# UK CAB
# HIV treatment advocates network

## CAB 36: Getting the most of your GP
## 22 October 2010

**Contents:**



Presentations are all available to download for the October 2010 meeting at:
http://www.ukcab.net/oct10/index.html

**List of attendees**

| Name | Organisation | Destination |
|---|---|---|
| Alastair Hudson | IPPF | London |
| Angelina Namiba | Positively UK | London |
| Ben Cromaty | North Yorkshire AIDS Action | Yorkshire |
| Brian West | Waverley Care | Edinburgh |
| Charity Nyirenda | HIV i-Base | London |
| Charlie Walker | HIV i-Base | London |
| Eunice Sinyemu | AHPN | London |
| Garry Brough | THT | London |
| Gertrude Wafula | Black Health Agency | Manchester |
| Maurice Herbert | Personal | London |
| Memory Sachikonye | UKCAB | London |
| Michael Marr | Waverley Care | Edinburgh |
| Quinet Akanoh | THT | London |
| Robert James | Personal | Brighton |
| Roger Pebody | NAM | London |
| Silvia Petretti | Positively UK | London |
| Simon Collins | HIV i-Base | London |
| Tsepo Young | NHS Dumfries and Galloway | Stranraer |
| Virginia Cucchi | Bloomsbury Patient Network/Brent Mind | London |
| Winnie Ssanyu Sseruma | HIV i-Base | London |
| **Speakers** | | |
| Dr Surinder Singh | Senior Lecturer in General Practice, UCL | London |
| Hilary Curtis | BHIVA Audit Committee | London |

**Apologies:**

Paul Clift
Gus Cairns

**Programme**

| | |
|---|---|
| **Chair:** Michael Marr | |
| 09:30 - 10:00 | Registration, refreshments and expenses |
| 10:00 - 10:05 | Welcome and UKCAB Updates |
| 10:05 – 10.30 | Pre-Meeting for ViiV Healthcare – **Brian West** |
| 10:30 - 11:15 | **Session One** – GP specialty for HIV patients – **Dr Surinder Singh,** Senior Lecturer in General Practice |
| 11:30 - 12:00 | **Session Two**: Accessing primary care – **Angelina Namiba,** Positively UK |
| 12:00 – 12:45 | Outcomes in HIV – **Hilary Curtis**, BHIVA Audit Committee |
| 12:45 - 14:00 | **Lunch** |
| 14:00 - 15:30 | Community meeting with ViiV, Q & A |
| 15.30 - 15.35 | **Break** |
| 15:35 – 16:30 | Conferences Feedback: Vienna, BHIVA – **Silvia Petretti**<br>UKCAB AOB |
| 16.30 | Close |

**Company pre-meeting**
Brian led the pre-meeting and gave a background of ViiV; established by GlaxoSmithKline and Pfizer to deliver advances in treatment and care for people living with HIV globally. He highlighted that they do not do Hep C drugs.

ViiV's pipeline drug S/GSK1349572 (known as'572) is going into phase III in clinical trials. It is a once-daily, unboosted investigational integrase inhibitor, includes two studies (SPRING-2 and SAILING) that will evaluate '572 in both treatment-naïve patients and treatment-experienced, but integrase-naïve patients. The meeting discussed the signing of confidentiality document on the '572 data to be presented, no one objected.

Abacavir and CVD
Their marketed drugs are some of the oldest, their researchers think nothing wrong is happening especially around abacavir and heart disease, but other researchers are finding other things. Their studies on that subject are not long-term studies. The meeting wanted to know if ViiV would talk about abacavir and CVD, the DAD results and if there was any further news on abacavir and CVD. Meeting would also ask for an update on forsemapvir.

***Q: Do we know portion of loss of sales?***
*A: Sales in Scotland plummeted. After the DAD results, sales dropped, but ViiV came up with other reasons for the drop in sales.*

Other issues to raise with ViiV:
- In the UK 5-10% of patients are on combivir, the meeting wanted to know if there had been any studies to deal with the anaemia side effect.
- Update on maraviroc – hasn't has a quick take off, issue with CCr5, blood sample has to be sent to San Francisco to se if it will effective. There are about six people on maraviroc in Scotland (not sure about England and Wales). Can we find out who pays for the tropism test?
- Pipeline and new drugs in development – ViiV would like attendees to sign a confidentiality agreement for them to present data on their phase 3 trials due to commercial reasons.
- Patent Pool - ViiV has refused to join the patent pool saying that its not just about HIV drugs, idea is good in principle but not clear in practice. Patent pool video on YouTube can be viewed at: http://www.youtube.com/watch?v=Vj0dbFgjoh4
- NHS will have standstill budgets for 4 years and that are supposed to cover treatment for patients starting treatment, as advocates we need to go back to the trusts and make a case for HIV. Pharmas need to lower their drug prices to ensure access to treatment continues for everyone.

ViiV Agenda:
1. Drug safety – abacavir and rosiglitazone (anti-diabetic drug, recently suspended in the UK)
2. Pipeline – '572 studies, treatment experienced patients who have failed on raltegravir, NNRTIs and choice
3. Current drugs – maraviroc and who pays for tropism testing?
4. UK pricing
5. Patent pool access – where are they at on that?

---

**General Practice and HIV/AIDS**
Dr Singh – Senior Lecturer in General Practice

Dr Singh is a senior lecturer in General Practice at University College London where he is the lead for the intercalated BSc in Primary Health Care. In the past he was lead medical officer at London Lighthouse, one of the first residential units for patients affected by HIV/AIDS in the UK. He has written and co-authored two books on the subject. More recently Dr Singh has been a member of the independent advisory committee on HIV/AIDS and sexual health services and the editorial board of the British Journal of General Practice. He is currently a performance assessor for the General Medical Council. He is a part time GP at the Amersham Vale training practice in New

Cross/Deptford, South-East London and holds an honorary Senior Academic GP post with Lewisham PCT.

Dr Singh's views as a GP are that he and other GPs have a part to play in HIV care. He made reference to the book he co-authored: *HIV in Primary Care, which* will soon be updated. GP services provide a cycle of continuous, comprehensive, co-ordinated, collaborative, community-oriented and family medicine care. He highlighted the challenges of what the patient desires, the care in some hospital departments and some GPs who do not have enough expertise to deal with HIV patients. In his practice the nursing team do have an opportunity to discuss sexual health matters and offer HIV testing.

The patients in his surgery are all different, some are complex and some have other medical conditions. On disclosure, the majority of meeting attendees said they had disclosed their HIV status to their GP. He admitted that treating patients who have disclosed made it much easier to manage.

**Issues for GPs in HIV**

1. Patient engagement – some patients choose not to disclose and this makes engaging with them difficult. In some cases the GP finds out by chance. There are cases where the patients is willing to speak with their GP about everything and once case is of a mother who needed to disclose to her child.
2. Confidentiality**:** The attendees acknowledged that the GPs like him were rare and also raised the issue of receptionists who sometimes are insensitive and discuss confidential information in front of other patients. Dr Singh said that they do take confidentiality serious and staff can be disciplined if they breach it. The practice would only know if someone complains. In other cases, confidentiality is inevitable as the hospital may write back to the GP about a patient with other medical conditions such as diabetes, CVD, etc who will need follow-up at the surgery.
3. Communication between the hospital, the patient and the GP often gets mixed up.
4. Good quality care – not all GPs have an interest in HIV and do not provide the needed for HIV patients.

He concluded by saying GPs can help, as they are more experienced in managing lots of complex conditions than HIV specialists.

**Discussion**

***Q: I am curious about mother with child who needs to be told, what kind of support do they access?***

*A: An HIV specialist and a support agency in the area, manages the mother. She wanted to disclose to child with GP (me) but I referred them to a psychiatrist, but regret that, as she may have felt comfortable disclosing with me.*

***Comment: In my GP practice and in remote areas has very few patients and therefore cannot provide the model you have, there are more co-morbidities happening earlier for patients with HIV. There is a lot training need for GPs to achieve your model of care.***

*A: I do agree; GPs need to be more aware of HIV co-morbidities and ageing.*

***Comment: I am in a discordant relationship and my husband only had one HIV test in the17 years I have been HIV positive. My GP doesn't encourage him to have another one or at least regularly and my husband would not go on his own. In terms of my own care, I keep being sent back and forth for results and get frustrated!***

*A: The service isn't co-ordinated in this case. There are communication problems, even in my surgery with the local hospital and this is not acceptable.*

***Q: What levels of GPs are trained for HIV care?***

*A: New registrar training now has HIV listed as a co-curriculum and some may choose not to take the course. Qualified registrars can go on courses.*

***Q: Is there an HIV GPs network?***
*A: There is none.*

***Q: Where does HIV fit into the new structure where all budgets are being shifted to the GP, extra budget for drugs?***
*A: It's too early to know what will happen with budgets. If a patient needs a prescription, I prescribe it despite the cost. Governance around this will be harder and more robust when the NHS reform is done.*

***Comment: I have good relationship with my GP, but he still sends me back to the clinic for minor ailments. I am a patient in the middle. It is difficult to switch from gold standard to effective care. Hospital-GP communications needs to be a 2-way process. Some people do not access their local GP due to confidentiality. GPs often misdiagnose certain conditions; newly diagnosed patients get pushed from gold care into effective.***
*A: Most of this about expectations, I disagree that confidentiality is not held up (in my surgery) but could be the biggest barrier in other surgeries. A study of few GPs on the issue of confidentiality said they take it seriously if patients complain.*

***Comment: Reception staff is really awful they talk about patients. There is never any information about HIV in the surgery but have lots of information about sexual health. I am an informed patient and get dismissed often as someone who thinks they know too much. GPs should be able to signpost HIV patients to relevant services.***

***Q: Results from the Stigma Index showed huge issues with GPs. What should we do with the resources that we have in the cash-strapped environment to be effective? We need a stigma awareness raising exercise, how do we do it?***
*A: its been very clear for the last 6-9months that the NHS has ring-fenced money and will be protected. Get hold of interested practices locally – two way process to get update.*

***Q: I was running a project for accessing GPs and emailed several GPs in London to come for training session and got no responses, what can I do, can you come?***
*A: Contact me after the meeting and we will work something out.*

***Q: Do you register HIV positive asylum seekers and other non-documented persons who do not have the lengthy list of identity and proof of residence documents in your surgery but needs a GP?***
*A: In my practice we register anyone, we ask for proof of address only. It's terrible when someone has to travel far to find a GP who can register him or her. The problem in the past was that people would disappear and we are required to keep a well-managed list and the PCT worries about the budget.*

---

**Accessing GP care**
Angelina Namiba – Positively UK

Angelina Namiba is a Project Manager at Positively UK, a national charity championing the rights of people living with HIV. She was project manager for the Accessing GP project.

Angelina gave a brief background about the project she worked on for a year – 2009 to 2010. The project was about accessing GP care and getting long-term conditions managed in the community. PLWHIV were living longer and developing associated health conditions that are better managed by GPs such as CVD, diabetes and other ailments that develop with age.

She then shared her experience/perspective of using her GP after her HIV diagnosis in 1992. She had not explored what the GP could offer and had had no encouragement to do so. She was happy then with full healthcare received at the clinic. On accessing her GP, she immediately disclosed her HIV status. She was accessing all her care, live vaccinations and baby booster vaccines and the 18-month HIV test for her baby that was all clear. She also spoke about GP accessibility: proximity; accessible hours; and having knowledgeable GPs in the surgery.

The research project she worked with the HIV community had concerns around:

- Clinical competence – whether GP are able to treat patient's HIV and other complications and also had issues around drug interactions.
- Accessibility and choice – some patients got rejected at registration and wondered if it it HIV related or just discrimination. Other patients did not know they could change their GP if they were not happy or having to repeating their story to different GPs at the same surgery.
- Quality of care – patients did not know who (GP or HIV consultant) has responsibility for which aspects of care.
- Confidentiality acted as a barrier to access as well.

Recommendation from the research were:

- To have GPs work within HIV clinics to support transition of positive patients in accessing primary healthcare services for a limited period.
- Increase the role for Community Nurse Specialists (CNS) who already work with HIV patients in the community.
- Develop a model of care with a pool of super GPs trained to care for HIV patients.
- GP training to increase the capacity for HIV testing; understanding of HIV treatment; understanding of social and psychological aspects of living with HIV.
- White paper on health – ground work needs to be done to ensure new arrangements with GP commissioning consortia doesn't disadvantage patients

For patients - Training support and skilling up of patients to access primary care with confidence on:

- Improving GP access; how to register; reasons to have a GP; what to ask; complaints procedures; what can a GP do for me; communication from GP to clinic and vice versa
- Improving ability to disclose to GP; how and when; what information do I need to include and why?
- Increase the ability to have control of your health care – self management; doctor patient relationship; asking questions; which ones?
- Getting involved in the GP consortia in your local area.
- Advocate for patients to ask questions without being rude, or have a choice to change their GP.

Angelina encouraged everyone people to have their GPs involved in their care because there are a lot of co-morbidities and we'll have to dealing with as we all age. GPs are best placed to deal with these things.

Angelina introduced herself and Garry Brough as the patient reps on the BHIVA Primary Care Working Group and gave a brief description of their role. She then led an interactive discussion followed on:

**What can the BHIVA PCWG do for you?**

- Develop signposting to GPs known for good HIV practice.
- Consider regional expertise and variance in knowledge and expertise; this will help identify gaps.
- Encourage GPs to test earlier to prevent co-morbidities and lookout for early onset of certain conditions due to HIV.
- Ability to monitor conditions not picked and working with complaints to ensuring action is taken to address them.
- Clinics should be help patients to locate good GPs, dentists, etc.
- The right to speak to, choose or change a GP; this should be included in the guidelines.
- GPs should have a mechanism to share good methods and practice.
- Need clear model of care on who does what!

**What resources exist for patients to better access their GPs?**

*Due to lack of time, both topics are to be posted on to the CAB forum for further input from members.*

**Outcomes in HIV**
Hilary Curtis – BHIVA Clinical Audit Coordinator

Hilary Curtis co-ordinates the British HIV Association's national clinical audit programme which is a rolling programme to assess the quality of routine NHS care for people with HIV with feedback to enable individual clinics to benchmark their own performance. She was speaking in a personal capacity.

Hilary's presentation was on the new government plans to bring about an *"NHS information revolution"*, giving people access to data about hospitals and health services in the hope that it will help us choose where to go for treatment, and that this will drive up the standard of care. The government also say that they want the information they provide to be "meaningful" to patients.

Most of the information provided was about the "outcomes" of healthcare (e.g. how many people got better after being ill). She defined process and outcomes; which are intertwined. An indicator is what you actually measure to get an outcome – e.g. viral load is an outcome of treatment. Process is being prescribed the right treatment.

The NHS Outcomes framework is to be made up of a focussed set of national outcome goals that will provide an indication of the overall performance of the NHS. The NHS Commissioning Board will work with clinicians, patients and the public to develop the set of indicators it will use to put into operation the national outcome goals.

***Q: Are we putting anything to change this proposal?***
*A: We need to look at what is HIV-relevant such as patient experience is not measurable and this where the CAB could come in.*

Which outcomes matter? What makes a good HIV service?
Hilary personally highlighted it is the excellence in managing complex/difficult cases, achieving viral load suppression, retention in care, engaging with patients. There is no good model, and how do you measure patient experience?

What information matters to us as HIV patients?
- To assist patients and commissioners in choosing providers – need not be measure of quality.
- To facilitate change and improvement through robust indicators, that reflects quality through effectiveness, patient experience and safety. What matters, is therefore not just what's measurable.

***Q: In terms of getting our views heard, how can we feed in the process, to whom?***
*A: Not clear who is going to be commissioning HIV. Don't know how to approach this at the moment.*

---

**Company meeting with ViiV Healthcare**
Presenters: Eric Le Fevre UK, Medical Director and Anna Lawson, Medical and Scientific Liaison Advisor

A minute's silence was held in memory of those who were and are unable to benefit from advances in treatments. An agenda from the pre-meeting was used as guidance.

Anna presented brief background about ViiV - established a year ago as a global specialist HIV company established by GSK and Pfizer to deliver advances in treatment and care for people living with HIV. Their aim is to take a deeper and broader interest in HIV/AIDS than any company has done before and then take a new approach to deliver effective and new HIV medicines as well as support communities affected by HIV.

Patent Pool *(see link in Pre-meeting section)*

When asked about ViiV's position on the patent pool, they did not have the information with them but gave a general answer. A decision to grant a patent depends on a number of factors including, in the case of HIV/AIDS, the severity of the epidemic in that country, local healthcare provision and the economic and manufacturing environment. ViiV support patents as they give patients in sub-Saharan Africa greater choice and contribute to better security of supply.
Positive Action is a programme established in 1992 to focus support for ViiV's vital global community work. They work with a number of partners to deliver sustainable projects at a grass-roots level in over 46 countries. Most programmes are identified proactively through needs analyses and consultation with partner organisations; local operating companies give grants to in-country HIV community organizations.

Discussion:
***Q: Do projects that apply for funding have to be in the home country?***
*A: No. They can be working with partners outside the country.*

***Q: Could you make it clear on the website that 2% of funding applications are likely to be successful?***
*A: We have noted this to manage expectations.*

***Q: It seems that the distribution of grantees is concentrated in one area (east Africa)?***
*A: The programme's aim is to have 80% of fund to go to sub-Saharan Africa.*

**Pipeline Drugs - S/GSK1349572 ('572)**

**Spring-2** is a Phase III, randomized, blinded, active-controlled (all patients are given both placebo and *active* doses in alternating periods of time during the *study)*, multicenter, parallel group, non-inferiority study. The study's primary objective will be to demonstrate the antiviral activity, compare efficacy and safety of 50mg/once daily '572 vs 400mg/twice daily raltegravir, at 48 and 96 weeks. Both treatment arms will be administered with two NRTIs, either abacavir/3TC or tenofovir/FTC in approximately 788 HIV-1 positive treatment-naïve patients. It will also compare the tolerability, long-term safety and antiviral and immunologic activity and to evaluate viral resistance in patients experiencing virological failure.

**SAILING** is a Phase III, randomized, double-blind, active-controlled, multicenter, parallel group, non-inferiority study to assess the antiviral efficacy of 50mg/once daily '572 vs 400mg twice-daily raltegravir at 48 weeks in both arms. It also evaluate the long-term antiviral activity, the relationship between PK and antiviral activity, tolerability and safety in approximately 688 HIV-1positive treatment-experienced, integrase-naïve patients.
*Pharmacokinetics (PK) is the action of drugs in the body over a period of time, including the processes of absorption, distribution, localization in tissues, metabolisation, and excretion.*

***Discussion:***
*The 16-week data showed high efficacy of 572. It will be exciting to have tiny 50mg doses.*

***Q: Will '572 be developed as a single standalone drug?***
*A: Yes, then we will look into a first combination with kivexa.*

***Q: Are you happy to have a combined drug with other companies such as truvada?***
*A: We would if Gilead would be interested.*

***Q: Will abacavir and 3TC be available in generic combination at generic prices?***
*A: We will come back to talk about prices.*

***Q: Why did you only have two women in the study?***
*A: Noted, will make conscious efforts in larger studies.*

***Q: Can '572 be used as monotherapy?***

*A: Increased dosing is good idea but there is a strong warning that no one should use '572 without supporting drugs.*

***Q: What is comparable data?***
*A: Safety profile of '572 – generally well tolerated. Drug-related adverse events of moderate or higher intensity were reported in more patients receiving EFV (18%) vs '572 (6 %).*

**Maraviroc update**

CCR5-tropic HIV (R5 virus) uses the chemokine receptor CCR5 to enter into human cells and is responsible for nearly all new sexually transmitted HIV-1 infections. The R5 virus predominates throughout infection and approximately 50% of patients with HIV-1 subtype B who die from AIDS have only R5 virus.

CXCR4-tropic (X4) uses the chemokine receptor CXCR4 to enter into human cells and emerges in patients after years of chronic HIV-1 infection subtype B. It is associated with low CD4+ cell counts, rapid CD4+ cell decline, and rapid disease progression. The X4 virus can be detectable at high CD4+ cell counts in untreated patients as in the Multicenter AIDS Cohort Study. It is unknown if it is the cause or consequence of immune deterioration.

Tropism detection guidelines
- Genotypic testing offers a more easily accessible, rapid, & inexpensive method for tropism diagnostics than phenotypic testing, and is therefore the preferred option.
- Naïve patients should consider test prior to starting HAART, especially if at risk of ARV toxicity. Test recommended for patients with virological failure.
- Test can be performed for patients with an undetectable viral load.

HIV tropism refers to the cell type that the HIV infects and replicates in.

Maraviroc is a CCR5 inhibitor that is used with other HIV medicines to treat CCR5-tropic HIV. It is not recommended in patients with dual/mixed or CXCR4-tropic HIV. Genotypic testing determines whether virus will be X4 or R5. A tropism test is needed before starting maraviroc. Trofile tests are sent to San Francisco and are expensive.

**Comment: The cost on the NHS of tropism and resistance tests is the same (£25-50 for naïve and up to £100 for treatment experienced). All HIV positive patients are recommended to have a tropism test done before March 2011.**

***Q: Are you doing any research on maraviroc? Who is using it?***
*A: A pilot study supports once daily with two other drugs combination. There was no resistance or change in phenotypic tropism and no unexpected safety events. Maraviroc is not licensed for once daily treatment naïve patients. It is good penetration in brain and genital sites, a phase 3 study is planned.*

***Q: Are there any studies to show maraviroc's profile on lipids?***
*A: Results from the MERIT study favoured maraviroc over efavirenz at 24 and 48 weeks with small differences. Study statisticians calculated that people taking maraviroc had about a 30% lower 10-year relative risk of coronary heart disease than people taking efavirenz.*

ABC and MI update
This has been an ongoing discussion, Dr Levre read out the company's stand on the issue of safety that states ViiV cannot confirm or refute association of MI risk, there is no established biological mechanism due to confounders – CKD, drug use, smoking, etc. Guidelines will advise use of abacavir with patients with a high CVD risk. Limitations in adjusting for other factors differ from study to study.

***Q: Are you sponsoring any kivexa studies?***

*A: We will continue to be involved with studies looking at CVD risk assessment, Framingham scale, etc.*

***Q: The NHS will soon have flat-line budgets to include new patients on top of the existing ones, how does this affect the tendering process and can you bring generic prices to the UK?***
*A: We are cautious about therapeutic tendering, but that depends on what the London consortium comes up with.*

---

**Vienna feedback**
Silvia Petretti, Positively UK, UKCAB Steering Group member

Silvia presented Paul Clift's slides. The conference had a strong humans rights theme, highlighted abuses for HIV positive people especially in Eastern Europe. There was a Human Rights march and Silvia was one of the speakers to address the rally highlighting the meaningful involvement of PLWHA.

The CAPRISA trial results of a vaginal microbicide with1% tenofovir gel in HIV negative women in South Africa. It was proof of concept trial, double-blind, placebo-controlled had 39% efficacy, with poor adherence. It's not ready for roll out and more research still needs to be done on rectal microbicides.

Garry Brough did a workshop on ageing from recent survey. Results showed that the main issues for the ageing population were financial security, self-care and mental health. It was suggested to have a comparable survey of HIV negative people.

Other highlights for Paul Clift included mental health, doctor to patient communication, criminalisation, African MSM and youth. Roger Pebody had a poster on criminalisation.

---

**Next meeting:**

Date: 04 February 2011
Topic: Treatment as prevention