Getting pregnant in antiretroviral clinical trials: women choice and safety needs. Experience from the ANRS12169-2LADY and ANRS12286-MOBIDIP trials.

Serris A¹, Toby R², Mpoudi Ngolle M³, Abessolo Abessolo H², Le Gac S⁴, Zoungrana J⁵, Diallo M⁶, Cournil A¹, De Beaudrap P⁷, Koulla-Shiro S²,⁸, Delaporte E¹,⁹, Ciaffi L¹.
Introduction

Pregnancy = non-inclusion criteria in most clinical trials involving ART

Even if contraception methods is systematically proposed to women, pregnancies are often observed.

• **Objective**: describe reproductive behavior and pregnancy outcomes among HIV-infected women on second line ART enrolled in two clinical trials and compare them with those of HIV-positive women in non-research settings.
Methods

- Number and outcomes of pregnancies recorded among 282 non menopausal women enrolled in ANRS 12169-2LADY and ANRS 12286-MOBIDIP Cameroon, Senegal and Burkina Faso.

- All participants agreed to use at least one contraceptive method provided freely during the study.

- Data collected through revision of notification forms and by data extraction from the study database.
## Results

<table>
<thead>
<tr>
<th>Study Population</th>
<th>Number of women</th>
<th>Number of pregnancies</th>
<th>Pregnancy rate per 100 WY (IC 95%)</th>
<th>Number of live births</th>
<th>Fertility rate per 100 WY (IC 95%)</th>
<th>General population fertility rate* (Urban pop: 30 - 34 yrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cameroon</td>
<td>179</td>
<td>48</td>
<td>7.49 (5.64-9.93)</td>
<td>33</td>
<td>5.15 (3.66-7.24)</td>
<td>17.8 (16.4)</td>
</tr>
<tr>
<td>Burkina Faso</td>
<td>59</td>
<td>17</td>
<td>7.88 (4.90-12.68)</td>
<td>10</td>
<td>4.64 (2.50-8.62)</td>
<td>20.6 (18)</td>
</tr>
<tr>
<td>Senegal</td>
<td>47</td>
<td>19</td>
<td>10.03 (6.40-15.73)</td>
<td>11</td>
<td>5.81 (3.22-10.49)</td>
<td>17.2 (18.9)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>285</strong></td>
<td><strong>84</strong></td>
<td><strong>8.03 (6.48-9.94)</strong></td>
<td><strong>54</strong></td>
<td><strong>5.16 (3.95-6.74)</strong></td>
<td></td>
</tr>
</tbody>
</table>

* Source: DHS Cameroon, Burkina Faso and Senegal
Results and discussion

• Despite the initial engagements women in clinical trial have the same reproductive behavior than HIV positive women in program settings

• Among 54 live births, 8 (14.8%) were born prematurely and 7 (13%) had a low birth weight.

• Sixteen miscarriage/stillbirths occurred (21%)=> comparable to general population

→ Pregnancy interdiction in CT should be based on risk evaluation

→ Prohibition of procreation can be a barrier to the inclusion of women , depriving them of access to research