Pregnancy & reproductive health updates/conundrums

Chair: Dr Rebecca Metcalfe

Co-chairs: Rebecca Mwebe
Pregnancy & breastfeeding update

Dr Laura Byrne
St George’s University Hospitals NHS Foundation Trust
In relation to this presentation I declare that I have no conflict of interest.
Pregnancy & breastfeeding update

- Epidemiology in the UK
- Conceiving on ART
- Other pregnancy outcomes
- Infant feeding
Epidemiology

• Universal antenatal HIV screening was introduced in England/UK in 2000 - 2002
• Uptake has exceeded 97% since 2011
• ISOSS (prev NSHPC) collects data on all diagnosed women who become pregnant, and their children
• Currently around 1000-1200 pregnancies py (85% live births)
## Epidemiology

### Maternal demographics, early 2000s and now (UK)

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>London</td>
<td>62.5%</td>
<td>37.5%</td>
</tr>
<tr>
<td>Rest of England</td>
<td>33.8%</td>
<td>56.3%</td>
</tr>
<tr>
<td>Scotland</td>
<td>2.8%</td>
<td>3.4%</td>
</tr>
<tr>
<td>Wales / N. Ireland</td>
<td>1.0%</td>
<td>2.7%</td>
</tr>
</tbody>
</table>

| Median Age (years)       | 29      | 34      |
| IDU-acquired HIV         | 2.6%    | 1.1%    |
| Perinatal HIV            | 0.03%   | 2.9%    |
| Sub-Saharan Africa-born  | 77.2%   | 67.1%   |
| Eastern Europe*-born     | 0.3%    | 6.1%    |

* Includes the Baltic states (Estonia, Latvia, Lithuania)

Source: pregnancies reported through ISOSS maternity scheme by June 2021
Epidemiology

Timing of diagnosis & ART at conception, UK 1998-2019

Conception on ART
20.3% in 2000-2004
75.5% in 2015-2019

* contains pregnancies lacking information on precise timing of diagnosis and/or ART use

UK pregnancies (all outcomes) reported to ISOSS by June 2021
In 2012-14 among the 87% of women delivering with suppressed virus the VT rate was 0.14%
Data gap

Importance of prospective studies in pregnant and breastfeeding women living with HIV. Angela Colbers et al, CID Feb 2019
Tania

→ 27 year old woman with PHIV
→ Longstanding adherence difficulties

→ TAF/FTC + DTG 50mg od
→ VL < 50 c/ml, CD4 201 cells/micL
→ No resistance

→ Period 5 days late
→ PT positive in clinic

→ Older son aged 3, HIV-
→ Difficult relationship with partner, live separately
→ 1 bedroom flat
→ Working part-time

→ Prev severe N&V in pregnancy
→ Prev CS with son at 39/40 (VL 500 c/ml)
→ Formula fed older son

Should I switch my ART?
TAF in pregnancy: pharmacokinetics

IMPAACT 1026s

→ boosted TAF ($n=31$) similar levels to postpartum / non-pregnant

→ un-boosted TAF ($n=27$) (25mg) lower AUC antepartum vs. postpartum
  but similar to non-pregnant

Brooks et al AIDS 2021
TAF in pregnancy: teratogenicity

<table>
<thead>
<tr>
<th>Drug</th>
<th>Defects/Live Births</th>
<th>Prevalence (%)</th>
<th>Lower 95% CI</th>
<th>Upper 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lamivudine</td>
<td>170/5472</td>
<td>3.11</td>
<td>2.68</td>
<td>3.60</td>
</tr>
<tr>
<td>Tenofovir DF</td>
<td>113/4576</td>
<td>2.47</td>
<td>2.04</td>
<td>2.96</td>
</tr>
<tr>
<td>Zidovudine</td>
<td>136/4229</td>
<td>3.22</td>
<td>2.70</td>
<td>3.79</td>
</tr>
<tr>
<td>Emtricitabine</td>
<td>110/4094</td>
<td>2.69</td>
<td>2.21</td>
<td>3.23</td>
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<tr>
<td>Ritonavir</td>
<td>84/3482</td>
<td>2.41</td>
<td>1.93</td>
<td>2.98</td>
</tr>
<tr>
<td>Alazanavir</td>
<td>30/1457</td>
<td>2.47</td>
<td>1.74</td>
<td>3.40</td>
</tr>
<tr>
<td>Lopinavir</td>
<td>30/1441</td>
<td>2.08</td>
<td>1.41</td>
<td>2.96</td>
</tr>
<tr>
<td>Abacavir</td>
<td>44/1391</td>
<td>3.16</td>
<td>2.31</td>
<td>4.22</td>
</tr>
<tr>
<td>Nelfinavir</td>
<td>47/1212</td>
<td>3.88</td>
<td>2.86</td>
<td>5.12</td>
</tr>
<tr>
<td>Efavirenz</td>
<td>28/1177</td>
<td>2.38</td>
<td>1.59</td>
<td>3.42</td>
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<td>Nevirapine</td>
<td>35/1173</td>
<td>2.98</td>
<td>2.09</td>
<td>4.13</td>
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<tr>
<td>Stanavudine</td>
<td>21/811</td>
<td>2.59</td>
<td>1.61</td>
<td>3.93</td>
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<tr>
<td>Darunavir</td>
<td>24/665</td>
<td>3.61</td>
<td>2.32</td>
<td>5.32</td>
</tr>
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<td>Dolutegravir</td>
<td>21/634</td>
<td>3.31</td>
<td>2.06</td>
<td>5.02</td>
</tr>
<tr>
<td>Tenofovir Alafenamide</td>
<td>23/606</td>
<td>3.80</td>
<td>2.42</td>
<td>5.64</td>
</tr>
<tr>
<td>Rilpirinone</td>
<td>9/583</td>
<td>1.54</td>
<td>0.71</td>
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<tr>
<td>Raltegravir</td>
<td>18/514</td>
<td>3.50</td>
<td>2.09</td>
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<td>MACDP</td>
<td>2.72</td>
<td>2.68</td>
<td>2.76</td>
<td></td>
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<td>TBDR</td>
<td>4.17</td>
<td>4.15</td>
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<td></td>
</tr>
</tbody>
</table>

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The graph shows a comparison of prevalence (%) between Miami and Texas.
DTG in pregnancy: teratogenicity

Table 1. Prevalence Difference of NTDs by Antiretroviral and HIV Exposure Categories, 2014-2021

<table>
<thead>
<tr>
<th>Exposure group vs. Comparison group</th>
<th>Prevalence Difference (%) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTG at conception vs. Non-DTG at conception</td>
<td>0.06 (-0.03, 0.20)</td>
</tr>
<tr>
<td>DTG at conception vs. EFV at conception</td>
<td>0.09 (-0.00, 0.23)</td>
</tr>
<tr>
<td>DTG at conception vs. DTG started in pregnancy</td>
<td>0.10 (-0.03, 0.24)</td>
</tr>
<tr>
<td>DTG at conception vs. Women without HIV</td>
<td>0.09 (0.01, 0.23)</td>
</tr>
</tbody>
</table>

Zash et al. Update on neural tube defects with antiretroviral exposure in the Tsepamo study, Botswana. IAS 2021 eposter.
DTG in pregnancy: teratogenicity

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TAF in pregnancy: other safety outcomes

IMPAACT 2010 ‘VESTED’

Key Eligibility Criteria
- Pregnant WLHIV 14-28 weeks gestation
- ART-naïve (up to 14 days ART in current pregnancy allowed)

Participants were enrolled at 22 sites in 9 countries

DTG = dolutegravir
EFV = efavirenz
TDF = tenofovir disoproxil fumarate
TAF = tenofovir alafenamide

Lockman & Brummel et al, The Lancet, 2021
TAF in pregnancy: other safety outcomes

IMPAACT 2010 ‘VESTED’
TAF in pregnancy: other safety outcomes

IMPAACT 2010 ‘VESTED’
TAF in pregnancy: other safety outcomes

IMPAACT 2010 ‘VESTED’
Further data presented at CROI 2022

Length-for-Age Z-scores lower in EFV vs DTG arms, similar TDF- vs TAF-DTG

Weight-for-Age Z-scores lower in EFV vs DTG arms, similar TDF- vs TAF-DTG
Would it be safe to breastfeed my baby?
## Breastfeeding

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Setting</th>
<th>Enrolment</th>
<th>N</th>
<th>cART</th>
<th>VT rate at 6 months (per 1000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nduati et al</td>
<td>RCT</td>
<td>Kenya</td>
<td>‘92–’98</td>
<td>401</td>
<td>nil</td>
<td>28 (bfeeding), 16 (formula)</td>
</tr>
<tr>
<td>Mitra Plus</td>
<td>Cohort</td>
<td>Tanzania</td>
<td>‘04–’06</td>
<td>378</td>
<td>ZDV/3TC/NVP</td>
<td>10</td>
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<tr>
<td>Marazzi et al</td>
<td>Cohort</td>
<td>Mozambique</td>
<td>‘05–’07</td>
<td>313</td>
<td>ZDV/3TC/NVP</td>
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<tr>
<td>Amata</td>
<td>Cohort</td>
<td>Rwanda</td>
<td>‘05–2007</td>
<td>227</td>
<td>D4T/3TC/NVP or ZDV/3TC/EFV</td>
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<tr>
<td>Mma Bana</td>
<td>RCT</td>
<td>Botswana</td>
<td>‘06–’08</td>
<td>263</td>
<td>ZDV/3TC/LPV-r</td>
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<tr>
<td>BAN</td>
<td>RCT</td>
<td>Malawi</td>
<td>‘04–’08</td>
<td>803</td>
<td>ZDV/3TC + NVP or NFV or LPV-r</td>
<td>26</td>
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<tr>
<td>Kesho Bora</td>
<td>RCT</td>
<td>B. Faso, Kenya, S. Africa</td>
<td>‘05–’08</td>
<td>349</td>
<td>ZDV/3TC/LPV-r</td>
<td>16</td>
</tr>
<tr>
<td>PROMISE</td>
<td>RCT</td>
<td>India, SSA (7 countries)</td>
<td>11–14</td>
<td>2431</td>
<td>mART vs. iNVP</td>
<td>3 (in both arms)</td>
</tr>
</tbody>
</table>
Breastfeeding: PROMISE

→ Women-infant pairs enrolled 1 week postpartum after negative infant PCR
→ Randomised to continuing mART (99% TDF/XTC+ LPV/r) or infant nevirapine
→ Infants in the mART arm received 6/52 NVP then stopped
→ 1220 woman-infant pairs were enrolled into the mART arm
→ 75% of these women had VL <1000copies/ml at baseline, this was 85% at week 50.
Breastfeeding: PROMISE
Breastfeeding: UK data

Among 9133 livebirth deliveries to HIV diagnosed women 2012-2020: 151/9133 (1.8%) were reported as supported to breastfeed

Wide range of duration:
→ range 1 day- 2 years
→ median duration: 7wk (IQR: 3, 16)

Variety of reasons for stopping:
→ part of a plan to stop (51)
→ mastitis (3)
→ viral load rebound (7)
→ travel/testing burden (1)
Tania
BHIVA
British HIV Association

2022 Spring Conference

Wed 20th - Fri 22nd April
Manchester Central, Manchester
Post-reproductive health in women living with HIV

Dr Shema Tariq
University College London/Mortimer Market Centre, UK
Post-reproductive health in women living with HIV

Shema Tariq, University College London/Mortimer Market Centre
I have received honoraria from Gilead Sciences for preparation of educational material and speaking engagements. The PRIME Study has been funded by the NIHR, the Wellcome Trust and BHIVA.
Maria
- Aged 53
- HIV diagnosed antenatally in 2007
- Disengaged from care post-partum
- Nadir CD4 180
- Re-presented to care in 2011
- TRU/NVP
- Irregular periods aged 45
- LMP aged 50
Maria
- Now has multiple symptoms
- Brain fog, hot flushes, fatigue, vaginal dryness, low mood, poor sleep
- Menopause Rating scale=32 (severe)
- Adherence challenges: VL<40
- Osteopenia on DEXA (also FH)
Maria
- Transdermal oestrogen + micronised progestogen (dose adjusted)
- Vaginal oestrogen pessary
- Lifestyle optimisation
- No FSH needed
- Qrisk documented, recent DEXA
- Breast and cervical screening
- Does not want to switch ART
- GP management with support
I just feel alive again. I feel like me.

Maria, 3 months after commencing HRT
Stages of Menopause

Understanding the changes in your body during menopause.

Stage 1: Perimenopause
- Estrogen production fluctuates

Stage 2: Menopause
- 12 consecutive months without a period

Stage 3: Postmenopause
- Estrogen production levels out
Menopause and HIV

Bone disease  CVD  HIV-related  Vasomotor  Psychological

**Findings:** Menopausal symptoms in women living with HIV

**Prevalence of menopausal symptoms**

- **Somatic**
  - hot flushes, palpitations, joint and muscle discomfort, sleep disturbance
  - 89%

- **Urogenital**
  - vaginal dryness, urinary tract symptoms, sexual problems
  - 68%

- **Psychological**
  - depression, anxiety, irritability, exhaustion
  - 78%

*It leaves you feeling ‘what is going on here’? Is it HIV? Is it the menopause?*

Source: Tariq S et al. (2017)
Severity of menopausal symptoms

Source: Okhai et al. (2021)
HIV and sexual function

Women with HIV reporting ≥1 sexual problem in past 1 year

69%

Women without HIV reporting ≥1 sexual problem in past 1 year

54%

Source: Toorabally et al. (2019); Mezones-Holguin et al. (2022)
Menopause Rating Scale

- Standardised scale
- 11 questions, 5-point Likert scale
- Somatic, psychological, urogenital
- Validated in diverse populations (not HIV)
- Can be used to measure response to HRT

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>none</th>
<th>mild</th>
<th>moderate</th>
<th>severe</th>
<th>extremely severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hot flashes, sweating (episodes of sweating)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Heart discomfort (unusual awareness of heart beat, heart skipping, heart racing, tightness)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>3. Sleep problems (difficulty in falling asleep, difficulty in sleeping through the night, waking up early)</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
</tr>
<tr>
<td>4. Depressive mood (feeling down, sad, on the verge of tears, lack of drive, mood swings)</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>5. Irritability (feeling nervous, inner tension, feeling aggressive)</td>
<td>☐</td>
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<td>6. Anxiety (inner restlessness, feeling panicky)</td>
<td>☐</td>
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<td>7. Physical and mental exhaustion (general decrease in performance, impaired memory, decrease in concentration, forgetfulness)</td>
<td>☐</td>
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<td>8. Sexual problems (change in sexual desire, in sexual activity and satisfaction)</td>
<td>☐</td>
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<td>9. Bladder problems (difficulty in urinating, increased need to urinate, bladder incontinence)</td>
<td>☐</td>
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<td>10. Dryness of vagina (sensation of dryness or burning in the vagina, difficulty with sexual intercourse)</td>
<td>☐</td>
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<td>11. Joint and muscular discomfort (pain in the joints, rheumatoid complaints)</td>
<td>☐</td>
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</tbody>
</table>

Score = 0 1 2 3 4

Source: https://zeg-berlin.de
Impact of menopausal symptoms

- Reduced adherence to ART\textsuperscript{1,2}
- Reduced clinic attendance\textsuperscript{1,2}
- Increased psychological distress\textsuperscript{3}
- Reduced quality of life\textsuperscript{4}

Source: 1. Solomon et al. (2020); 2. Haag et al. (2022); 3. Sabin et al. (2021); 4. Okhai et al. (2022)
Hormone replacement therapy

- Under-used in general and in HIV
- Not contraindicated in HIV
- Improves QoL/CVD/bone health
- For vasomotor/mood symptoms
- No FSH if >45
- DDIs can be managed
- Transdermal oestrogen
- Micronised progestogen

Source: Tariq at el. (2022); Hachfeld et al. (2022)
Avoid bioidentical HRT

- Customised compounded formulations
- Doses based on saliva/serum profiles
- No evidence
- Unregulated
- Very little safety advice
- Expensive
• Increased prevalence of menopause ≤45 in HIV

• ALL women with menopause <40 should be prescribed HRT (or COC) until at least 50
Beyond HRT

- Other treatments (SSRIs, CBT, vaginal moisturisers)
- Lifestyle optimisation
- Screening for comorbidities
- Information and support
The case of dolutegravir
Key points

- Natural transition with wide ranging health impacts
- Clinical diagnosis in women aged >45
- HRT improves symptoms & reduces comorbidity risk
- Establish clinical pathway
- Support and information are key
Ask about symptoms and periods
Acknowledgements

- NIHR, Wellcome Trust, BHIVA, FTCI
- The PRIME Study Team: Fiona Burns, Richard Gilson, Alexandra Rolland, Caroline Sabin, Abigail Severn, Tuhina Bhattacharyya & Saliha Abbassi
- GROWS Team: Sarah Fraser, Rebecca Mbewe, Juddy Otti, Silvia Petretti, Jacqui Stevenson
- PRIME participating clinics and study participants
Thanks!

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BHIVA
British HIV Association

2022 Spring Conference

Wed 20th - Fri 22nd April
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Panel discussion additional members

Professor Yvonne Gilleece
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University of Oxford, UK
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