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First reports from BHIVA/BASHH 2018

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HIV TREATMENT BULLETIN

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EDITORIAL

This 1st May issue of HTB celebrates International Workers Day with news from the 4th Joint BHIVA/BASHH Conference held in Edinburgh from 17 to 20 April 2018.

The joint meeting had many highlights with more than 400 research studies as either oral presentations or posters.

While these first reports focus on some of the headline news, we will include additional poster coverage in the next issue.

Perhaps most important was a survey that showed how sexual health services are unable to meet current demand. While difficulty in getting an appointment has been an increasing problem for many clinics, a simple snapshot survey from November 2017 showed how serious this has become.

Other news includes the launch of the new BHIVA Standards of Care and key changes that are expected in the upcoming UK pregnancy guidelines - together with a review of other pregnancy studies.

Other reports cover dolutegravir, TAF, generics in the UK and oral STIs – and find out why one of the catchiest hashtags from the meeting became “We Love Kissing”.

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i-Base 2018 appeal: we still need your help...

Last year we launched a funding appeal to help i-Base continue to provide free publications and services.

Your help has been inspiring – and we hope this support will continue during 2018. If 1000 people support us with £5 a month we will be on course to meet our shortfall.

HTB is the UK's longest running activist HIV treatment publication - starting as DrFAX from 1996-2000 and relaunched as HTB from 2000-2018.

We are the only HIV organisation to provide free booklets to NHS clinics on HIV treatment. All support is appreciated.

<http://i-base.info/i-base-appeal-we-need-your-help>



CONFERENCE REPORTS

Fourth Joint Conference of BHIVA/BASHH (4th BHIVA/BASHH)

17–20 April 2018, Edinburgh

Introduction

The Fourth Joint Conference of the British HIV Association (BHIVA) with the British Association for Sexual Health and HIV (BASHH) was held from 17 – 20 April in Edinburgh.

As with previous joint meetings, the programme expanded to include a broader focus on sexual health with almost 1000 delegates and 400 poster presentations.

Materials from the conference, including the programme and abstract book are now online, together with slides for many of the oral presentations. Webcasts from the oral presentations are posted shortly after the conference.

<http://www.bhiva.org/AnnualConference2018.aspx>

Abstract book (direct link):

<http://www.bhiva.org/documents/Conferences/2018Edinburgh/AbstractBook2018.pdf> (PDF)

Short summaries articles of some of the highlights are included below.

- Almost 1 in 8 people with symptoms turned away from sexual health clinics in SE London: 40% are under 25 and 6% under 18 years old
- A new framework for best HIV care: BHIVA Standards of Care revised and updated (2018)
- Key changes to upcoming UK HIV pregnancy guidelines (2018)
- Pregnancy studies at 4th Joint BHIVA/BASHH Conference
- Meta-analysis of TAF vs TDF in boosted vs unboosted regimens
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Almost 1 in 8 people with symptoms turned away from sexual health clinics in SE London: 40% are under 25 and 6% under 18 years old

Simon Collins, HIV i-Base

A pilot survey of people unable to access sexual health services in three London boroughs revealed the lack of capacity in these services. The majority of people had symptoms and a quarter reported previously being unable to access another service.



Results from this commissioner-initiated survey were presented at the 4th BHIVA/BASHH conference by Aileen Dunne, on behalf of the Southwark Public Health Directorate.

This snapshot survey was run from 1 - 30 November 2017 to find out the numbers and characteristics of people being turned away from sexual health clinics in inner south east London and to see whether these people had already been turned away from other services.

Anyone who was turned away from one of eight clinics in Southwark, Lewisham and Greenwich was asked to anonymously complete either a paper or online survey.

Overall, there were 8859 attendances with 1094 people completing a survey about being turned away. An additional 1116 residents were turned away from online testing services.

Almost 75% of people were residents of the participating boroughs. An alarming proportion of surveys were completed by younger people: 40% were 24 or younger, including 19% aged 22–24, 15% aged 19–21 and 6% were 16–18.

The main reasons for the clinic visit was answered by 90% of respondents, of whom only 11% were asymptomatic and applying for a routine check up. More than half (54%) reported STI symptoms, 29% were for contraception services, including 4% needing emergency contraception, and 2% had partners who had recently been diagnosed with an STI.

More than 1 in 4 (26%) reported having been previously turned away from another service, of which 44% were from a GP and 42% from a sexual health service. Of the people previously turned away, one third (33%) were under 25, and 3% were under 18 years old. The survey did not collect information on how many times people had been turned away or whether this was for the same reasons.

The study concluded that in addition to showing the feasibility of running a turn-away survey. It also noted that while the results demonstrated unmet need, actual need was expected to be higher still.

Based on these pilot results, an updated survey has been rerun during the last two weeks of April.

C O M M E N T

This lack of capacity at sexual health clinics, especially for young people, is likely to be common in many regions and similar surveys to measure currently unmet needs should be initiated by other centres.

The findings also suggest that similar audits should be routinely included in the commissioning specifications.

It is likely to be a direct outcome from the decision to make local authorities responsible for sexual health at a time when local authority budgets are increasingly being cut.

These results are likely to underestimate the numbers of people unable to access sexual health care as it only presents results from those who completed the survey.

The alarming outlook for sexual health services is further threatened by the proposal for ring-fencing for local authority funding to be removed for these services in 2020. This was highlighted by BHIVA and BASHH earlier in the year, who jointly call for the ring-fencing to remain. [2, 3]

A useful article in the Lancet HIV this month also summarises other aspects of these threats to our services. [4]

Reference

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A new framework for best HIV care: BHIVA Standards of Care revised and updated (2018)

Roy Trelvelion, HIV i-Base

The revised BHIVA Standards of Care (SoC) for people living with HIV are primarily produced as a reference for commissioning HIV services. It also describes a minimum standard of care that HIV positive people can use as a reference.



These 90-page guidelines were last updated in 2013 and this third edition was launched at the 4th Joint BHIVA/BASHH Conference in Edinburgh.

The Standards was produced by a writing group of more than 90 individual doctors, health workers and people living with HIV. It was a collaboration with numerous professional associations, commissioners and community groups.

The main changes to this edition include:

- Reducing the number of standards from 12 to 8, but with each one covering broader themes.
- A new section is included on person-centred care. This includes wider aspects of social circumstances, including stigma and discrimination, self-management, peer support and general well-being. The importance of these issues are emphasised by this being an early chapter.
- Recognising the new U=U consensus: an undetectable viral load means HIV cannot be sexually transmitted - with or without a condom (although some sections of the document have inconsistent information on U=U that will hopefully be quickly updated).
- The section on complex care has been broadened with more detail about access to specialist non-HIV treatment.
- Another new section covers HIV across the life course and covers HIV treatment and care from adolescence to end of life. This includes palliative care in the context that ART might continue to work well to the very end of life.

There are now eight chapters covering major themes. Each chapter and subsection includes quality statements and auditable targets.

Standard 1: testing, diagnosis and prevention and the 90:90:90 goals to eradicate HIV. All three areas are ways to maintain and develop combination prevention. This includes increased testing, early treatment, viral suppression and PrEP. Combination prevention helped bring about the dramatic reduction in HIV transmission seen recently in the UK. HIV positive people are important partners in combination prevention.

Standard 2: person-centred care. This has been described as “the fourth 90” and focusses on the whole person, not just HIV. BHIVA say it considers, “desires, values, family situations, social circumstances, and lifestyles. And in so doing, the needs

and preferences of HIV positive people can be responded to in humane and holistic ways.” It challenges HIV stigma and discrimination and works towards equality in health and social care. Social inclusion and well-being – crucially aided by peer support – are key to person-centred care.

Standard 3: HIV outpatient care and treatment. Anyone newly diagnosed must be seen by a specialist HIV doctor within two weeks and given access to psychological and peer support. In some cases this referral needs to be within 24 hours. There is no gold standard for measuring engagement in care, but transfer of care should be seamless whether a person moves home, is incarcerated or simply moves to another clinic. Increasing numbers of children living with HIV from birth are now becoming adolescents. Management by interdisciplinary teams must ensure successful transition to adult HIV services. A qualified doctor must prescribe ARVs and monitoring according to current national guidelines.

Standard 4: complex HIV care. Inpatient care must ensure that an HIV specialist is included in the hospital multidisciplinary team. HIV positive people are living longer and often go into hospital for non-HIV related problems. They may be cared for safely and appropriately in a local ward or clinic. But they must also be supported by immediate and continued HIV expertise and advice. HIV positive people must have access to specialist services for other conditions such as cancer. But clear protocols and agreed pathways are essential for safe delivery of services. This section also includes supporting people with higher levels of need. It includes successful management of multiple long-term conditions, poor mental health, poor sexual health, and problems with alcohol or substance use.

Standard 5: sexual and reproductive health. It is important that HIV positive people are supported in maintaining healthy sexual lives for themselves and their partners. In addition, anyone at risk of other STIs and infectious hepatitis, perhaps through drug use, should be supported and given advice. Care should be given for contraception, fertility services, pregnancy planning, and access to abortion services. Care must ensure that babies are born healthy and HIV negative. Care for the mother’s health is key to giving birth to a healthy baby.

Standard 6: psychological care. HIV positive people should receive care and support that assesses, manages and promotes their emotional, mental and cognitive wellbeing and health. This should be sensitive to the unique aspects of living with HIV. HIV positive people have higher rates of depression, anxiety, addictions, self harm, and other mental health issues than the general population. Mental health needs must be screened on an annual basis. This includes screening for poor cognitive function that can cause memory problems and reduce ability to perform simple tasks.

Standard 7: HIV across the life course. This section looks at standards of care for everyone who is HIV positive. Management of ART should be individualised at every age. It starts with adolescents (aged 10 to 19 years) and young adults (aged 20 to 24 years). Education and personal development – as well as achieving healthy sex lives and relationships – should be supported by experienced sexual health advisers and specialist nurses.

The years from 25 to 65 are described as early to middle adulthood. Most people in this age group are diagnosed as

adults. Care for early diagnosis and treatment should include peer support as well as psychological support. HIV positive people should be supported in having healthy and fulfilling sex lives and engaged in treatment as prevention (U=U).

The over 65s – whether newly diagnosed or long-time positive – should be given access to treatment for complex comorbidities. This is an area of significant emerging knowledge and will likely develop over the course of these standards. Successful care may be achieved through co-speciality clinics, mentoring schemes, or by identified experts in advice and guidance. Palliative care is now included here.

Palliative care ensures that the individual and their family are supported, receive appropriate care that meets their needs and preferences, and do not experience unnecessary suffering

Standard 8: developing and maintaining excellent care.

This standard covers knowledge and training to ensure specialist services are provided. It sets standards for monitoring, auditing, research and commissioning. It also sets standards for public health surveillance, confidentiality and information governance.

Roy Trevelion is a community representative on the Standards writing group.

C O M M E N T

These comprehensive Standards are very welcome.

The community was involved at every stage from planning to the final draft, with at least one community representative on each chapter and more than 15 UK-CAB members collaborating overall.

The result is a comprehensive benchmark for health and wellbeing for HIV positive people.

All sections provide bullet points for measurable and auditable outcomes and must be promoted in primary and secondary care, health & social care, public health, and local authority healthcare provision.

As bureaucratic and structural changes affect the structure of HIV services, these Standards should be a reference for ensuring that high-quality care for HIV positive people is maintained.

The inconsistent messaging over undetectable viral load and HIV transmission will hopefully be rapidly corrected. As the publication is only available in PDF format, this should be relatively easy. Several formatting problems, including difficult legibility (light text etc) are also being revised.

It is good to see the inclusion of HIV positive people in the photographs throughout the report, supported by the UK-CAB and Positively UK.

Reference

BHIVA. British HIV Association Standards of care for people living with HIV 2018. April 2018.

<http://www.bhiva.org/standards-of-care-2018.aspx>

Key changes to upcoming UK HIV pregnancy guidelines (2018)

Polly Clayden, HIV i-Base

An overview of the key changes to the upcoming UK pregnancy guidelines was presented at the Fourth Joint Conference of BHIVA/BASHH by writing group chair Yvonne Gilleece. [1]



The guidelines will be revised to include “treat all”, updated guidance on use of integrase inhibitors, infant PEP and infant feeding, an expanded section on psychosocial issues in pregnancy, a new section on postnatal management and community-friendly language.

The guidelines are still in draft form following public consultation and will be published later this summer after the writing group responds to comments.

The 2018 revisions include:

Antiretroviral therapy (ART) in pregnancy

- All treatment naive pregnant women are recommended to start lifelong ART in accordance with BHIVA adult and other guidelines worldwide (as this includes elite controllers, the section on elite controllers has been removed).
- Expanded guidance on use of integrase inhibitors: raltegravir 400 mg twice daily but insufficient data to recommend 1200 mg once daily; elvitegravir/cobicistat may be continued with close monitoring if a woman receiving it with undetectable viral load becomes pregnant but not recommended starting in pregnancy; dolutegravir 50 mg appears to be safe but still has limited data.

Psychosocial issues

- Comments on additional factors that might affect a woman living with HIV in pregnancy: family, asylum status and confidentiality.
- Antenatal HIV care should be delivered by a multidisciplinary team – the composition of which will vary.
- Assessment of antenatal and postnatal depression should be undertaken at booking, 4–6 weeks and 3–4 months postpartum as recommended in NICE guidelines.
- Postnatal contraception, breastfeeding and cabergoline use should also be addressed antenatally.

Hepatitis

- Hepatitis B agents as part of ART should be continued as the potential risk to the foetus from drug exposure is outweighed by that of hepatitis flare, liver disease progression or HIV/HBV virological rebound and risk of vertical transmission.
- Although there are very limited data on tenofovir alafenamide in pregnancy, animal data do not indicate direct or indirect harmful effects.

- Women living with HIV/HCV should not be treated for HCV with ribavirin-based DAA therapies. Women who discover they are pregnant while receiving treatment should discontinue both therapies immediately.
- Women living with HIV/HCV of child-bearing age wishing to get pregnant should be prioritised for DAA-based HCV therapy.

Infant PEP

- Length of infant PEP has been shortened where risk of vertical transmission is very low.
- Very low risk is defined as mother has received ART for at least 10 weeks has two viral load tests <50 copies/mL during pregnancy at least four weeks apart and at 36 weeks gestation or more.
- If these criteria are met, infants should receive two weeks AZT monotherapy.

Infant feeding

- Exclusive formula feeding is still recommended.
- Updated infant feeding advice to include new data on breastfeeding and the emotional impact that not breastfeeding might have on women.

Postnatal management

- Opportunity to provide guidance on mental health assessment postpartum at 4–6 weeks.
- Ensure cytology and contraception provided or planned for.
- Testing of partner and/or other children if not already tested.
- Women not breastfeeding their infant should be offered cabergoline to suppress lactation.

Language

- Significant changes in the language used in the text, for example: vertical transmission vs MTCT; and woman living with HIV vs HIV infected or HIV positive woman.
- Language received well in public consultation.

COMMENT

Several presentations at the BHIVA/BASHH meeting showed real-world findings on HIV and pregnancy in the UK and revealed how clinical practice relates to the recommendations in the guidelines.

These are reported in the following article below. [2]

References

All references are to the Programme and Abstracts of the **Fourth Joint Conference of BHIVA/BASHH, Edinburgh, 17–20 April 2018**. Published in *HIV Medicine*, 19 (Suppl. 2), s5–s20.

<http://www.bhiva.org/AnnualConference2018Presentations.aspx>

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2. Clayden P. Pregnancy studies at 4th Joint BHIVA/BASHH Conference. HTB 30 April 2018. <http://i-base.info/htb/34011>

Pregnancy studies at 4th Joint BHIVA/BASHH Conference

Polly Clayden, HIV i-Base

Several presentations at the BHIVA/BASHH meeting showed real-world findings on HIV and pregnancy in the UK and revealed how clinical practice relates to the recommendations in the upcoming BHIVA pregnancy guidelines. [1]



One study looked at the influence of the guidelines on trends ART use in pregnancy in the UK/Ireland in 2005–2016. [2]

This analysis of 10,009 women, 13,757 singleton pregnancies and 54,119 individual drug exposures found that whenever BHIVA guidelines were updated, clinical practice followed.

For example, in 2005 when tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) was not yet a recommended as backbone, only 0.2% of pregnancies were exposed to FTC and 2.7% to TDF, compared with 2016, when TDF/FTC was introduced as a "preferred option", and 20.5% of women received FTC and 21.1% TDF. Similar findings were shown for other antiretrovirals. Overall the analysis demonstrated the responsiveness of antiretroviral prescription, both before and during pregnancy to changes in clinical guidance.

A presentation from the ongoing UK/Ireland audit of perinatal HIV infection showed an all-time low rate of vertical transmission in diagnosed women – less than 0.3% in 2012–2014. [3] A total of 108 cases were reported between April 2006 and April 2014; over two-thirds of these were born to undiagnosed women.

There were 25 children with perinatal HIV reported since 2014. Similarly, two-thirds (17/25) of the children were born to undiagnosed women, three mothers were diagnosed during, and five before pregnancy. Children's age at diagnosis ranged from birth to eight years. Of the 17 women diagnosed after pregnancy, 12 infections were seroconversions, four women declined HIV tests (no recent cases) and one woman booked late.

At least 13 women had major complicating circumstances, including immigration, housing or mental health issues, intimate partner violence, and social services involvement.

A poster from Leeds Teaching Hospitals Trust described its policies for pregnant women who decline an HIV test. [4] The policies were developed after a pregnant woman at high risk for HIV repeatedly declined testing, and the lack of local or national policies became apparent.

The Trust states that a woman declining HIV testing at booking and 20 weeks will be seen by the obstetric consultant and offered cord blood testing at birth. If this is declined a full HIV risk assessment of her and her partner will be done and she will be informed that infant testing might be required. Women in the third trimester still declining HIV or cord blood testing will be discussed by the multidisciplinary team. The team applies a risk stratification for infant testing using a risk of 1:1000 (as in adult PEP) to start a court authority request.

Two posters reported on women who chose to breastfeed their infants. [5,6] Although formula feeding is still recommended, forty babies have been breastfed by women with HIV in the UK since 2012 with no transmissions.

A study conducted by Imperial Healthcare NHS Trust, and Chelsea and Westminster NHS Trust, London, UK looked at the experiences of eight women who breastfed 10 babies. All women had partners of which five were documented as aware of the mother's HIV. Three mothers identified extended family being unaware of their HIV as a reason for breastfeeding.

Three babies were breastfed for less than one week. Of remaining seven, average breast feeding duration was 33 weeks, three exclusively and four mixed fed. All mothers remained fully suppressed throughout duration of breastfeeding and all babies had negative viral load after completing breastfeeding.

Women who breastfed in this group faced many challenges. A higher proportion than expected had not informed their partners, family, or healthcare team about their HIV, raising concerns breastfeeding could be part of maintaining "the secret".

A related poster from Leeds reported on five women who breastfed six babies over the past three years. Breastfeeding duration ranged from five days to 20 months. All women had good adherence to ART and blood tests during pregnancy and breastfeeding and there were no transmissions. All but one woman discussed breastfeeding plans with their doctor. This woman had not disclosed her HIV status to her partner and had financial pressures to breastfeed.

Both reports emphasised the importance supporting and understanding women's decisions, and that it is considered safer for women to engage with services during breastfeeding than to do so without disclosing or engaging with care. Women with undetectable viral load who choose to breastfeed should be encouraged to inform those who need to know, so they can be appropriately supported.

Intimate partner violence often escalates in pregnancy. It is independently associated with adverse obstetric perinatal outcomes, and is documented to increase adverse health behaviour including smoking, alcohol and substance use.

BHIVA guidelines recommend screening HIV positive pregnant women for intimate partner violence and offering appropriate intervention as well as documenting other key social circumstances including sexual history, mental health status, housing issues, smoking, drug use and alcohol consumption.

A poster from St George's University Hospital, London, described high levels of psychosocial vulnerability in pregnant women with HIV. [7]

In this cohort, there were 81 pregnancies were identified in 64 women. Of these, 21% of pregnancies were documented as having significant difficulty engaging with HIV care. Among those disclosing 51% (24/47) reported mental health issues, 18% (8/45) intimate partner violence and 50% (19/38) housing problems. Smoking, alcohol and substance use were frequently reported.

Significant levels of social vulnerability were seen in this small cohort of pregnant women but the authors noted that documentation was variable and they needed to find ways to improve this. Plans are underway to develop and evaluate a

clinical proforma to aid documentation and adherence to BHIVA guidelines.

Overall vertical transmission is very low in the UK and the availability of safe and effective ART (combined with good multidisciplinary care) has been a major reason for this success.

But women with HIV can face many challenges against a background of draconian government cuts and policies that target the most vulnerable. The ongoing pregnancy audit continues to reveal that vertical transmission takes place against a background of complex social circumstances like housing, immigration, intimate partner violence and mental health issues.

So, as well as guidance on the clinical management of HIV in pregnancy, the emphasis on psychosocial issues (this section was both expanded and moved forward) in the BHIVA guidelines is welcome and hopefully will provide guidance to continue to deliver critical additional support to those women that need it.

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All references are to the Programme and Abstracts of the Fourth Joint Conference of BHIVA/BASHH, Edinburgh, 17–20 April 2018. Published in HIV Medicine, 19 (Suppl. 2), s5–s20.

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Meta-analysis of TAF vs TDF in boosted vs unboosted regimens

Polly Clayden, HIV i-Base

Tenofovir disoproxil fumarate (TDF) boosted with ritonavir or cobicistat, led to higher risks of bone and renal adverse events, and lower rates of viral load suppression, compared with tenofovir alafenamide (TAF). But, unboosted, there were no differences between the two versions of tenofovir for efficacy and only slight differences in safety.



Results from a meta-analysis of TDF versus TAF, authored by Andrew Hill and colleagues, were presented at the Fourth Joint Conference of BHIVA/BASHH.

Boosting agents significantly increase plasma AUC concentrations of TDF (25–37%). Higher plasma tenofovir levels are associated with higher risks of renal and bone adverse events. The TAF dose is reduced from 25 to 10 mg daily when boosted but TDF remains at 300 mg daily. TDF is most commonly used worldwide in unboosted regimens, combined with 3TC and either efavirenz or dolutegravir.

Using a PUBMED/Embase search the authors found 11 randomised head-to-head trials of TDF vs TAF – including 8110 participants.

Nine trials compared TDF vs TAF in HIV positive people and two in people with hepatitis B. There were 4,574 participants who received boosting agents (with both TDF and TAF) representing 7,198 person years (p/y) follow up. The remaining 3,537 participants received unboosted regimens, giving 3,595 p/y follow up.

The authors noted that participants were largely young to middle aged, with no pre-existing osteoporosis or kidney damage.

The analysis revealed boosted TDF treated participants had marginally lower viral load suppression rates <50 copies/mL ($p=0.05$), more bone fractures ($p=0.04$), lower bone mineral density ($p<0.001$) and more discontinuation for bone ($p=0.03$) or renal ($p=0.002$) adverse events.

In contrast, there were no significant differences in viral load suppression rates or clinical safety endpoints (except bone mineral density) between unboosted TDF and TAF. (See Table 1).

Table 1: Meta-analysis of safety and efficacy TDF vs TAF

Efficacy/safety	TDF vs TAF Boosted	TDF vs TAF Unboosted
Viral load <50 copies/mL	86 vs 90, ($p=0.05$)	Both 91% ($p=NS$)
Grade 1–4 AEs	57 vs 55%, ($p=NS$)	72 vs 70%, ($p=NS$)
Grade 3–4 AEs	6 vs 5%, ($p=NS$)	4 vs 5%, ($p=NS$)
Bone fractures	1 vs 0, ($p=0.04$)	0 vs 1%, ($p=NS$)
D/C for bone AEs	1 vs 0, ($p=0.03$)	Both 0%, ($p=NS$)
D/C for renal AEs	1 vs 0, ($p=0.002$)	Both 0%, ($p=NS$)

Key AE, adverse events; D/C, discontinue; NS, not significant

C O M M E N T

More details from this meta-analysis are included in the version recently published online in the Journal of Virus Eradication. [2]

The first generic TAF-containing fixed dose combination (FDC) was tentatively approved by the US FDA earlier in the year (dolutegravir/FTC/TAF). [2] The new FDC could offer several programmatic benefits to low- and middle-income countries where genetics are accessible including lower cost and smaller tablet size (easier to swallow, transport and store).

But evidence gaps, particularly for pregnancy and TB coinfection have meant that TAF is not yet included in WHO guidelines or Essential Medicines List.

In high-income countries (including in the UK), where generic versions of newer antiretrovirals are not available but generic TDF is or shortly will be, the significant difference in price will limit access to TAF to people with reduced renal and bone health.

In the UK, the list price for TAF/FTC is £4268 per year, which although discounted for bulk purchasing, is still considerably higher than Hill et al's estimated £600 price for generic TDF/FTC. [4]

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Meta-analysis of dolutegravir in naive, experienced and switch studies

Polly Clayden, HIV i-Base

A meta-analysis of 7340 participants in 13 randomised trials found efficacy and safety benefits for starting dolutegravir compared with other antiretrovirals in both naive and experienced participants. [1] In the four switch studies in participants with undetectable viral load on their current ART, however, changing to dolutegravir was associated with more adverse events and discontinuations.



Investigators from Liverpool University, Imperial College London, London, and Chelsea and Westminster Hospital in the UK are conducting ongoing reviews of antiretrovirals under consideration for recommendation by WHO and national departments of health in low- and middle-income countries. [2–5] An update of the dolutegravir meta-analysis was presented at the Fourth Joint Conference of BHIVA/BASHH.

For this update, a PUBMED/Embase search identified 13 trials. Of these, seven were in ART naive participants (ARIA, FLAMINGO, Gilead-1489, Gilead-1490, SINGLE, SPRING-1, SPRING-2), two were in ART experienced (DAWNING, SAILING) and there were four switch trials in people with viral load suppression (NEAT 022, STRIVING, SWORD-1, SWORD-2).

In the nine trials of naive and experienced patients (n=5348), dolutegravir showed 7% higher rates of viral load suppression <50 copies/mL (p=0.002). This effect was consistent for all three comparator drug classes: NNRTIs (p=0.002), PIs (p=0.0003) and integrase inhibitors (p=0.05).

There was also a 2% lower risk of discontinuation for adverse events (p=0.03) in these nine studies for people starting in dolutegravir arms. There was consistent effect for comparison of with NNRTIs, PIs and other integrase inhibitors, but no decline in protocol-defined virological failure or risk of drug resistance.

But, in the four switching studies (n=1992), there were significantly more Grade 1–4 adverse events and adverse events associated discontinuation (both p<0.001) in people taking dolutegravir. The investigators noted that this increased risk of adverse events after switch has not been observed in switching studies of other antiretrovirals, including elvitegravir, bictegravir and darunavir/r.

They concluded that “If patients are already tolerating current antiretroviral treatment, the risks of switching to dolutegravir could outweigh the benefits.”

C O M M E N T

These findings need to be considered in the context that people who are stable on antiretroviral regimens before entry to a switch study are likely to be doing well and tolerating their regimen.

The observation that this increased risk of adverse events has not been seen in switching studies of other antiretrovirals is notable, but might not allow for the change in dosing recommendations that have developed post-approval.

For example, sleep disturbance and insomnia that were early reasons for switching but that anecdotally resolved by taking dolutegravir as a morning dose.

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Not claptrap: kissing as strongest route for oral gonorrhoea

Simon Collins, HIV i-Base

Understanding how infections are transmitted is essential if information about prevention is to be accurate, and a very interesting study challenged common assumptions about both kissing and oral sex.

Eric Chow from the Melbourne Sexual Health Centre, Australia, provided data from a cohort of gay men to support the importance of the link between kissing and oral gonorrhoea.



This was based on results from a sexual activity survey completed by 3769 gay men between March 2016 and February 2017, who were tested for oropharyngeal gonorrhoea on the same day. The survey asked about sexual activity during the previous three months, with categories of (i) kissing only, (ii) oral and/or anal sex without kissing or (iii) both.

Median age was 30 (IQR: 25 to 37) and 235 men (6.2%) tested positive for oral gonorrhoea.

Although the majority of men did not have sex-only partners, participants who reported ≥ 4 kissing-only partners was significantly associated with oropharyngeal gonorrhoea compared to no kissing-only partners (62.5%; aOR=1.6; 95% CI: 1.1 to 2.33; $p=0.012$). This analysis adjusted for potential confounders such as demographic characteristics, HIV status, contact of gonorrhoea and urethra and anorectum gonorrhoea infection.

As the association for the kiss-and-sex group was not significant in the multivariate analysis (aOR = 1.53, $p=0.067$) the results showed that kissing was the strongest risk factor and that in this group of gay men, sex was not the principal route for acquiring oropharyngeal gonorrhoea.

The same research group is also leading an ongoing study on whether antibacterial mouthwash prevents gonorrhoea in the throat. [2, 3]

When told about the results, the majority of participants said that this wouldn't stop them from kissing.

When asked about whether there should be a public health message from these results, the presenter was just as clear: "Oh no, we all love kissing".

This study was a highly commended poster and was selected for a short oral presentation.

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Rapid PrEP uptake in Scotland exceeds expectations

Simon Collins, HIV i-Base

Impressive results from NHS Scotland showed that providing PrEP in sexual health clinics is feasible with higher than expected uptake and reaches people at high risk who were previously not engaging in care.



These results on the first eight months of PrEP implementation were included in a poster presented by Nicola Steedman from NHS Scotland and colleagues. The coding system included eligibility (reasons for PrEP), dosing regimen and outcomes for whether PrEP was prescribed.

From July 2017 to February 2018, more than 117,000 individuals attended sexual health services and 8082 (7%) were gay or bisexual men. During the same period, 2517 PrEP prescriptions were provided to 1295 individuals, 96% of who were gay or bisexual men, with much lower use by women ($n=10$) or other/unknown ($n=31$).

This exceeded the 1000 places initially planned for the first year, with 16% of gay and bisexual men wanting to use PrEP. Of the 1780 people attending primarily for PrEP, 18% ($n=328$) were attending clinics for the first time and 27% ($n=477$) had not visited for more than two years, with similar percentages (17% and 24% respectively) going on to take PrEP.

Although limited details were provided on age, approximately 19% were under 25, 22% were 25-29, 29% were 30-49 and 30% were older than 40.

Results on dosing was available for 1028 people with 82% of people using daily dosing, 14% using event-based dosing and 3% using both.

Participants could have multiple codes for eligibility, but most common reasons were recent sex without condoms (80% of reasons) and recent STI (17% or reasons).

Of the 83 people offered PrEP who initially declined, 10 later decided to use PrEP, and most fulfilled eligibility criteria. Only 13 people decided to self-source PrEP online. PrEP was only contraindicated in six people.

C O M M E N T

These remarkable results show that providing PrEP within NHS clinics is both feasible for clinics and highly acceptable for patients.

That approximately 25% of people had not attended a clinic in the previous two years and 20% were attending for the first time, with nearly all participants meeting eligibility criteria, shows the programme was highly effective at reaching people at high risk.

The rapid presentation of early results also shows that real world data collection from open-access services is also easily possible.

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Drug cost savings from routine use of generic ARVs: safety and efficacy in practice

Simon Collins, HIV i-Base

Several presentations provided results on commissioning guidelines relating to use of generic versions of commonly used HIV drugs. These showed the potential for large savings was driven by routine switching to generics with minor gains from other approaches.

NHS England saves £10 million from use of generics

The first of these was an oral presentation by Laura Waters from Mortimer Market Centre, on behalf of the NHS England HIV Clinical Reference Group (CRG). These were results for 2016/17 from a pharmacy audit of five clinically appropriate and acceptable prescribing switches that were aimed to save 2.5% from the £429m costs for 2015/16. [1]

This involved both new prescriptions for participants starting ART and switches for people currently stable on ART. The programme was developed by a multidisciplinary group, including doctors, pharmacists, patient representatives and commissioners.

The generic switches included switching to generic versions of abacavir/3TC, efavirenz, nevirapine and to coformulated cobicistat rather than separate ritonavir with darunavir or atazanavir. This results in total savings of almost £10m, driven mainly by use of generic abacavir/3TC and efavirenz, see Table 1.

Even though this programme was not fully rolled out in all regions, with some areas starting later, the switches reduced the drug budget to \$413.7m, achieving a 3.5% saving compared to the

total ARV budget compared to 2015/16. An additional £2m savings were made in other secondary savings.

Additional costs, however, were not adjusted for or included in these results, for example, from more frequent clinic visits, switching back when appropriate, and the suspension of VAT-free prescribing. Also, this was only a financial analysis, with no details on clinical outcomes.

Clear communication to individual patients and community engagement in this process overall were both emphasised as being essential. The lack of an updated CRG website to help with information and transparency was noted as a weakness.

Allowance for additional visits and switchbacks

In a second oral presentation in the same conference session, Elizabeth Okecha from Manchester University NHS Trust presented a review of total costs from a case note review of 432 patients from single clinic in Manchester (The Hathersage Centre). [2]

This involved some of the same switches to the CRG study reported above, but also included switching from the fixed dose combination (FDC) of dolutegravir/abacavir/3TC to separate dolutegravir plus generic abacavir/3TC.

The results included the 29/432 of people who had to modify treatment again after the first switch, requiring an additional 89 clinic visits.

Two cases of viral failure were reported in patients who were previously on stable ART, one with resistance to efavirenz (K103N) and one with resistance to lamivudine (M184V).

Table 1: Drug switches and savings by NHS England 2016/17

Switch ARVs	2016/17 savings (£)
Abacavir/lamivudine - originator to generic	6,946,811
Atripla to Truvada + generic efavirenz	1,131,212
Nevirapine PR - originator to generic	722,022
Darunavir/ritonavir to Rezolsta	752,172
Atazanavir/ritonavir to Evotaz	240,404
Total	£ 9,792,621

Table 2: Drug switches and savings in Manchester clinics (n=432)

Switch ARVs	n	Further switches (n)	extra visits	extra clinic costs (£)	drug wastage (£)	Net saving (6 months)
Atripla to Truvada + generic efavirenz	187	8	11	4550	4654	£71,319
Triumeq to dolutegravir + generic ABC/3TC	76	10	14	5997	3193	£42,760
Darunavir/ritonavir to Rezolsta	152	11	59	20,346	4515	-£7,132
Atazanavir/ritonavir to Evotaz)	17	0	5	1,755	0	£227
Total	432	29	89	£32648	£12,362	£107,175

In addition to drug savings, results were also presented for additional costs including clinic visits and drug wastage. Although large savings were switching to generic formulations, especially from the two FDC Atripla and Triumeq, additional costs from extra clinic visits and drug wastage resulted in increased costs when switching to darunaivir/cobicistat coformulation, see Table 2.

Overall patient acceptability however was reported as good.

Several posters presented additional aspects relating to switching and implications for costs and savings.

Complications from switching ritonavir to cobicistat

A poster presented by Colver et al from Luton Sexual Health presented results from a case note review of 48 patients who switched from ritonavir- to cobicistat-boosted PIs. NHS England CRG has set target to switch 50% of patients on darunavir and 60% on atazanavir to the FDCs Rezolsta and Evotaz, respectively. [3]

Mean age of this group was 44 (range: 29 to 56), with 77% black African and 56% women. Most people were on darunavir (65%), with one third on atazanavir. Overall 8-5% were using tenofovirDF/FTC backbone but only 39/48 had viral load <40 copies/mL before the switch (those with detectable ranged from 116 to 4935 copies/mL).

New side effects were reported by 21% of patients (including headache, diarrhoea, generalised itch, leg/foot pain and rash) resulting in four individuals switching back to ritonavir (8%).

Although the poster concluded that majority of patients switching from ritonavir to cobicistat benefit from a reduced pill burden, a small number switch back to their original regimen because of side effects. They recommended using a short course of the cobicistat-containing regimen first to avoid wasting larger quantities in those who do switch back.

A second poster on switching to cobicistat was presented by Pires and colleagues from the Lawson Unit in Brighton. [4]

This case note review included 173 patients who switched from darunavir plus ritonavir to darunavir/cobicistat. Of these, 15/173 (8.6%) later discontinued darunavir/cobicistat, with 7/15 returning back to ritonavir: 3/7 tablet size; 3/7 side effects (stomach cramps, headache, foot pain) and 1 due to patient choice. Of the 8/15 changing to alternative combinations, 5/8 were due to diarrhoea, 3/8 for cardiovascular risk and 1/8 due to pill burden and raised creatinine.

Of the 17 people on atazanavir, 2/17 returned to atazanavir/ritonavir (1 due to dizziness, 1 to acne and alopecia) and 2/17 changed to alternative combinations (1 due to pill burden and jaundice and 1 for simplification).

There were no virological failures from switching to cobicistat. Although the study reported saving approximately £25,000 from this switch, the poster was unclear whether additional costs from clinic visits and additional treatment changes had been included.

Switching from Atripla to generic efavirenz plus separate TDF/FTC

Three posters provided more details from switching from the FDC Atripla to generic efavirenz plus separate TDF/FTC.

The first, from the large Chelsea and Westminster cohort, was presented by Tyler and colleagues. [5]

The database review identified 2547 patients in April 2016 who were taking Atripla. Since then, 1556/2547 (61%) switched to generic efavirenz plus TDF/FTC and 48 (2%) to generic efavirenz with new NRTIs. Of the 648 patients (25%) switching to alternative combinations, 31/648 (5%) changed to an alternative single pill combination.

The remaining 295/2547 (12%) who did not switch are either lost to follow-up, have not yet been reviewed or have died.

Of the people who switched, 94% remained on generic efavirenz and 6% (n=97) subsequently switched to an alternative ART.

The most common reason for switching from generic efavirenz were: side effects (75/97; including CNS in 63/75), drug-drug interactions (10/97), single pill request (6/97), TDF side effects (4/97) and viral failure (2/97).

Notably, approximately half of the people stopping due to side effects reported that these were new-onset with the generic formulation.

The second was a case note review from Nottingham University Hospital presented by Darley and colleagues. [6]

Switching from Atripla was discussed with 157/188 patients (88%) recorded as taking Atripla in December 2016. Of these, 21 were not offered this switch because ATP was no longer suitable due to side effects (14), drug interactions (5) or virologic failure (2): showing the importance of regular assessment of stable ART. One patient was identified as not being suitable for a switch.

At this time, switch was voluntary, with 110 people accepting the switch and 47 continuing with the FDC (largely to avoid increase in pill count). Of the 110 who switched, 11/110 (10%) switched back due to new side effects (9/11) or problems with pill swallowing (2/11).

In this Atripla cohort overall, 99/188 (52%) have successfully switched to generic efavirenz with 30% remaining on Atripla and 18% switching to alternative combinations.

Although not meeting the commissioner target to switch 60% of patients on the FDC, this group reported that patient education and clear explanations were particularly important for switching to be successful and that switches for cost-saving rather than clinical need should not be compulsory.

Finally, the NHS commissioning response in Birmingham stopped prescription of Atripla entirely, with the Trust no longer ordering supplies. [7]

Patients were informed of the new policy at their routine clinic and they were assured that their new two-pill combination contained the same medicines as Atripla.

Of the 445 people switching (63% men, 37% women), 97% of who had viral load <40 copies/mL pre-switch, 436/445 (98%) had undetectable viral load six months after the switch to generic efavirenz.

This led to an annual saving of almost £2m with an average annual saving of £4336 per patient who switched from Atripla, reducing the overall drug cost in the Atripla cohort from £2,877,498 to £948,042.

C O M M E N T

As with all other health areas, the routine switch to generic drugs enables the NHS to continue to provide free HIV testing and treatment. The policy also led to successful price reductions by originator companies. For example, ViiV Healthcare reduced the price for Trumeq to match comparable generic prices for the abacavir/3TC components.

However, even for simple switches, the importance of generally rare reactions is important in the framework of individualised care. This becomes even more important when commissioning guidelines are based on target goals (CQUINS etc) for cost-based prescribing. The use of the MHRA yellow card reporting scheme is important for all such cases. [8]

Patient engagement and accurate information seems key to successful switching programmes and can lead to significant savings.

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Unless stated otherwise, all references are to the Programme and Abstracts of the 4th Joint BHIVA/BASHH Conference, 17 - 20 April 2018, Edinburgh. HIV Medicine (2018), 19 (Suppl. 2).

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OTHER NEWS

Continued demands to stop NHS Digital linking medical records to deportation services

Roy Trelvelion, HIV i-Base

On 15 April 2018 the National AIDS Trust (NAT) and Doctors of the World (DOTW) UK issued a joint statement that called on NHS Digital (NHSD) to immediately stop sharing confidential patient details with Home Office immigration enforcement. [1, 2]

That same day, the Commons Health and Social Care Select Committee called – for the second time – for NHSD to suspend the Memorandum of Understanding (MoU) that allows immigration tracing by the Home Office. [3]

Both NAT and DOTW believe the MoU creates a public health risk. It will deter vulnerable migrant groups from seeking antenatal care or urgent care for infectious diseases.

Migrants can include people who have been tortured, or trafficked, people who have serious communicable diseases, people who have vulnerable dependents including children. Migrants should retain the right to access a wide range of NHS services perfectly lawfully.

Deborah Gold, Chief Executive of NAT said: “It is scandalous that our data is being shared and our privacy corroded with less and less justification. As an HIV charity, we understand the importance of treating infectious conditions and limiting the spread of epidemics. When people can’t trust the NHS with their data, that good work is undone and we face a public health risk.”

Lucy Jones, Director of Programmes at DOTW, said: “While confidentiality is in such a precarious state, mothers are not accessing the antenatal care they need, public health is put at risk, and we fear this is only going to get worse.”

Dr Sarah Wollaston MP, Chair of the Commons Health Select Committee, says: “NHS Digital’s decision to routinely share information with the Home Office with a lower threshold is entirely inappropriate. It is absolutely crucial that the public have confidence that those at the top of NHS Digital have both an understanding of the ethical principles underpinning confidentiality and the determination to act in the best interest of patient.”

Fear of deportation is just one of a number of barriers for migrants’ accessing healthcare. Others include discrimination, uncertainty over entitlements, and stigma. An understanding of these issues is crucially important for optimal HIV treatment and care. Any practice that deters HIV testing and treatment undermines the aim of eradicating HIV through 90:90:90.

There has been no public consultation on this MoU. No engagement with doctors or patients’ and migrants’ rights groups. And there has been no work to establish potential impacts on patients, NHS staff and public health.

NAT, DOTW and the Commons Health Select Committee all call on NHSD to suspend this MoU until a transparent and public review of its merits has taken place.

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FUTURE MEETINGS

Conference listing 2018/19

The following listing covers some of the most important upcoming HIV-related meetings and workshops.

International Workshop on Clinical Pharmacology of Antiviral Therapy 2018

22–24 May 2018, Washington

www.virology-education.com

12th INTEREST

29 May – 1 June 2018, Kigali

interestworkshop.org

10th HIV Paediatrics Workshop

20 – 21 July 2018, Amsterdam

www.virology-education.com

22nd International AIDS Conference (AIDS 2018)

23 – 27 July 2018, Amsterdam

www.aids2018.org

International Workshop on HIV & Ageing

13 –14 September 2018, New York, USA.

www.virology-education.com

Australasian HIV&AIDS Conference 2018

24 – 26 September 2018, Sydney

www.hivaidsconference.com.au

HIV Glasgow 2018

28 – 31 October 2018, Glasgow

www.hivglasgow.org

26th Conference on Retroviruses and Opportunistic Infections (CROI 2019)

4–7 March 2018, Seattle

www.croiconference.org

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Publications and regular subscriptions can be ordered online.

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<http://www.i-base.info/qa>

i-Base treatment guides

i-Base produces six booklets that comprehensively cover important aspects of treatment. Each guide is written in clear non-technical language. All guides are free to order individually or in bulk for use in clinics and are available online in web-page and PDF format.

<http://www.i-base.info/guides>

- Introduction to ART (September 2016)
- HIV & quality of life: side effects & long-term health (Sept 2016)
- Guide to PrEP in the UK (November 2016)
- HIV testing and risks of sexual transmission (June 2016)
- Guide to changing treatment and drug resistance (Dec 2017)
- Guide to HIV, pregnancy & women's health (December 2015)

New pocket guides

A new series of pocket-size concertina folding leaflets that is designed to be a very simple and direct introduction to HIV treatment.

The first five pocket leaflets are: Introduction to ART, HIV and pregnancy, ART and quality of life, UK guide to PrEP and HCV/HIV coinfection.

We hope these are especially useful as low literacy resources.

The leaflets use simple statements and quotes about ART, with short URL links to web pages that have additional information in a similar easy format.

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Pocket ART quantity _____ Pocket pregnancy quantity _____

Pocket side effects quantity _____ PrEP for women quantity _____

• **Booklets about HIV treatment****ART in pictures: HIV treatment explained** (*June 2017*): 32-page A4 booklet quantity _____**Guide to hepatitis C coinfection** (*April 2017*): 52-page A5 booklet quantity _____**UK Guide To PrEP** (*November 2016*): 24-page A5 booklet quantity _____**Introduction to ART** (*September 2016*): 48-page A5 booklet**HIV and quality of life: guide to side effects and long-term health** (*Sept 2016*): 96-page A5 quantity _____**Guide to HIV testing and risks of sexual transmission** (*July 2016*): 52-page A5 booklet quantity _____**Guide to HIV, pregnancy and women's health** (*November 2015*): 52-page A5 booklet quantity _____**Guide to changing treatment: what if viral load rebounds** (*Jan 2018*): 24-page A5 booklet quantity _____• **Other resources****HIV Treatment 'Passports'** - Booklets for patients to record their own medical history quantity _____**Phoneline posters (A4)** quantity _____

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