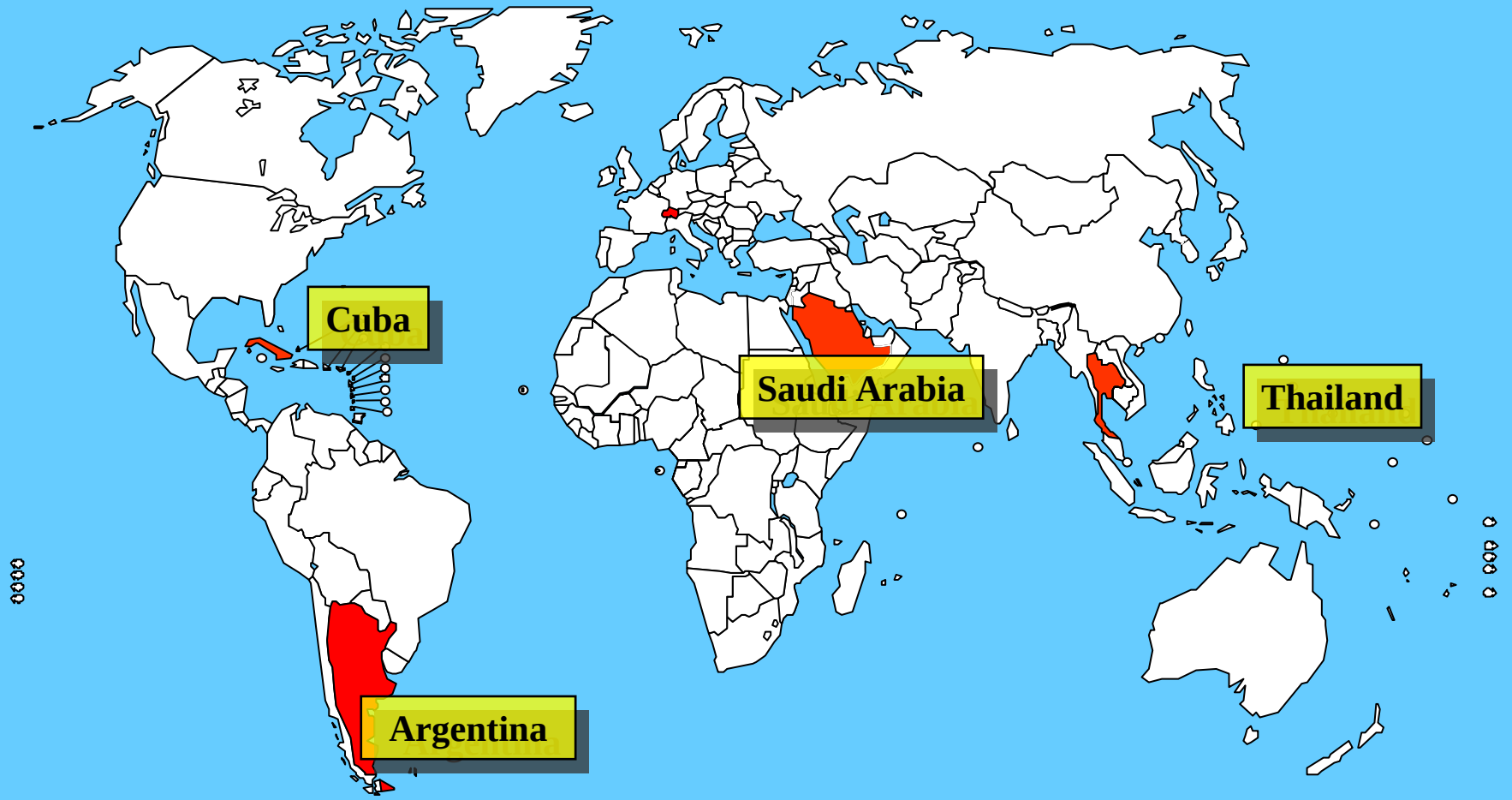
- Systematic review of randomized clinical trials that evaluated the effectiveness of different models of antenatal care. Cochrane Library 2000 No. 3

Hypothesis

A new model of antenatal care based on components shown to improve maternal, perinatal, and neonatal outcomes would be as effective as the traditional package in terms of :

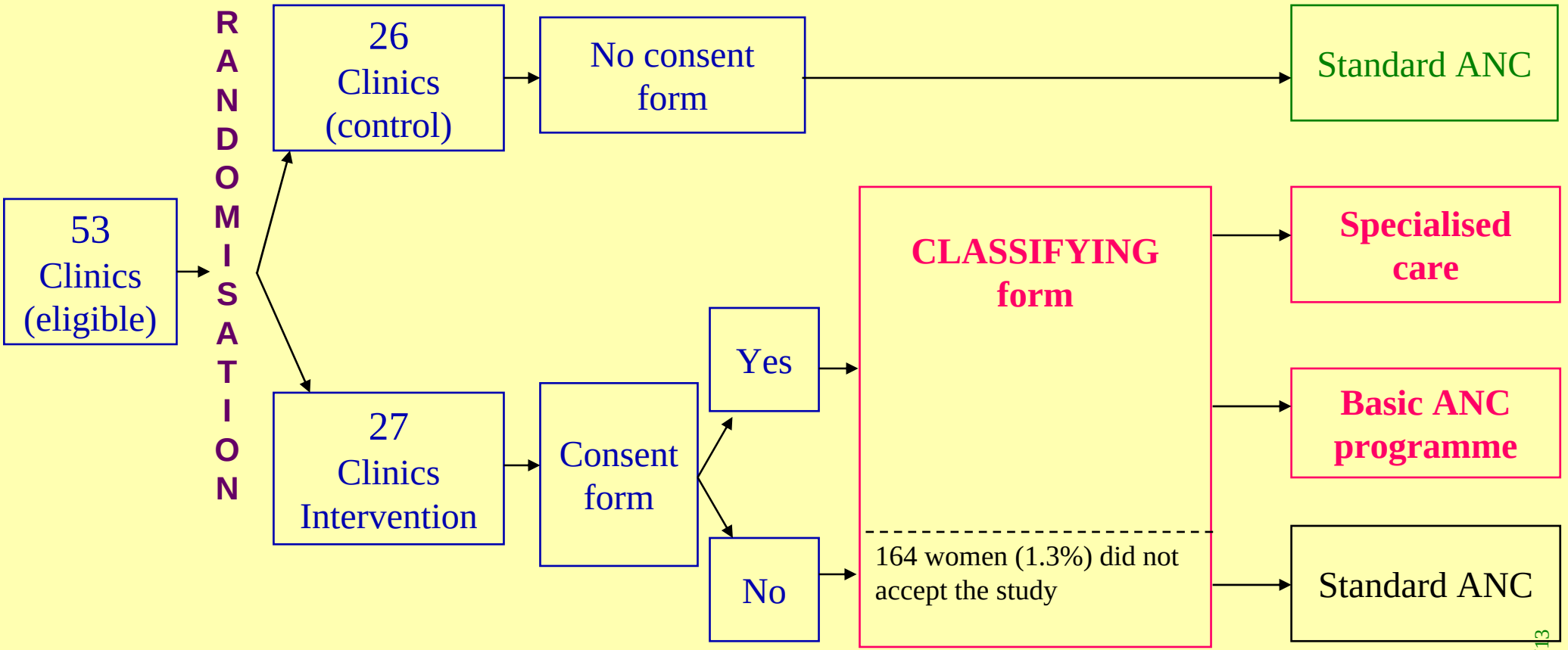
- Low birth weight and maternal morbidity,
- Cost
- Acceptability by women and providers

WHO Collaborating Centres participating in the trial



City	# of clinics	# of women
Rosario, Argentina	2 large	3.461
	15 small	3.642
La Havana, Cuba	12 small	6.210
Jeddah, Saudi Arabia	4 medium	1.961
	8 small	2.510
Khon Kaen Province, Thailand	2 large	1.916
	6 medium	3.300
	4 small	1.526
Total:	**53**	**24.526**

Study design and patient flow



Study population

All women attending prenatal care for the first time after the start of the study at each of the selected clinics, irrespective of the duration of gestation, medical or obstetrics characteristics, or previous antenatal care, were enrolled in the trial.

Study design

- Study design: stratified cluster randomization design
- Unit of randomization: clinics (cluster) within each site randomly assigned to the new or satndard model of care

The new ANC model

At the first antenatal visit to the new model clinics, women were classified as to whether or not they needed further assessment care by means of the classifying form

HRP

WORLD HEALTH ORGANIZATION	STUDY 93043 - ANTENATAL CARE TRIAL CRITERIA FOR CLASSIFYNG WOMEN FOR THE BASIC COMPONENT OF THE NEW PROGRAMME	CLASSIFYING

Name of Subject: _____ Address: _____

Study site: ☐☐ Clinic No: ☐☐ Subject No: ☐☐☐—☐ Clinic Record No: ☐☐☐☐☐☐

INSTRUCTIONS: Answer to all of the following questions by marking corresponding box.

OBSTETRIC HISTORY	NO	YES
1. Previous stillbirth or neonatal loss?	☐	▒
2. Previous 3 or more consecutive spontaneous abortions?	☐	▒
3. Last baby birthweight < 2500g or > than 4500g?	☐	▒
4. Last pregnancy - hospital admission for hypertension or pre-eclampsia/eclampsia?	☐	▒
5. Previous surgery on reproductive tract? -Myomectomy,removal of septum, cone biopsy, classical CS, cervical cerclage	☐	▒

CURRENT PREGNANCY	NO	YES
6. Diagnosed or suspected multiple pregnancy?	☐	▒
7. Age less than 16 or more than 40 years?	☐	▒
8. Iso-immunization Rh (-) in current or in previous pregnancy?	☐	▒
9. Vaginal bleeding?	☐	▒
10. Pelvic mass?	☐	▒
11. Diastolic blood pressure 90mm Hg or more at booking?	☐	▒

JV_FIGO_00/17

The classifying form contained 18 binary responses (yes/no) covering:

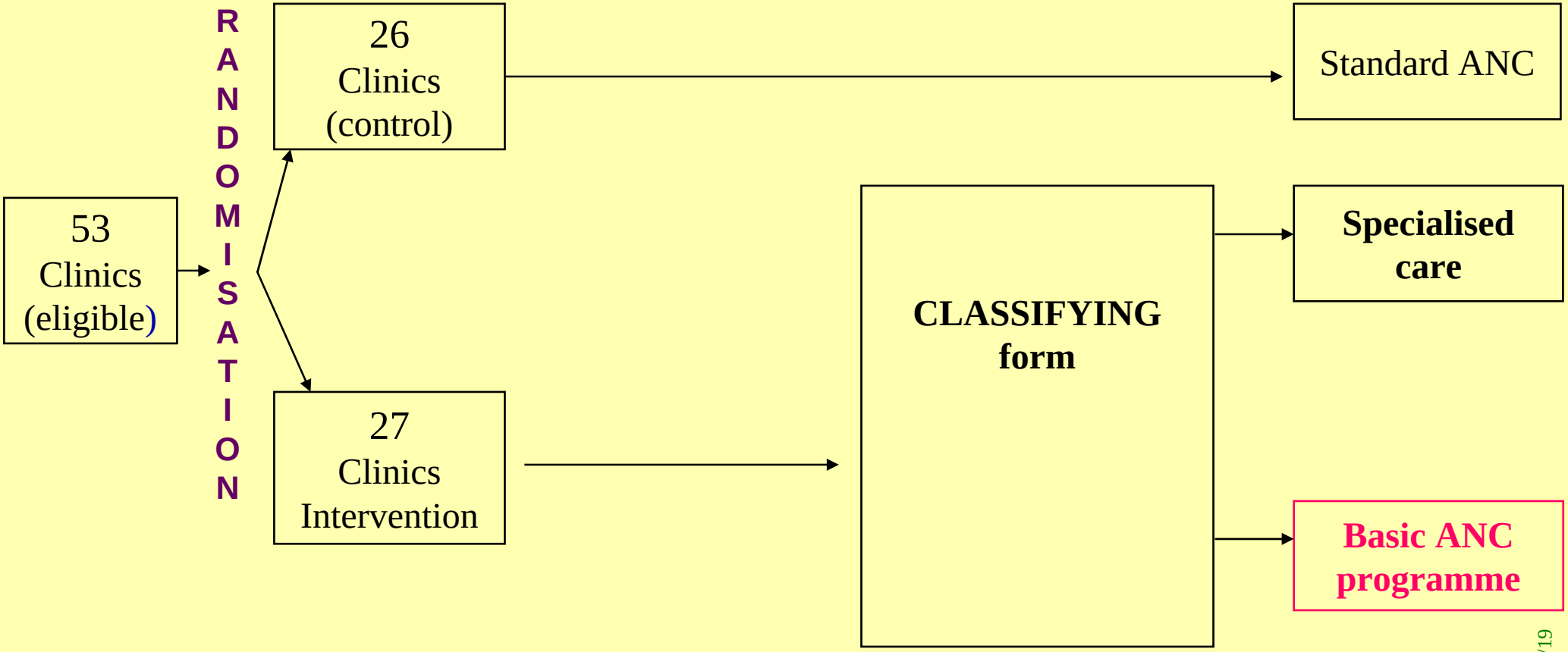
Obstetric history

General medical conditions

Present clinical and laboratory evaluation

Women with a a positive response to at least one of the questions were not eligible for the basic component of the new model.

Study design and patient flow



Activities included in the new basic program

1. Screening for health conditions likely to increase the risk of specific adverse outcomes.

2. Therapeutic interventions known to be beneficial.

3. Alerting pregnant women to emergencies and instructing them on appropriate responses.

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

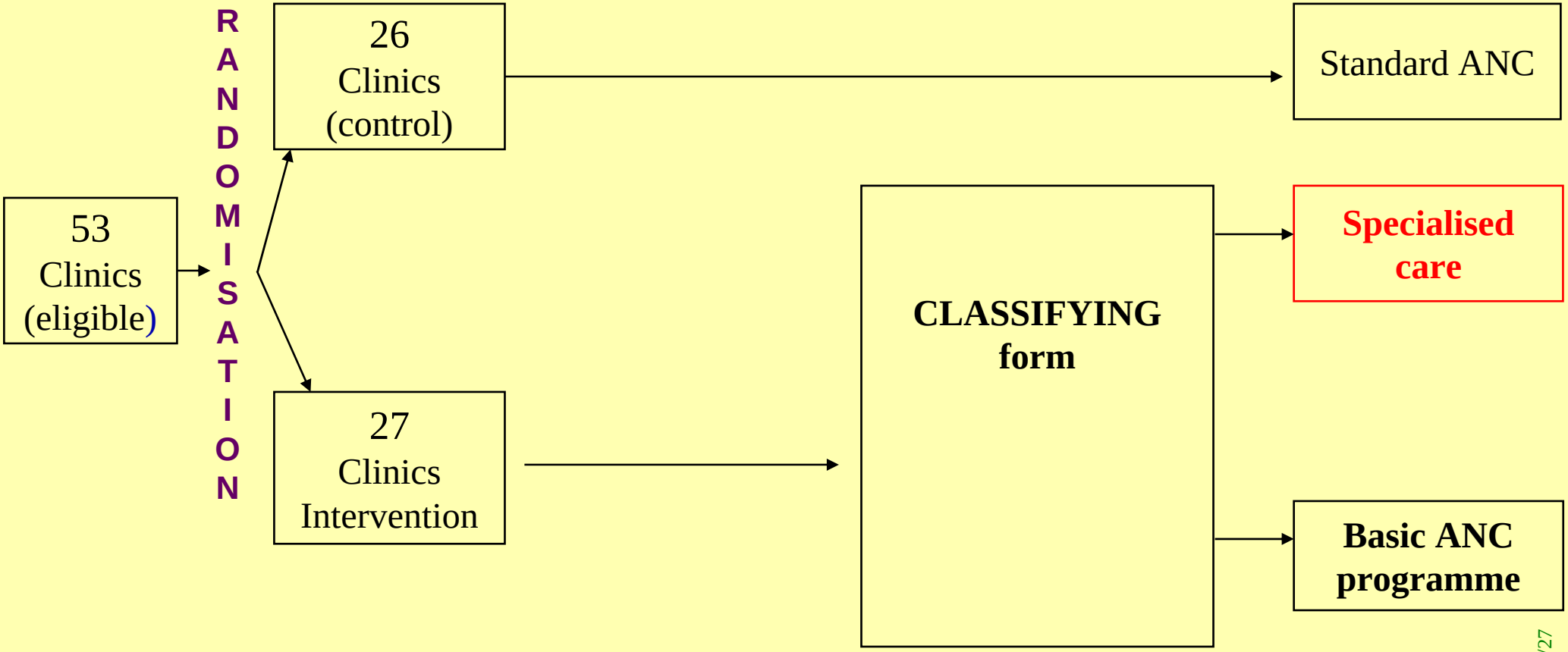
- Repeat Syphilis test for high-risk populations
- Haemoglobin level
- Tetanus toxoid (second dose)
- Instructions for delivery
- Recommendations for lactation/contraception

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

Study design and patient flow



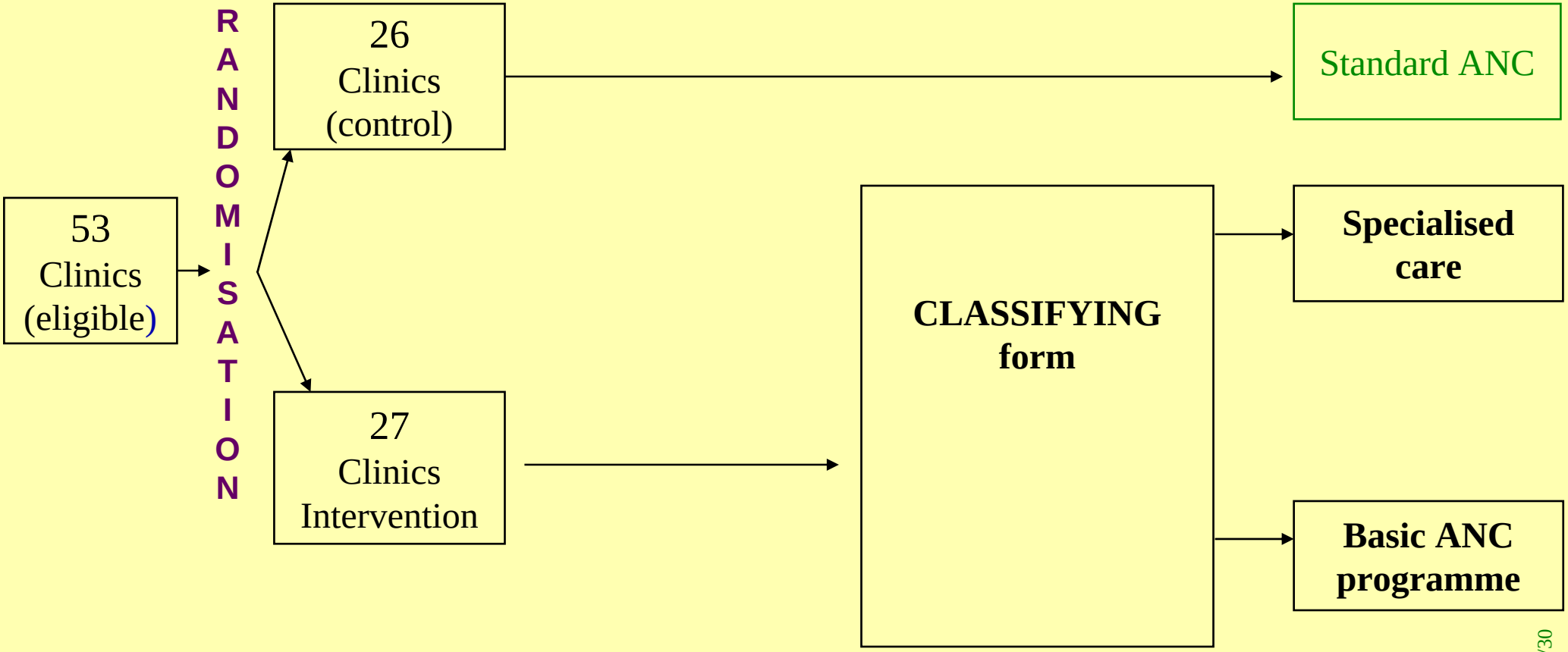
Special Care

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

- 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.

Study design and patient flow



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

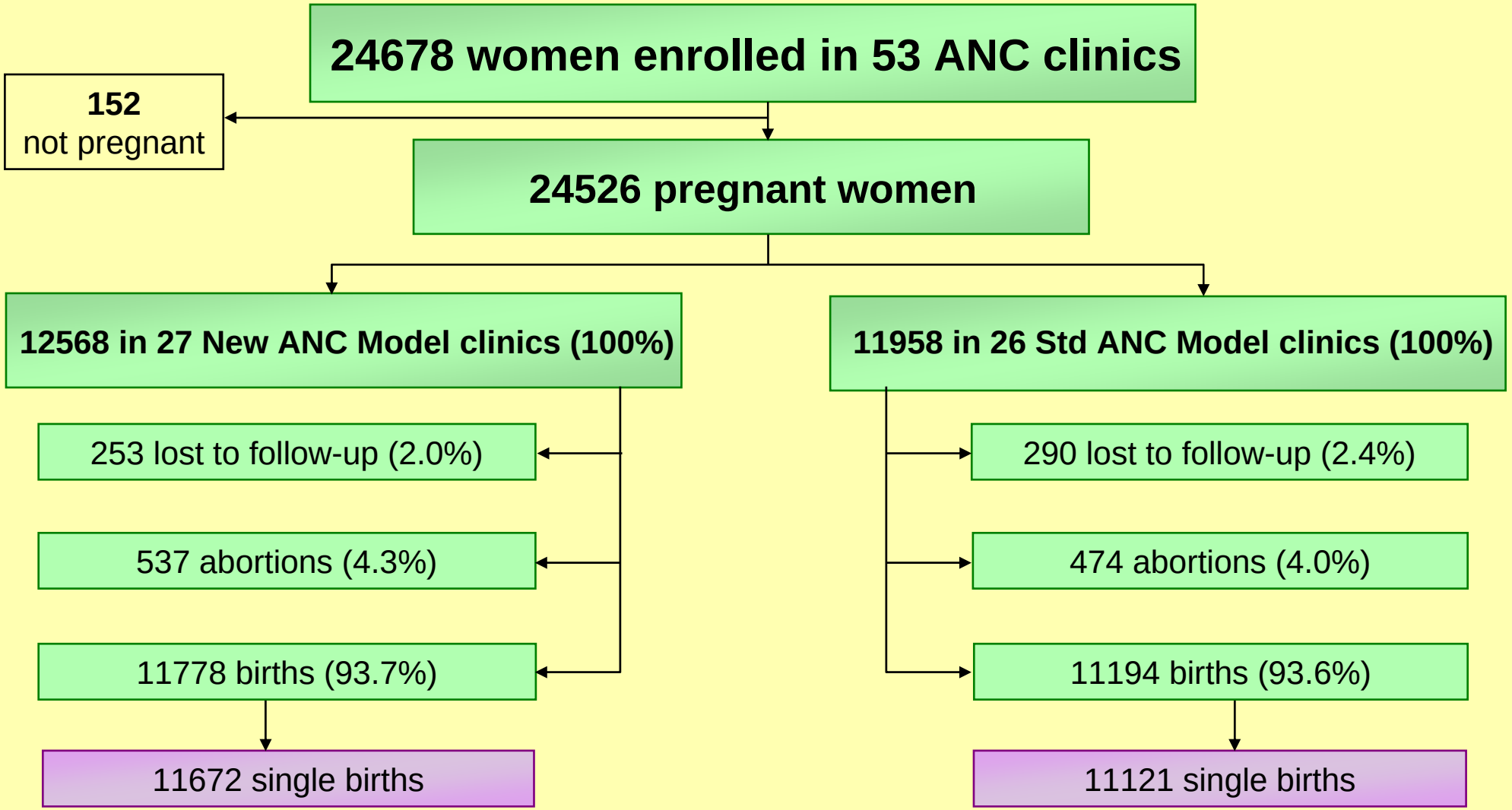
Standard ANC

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

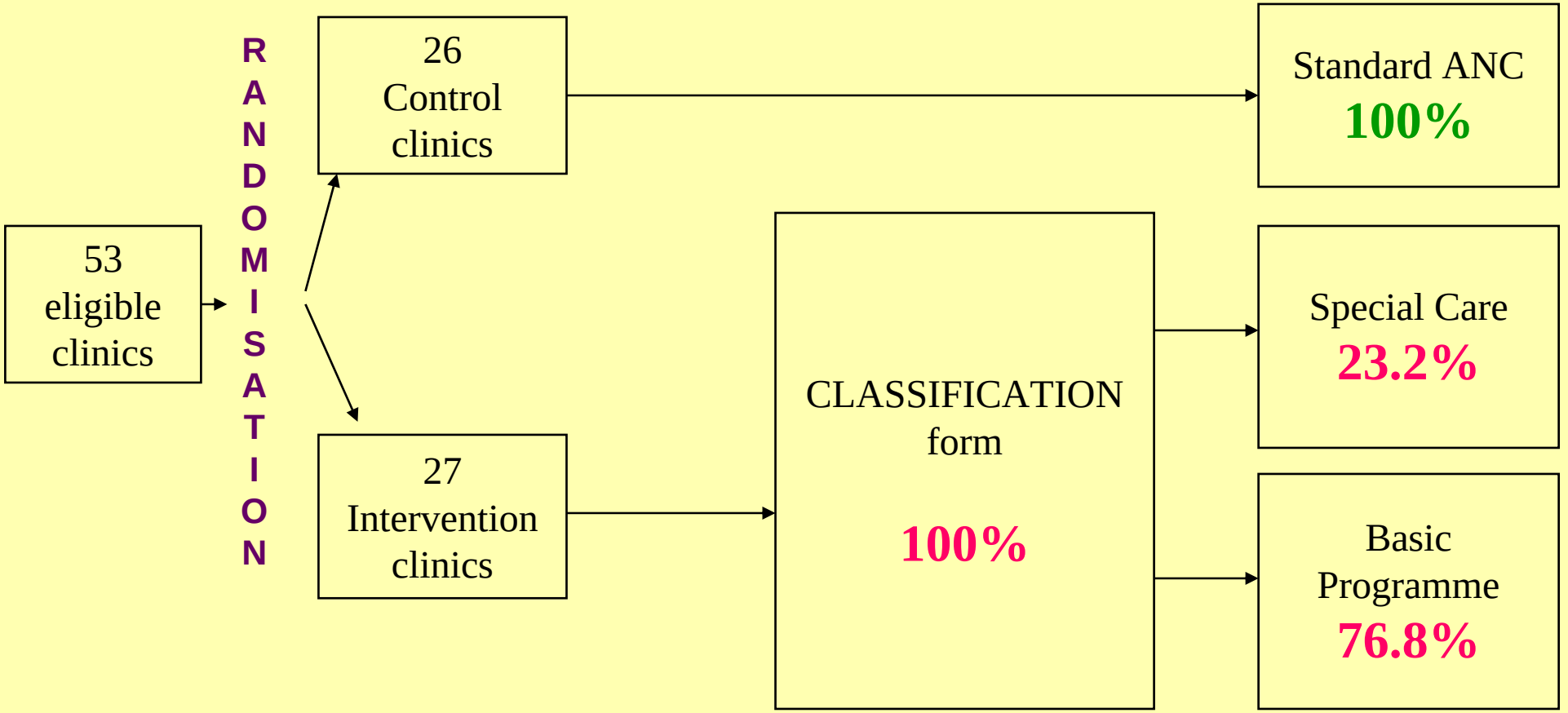
ANC Randomized Controlled Trial: Summary Profile



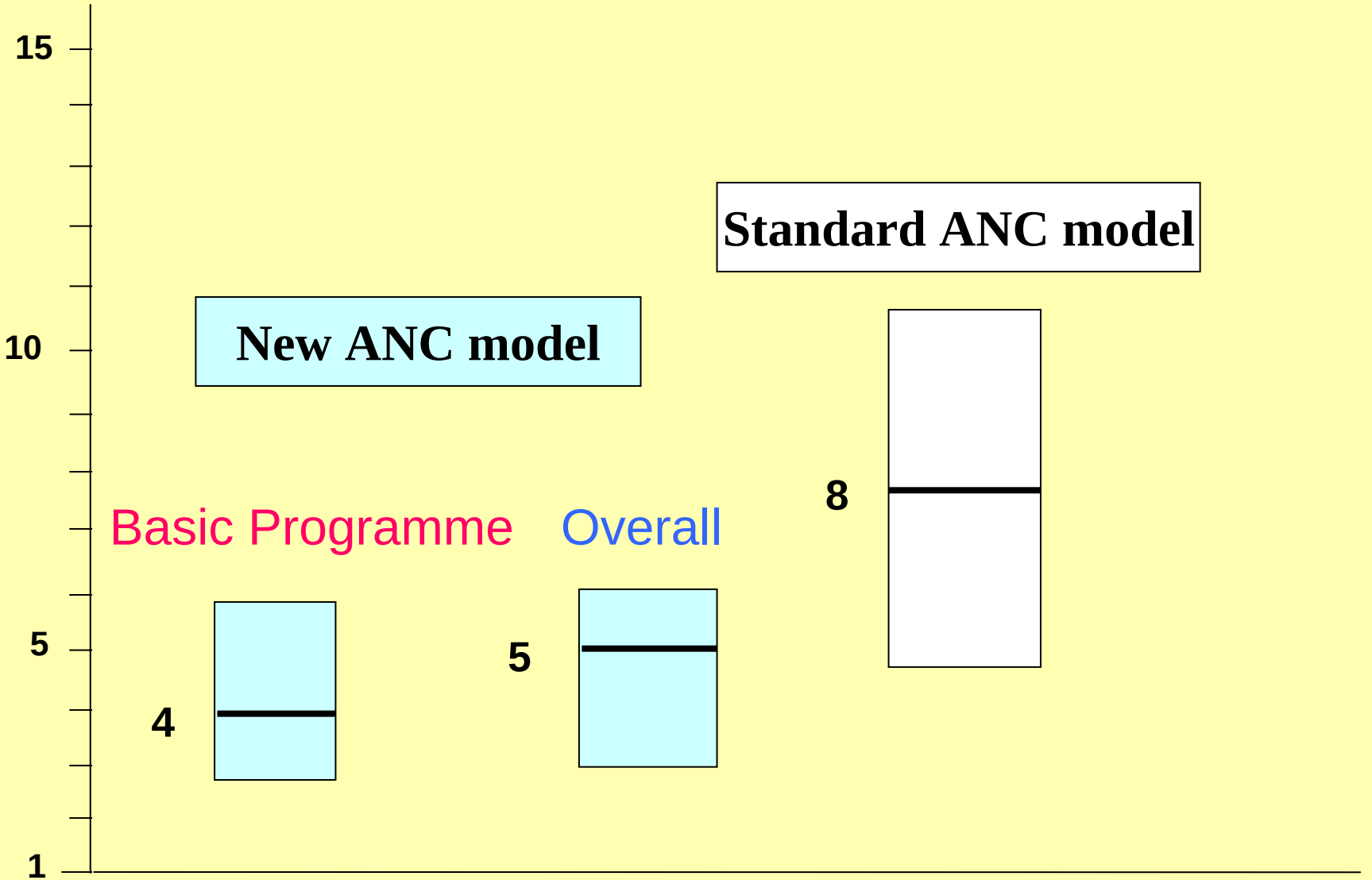
Baseline characteristics

- Clinic characteristics: location, new patients, resources
- Enrolled women: demographic, obstetric-gynaecologic 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

Primary outcomes

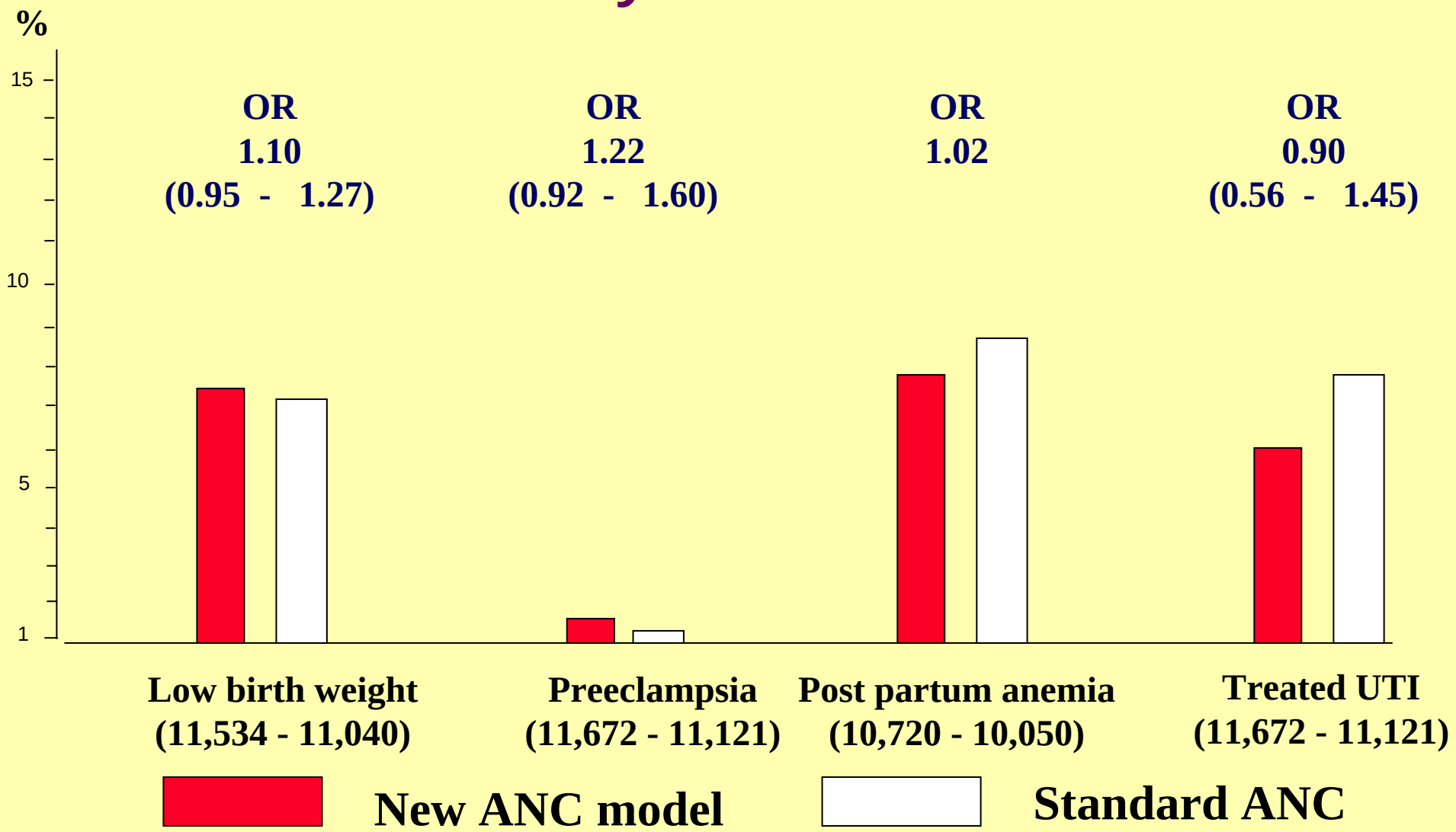
- Maternal morbidity:
  - ***Preeclampsia.***
  - ***Eclampsia***
  - ***Severe anemia***
  - ***Treated urinay tract infection***

- Low birth weight (<2500g)

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)

Primary Outcomes



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

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

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

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

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

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

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

WHO Antenatal Care Trial -Conclusions-

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

WHO Recommendations

For populations with low ANC coverage

- Extend coverage to all pregnant women with the new ANC
- Special care for women with complications should be always availabe

For populations which are already receiving standard ANC

- Evaluate the evidence base of each activity which is performed
- If appropriate, develop a simple model with less visit

From Research to Practice