Professor Chloe Orkin
Barts Health NHS Trust, London
Advances in HIV Care for 2018

Professor Chloe Orkin
Barts Health NHS Trust
Disclosures

- Educational grants (HIV Unit): Merck Sharp & Dohme, Gilead Sciences, Janssen, ViiV Healthcare and Barts Charity
- Honoraria and travel sponsorship for lectures and advisory board contributions
- Member of the BHIVA Guidelines Subcommittee (2008–2017)
- Chair and executive trustee of BHIVA
- Not a patent holder or a shareholder
- No disclosures for spouse or family members
Advances in HIV Care

Engagement

Ageing

Cost/Generics

Comorbidity

Testing

GP liaison

Context

ART
Advances in ART

PRESENT

FUTURE
### Reducing ART exposure

- Drug dose
- Dosing frequency
- Number of drugs

### New agents

- Investigational ARTs
- Monoclonal antibodies

### Different ART formulations

- Long-acting oral
- Implantable
- Long-acting injectable
HIV drug pipeline under clinical evaluation (Phase I–III)

<table>
<thead>
<tr>
<th>Stage</th>
<th>Key Processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attachment</td>
<td>CD4 interacts with HIV-1 envelope protein gp120.</td>
</tr>
<tr>
<td>Fusion</td>
<td>gp120 binds to CD4 co-receptor.</td>
</tr>
<tr>
<td>Reverse transcription</td>
<td>HIV RNA is transcribed from viral DNA into RNA by reverse transcriptase.</td>
</tr>
<tr>
<td>Integration</td>
<td>Viral RNA integrates into the host cell genome.</td>
</tr>
<tr>
<td>Transcription</td>
<td>Viral DNA is transcribed into mRNA.</td>
</tr>
<tr>
<td>Translation</td>
<td>mRNA is translated into viral proteins.</td>
</tr>
<tr>
<td>Maturation</td>
<td>Nef promotes viral budding, allowing viral capsid to assemble and release.</td>
</tr>
</tbody>
</table>

### HIV LIFE CYCLE

**Entry inhibitors**
- Fostemsavir (GSK-934; FTR)
- Cenicriviroc (TBR-652; CVC)
- Sifuvirtide (FS-0101)
- Albuviride (FB006M; ABT)

**Monoclonal antibodies (mAb)**
- UB-421 (CD4 receptor)
- PRO-140 (CCR5 receptor)
- Ibalizumab (TMB-355)
- VRC01
- VRC01-LS

**NRTIs/NtRTIs (‘nukes’)**
- Efavirenz (MK-8591)
- GS-9131

**NNRTIs (‘non-nukes’)**
- Doravirine (MK-1439)
- Elsulfavirine (VM1500)
- Rilpivirine-LAI (TMC278; RPV)
- Dapivirine (TMC120; DPV)
- PC-1005 (MIV-150/zinc acetate)

**Integrate inhibitors**
- Bictegravir (GS-9883)
- Cabotegravir-LAI (GSK-744; CAB)

**Protease inhibitors**
- GS-PI1
- GS-CA1
- GSK2838232
- MK-8507
- ABX464
- LEDGINs

**Capsid inhibitors**
- MK-2048

**Maturation inhibitors**
- VRC01

**Unique/unknown MoA**
- Ibalizumab (TMB-355)
- VRC01
- VRC01-LS
- PC-1005 (MIV-150/zinc acetate)
- VRC01
- VRC01-LS
- PC-1005 (MIV-150/zinc acetate)
### Modes of delivery

#### Oral
- **ABX464**
- **EFdA (MK-8591)**
- **Bictegravir (GS-9883)**
- **Elsulfavirine (VM1500; FTR)**
- **Fostemsavir (GSK-934; FTR)**
- **GSK2838232**
- **Doravirine (MK-1439)**
- **Cenicriviroc (TBR-652; CVC)**
- **GS-9131**
- **Doravirine**

#### Injectable
- **Albuvirtide (FB006M; ABT)**
- **Ibalizumab (TMB-355)**
- **PRO-140 (CCR5 receptor)**
- **Sifuvirtide (FS-0101)**
- **GSK9131**
- **Rilpivirine-LAI (TMC278; RPV)**
- **UB-421 (CD4 receptor)**
- **VRC01**
- **VRC01-LS**

#### Other (Topical, implantable, gel)
- **Dapivirine (TMC120; DPV)**
- **MK-2048**
- **PC-1005 (MIV-150/zinc acetate)**

#### Long-Acting Injectable
- **Cabotegravir-LAI (GSK-744; CAB)**

**LEDGINs**: Not currently under clinical investigation
Is there demand for long-acting injectable or implantable ART?

Patients in LATTE-2 trial preferred LA injectable CAB/RPV to taking pills\textsuperscript{1,2}

Lessons from women using contraception:

- **multiple** modalities
- **different** modalities at **different** times
- **variety** makes it easier

CAB, cabotegravir; LA, long-acting; RPV, rilpivirine.
PRESENT
Life Expectancy = near normal, UK CHIC Cohort

### Guidelines: Recommended and preferred regimens

<table>
<thead>
<tr>
<th>GUIDELINES</th>
<th>NRTI BACKBONE</th>
<th>NNRTI</th>
<th>INSTI</th>
<th>PI</th>
</tr>
</thead>
</table>
| EACS (2017)
(European AIDS Clinical Society) | TAF/FTC TDF/FTC ABC/3TC* | RPV* | DTG RAL EVG | DRV/c or /r |
| DHHS (2018)
(Department of Health and Human Services) | TAF/FTC TDF/FTC ABC/3TC* | – | BIC DTG RAL EVG/c | – |
| IAS USA (2016)
(International Antiviral Society–USA) | TAF/FTC ABC/3TC* | – | DTG RAL EVG/c | – |
| BHIVA (2016)
(British HIV Association) | TAF/FTC TDF/FTC | RPV* | DTG RAL EVG/c | DRV/r ATV/r |
| WHO (2016)
(World Health Organization) | TDF/XTC | EFV | – | – |

*Use recommended only if baseline viral load <100,000 copies/mL.*

3TC, lamivudine; ABC, abacavir; ATN, atazanavir; AZT, zidovudine; BHIVA, British HIV Association; c, cobicistat; DHHS, Department of Health and Human Services; DRV, darunavir; DTG, dolutegravir; EACS, European AIDS Clinical Society; EFV, efavirenz; EVG, elvitegravir; FTC, emtricitabine; IAS USA, International Antiviral Society–USA; LPV, lopinavir; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; NVP, nevirapine; PI, protease inhibitor; r, ritonavir; RAL, raltegravir; RPV, rilpivirine; TAF, tenofovir alafenamide fumarate; TDF, tenofovir disoproxil fumarate; WHO, World Health Organization; XTC, FTC or 3TC.

First-line ART

Recommended, preferred regimens + ALTERNATIVE

<table>
<thead>
<tr>
<th>GUIDELINES</th>
<th>NRTI BACKBONE</th>
<th>NNRTI</th>
<th>INSTI</th>
<th>PI</th>
<th>NRTI-REDUCING</th>
</tr>
</thead>
<tbody>
<tr>
<td>**EACS (2017)**¹</td>
<td>TAF/FTC</td>
<td>–</td>
<td>RPV*</td>
<td>DTG</td>
<td>DRV/c or /r</td>
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<tr>
<td></td>
<td>TDF/FTC</td>
<td></td>
<td></td>
<td>RAL</td>
<td>ATV/c or /r</td>
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<td></td>
<td>ABC/3TC*</td>
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<td>EVG</td>
<td></td>
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<tr>
<td>**DHHS (2018)**²</td>
<td>TAF/FTC</td>
<td>–</td>
<td>–</td>
<td>EFV</td>
<td>ATV/c or /r</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>RPV*</td>
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<td></td>
<td>ABC/3TC*</td>
<td></td>
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<td>BIC</td>
<td>ATV/c or /r</td>
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<td>DTG</td>
<td>DRV/c or /r</td>
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<td>RAL</td>
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<td>EVG/c</td>
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<tr>
<td>**IAS USA (2016)**³</td>
<td>TAF/FTC</td>
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<td>–</td>
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<td></td>
<td></td>
<td>EVG/c</td>
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<tr>
<td>**BHIVA (2016)**⁴</td>
<td>TAF/FTC</td>
<td>–</td>
<td>–</td>
<td>EFV</td>
<td>DRV/c or /r</td>
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<td></td>
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<td>RAL</td>
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<td>EVG/c</td>
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<tr>
<td>**WHO (2016)**⁵</td>
<td>TDF/XTC</td>
<td>–</td>
<td>–</td>
<td>EFV</td>
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<td>400 NVP</td>
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<td>DTG</td>
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</tbody>
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*Use recommended only if baseline viral load <100,000 copies/mL.

3TC, lamivudine; ABC, abacavir; ATV, atazanavir; AZT, zidovudine; BHIVA, British HIV Association; c, cobicistat; DHHS, Department of Health and Human Services; DRV, darunavir; DTG, dolutegravir; EACS, European AIDS Clinical Society; EFV, efavirenz; EVG, elvitegravir; FTC, emtricitabine; IAS USA, International Antiviral Society–USA; LPV, lopinavir; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; NVP, nevirapine; PI, protease inhibitor; r, ritonavir; RAL, raltegravir; RPV, rilpivirine; TAF, tenofovir alafenamide fumarate; TDF, tenofovir disoproxil fumarate; WHO, World Health Organization; XTC, FTC or 3TC.

Describing efficacy outcomes (FDA snapshot)

3 categories:

VL < 50 c/mL

VL >50 c/mL driven by

No data in window = did not get to end

FDA, The Food and Drug Administration; VL, viral load.
Women-only studies

Efficacy outcomes at week 48

- ATV, atazanavir; BD, twice daily; BIC, bictegravir; c, cobicistat; DRV, darunavir; DTG, dolutegravir; EFV, efavirenz; EVG, elvitegravir; FTC, emtricitabine; LPV, lopinavir; QD, once daily; r, ritonavir; RAL, raltegravir; RPV, rilpivirine; TAF, tenofovir alafenamide fumarate; TDF, tenofovir disoproxil fumarate.

Describing efficacy (FDA snapshot)

VL >50 c/mL driven by:
- Baseline VL
- Barrier to resistance

FDA, The Food and Drug Administration; VL, viral load.
Not all regimens work well if baseline VL >100,000 c/mL
Who is represented in these studies?

Trials where participants are:
- 50% white
- >70% male
- 100% CD4 >300
- >75% VL <100,000

13. TBA;
We need longer term data AND...

Trials enrolling:
- Older adults
- Women
- Trans and non-binary
- Ethnically diverse
- Adolescents
- People who inject drugs
- HCV and HBV co-infected
- CDC C diagnoses
- Comorbidities allowed
Towards zero resistance when failing INSTIs Wk 48

<table>
<thead>
<tr>
<th>STUDY</th>
<th>FLAMINGO¹</th>
<th>ARIA²</th>
<th>SINGLE³</th>
<th>GS-1489 (ABC)⁴</th>
<th>GS-1490 (TDF)⁵</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug</td>
<td></td>
<td></td>
<td></td>
<td>BIC</td>
<td>DTG</td>
</tr>
<tr>
<td>NRTI</td>
<td></td>
<td></td>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>INSTI</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

INSTI, Integrase strand transfer inhibitors DTG, dolutegravir; BIC, Bictegravir

¹ BIC, bictegravir.
Very few fail virologically, ‘no data’ group important

No data in window = did not get to end:
- Disengagement from care
- Tolerability (discontinuations)
- Safety (withdrawals)

FDA, The Food and Drug Administration; VL, viral load.
We can reduce this category by Improving quality of life: The 4th 90

Keeping people engaged with their care
Avoiding side effects and comorbidity

90 90 90
Diagnosed On treatment Undetectable

4th 90

Enhancing engagement = make meds convenient

<table>
<thead>
<tr>
<th>DRUG</th>
<th>ATRILA(^1)</th>
<th>EVIPLERA(^2)</th>
<th>STRIBILD(^3)</th>
<th>TRIUMEQ(^4)</th>
<th>GENVOYA(^5)</th>
<th>ODEFSEY(^6)</th>
<th>SYMTUZA(^7)</th>
<th>BIKTARVY(^8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>COMPONENTS</td>
<td>Generic FDC</td>
<td>TDF/FTC/EFV</td>
<td>TDF/FTC/RPV</td>
<td>ABC/3TC/DTG</td>
<td>TAF/FTC/EGV/c</td>
<td>TAF/FTC/RPV</td>
<td>TAF/FTC/DRV/c</td>
<td>TAF/BIC/FTC</td>
</tr>
<tr>
<td>CONSIDERATIONS</td>
<td>Premorbid</td>
<td>VL &lt;100,000</td>
<td>Drug–drug interactions</td>
<td>HLAB*5701 co-infection</td>
<td>Drug–drug interactions</td>
<td>VL &lt;100,000</td>
<td>Drug–drug interactions</td>
<td>Long-term data</td>
</tr>
</tbody>
</table>

Licensed once-daily fixed-dose combinations. Pill sizes are not to scale.

Filed for licensing: TDF/3TC/DOR (1439A)

What else could we do to stop disengagement from care?

Address stigma and societal barriers

Different modalities (longer acting)

More peer mentoring and navigation

Behavioural interventions:
- App and SMS-based reminders
- Behavioural prompts
Toxicity and tolerability drives efficacy: ACTG 5257

Equivalent in terms of virologic failure endpoint but…

<table>
<thead>
<tr>
<th>Any toxicity discontinuation</th>
<th>RAL (N=603)</th>
<th>ATV/r (N=605)</th>
<th>DRV/r (N=601)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 (1%)</td>
<td>95 (16%)</td>
<td>32 (5%)</td>
<td></td>
</tr>
</tbody>
</table>

Cumulative failure*

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Outcome</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATV/r vs RAL</td>
<td>RAL superior</td>
<td>15% (10%, 20%)</td>
</tr>
<tr>
<td>DRV/r vs RAL</td>
<td>RAL superior</td>
<td>7.5% (3.2%, 12%)</td>
</tr>
<tr>
<td>ATV/r vs DRV/r</td>
<td>DRV/r superior</td>
<td>7.5% (2.3%, 13%)</td>
</tr>
</tbody>
</table>

*Difference in 96-week cumulative incidence (97.5% CI)
# Safety outcomes in RCTs vs cohort studies

<table>
<thead>
<tr>
<th>RCT: Surrogate markers</th>
<th>Cohort: Serious non-AIDS events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal = GFR, tubular biomarkers</td>
<td>Renal events e.g. CKD</td>
</tr>
<tr>
<td>Bone = DEXA &amp; bone biomarkers</td>
<td>Fractures</td>
</tr>
<tr>
<td>CVS = lipids</td>
<td>CVS outcomes</td>
</tr>
<tr>
<td>CNS = side effects; questionnaires</td>
<td>Neurocognitive/psychiatric events</td>
</tr>
<tr>
<td>AEs</td>
<td>Hepatic events</td>
</tr>
<tr>
<td></td>
<td>Non-AIDS malignancy</td>
</tr>
</tbody>
</table>
| | Unexpected AEs:  
  - ABC hypersensitivity |

ABC, abacavir; AE, adverse event; CKD, chronic kidney disease; CNS, central nervous system; CVS, cardiovascular; DEXA, dual-energy X-ray absorptiometry; GFR, glomerular filtration rate; RCT, randomized controlled trial.
Ways to avoid the safety concerns of the NRTI ‘backbone’

Options:
- TAF backbone in triple ART
  - TAF and ABC similar for renal and bone
- Two-drug regimens (2DR)


2DR, two-drug regimen; ART, antiretroviral therapy; HBV, hepatitis B; NRTI, nucleoside reverse transcriptase inhibitor; TAF, tenofovir alafenamide fumarate.
TAF and ABC - similar outcomes for bone and renal biomarkers

- EVG/c + TAF/FTC vs TDF/FTC
- TAF: favorable renal biomarkers and BMD
- No renal or bone discontinuations to Week 144
- Switch from ABC/3TC/DTG to TAF/FTC/BIC
- No differences in renal or bone biomarkers at Week 48

First-line ART

3TC, lamivudine; ABC, abacavir; BIC, bictegravir; BMD, bone mineral density; c, cobicistat; DTG, dolutegravir; EVG, elvitegravir; FTC, emtricitabine; TAF, tenofovir alafenamide fumarate; TDF, tenofovir disoproxil fumarate.

2 Drug Regimes (2DR)-naïve studies: Efficacy data only

- **WK 48 ANDES** (N=145)
  - FDC DRV/r + 3TC vs DRV/r + TDF/3TC
  - Non-inferior 93% DT, 94% TT

- **ACTG 5353** (N=120)
  - Single-arm study DTG + 3TC
  - 3 PDVF
  - n=1 [emergent M184V, R263R/K]

No safety outcomes

Near Future
- GEMINI (DTG 3TC)
  - NCT02831673 NCT02831764
- FLAIR (CAB RPV)
  - NCT02938520

Adapted from clinicaloptions.com

2DR, two-drug regimen; 3TC, lamivudine; ACTG, AIDS Clinical Trials Group; CAB, cabotegravir; DRV, darunavir; DTG, dolutegravir; PDVF, protocol-defined virologic failure; RPV, rilpivirine; RTV, ritonavir; TDF, tenofovir disoproxil fumarate.
2. Taiwo BO, et al. IAS 2017, Paris, France; abstract #MOAB0107LB.
3. Figueroa M CROI 2018 Poster 489
**Current challenges of the INSTI as third agent**

<table>
<thead>
<tr>
<th>CNS AEs</th>
<th>Resistance</th>
<th>DDIs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase III FDA trials DTG</strong>¹</td>
<td>First-generation INSTI</td>
<td>INSTI drug–drug interactions</td>
</tr>
<tr>
<td>- Only insomnia reported</td>
<td>- RAL and EVG more resistance than PI</td>
<td>- RAL/DTG chelation</td>
</tr>
<tr>
<td><strong>Six cohorts</strong>³⁻⁹: CNS discontinuations</td>
<td></td>
<td>- EVG/c booster, so DDIs</td>
</tr>
<tr>
<td>- More DTG discontinuations than other INSTIs</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Opera cohort</strong>⁶</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Similar CNS incidents</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Wohl series</strong>⁹</td>
<td></td>
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</tr>
<tr>
<td>- Depression and sleep disturbances were significantly higher in DTG</td>
<td></td>
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</tr>
</tbody>
</table>

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When to start

Rosen et al Plos medicine 2016
Koenig et al PLOS medicine 2017
Bacon et al.CROI 2018

- Engagement with care
- Infrastructure
- Resistance
- Virologic outcomes
- Safety
RAPID ART in San Francisco: Accelerated ART Initiation for newly diagnosed HIV

• Getting to Zero Consortium’s Citywide RAPID programme:
  • Time to first VL <50 decreased by 50% (from 134 to 61 days)
  • Time from care linkage to starting ART decreased by 96% (from 27 days to 1 day)


Adapted from: clinicaloptions.com
Switching when VL <50 c/mL

**Principles of Switch: 2017-18 Guidelines**

- Switch safely and for a good reason
  - Review ART history, genotype, interactions, co-infection
- Consider efficacy-based triple-therapy switch
- Consider efficacy-based 2DR switch

### 3TC + PI/r-based¹:
- DRV/r or /c + 3TC
- ATV/r or /c + 3TC

### INSTI + NNRTI¹:
- DTG + RPV

### 3TC + PI/r-based²:
- DRV/r + 3TC
- ATV/r + 3TC
- LPV/r + 3TC

### INSTI + NNRTI²:
- DTG + RPV

---

2DR, two-drug regimen; 3TC, lamivudine; ART, antiretroviral therapy; ATV, atazanavir; c, cobicistat; DHHS, Department of Health and Human Services; DRV, darunavir; DTG, dolutegravir; EACS, European AIDS Clinical Society; LPV, lopinavir; NNRTI, non-nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; r, ritonavir; RPV, rilpivirine; VL, viral load.

Safety data studies of 2DR ‘n=100’

- 2DR
- bPI + MVC
  - MARCH²
  - bPI + MVC vs bPI + 2 NRTIs
  - N=395
  - −17.4%

- bPI + INSTI
  - HARNESS³
  - DTG + RPV vs CAR (NRTI + other)
  - N=1024
  - −0.2%

- bPI + 3TC
  - SALT, ATLAS⁴,⁵
  - ATV/r + 3TC vs ATV/r + 2 NRTIs
  - N=286; 266
  - +6%, +9.8%

- NNRTI + INSTI
  - SWORD 1 & 2⁶
  - DTG + RPV vs CAR (NRTI + other)
  - N=1024
  - −0.2%

Switching when VL <50 c/mL

Difference = % of virologically suppressed patients in triple ART compared with 2DR at Week 48. Minus value is in favor of triple therapy; positive value is in favor of 2DR

- % difference >12%
  - MARCH²
  - HARNESS³

- % difference <12%
  - SALT, ATLAS⁴,⁵
  - OLE⁶
  - LATTE⁷
  - LATTE-2¹⁰

References:
7. Pulido F, et al. HIV Glasgow 2016, Glasgow, United Kingdom; abstract #031;
8. Llibre JM, et al. CROI 2017, Seattle, WA, United States; abstract #44LB;
Switching when VL <50 c/mL

Safety data studies of 2DR ‘n=100’

2DR

bPI + MVC

MARCH²

- bPI + MVC vs bPI + 2 NRTIs
- N=395
- -17.4%

bPI + INSTI

HARNESS³

- bPI + INSTI vs bPI + 2 NRTIs
- N=109
- -17.1%

bPI + 3TC

SALT, ATLAS⁴,⁵

- ATV/r + 3TC vs ATV/r + 2 NRTIs
- N=286; 266
- +6%, +9.8%

NNRTI + INSTI

SWORD 1 & 2⁶

- DTG + RPV vs CAR (NRTI + other)
- N=1024
- -0.2%

More studies awaited

DTG+ 3TC or FTC

- TANGO SIMPL’ HIV

DTG/DRV/r

- DUALIS (NCT02486133)

LA CAB + RPV

- ATLAS (NCT02951052)
- ATLAS-2M (NCT03299049)

Adapted from clinicaloptions.com

7. Pulido F, et al. HIV Glasgow 2016, Glasgow, United Kingdom; abstract #0331;
8. Llibre JM, et al. CROI 2017, Seattle, WA, United States; abstract #44LB;
2DR…questions for the future

Data gaps

• Hep B an exclusion
• Long-term data
• VL > 500,000 c/ml; Low CD4
• Resistance*
• Reservoir/ inflammation

2DR…questions for the future

Data gaps
- Hep B an exclusion
- Long-term data
- VL > 500,000 c/ml; Low CD4
- Resistance
- Pregnancy
- Inflammation
- Sanctuary site penetration
- Viral reservoir
- Immune senescence

Questions that occur in clinic
- How much adherence is enough?
- Is it ok to monitor VL for 2DR twice or once a year?
- Can it be used for those with unclear history of suppression/unknown genotype at failure?
- How does one salvage a failure on 2DR?
Using LPV/r + recycled NRTI was non-inferior to using LPV/r + RAL

Using DTG+ NRTIs superior to NRTI+LPV/r
Triple-class experience

- Drug dose varies for triple-experienced vs triple-class resistance (QD vs BID)
- INSTI naïve pts can dose drugs OD
- INSTI –resistant pts need to dose BD
Investigational agents for treatment-experienced patients

FOSTEMSAVIR

- Fostemsavir is an attachment inhibitor to gp120
- HIV VL decline of 0.79 log$_{10}$ in 8 days functional monotherapy

IBALIZUMAB$^{2,3}$ & PRO-140$^{4}$

- Ibalizumab is a humanised monoclonal antibody to CD4 receptor (FDA licensed)
- PRO-140: is a humanised monoclonal antibody to CCR5 receptor-subcutaneous weekly
- 83% achieved ≥0.5 log$_{10}$ drop at Day 14

References:
Comorbidity and traditional risk factors interact to cause mortality
OUR Role: Communicate with GPs
Ensure modifiable traditional factors are addressed

- BP
- Obesity
- Mental health
- Alcohol
- Smoking
- Lipids
- Diabetes

Image courtesy of png images
Advances in HIV Care for 2018

- **Caring** for people living with HIV is more than just tablets and GP referrals
- Societal and political difficulties arise can challenge our ability to provide care

**Affect testing/engagement**

- Charging to Overseas Visitors
- Data-sharing between the NHS and Immigration

**Life free from stigma**

- Bill considering prosecuting people who refuse testing for BBVs when they spit/bite emergency workers
- Civil Aviation Authority preventing HIV + pilots from flying
- Use of spit-hoods by emergency services

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1. Health and Social Care Bill 2012
Health care professionals not policy specialists

- BUT we can provide medical evidence to support the work of policy specialists
- Engage with social media, traditional media, MPs, the police, the crown prosecution service, the Home Office

Spit guards can protect our officers from diseases like HIV, hepatitis and tuberculosis, as well as the lasting psychological impact.

Sgt John Shaddick explains how it affected his team. More here: bit.ly/2hKJOFL

#ProtectTheProtectors #SpatAt
Health care professionals not policy specialists

- BUT we can provide medical evidence to support policy specialists
- Actions: position statements, challenge medical evidence, petitions, review articles, respond to consultations

Pinned Tweet
BASHH @BASHH_UK · 01/12/2017
We are proud to be supporting the petition to reverse the #publichealth #cuts and save our #sexualhealth services – join us and sign up here you.38degrees.org.uk/p/Save-our-sex...
#sexualhealthSOS #NHS

RESPONSE TO FORMAL REVIEW OF "THE NATIONAL HEALTH SERVICE (CHARGES TO OVERSEAS VISITORS) (AMENDMENT) REGULATIONS 2017"

Summary
The British Association for Sexual Health and HIV (BASHH) and the British HIV Association (BHIVA) welcomes this consultation on the formal review of the National Health Service (Charges to Overseas Visitors) Amendment Regulations 2017 (Amendment Regulations) and appreciates the opportunity to respond.

As the Amendment Regulations have only been in place for several months, with those extended to include non-HIV providers of relevant services from 27th October 2017 onwards, it is difficult for respondents to provide clear evidence on the impact that the legislative changes have had thus far. Despite this, BASHH and BHIVA have been receiving concerns around the negative long-term impact we believe the Amendment Regulations and the requirement to charge upfront for certain services will have on public health outcomes are a whole in the country. We also have specific concerns around the impact the Regulations will likely have on overseas visitors who are HIV positive - an already marginalised group that faces a particularly complex and challenging set of health requirements.

With this in mind, and as supported by the evidence set out below, BASHH and BHIVA strongly believe that overseas visitors who are HIV positive should be excluded from these Amendment Regulations due to the detrimental impact they will likely have on access to care and public health outcomes more broadly. Ultimately, we believe that the Amendment Regulations should be withdrawn until a comprehensive assessment has been carried out on the full impact that they will likely have.

HIV¹
P66

Hepatitis²
P140

Risk of transmission via biting /spitting

Literature reviews
EACS Invited symposium October 2017

BHIVA-EACS
Inaugural ‘Standards of Care’ symposium

Advancing standards of care AIDS 2018
The next 25 years…… how will you advance HIV Care?

Managing comorbidity
- Identifying traditional risk factors

Safety trials
- 2DR vs triple ART
- Cohorts and cohorts for SNAE

Representative studies
- Widen RCT inclusion

Access
- Negotiating health policy / drug access
- Access to generics
- Infrastructure investment

New compounds
- Supporting pipeline research
- Long-acting formulations

Social justice, standards
- Challenge stigma
- Challenge discriminatory legislation
- Standards of care

Measures to improve engagement
- Behavioural measures

2DR, two-drug regimen; BID, twice daily; NRTI, nucleoside reverse transcriptase inhibitor; RCT, randomized controlled trial.
Thank you

Royal London Hospital
Vanessa Apea
Rageshri Dhairyawan
James Hand
Jane Deayton
Nashaba Matin
Maurice Murphy
Simon Rackstraw
Liat Sarner
Sadna Ullah
Andy Williams

Mentor
Jane Anderson

Slides
Michael Aboud
Marta Boffito
Andrew Carr
Annemiek de Ruiter
Bojana Dragovic
Joe Eron
Clifford Leen
Nneka Nwokolo
Adrian Palfreeman
Erin Quirk
Jürgen Rockstroh
Caroline Sabin
Laura Waters
Gary Whitlock

Wonderful Wife
Flick Thorley

Graphics by John Wong
Nucleus Central
• Retrospective Antiretroviral Resistance Cohort Analysis database

• Conclusions:
  • Risk of virological failure similar ($P=0.323$)
  • Higher rates of virological blips in 2DR regimes ($P = .016$)
  • More likely be blip free and suppressed if on ART > 6 years