United Kingdom Community Advisory Board (UK CAB)

HIV treatments advocates network

Meeting Report
CAB 33 – African Treatment Issues and Late Diagnosis
19 March 2010

Contents:

Presentations are all available to download for the Marc2010 meeting at:

http://www.ukcab.net/mar10/index.html

Members attending

	Name	Organisation	Destination
1	Adela Mugabo	GHT	Manchester
2	Angeline Marang	HIV i-Base	London
3	Badru Make	CHAT	London
4	Beatrice Osoro	Positively Women	London
5	Ben Cromaty	North Yorkshire AIDS Action	Yorkshire
6	Ben Whalley	The Brunswick Centre	Halifax
7	Bisi Alimi	NAZ Project	London
8	Brian West	Waverley Care	Edinburgh
9	Charlie Walker	HIV i-Base	London
10	David Kakande	AHPN	London
11	Fabiola Bayavuge	Black Health Agency	Manchester
12	Gertrude Anyango-Wafula	Black Health Agency	Manchester
13	Gus Cairns	NAM	London
14	Jabulani Chwaula	AHPN	London
15	Katie Walker		London
16	Kenneth Igba	Hope Gate Trust	London
17	Kingsley Oturu	Inst for Int. Health & Development	Edinburgh
18	Maurice Hebert	National AIDS Trust	London
19	Memory Sachikonye	UKCAB	London
20	Michael Marr	UKCAB	Edinburgh
21	Young Person		Manchester
22	Nakamba N'gambi	Zambia Leeds Comm Assoc	Leeds
23	Quinet Akanoh	THT	London
24	Roger Pebody	NAM	London
25	Rupert Jones	West Yorkshire African Group	Leeds
26	Sanna Savolainen	THT	London
27	Simon Collins	HIV i-Base	London
28	Tsepo Young	NHS Dumfries and Galloway	Stranraer
29	Winnie Sseruma	HIV i-Base	London

Programme

Chair: Tsepo Young Timekeeper: Brian West	
09:30 - 10:00	Registration, refreshments and expenses
10:00 - 10:05	Welcome and UKCAB Updates
10:05 – 10.30	Pre-Meeting for Gilead - Brian West
10:30 - 11:15	**Session One** – African Treatment Issues and Late Diagnosis • Clinical Issues – Dr Ade Fakoya, HIV Consultant • HPA Late Diagnosis data – Dr Ade Fakoya
11:00 - 11:15	**Break**
11:30 - 12:30	**Session Two** – Issues for African sub-groups • Men – Jabulani Chwaula, AHPN, NAHIP • MSM – Bisi Alimi - NAZ project • Women – Beatrice Osoro, Positively Women • Young People – Munya Mudarikiri
12:30 - 14:00	**Lunch**
Chair: Brian West Timekeeper: Gertrude Anyango-Wafula	
14:00 - 15:00	Community meeting update from Gilead, Q & A
15.00 - 15.15	**Break**
15:15 - 15:45	CROI Feedback – Simon Collins
15:45 - 16:00	UKCAB AOB
16.00	Close

Morning Session
Chair: Tsepo Nakamba **Timekeeper**: Brian West

Gilead Pre-meeting – Brian West

This was discussion in preparation for the afternoon session with Gilead. Brian went through Gilead's existing and pipeline drugs and then collected questions to ask them that concern the community.

Current drugs:
- NRTIs
- Tenofovir (Trade name Viread or TDF)
- FTC (Emtriva or emtricitabine)*
- Truvada (TDF + FTC)*
  *Both active against hepatitis B.

Fixed dose NNRTI + dual nuke combination
- Atripla - a fixed-dose triple combination of tenofovir, FTC and efavirenz (EFV)

Suggested questions:
- New studies on genetic differences in the absorption of EFV in Africans?
- Is the EFV paed formulation easily accessible in the UK, worldwide?
- Any studies to improve the side effects of EFV?
- Resistance – what research is Gilead doing?
- Overview of new drug interactions?
- What is Gilead's perspective on pregnancy and conception while on EF
- FTC in PrEP studies, does Gilead any input into that research?
- Will there be a second generation Atripla?
- A few people in meeting are on Truvada. Are they developing drugs of other classes for people who fail or can't take Truvada?

Q: If Truvada affects bone density, how do you feel or know if you have a bone problem, are there any symptoms?
A: You will not notice anything until you have a fracture or a break, bone density tests are a marker, and HIV positive people are at risk of low bone density. Studies have recommended that the clinic look for these early signs. Some clinics now check your height every year to check for any deterioration in the spine. New technologies other than the DEXA scan have been developed to check for bone density.

Comment: The issues of bones and tenofovir are important, but you can also look at a whole spectrum of what you can do to maintain healthy bone density such as stop smoking, healthy diet and taking a vitamin D and calcium supplements.

Comment: Another issue for Africans is that their skin doesn't absorb enough vitamin D.

Pipeline Drugs:
- Quad pill: a co-formulation containing the experimental integrase inhibitor elvitegravir, the new boosting agent cobicistat (GS 9350), tenofovir, and FTC
- Elvitegravir – will be 150mg one pill, once daily, combined with either a 100mg Norvir (ritonavir) or GS booster. Norvir is used to boost elvitegravir.
- GS-9350: heat stable PI booster
- GS-8374 (formerly TMC-126) - a protease inhibitor formerly from Tibotec.

Questions:

- What is the update on new quad pill, including pricing?
- Studies on the quad pill have shown problems with kidney function (low eGRF), which will need monitoring.
- Timeline for approval of the quad pill in the UK, EU and elsewhere?
- A related study showed that cobicistat equalled ritonavir (Norvir) as a booster for atazanavir (Reyataz) – is this a potential to replace ritonavir?
- What will the cost of the booster cobicistat be?
- Is Gilead talking to Tibotec for a darunavir co-formulation?

African Treatment Issues and HPA data on late diagnosis:
Dr Ade Fakoya: HIV Consultant, Newham General Hospital

Black Africans are one of the groups particularly affected by HIV in the UK. The global HIV epidemic continues to have an impact on communities in the UK that originate from countries with current high prevalence, particularly individuals from sub-Saharan Africa where an estimated two thirds of the 33 million people living with HIV worldwide reside. Generally but not always, black Caribbean populations in the UK experience a higher burden of acute bacterial STIs, such as gonorrhoea, chlamydia infection and syphilis and a high, but lower burden of HIV. People general caught HIV in their home countries, HIV subtypes vary within Africa – West Africa is HIV2, C A and D from East, central and southern Africa, recombinations and mixed infections are common. In all groups there are substantial number of people not diagnosed and a third of those living with HIV are unaware of their status.

Epidemiology - numbers

- After adjusting for missing information, an estimated 55% of persons diagnosed in 2007 acquired their infection through heterosexual contact and 41% through sex between men. The number of HIV diagnoses among persons infected heterosexually has declined from a peak of approximately 4,850 in 2004, whereas new diagnoses among men who have sex with men (MSM) have continued to increase. Numbers of HIV diagnoses acquired through injecting drug use and mother-to-child transmission have remained low over the past five years.
- In 2007, there were an estimated 77,400 persons living with HIV (both diagnosed and undiagnosed). Among the 73,300 persons aged 15-59 years living with HIV, 28% (20,700 [16,300-25,800]) were unaware of their infection.

Late diagnoses- opportunistic infections

- HIV-infected individuals diagnosed late may not fully benefit ART and are at an increased risk of early death. Late diagnosis also means that options for avoiding ongoing transmission through clinical and behavioural preventive measures are reduced.
- In the UK in 2007, an estimated 31% of adults were diagnosed late and 8% had AIDS at the time of HIV diagnosis. The proportion of adults diagnosed late was lowest among MSM increased through heterosexual women, IDUs and heterosexual men respectively. Late diagnosis also increased with age.
- Among MSM newly diagnosed in 2007 more than four-fifths probably acquired their infection in the UK. This proportion was higher among white MSM this compared to MSM of all other ethnic groups. There is evidence that MSM born abroad are also at risk of acquiring HIV infection within the UK.
- Among persons infected heterosexually, the majority were probably infected abroad, mainly in sub-Saharan Africa. Ninety per cent of new-diagnosed black African

heterosexuals probably acquired their infection in Africa. The proportion of heterosexual diagnosis who acquired their infection in the UK is increasing.
- Half of injecting drug users (IDUs) probably acquired their infection in the UK with an additional 39% probably infected elsewhere in Europe.

Access to HIV care
- The overall prevalence of diagnosed persons accessing HIV care aged 15-59 years was 143 per 100,000. This rate was higher in men than women and higher in London than in the rest of the UK. There was substantial geographic variation in the rates of diagnosed HIV infection across the country.

Pregnancy
- In 2007 prevalence was highest among women born in sub-Saharan Africa and Central America and the Caribbean.
- Whilst the prevalence of HIV in UK-born women remained low in 2007 a gradual, statistically significant increase has been observed since 2000.

Treatment issues
Since 2000, the average CD4 count at HIV diagnosis of women detected through antenatal screening has been consistently higher than among other women and heterosexual men. This indicates that the recommendation of testing during pregnancy provides an opportunity for women to be diagnosed earlier in the course of their infection reducing their risk of developing opportunistic infections and potential early death. However, the CD4 count of women diagnosed via antenatal screening remains lower than that of MSM due to the relatively large number of women from abroad, indicating that HIV-infected MSM on average are tested earlier.

Care pathways – prevention and treatment
HIV treatment works well, regardless of the subtype of HIV. One study involved 2116 patients who started HIV treatment for the first time between 1996 and 2006. These patients were infected with a variety of HIV subtypes including subtype B, C, A; circulating recombination forms (CRF)AE and D. The remaining 6% of patients were infected with rarer subtypes including G, F, I, J and unclassifiable types.

Analysis was then undertaken to determine the effect of ethnicity and HIV risk group on the virological outcome of treatment. This showed that the interval between starting HIV treatment and achieving an undetectable viral load was shorter in patients of black African origin than white patients and amongst heterosexual women than gay men.

Treatment as prevention
For HIV negative:
- Pre- exposure Prophylaxis- **PREP**
- Post- Exposure Prophylaxis – **PEP(SI)**

For HIV positive
- Prevention of Mother to child transmission
- Treatment as Prevention – 'test and treat'

The Rakai study showed that when viral load is undetectable, there was no HIV transmission in sero-different couples.

Swiss consensus statement from a study of 340 heterosexual monogamous couples where an HIV positive individual in a sero-different relation who has had an undetectable viral load for six months, is fully adherent to ART and does not have a sexually transmitted infection is <u>not</u> infectious.

Primary care use prior to HIV diagnosis

SONHIA (Study of newly diagnosed HIV infection amongst Africans in London) aimed to describe the health beliefs, health care utilisation and clinical presentation patterns of newly diagnosed HIV positive Africans in London. Specific objectives included:

- To measure utilisation of health services in the UK prior to HIV diagnosis.
- To measure attitudes towards and knowledge of HIV and HIV services, and to examine their relationship with behaviour.
- To assess the proportion of HIV infections amongst Africans acquired within the UK
- To determine the probability of onward transmission of HIV infection related to undiagnosed HIV infection.
- To determine the demographic, social and behavioural characteristics of those who present with advanced HIV disease
- To explore the contextual and social factors which influence service utilisation.

Results showed that:

- 84% were registered with a GP for an average of 3 years
- 73% saw GP on average two times in 2 years prior to diagnosis with for flu or chest infection, skin condition, contraception/pregnancy, minor injury, child, etc

Specific drugs to consider

- A study on efavirenz (EFV) clearance in Africans showed that it might be slower. Africans vs Caucasians. Ethnicity was very strongly associated with EFV clearance: African-Americans and Hispanics had on average a 32% slower clearance of EFV than Caucasians. African women were found to still have high levels of EFV 2 weeks after stopping the drug. All the African women also had very high peak levels of EFV prior to stopping the drug. Weight was also a significant factor in both clearance and volume of distribution: those who weighed less cleared EFV slower.
- Abacavir (ABC) hypersensitivity reactions are less common in Africans than whites because the HLA-B*5701 gene is less common.
- Pigmentation and nail discolouration with zidovudine
- Is risk of hypersensitivity with abacavir lower among African patients?
- Is there a link between CYP 2B polymorphism, efavirenz levels and adverse effects?
- Increased risk of dyslipidemia (high lipids) and CV risk with some protease inhibitors

The benefits of increasing HIV testing and immediate therapy will result in:

- Increasing the number of people who are aware of their HIV status.
- Improving the health outcomes at all CD4 counts.
- Reducing the incidence of new infections; could be the eradication HIV?

Summary

- HIV affects many African people in the UK
- Late presentation and anxiety about testing is common
- For Africans, HIV makes difficult lives even more complicated
- There are substantial issues with disclosure, access to care and stigma
- The treatment of HIV may be complicated by viral diversity and resistance
- Other complex medical problems frequently coexist and complicate therapy
- Drug handling differs and may impact on adverse effects
- Longer term ARV side effects remain poorly understood
- There are continued imported and late diagnosis infection in the UK
- The solution to the problem is wider than just focussing on HIV testing
- Improving community knowledge on the advantages of ' knowing one's status early' and addressing the structural barriers that prevent testing are paramount

Q: In terms of epidemiology studies – is it home addresses or where people access care?
A: The data is from treatment centres.

Q: How do you address the issue of testing – there are missed opportunities such as GP, is it the same in Africans?
A: There is need to improve ways to get people tested, such as addressing stigma and criminalisation that stops people from getting tested.

Q: What do we do to break those barriers?
A: It's for the community to look into such issues and address them.

Q: There are some key issues not addressed – how do people actually access care, most people wait to get sick before they can access care, HIV fatigue, non-involving messages.
A: There are many different levels that need to be addressed such as funding. Commissioners fund leaflets that are not effective.

C: The major is political migration issues, most people do not have papers and are afraid to come forward and be treated, need to look at the social aspects.

C: We do not link prevention to treatment very well in the UK; need to look at a holistic picture. Lets flood the community with different testing methods.

C: There are different assumptions, e.g. if you give blood at the GP you have been tested for HIV giving wrong interpretations of testing plus the stigma that still surrounds HIV. People at the highest risk are usually reluctant to test.

C: People are registered with a GP but reluctant to visit and wait till they are sick; an attitude that still exists in the UK amongst Africans.

C: Cultural health beliefs – people test and wait for opportunist infections

C: There is a lot of work to be done in community setting, need build capacity. Treatment works well, regardless of HIV subtype. With good adherence, CD4 goes up faster in Africans (UKCHIC data).

African sub-groups session

Issues for Men: Jabulani Chwaula, AHPN – NAHIP Programme Manager

Jabulani is the programme manager of the National African HIV Prevention Programme (NAHIP) at the African HIV Policy Network (AHPN) that works with community-based organisations to implement prevention initiatives at national level. He was speaking from the Bass Line report 2008-9 entitled Assessing the sexual HIV prevention needs of African people in England.

Perception to risk of infection:
Bass Line 2008-09 survey- Assessing the sexual HIV prevention needs of African people in England specifically drawing on the responses from men (2580 responses, 82.4% of men) indicates that; more men than women practiced sex that put them at risk of infection. This is seen in sexual relationship outside regular ones and also having sex with someone whose status they thought was different from theirs and not using a condom.

Response to avert risk of infection:
There should therefore be interventions to reduce potentially sero-discordant unprotected intercourse that should target those in multiple sexual relationships, particularly men.

Q: How many HIV prevention interventions do we know that seek to exclusively meet the prevention need of African men and MSM?

Comment: There are cultural issues that influence how men think about their sexuality, given MSM prosecutions in some countries.

Comment: In Leeds we have football tournaments for Africans and other activities to bring them together and also bring in HIV prevention messages on those occasions.

Where interventions do not seek to meet the HIV prevention needs of those with the greatest opportunity to participate in the acquisition and transmission of HIV are less likely to have any impact. Men and access to testing for HIV compared to women differ greatly. This is clearly reflective of both the wider range of testing services serving women, and men's greater reluctance to use health services.

Gender, sexuality and testing behaviours:
Tabulated results on behaviours concluded that:
- Among those who were sexually active, behaviourally bisexual men were least likely to have tested but were slightly more likely to be have diagnosed HIV than men who had no sex or sex only with women.
- HIV was most common among the men who had sex with men only.
- Men were significantly more likely to indicate all sexual risk behaviours than were women.
- Men were more likely to report multiple sexual partners, extra-relational sex, unprotected intercourse, sero-discordant intercourse and condom failure.
- This pattern is very similar to the Bass Line 2007 findings.

Response to risk of infection and prevention interventions
Compared to women, men were more likely to be unconcerned about being involved in HIV transmission, and more likely to have a problem getting hold of condoms, and were significant.

Women on the other hand were more likely to have a problem with communicating about safer sex and HIV with their sexual partners (but were not less confident about getting partners to use condoms or any less empowered to reduce their HIV risk). Concern about carrying condoms did not vary by gender. There is less knowledge about HIV in general.

What does this mean for treatment?
- Testing: Men less likely to have tested for HIV or know where to test for HIV.
- Sex: Men had more sexual intercourse partners, more extra-relational sex, and were more likely to have sero-discordant unprotected intercourse.
- Needs: Men were less motivated to avoid sexual HIV exposure and had more problems accessing condoms.

The findings of the Bass Line survey suggest interventions and programmes should prioritise encountering men over women to maximise their impact on HIV transmissions. Therefore where prevention fails, diagnosis must never be missed and treatment made available. In addition, there are high levels of need among those with limited schooling.

Advocates/Health promoters need to pay particular attention to the needs of men who have sex with both men and women, and those who only have sex with men.

HIV and MSM in England: A new wave of challenge - Adebisi Alimi, NAZ Project

Adebisi is the African MSM Sexual Health Worker at NAZ for the Monya Project that is designed to provide sexual health services for African MSM living in Newham borough of East London through outreach, condom distribution, support group and workshops.

MSM in African communities is a new challenge; there is no focal or person, no spokesperson as in the white gay community. A lot of African MSM are secretive about their sexuality. Sex between men occurs in every culture and society.

Estimates show 3-20% men who have had at sex with another men at least once worldwide. There is still a lot of social stigma and discrimination making these men who would otherwise live openly as homosexual to engage in heterosexual relationships thereby potentially exposing their male and female partners to STIs and HIV.

Of the 53 states in Africa, South Africa is the only country with legislation that is not discriminatory against MSM, but people in the community discriminate. In the African community in the UK, MSM accounts for the second highest HIV prevalence after women.

There is not enough data to show the uptake of HIV testing within the African MSM and some of the reasons are:

- Unprotected anal sex, no understanding of using condoms (only known for contraception in some African settings)
- Drug use makes people prone to exposure of unsafe sex
- Lack of information/understanding of HIV and condom use
- Lack of capacity to negotiate safe sex
- Poverty leads people to take risks of unsafe sex
- Immigration status - some men unable to access services for fear of being found out
- Stigma and discrimination within communities

Factors leading to late diagnosis

Most MSM lack the knowledge of need to test, or where to access to testing centres; there is need for community based testing. Confidentiality issues and fear of immigration and deportation also stop them from going for tests. At testing centres, the type of questions asked show there is a lot of stigma and discrimination.

Treatment options

Many MSM do not know that treatment is free and assume its based on immigration status. For those that access treatment, there is worry about side effects and other demands associated with treatment and this leads to adherence problems. Some still mix ARTs with alternative medicines unaware of potential interactions.

Care and support

It is important to for all to know where to get care and support, what kind of support is available and how long they will be supported. An example is the Monya Project established in 2007 in Newham, London. It is the first project with a membership of over 50 self-identified African MSM and has been a support base for them.

Adebisi concluded by recommending:

- More research into the sexual and identity behaviour of African MSM.

- Development of specific intervention packages for that community such as re-designing of the pre-test discussion to get the right answers with more testing areas that are different from the conventional ones.
- More funding for prevention work and a campaign to address the identity, language and needs of African MSM.

Women's Issues: Beatrice Osoro, Positively Women

Beatrice is a Caseworker at Positively Women, the only national charity providing support for *women living with HIV* by *women living with HIV*.

African women are twice as likely to be HIV positive as compared to African men; and face complex issues. Like women elsewhere, African women are rendered useless by circumstances largely beyond their control. The culture of silence surrounding sexual practices in general, the stigma of HIV, women's lack of control over their bodies, and vulnerability to dispossession by a vexed husband or sex partner are no help. Low literacy rates, lack of information, limited choice, and little access to paid work outside the home result in morbid dependency and crushing poverty that are terrible burdens.

Issues for African women:

- Sexual Health and reproductive Rights
    - The need be free from stigma, discrimination, blame and denial
    - Lack of the right to live with dignity and equality, bodily integrity, health and healthcare, including treatment
    - Safety, security and freedom from fear of physical and sexual violence after testing HIV positive
    - Lack of education and information, economic independence
- Social/cultural issues
    - Social and cultural expectations – e.g. breastfeeding
    - Social interactions with family and friends
    - Women are decision takers and not makers
    - Physco-social issues such as unsettled immigration status
    - Poverty, shared living conditions
- Treatment
    - Coping with own regime
    - Coping with family's regime
    - Coping with side effects
    - Spiritual and cultural beliefs vs. western medicine
    - Lack of access to treatment due to immigration status
    - Parental concern over children- testing, treatments and after care
- Relationships
    - Disclosure and associated issues
    - Safer sex and negotiation skills
    - Changing dynamics of families – HIV takes a back seat leading to late diagnosis
    - Perceived low risk by older or married women

Summary

Tackling these issues will involve educating men to have greater respect for women, and increasing access to testing. Training women in negotiating skills may help both them and their spouses to obtain HIV testing and counselling.

Women with HIV face complex challenges, but have a wealth of experience in forming support networks to deal with these challenges. Support for women living with HIV by women living with HIV is vital.

Note: *Due to limited time there was not enough time to have further discussions and the meeting should probably consider re-visiting the subject in future.*

Young Persons: *A young person shared his thoughts and experiences as a young person living with HIV:*

- Being HIV positive is a magnification of a person's life – everything around you is defined by your HIV status.
- He and other young people do not want to be under scrutiny would like to see HIV normalised like everything else and be similar to his peers.
- Young people unaware of their mortality unlike adults, they have a lot going in their lives to worry about HIV.
- He wanted to know how adults can make HIV prevention interesting and for young people to participate. A lot of the medical things disinterest young people.

There a lot of other issues such as stigma, prejudice and culture issues amongst young people. He highlighted issues with treatment: there are problems with sleepovers, having to keep pills in dosette boxes. His doctor gave him keychain that doubled as a dosette box so no one would know he was taking medication.

On disclose he asked the question: "*How can be accept ourselves if the world doesn't accept us?*" He explained that he had disclosed to a group and friends and they had accepted him as he is. As with sexual relationships, everyone should be comfortable enough to disclose.

He would like to see how can the older persons teach young persons on "*how can we accept it ourselves if they cannot accept their own HIV status?*" He spoke of how is father had died of an opportunist infection after living with HIV for 16 years and wouldn't take treatment. There are also cultural issues: African pride vs British upper lip; some issues are never discussed in the open, as they are deemed inappropriate, such as sex or HIV.

He would like to see young Africans living with HIV accessing treatment in time and he wouldn't want HIV to defeat him the way it did to his father. There is abundance in support systems in the UK, such as Body and Soul and other service providers.

He concluded by saying:
- There is need to empower young people so they can be tomorrow's advocates.
- We need to push things and get them done; we talk about issues and do not do anything.
- To be a good advocate, you should have the ability to relate something to yourself.

Q: What response did you get when you told your friends that you were HIV positive?
A: They were quite positive and wanted to know if I was OK and healthy. They did not say anything bad to me; they are still my friends.

Comment: It is necessary to make people that realise that treatment normalises HIV, you can live for 50 or more years with HIV.
Comment: There is also need to address to stigma; my son started asking more questions as he got older. We had not told him he was HIV positive.

Afternoon session:
Chair – Brian West **Timekeeper:** Gertrude Wafula-Anyango

A minute silence was held prior to Gilead's presentation in memory of those who were and are unable to benefit from advances in treatments

GILEAD Community Update: Dr Charm Herath, Medical Director

Sciences Overview
Gilead's primary areas of focus include HIV/AIDS, liver disease and serious cardiovascular and respiratory conditions.

HIV/AIDS
- Atripla (with Sustiva (efavirenz), manufactured by Bristol-Myers Squibb) - the first and only once-daily single tablet regimen for the treatment of HIV infection in adults. It is intended for use as a stand-alone therapy, or in combination with other ARVs.
- Emtriva is a once-daily oral nucleoside reverse transcriptase inhibitor (NRTI) used in combination with other antiretroviral agents for the treatment of HIV infection in adults. Emtriva is also available as an oral solution for use in paediatric patients.
- Truvada is a fixed-dose once-daily combination pill containing Viread® and Emtriva®. It is used in combination with other antiretroviral agents for the treatment of HIV infection in adults.
- Viread is a once-daily oral nucleotide reverse transcriptase inhibitor (NtRTI) for the treatment of HIV infection in adults in combination with other antiretroviral agents.

Liver Disease
- Hepsera is a once-daily, oral NtRTI for the treatment of patients with chronic hepatitis B.
- Viread is a once-daily oral NtRTI for the treatment of chronic hepatitis B infection in adults.

Cardiovascular
- Letairis, Lexiscan and Ranexa

Respiratory
- Cayston (aztreonam for inhalation solution) is a treatment to improve respiratory symptoms in cystic fibrosis (CF) patients
- Tamiflu (oseltamivir phosphate) is the first neuraminidase inhibitor tablet for the treatment and prevention of influenza A and B.

Other
- AmBisome is a treatment for life-threatening, systemic fungal infections in adults.
- Macugen is an injection for the treatment for an eye disease that destroys central vision in elderly patients and marketed in the US by Eyetech Inc.
- Vistide is an antiviral injection for the treatment of cytomegalovirus retinitis in adult patients with AIDS.

Q: Are you not bringing out a combination for cobicistat and elvitegravir so they can be used without Truvada?
A: It's a capacity issue within Gilead.

Q: What is a PK enhancer?

A: It is used solely to boost the blood levels of other drugs It's a booster than slows down the virus enzyme to keep the drug the in blood for 24 hrs. Be careful however about not getting toxicity from other drugs; caution when prescribed with other drugs such as statins.

Q: In case someone becomes resistant to Truvada and needs a different combination; are you looking at other co-formulated combinations with other manufacturers?
A: We are data driven, keep a close eye on what's going on and are looking at some drugs in 2010, happy to explore integration with other companies.

Q: Do you expect Quad to be used as a 1st line treatment?
A: In Europe we want to do that, if you have been on Truvada and EFV, people can switch, the UK and France are happy but other EU countries are not. We need to compare Quad with existing drugs to get licensed.

Q: Why not compare with use of Truvada rather than Atriprila if they are placebo controlled studies?
A: Its more of the scientific benefit.

Q: Why not compare it to raltegravir?
A: These are al licensing discussions and ongoing.

Gilead Access Program
In 2003, the Gilead Access Program was established to ensure sustainable access for patients suffering from HIV in some 130 developing countries around the world with substantial price reductions on ARVs; tenofovir and truvada. This represents two-thirds of the countries in the world, and the regions hardest hit by the HIV/AIDS epidemic.

Gilead's Access Principles
- Antiretroviral products for the developing world should be of the same quality as those sold in wealthy nations.
- Tiered pricing for antiretroviral products, reflecting each country's economic status and disease prevalence, is an essential tool for broadening access.
- Partnerships – government, industry, academic and community – are critical for success.

Q: Can you get drugs licensed quicker by using the World Health Organisation (WHO)?
A: D4T was replaced with tenofovir through WHO recommendation, have gone with the cheap but not looking at toxicity. Access is also determined by cost.

C: It is important to involve co-infected people in the last phases of the new HCV drugs.

Q & A

Q: Co-formulations - have you approached Tibotec and GSK for co-formulations?
A: Nothing happening yet, but we are open to work with them.

Q: The data on Quad shows a slight problem with eGRF on GS9350, comment?
A: Phase 2 studies shows that the PK enhancer was blocking the drug from coming through the system, particular problem in particular individuals, will get answers in phase 3, could be a genetic profile of the individuals.

Q: How much support were you giving in Truvada on microbicides trials?
A: The results of that microbicide trial were not good.

C: Studies of microbicides with TFV coming out this year.

Q: How much to do you contribute to a vaccine development?
A: We haven't done any vaccine research; it's a capacity issue.

Q: Most women are not benefit from Atripla when planning to be pregnant; will Quad pill be any different? And what about children?
A: There is a requirement to have a paed programme in place for new drugs as well, it takes a long time to collect safety data for pregnant women.

Q: Are your prices going to come down?
A: We are open transparency for hospitals to see how much they buy drugs with discounts, not simple process, but it depends on each hospital and the amount of bulk buying they do.

C: If Quad comes in as a first line drug, it could be very competitive.

Q: What is the cost of treating an HIV positive person per year?
A: Average cost of £6 - 7 000.

Q: How will you market Quad?
A: We will have to look at data first.

Q: There is a shortage of new drugs in development, we need some new drugs to replace the ones that have been around for a long time, is Gilead looking at developing any new drugs?.
A: No, but feel free as the community to send a message to Gilead.

Poster: Africans in UK present late and are likely to be on ARVs soon after an HIV diagnosis
Dr Getrude Wafula-Anyango

This is a poster from a study to undertake the assessment of the treatment information and nutrition needs of people living with HIV attending support groups in the North of England.

Conclusions:
- Late presentation is associated with early start of ART among Africans
- Suggests early testing to improve health outcomes of African communities affected by HIV
- More ARVs knowledge is crucial for management and care of HIV-related conditions
- ARVs are effective with good adherence, support groups can provide support to enhance adherence.

CAB working groups
Members urged to sign up to the working groups of their choice, the working groups are:
1. UKCAB Email forum discussions
2. UKCAB Speaker Group
3. Patient Forums
4. Other (please specify) Media or PR

CROI 2010 feedback: Simon Collins, HIV i-Base

The 17th Conference on Retroviruses and Opportunistic Infections (CROI), one of the major scientific conferences of the year for the HIV world, was held in San Francisco in February. There is a lot of data from the conference and Simon recommended that members take time to watch the online webcasts for detailed presentations.

Some webcasts and abstracts are accessible from the i-Base website: http://i-base.info/home/croi-2010-online/

Summary handouts from Simon Collins and Gus Cairns are also available to download from the UKCAB website. Since there was so much to cover, the meeting agreed to focus on one study to discuss, Partners in Prevention HSV/HIV Transmission Study.

The Partners study on transmission was run in seven Southern African countries, included 3381 couples where one partner was HIV-positive and one was HIV-negative. This study was originally designed to see whether acyclovir, a treatment for herpes, could reduce HIV transmission.

Although acyclovir did not reduce HIV infections, about 350 HIV-positive people during the study needed to start HIV treatment for their own health. The rate of new HIV infections was 92% lower in the partners of people using HIV drugs compared to those who were not on treatment. Of the 103 infections between partners, only one occurred from someone who was using treatment. The single transmission also occurred very soon after ARV treatment was started, when viral load was still likely to be very high.

These clear results bring a powerful message: ARV treatment in this context had a greater protective effect than almost any other prevention method.

Conclusions: This large prospective study demonstrates that ART use is associated with substantially lower risk for HIV transmission among heterosexual, African, HIV sero-different couples, where the HIV-infected partner did not meet national criteria for ART initiation at enrolment. A single transmission occurred within 1 month after ART initiation.

The Swiss study also concludes that ART reduces plasma viral load, reduces semen and cervical viral load. There is 92% less chance of catching HIV if partner is on treatment.

Q: Why is there is not much information like this being given to the media?
A: UKCAB media group could issue a press release.

C: We don't know if the Swiss study applies to other sexual groups

Q: What is the cost of treatment as prevention?
A: There was a presentation from Brian Williams theoretical modelling that showed that providing treatment to every HIV-positive person in South Africa with a CD4 count below 200, could stop new transmissions within 5-10 years. This would cost no more that will currently be spent, but would save at least 3 million lives. Using higher CD4 counts to start, for example at 350, 500 or on diagnosis, also had similar costs.

AOB

20 - 23 April 2010 BHIVA Conference, Manchester

BHIVA Community dinner will be at Taurus Bar and Restaurant in central Manchester on Wednesday 21st April at 8 pm, contact Silvia Petretti via the forum as spaces are limited.

NEXT MEETING: DHICE Project Community meeting

Date: 18 June 2010