Evidence Based Antenatal Care

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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

53 eligible clinics

Randomisation

26 Control clinics
Do not seek consent
Standard ANC

27 Intervention clinics
Seek consent
New ANC model
Yes
New ANC model
No
Study Design and Women’s Flow Chart

53 eligible clinics

26 Control clinics

Do not seek consent

Standard ANC

27 Intervention clinics

Seek consent

CLASSIFICATION form

Yes

Special care

No

Basic Programme

164 women (1.3%) did not agree to participate

Standard ANC
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

53 eligible clinics

26 Control clinics

27 Intervention clinics

26
Control clinics

Standard ANC

Special care

Basic Programme

53 eligible clinics

CLASSIFICATION form
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

Randomisation

53 eligible clinics

26 Control clinics → Standard ANC

27 Intervention clinics → Special care

Classification form

Basic Programme
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

53 eligible clinics

26 Control clinics

27 Intervention clinics

CLASSIFICATION form

Standard ANC

Special care

Basic Programme
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

24678 women enrolled in 53 ANC clinics

152 not pregnant

24526 pregnant women

12568 in 27 New ANC Model clinics (100%)

253 lost to follow-up (2.0%)

537 abortions (4.3%)

11778 births (93.7%)

11672 single births

11958 in 26 Std ANC Model clinics (100%)

290 lost to follow-up (2.4%)

474 abortions (4.0%)

11194 births (93.6%)

11121 single births
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

53 eligible clinics

26 Control clinics

27 Intervention clinics

CLASSIFICATION form

100%

Standard ANC
100%

Special care
23.2%

Basic Programme
76.8%
Number of Visits by ANC Model

- Basic Programme: 4 visits
- New ANC model: 5 visits
- Standard ANC model: 8 visits
- Overall: 5 visits
## Who was the principal provider of ANC?

(Percentages of women)

<table>
<thead>
<tr>
<th></th>
<th>New Model</th>
<th>Standard Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialist in Obst. Gynecol</td>
<td>61.7</td>
<td>57.1</td>
</tr>
<tr>
<td>General practitioner</td>
<td>18.9</td>
<td>19.0</td>
</tr>
<tr>
<td>Midwife</td>
<td>19.1</td>
<td>18.8</td>
</tr>
</tbody>
</table>
The WHO ANC Randomised Controlled Trial
Primary outcomes

<table>
<thead>
<tr>
<th></th>
<th>ANC Model</th>
<th>Women N</th>
<th>(%)</th>
<th>Stratified OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Low birth weight (&lt; 2500g)</strong></td>
<td>New Standard</td>
<td>11534</td>
<td>7.68</td>
<td>1.10</td>
<td>(0.95 to 1.27)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>11040</td>
<td>7.14</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Preeclampsia/eclampsia</strong></td>
<td>New Standard</td>
<td>11672</td>
<td>1.69</td>
<td>1.22</td>
<td>(0.92 to 1.60)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>11121</td>
<td>1.38</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Postpartum anaemia</strong></td>
<td>New Standard</td>
<td>10720</td>
<td>7.67</td>
<td>1.02</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10050</td>
<td>8.72</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Treated urinary tract infection</strong></td>
<td>New Standard</td>
<td>11672</td>
<td>5.95</td>
<td>0.90</td>
<td>(0.56 to 1.45)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>11121</td>
<td>7.41</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Rate of severe postpartum anaemia (Hb < 90g/l)

#### Argentina

<table>
<thead>
<tr>
<th></th>
<th>New ANC Model</th>
<th>Standard ANC Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron supplementation</td>
<td>85.5% women</td>
<td>20.6% women</td>
</tr>
<tr>
<td>during pregnancy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe postpartum</td>
<td>8.8% women</td>
<td>13.3% women</td>
</tr>
<tr>
<td>anaemia</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### The WHO ANC Randomised Controlled Trial

#### Secondary outcomes

<table>
<thead>
<tr>
<th>Event</th>
<th>New ANC Model N=11534 %</th>
<th>Standard ANC Model N=11040 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small for dates</td>
<td>15.2</td>
<td>15.1</td>
</tr>
<tr>
<td>Preterm delivery (&lt;37 weeks)</td>
<td>7.9</td>
<td>7.7</td>
</tr>
<tr>
<td>Very low birth weight (&lt;1500g)</td>
<td>1.1</td>
<td>1.0</td>
</tr>
<tr>
<td>Medically indicated preterm delivery (&lt;35 weeks)</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Medically indicated preterm delivery (35-36 weeks)</td>
<td>0.6</td>
<td>0.7</td>
</tr>
<tr>
<td>PROM (&lt;35 weeks)</td>
<td>0.7</td>
<td>0.6</td>
</tr>
<tr>
<td>PROM (35-36 weeks)</td>
<td>0.6</td>
<td>0.8</td>
</tr>
<tr>
<td>Apgar Score 1 minute &lt; 7</td>
<td>3.5</td>
<td>3.2</td>
</tr>
<tr>
<td>Apgar Score 5 minutes &lt; 5</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Admission to neonatal intensive care &gt; 2 days</td>
<td>5.4</td>
<td>6.4</td>
</tr>
</tbody>
</table>
### The WHO ANC Randomised Controlled Trial

**Secondary outcomes**

<table>
<thead>
<tr>
<th></th>
<th>New ANC Model N=11672 %</th>
<th>Standard ANC Model N=11121 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fetal death</td>
<td>1.4</td>
<td>1.1</td>
</tr>
<tr>
<td>Neonatal Mort. (&lt;1(^{st}) day)</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td>Neonatal Mort. (&gt;1(^{st})-discharge)</td>
<td>0.4</td>
<td>0.4</td>
</tr>
<tr>
<td>Perinatal Mortality</td>
<td>2.0</td>
<td>1.7</td>
</tr>
</tbody>
</table>
## The WHO ANC Randomised Controlled Trial
### Stratified analysis according to baseline ANC visits: >=12 ANC visits

<table>
<thead>
<tr>
<th></th>
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<th>Standard ANC Model</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=2852 (6 clinics)</td>
<td>N=2721 (6 clinics)</td>
</tr>
<tr>
<td>LBW (&lt;2500g)</td>
<td>7.2%</td>
<td>6.7%</td>
</tr>
<tr>
<td>Preeclampsia/eclampsia</td>
<td>2.0%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Postpartum anaemia</td>
<td>9.4%</td>
<td>10.3%</td>
</tr>
<tr>
<td>Treated UTI</td>
<td>7.2%</td>
<td>9.3%</td>
</tr>
</tbody>
</table>

*(median ANC visits 6)*

*(median ANC visits 13)*
# The WHO ANC Randomised Controlled Trial

## Women’s perception and satisfaction (%)

<table>
<thead>
<tr>
<th></th>
<th>New ANC Model N=790</th>
<th>Standard ANC Model N=748</th>
<th>Stratified Rate Difference (%) (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of visits was right</td>
<td>77.6</td>
<td>87.2</td>
<td>-7.9 (-16 to 0.2)</td>
</tr>
<tr>
<td>Happy with the spacing between visits</td>
<td>73.2</td>
<td>84.0</td>
<td>-8.3 (-16.8 to 0.3)</td>
</tr>
<tr>
<td>Happy with waiting time</td>
<td>81.9</td>
<td>82.1</td>
<td>0.7 (-7.4 to 8.8)</td>
</tr>
<tr>
<td>Time with provider right</td>
<td>86.7</td>
<td>80.1</td>
<td>6.6 (-0.5 to 13.7)</td>
</tr>
</tbody>
</table>
# The WHO ANC Randomised Controlled Trial

Women’s perception and satisfaction (%)

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<tbody>
<tr>
<td></td>
<td>N=790</td>
<td>N=748</td>
<td></td>
</tr>
<tr>
<td>ANC in this clinic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very satisfied</td>
<td>40.5</td>
<td>40.7</td>
<td>0.4 (-8.6 to 9.3)</td>
</tr>
<tr>
<td>Satisfied</td>
<td>58.5</td>
<td>57.6</td>
<td>-0.1 (-9.1 to 8.8)</td>
</tr>
<tr>
<td>Would you come back next pregnancy</td>
<td>96.7</td>
<td>94.7</td>
<td>1.4 (-2.2 to 4.9)</td>
</tr>
<tr>
<td>Would you recommend this clinic</td>
<td>97.4</td>
<td>95.0</td>
<td>1.6 (-1.4 to 4.7)</td>
</tr>
</tbody>
</table>
## The WHO ANC Randomised Controlled Trial
### Provider’s perception

<table>
<thead>
<tr>
<th></th>
<th>New ANC Model</th>
<th>Standard ANC Model</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N= 92%</td>
<td>N= 82%</td>
</tr>
<tr>
<td>Number of visits was right</td>
<td>68.5</td>
<td>64.6</td>
</tr>
<tr>
<td>Time spent with women was right</td>
<td>85.9</td>
<td>69.5</td>
</tr>
<tr>
<td>Information provided (score 0-6)</td>
<td>Mean 5.6, SD 0.9</td>
<td>Mean 5.2, SD 1.3</td>
</tr>
</tbody>
</table>
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
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
Antenatal Care: From Research to Action

Preventing postpartum haemorrhage: From Research to Action

WHO Programme to Map Best Reproductive Health Practices

UNDP / UNFPA / WHO / WORLD BANK