United Kingdom
Community Advisory Board (UK CAB)
HIV treatment advocates network

UK CAB 30
Meeting Report
Friday 31 July 2009

Contents:

Presentations from this meeting
are available to download from the UKCAB website at:
http://www.ukcab.net/jul09/index.html

PROGRAMME:

09:30 - 10.00	Registration, refreshments and expenses
10:00 -10:15	Welcome and UKCAB Updates – Michael Marr
10:15 - 11:00	BHIVA Routine Monitoring Guidelines - Matt Williams
11:00 - 11:15	**Refreshment Break**
11:15 - 12:15	HIV Treatment Advocacy Overview: • Definitions of Advocacy – Michael Marr • History of Advocacy Film highlights • Advocacy Training in Practice – Winnie Sseruma
12.15-12.30	Pre-Meeting for BMS – Simon Collins
12:30 - 14:00	**Lunch**
14:00 - 15:15	BMS
15:15 - 15:30	**Refreshment break**
15:30 - 16:00	Conference Feedback - Simon Collins or other member AOB
16:00	Close

Attendees:

Adela Mugabo	George House Trust	Manchester
Angelina Namiba	Positively Women	London
Angeline Marang	HIV i-Base	London
Ben Cromaty	North Yorkshire AIDS Alliance	Yorkshire
Bernard Forbes	Wharfside Clinic	St Alban's
David Kakande	Rise Community Action	London
Emma Hudson	The Brunswick Centre	Halifax
Jeff Ukiri	Black Health Agency	Manchester
Joram Barigye	Terence Higgins Trust	Woking
Matthew Williams	Monument Trust	London
Memory Sachikonye	UKCAB	London
Michael Marr	UKCAB Chair/Waverly Care	Edinburgh
Pamela Mahaka	AHPN	London
Patricia Bimbe	Africa Focus/AAEGRO	Liverpool
Paul Clift	Kings College Hospital	London
Richard Blackburn	Brunswick Centre	Halifax
Robert James	NAT	Brighton
Roger Pebody	NAM	London
Rupert Jones	Leeds Skyline	Leeds
Samuel Serunjogi		London
Simon Collins	HIV i-Base	London
Toju Cline-Cole	Terence Higgins Trust	London
Walter Zonke	HIV i-Base	London
Winnie Sseruma	HIV i-Base	London
Zhana Books	Zhana Productions	London

Apologies:

Gus Cairns	NAM	London
Brian West	HIV Scotland	Edinborough
Elijah Amooti	The African Eye Trust	London
Rachel Wookey	Positive Action/Portsmouth PTH	Southampton
Tsepo Young	NHS Dumfries & Galloway	Stranraer

Welcome and UKCAB Updates
Michael Marr, UKCAB Chair

Michael welcomed all members to the meeting and announced that:

- Maria Phelan has been appointed as the CHIVA Community representative for UKCAB
- Swine flu posting on the UKCAB forum for HIV positive people, need to be registered with GP to access Tamiflu. Noted that there could be a problem for people who do not have leave to remain in the UK and are not registered with GPs.
- BHIVA executive committee - the current post holders' term of office is coming to a close, nominations are sought for the position by the UKCAB Steering Group (SG). The terms of reference for this committee are on the BHIVA website: http://www.bhiva.org/cms1191688.asp An application pack explains the main responsibilities and duties of community representatives and is available on request from the UKCAB coordinator. The SG will ensure a period of mentoring/shadowing is provided for the new rep by the existing post-holder, Gus Cairns. Deadline for applications is Tuesday, 25th August 2009.

BHIVA Routine Monitoring Guidelines
Matt Williams, Writing Committee Community Rep

This is the first guideline of this kind and was still out for consultation and is supposed to be published by October 2009. The monitoring guideline should be out for consultation by now but is a bit late. There is old and some new stuff and the highlights of the new guidelines include:

- Diagnosis recommended and confirmed using 4th generation tests (can detect HIV before seroconversion) and this eliminates the "three-month window" period down to two weeks (effectively eliminating it).
- Viral load cut off where clinics must decide the lower level of reporting detectable viral load – should it be >40/50/10 copies/ml? There is no firm recommendation on cut off when sensitive tests report mini spikes, clinics need to be aware of the nature and choose viral load tests they use.
- Should there be two baseline CD4 tests – at diagnosis and 1st follow-up visit?
- Formalised comprehensive history at first visit, with an annual review, or should mood and cognition be included at every clinic visit?
- Baseline screening to include tropical diseases, there is still a debate over measles.
- Dexa scans for bone density for general population at risk: higher risk of osteoporosis etc will be monitored and managed as per other populations at high risk, as per existing bone health guidelines; there is no automatic DEXA scan (in the draft, we can ask...)

Q: How do they determine normal?
A: Should measure person at diagnosis and continue to monitor annually.

Lipodystrophy, lipoatrophy, metabolic syndrome, peripheral neuropathy will be referred to in the forthcoming side effects and toxicity /other treatment guidelines. Age in relation to CVD, bone density and cognition, require special recommondations.

Phylogenetic testing: a research test to related infections (as per criminal cases) – no routine clinical use.

STARHS is used to for detecting recent infection (in last 6 months) and is recommended as a routine. Because people seem to want to know if their infection is recent, and this information has clinical value.

4th generation tests can detect HIV from a recent infection, no window period, 6-week time frame. Negative test for antigen (bits of HIV) and antibodies on 2 different tests AND no symptoms after 6 weeks = does not have HIV, by extrapolation from the section on confirming diagnosis. 4th generation tests can detect HIV before seroconversion, in a matter of days in cases, and should be standard of care (the draft says).

Q: Do they have evidence for 6 or 4 weeks?
A: Yes, there is evidence, its important.

Q: On viral load cut-offs, is advocacy same for those with 200?
A: It is by mutual agreement.

Comment: no clinical justification for doing it more often.

Q: What is the clinical evidence of CD4 variation if you have an infection?
A: None, it is better to have another test in about 6weeks.

Comment: If you stop treatment your CD4 will go back to the original level very quickly within a few weeks.

Q: Should mood and cognition be included at every clinic visit?
A: If someone is depressed, the clinic should do something about it. People may give false information due to other physco-social issues such as, immigration fugitives. The clinic should some trigger questions that can be asked to get this information from patients.

Comment: Add on routine monitoring: people who do shift work.

Q: If there is no baseline dexa scan, what do they compare it with?
A: Everyone should have one soon after diagnosis. Currently most information is from the blood test. Most people concerned about lipodystrophy when starting treatment. Chelsea & Westminster have started an ageing clinic.

Comment: The dexa scan can be dually used to track lipodystrophy and bone density.

- TDM - separate guideline
- Phylogenetic test: What do people think? (see notes)

Comment: STARHS: not useful info to docs, sometimes helpful for viral load, and how fast your HIV is progressing. Information tells you about the virus and not people's behaviour. Anna Maria's study at BHIVA (see HTB) no link between study findings and need for people to use treatment, 2 things not connected at all.

- Treatment as prevention – encourages people to test
- Superinfection: if detected, this is NOT (the draft says) a useful indicator on a person's sexual lifestyle, such as putting others at risk (normally identified in viral load and jumps expectedly high).

Not covered:
- Clinics refusing health workers to get into clinics, clinic claim to be doing it.
- Lost follow-up; doctors being charges for losing patients

HIV Treatment Advocacy Overview:

Definitions of Advocacy
Michael Marr, Advocacy and Information Worker, Waverley Care

This was a Scottish example of advocacy that Michael he felt was applicable in making members understand how his organisation uses advocacy. The main themes of advocacy are:

- Safeguarding people who are vulnerable and discriminated against or whom services find difficult to serve.
- Empowering people who need a stronger voice by enabling them to express their own needs and make their own decisions.
- Enabling people to gain access to information, explore and understand their options, and to make their views and wishes known.
- Speaking on behalf of people who are unable to do so for themselves.

Principles of advocacy:

1. Advocacy puts people who use it first
2. Advocacy is accountable
3. Advocacy is free as it can be from conflicts of interest
4. Advocacy is accessible

Types of advocacy:

1. Active information, sign-posting and explanation
2. Casework
3. Advocacy, representation and mediation

Q: How is advocacy accountable for people who use it?
A: There are different models for different needs: types 1-3. It should be in a simple language.

Denver principles: http://www.denverprinciplesproject.com/
The Denver principles are from 1983 from a group of people living with AIDS got together in Denver at a medical conference and wrote a manifesto of self

empowerment, known as the Denver Principles, for those living with HIV. The Denver Principles demanded that the voices of people living with HIV be heard. It asserted the right of people living with HIV to participate in the decision-making processes - at all levels- that would fundamentally affect their lives. Members were urged to look up the NHS principles from the constitution, and the Kennedy report with 101 recommendations on how the Denver principles have been adapted with NHS care.

- NHs principle, chapter 10: http://www.nhs.uk/NHSEngland/aboutnhs/Pages/NHSCorePrinciples.aspx

- NHS constitution, Kennedy report (lookup) 101 recommendations: http://www.nice.org.uk/newsroom/podcasts/index.jsp?pid=3&t=1

History of Advocacy Film highlights
These are short clips from this excellent presentation by Harold Jaffe from the Glasgow conference that includes clips from the film '*And the band played on*'. Recommended viewing for anyone interested in the history of the response to the earliest AIDS epidemic. This is now available online on the following webcast from that meeting:
http://www.hivdrugtherapy.org/Jaffe_Presentation/index.html

Advocacy Training in Practice
Winnie Sseruma

This is the i-Base pilot Advocacy training programme. The need arose from a research on assessing treatment information needs of Africans living with HIV. Phase one was a structured two-hour training session with a manual has been run at Body and Soul charity during their drop-in and facilitated by two –Base staff. Phase 2 took on 12 aspiring treatment advocates through eight weeks of training. Some of the participants are ready to co-facilitate Treatment sessions and also ready to become active UKCAB members. Another training programme is set to start late September 2009.

Some recommendations from the report:
- Treatment information was in a language they did not understand.
- There are not enough people within the African communities who are treatment advocates.
- It would a perfect opportunity to catch up on treatment information.
- It would be a useful way of learning, interactive, quizzes, etc,

One of the trainees from the project said:
'I initially attended the Treatments Advocates course run by Winnie and the team, in order to keep up to date with and to better understand treatment information/issues. As a single mum who works full time, this was the only way I could keep myself updated. The course also appealed to me as a person who takes in information, and especially treatments information, in a structured, group format.

Key things I found useful with the training included, the varied trainers, the structured way of breaking down each topic and complementing it with written information and Q & A sessions, and I even enjoyed doing the quizzes!
As a direct result of attending the course, I felt better equipped to and attend my first UKCAB meeting.' Angelina Namiba

Q: Will childcare and transport reimbursement be available to come for training if the course is held elsewhere?
A: Future plans are to cover transport and maybe childcare, also looking at plugging into community groups with existing facilities.
Comment: There is a need to incorporate "train for trainers" and offer ongoing support to the trained advocates.

Q: Could another model have expert patients?
A: We decided to start with a pilot of general people who want to learn about treatment, and worked with existing peer support groups. We also do one-off treatment training sessions on request.

Q: Is there anything that says how you do advocacy ?
A: The course is about treatment.

Q: Have you built in supervision/re-enforcement/refresher courses in your training?
A: This is in the 1-off training session and will look into that in future.

Q: What about convincing funders?
A: It is about convincing people that they have more knowledge than they are aware of, its not a rigid programme, encouraging treatment discussions. It is difficult to measure the outcomes and there is no commissioner funding for such projects.

Comment: Peer groups – which group do these belong in? Can't measure outcomes of peer support therefore difficult to convince funders.

Pre-Meeting for Bristol-Myers Squibb (BMS)
Simon Collins

Meeting looked the drugs manufactured by BMS and encourages members to raise any issues or question around they may have. Some issues are:

- DAD study – long term effects of EFV (no CVD risk) check drug levels for Africans
- D4T – world-wide use (not in Europe) lower dose??
- ATV – tolerable lipid-friendly, TDM for alternative dosing option
- Secure the future programme
- Pipeline drugs?

NOTE: A drug chart by manufacture handout was highlighted, is available on the UKCAB website as a resource.

Bristol-Myers Squibb
Dr Keith Aizen and Victoria Adamson

Agenda as set in the pre-meeting:

1. Minute Silence
    a. Chair announced the passing away of Richard Day from MESMAC in Yorkshire who had last attended CAB28.
    b. A minute's silence was observed in remembrance of those who were not fortunate enough to benefit from the available treatments.
2. Introductions
3. BMS products update:
    a. Atazanavir :
        i. Side effects (TDM)
        ii. Alternative dosing
        iii. Individual dosing
        iv. Tenofovir interaction
    b. Efavirenz:
        i. Side effects (TDM)
        ii. 100mg paed formulation
        iii. Atripla
    c. D4T
    d. ddI
4. DAD study support
5. Secure the future update (treatment as prevention)

BMS acknowledged that they did not have answers to some of the questions raised and would be happy to come and feedback at another meeting.

Data update:

BMS Virology portfolio:

- HIV Drugs:
    - Atriprila (efavirenz, FTC and tenofovir)
    - Reyataz (atazanavir)
    - Sustiva (efavirenz or EFV)
    - Videxec (didanosine or ddI)
    - Zerit (stavudine or D4T

- Hepatitis
    - Baraclude (entecavir)

ddI and D4T safety update

Peripheral neuropathy

1. Distal symmetric polyneuropathy - in arms, ankles and feet, contact sensitivity
2. Inflammatory demyelinating polyneuropathy – facial and nerve paresis, ascending weakness, generalised areflexia, mild sensory involvement
3. Progressive polyradiculopathy – radiating pain in back and legs
4. Mononeuritis multiplex – eg. Facial palsy, hands legs and feet

Peripheral neuropathy linked to the D-drugs (DDI and D4T).

Do drugs for HIV drug induced peripheral neuropathy work?

Pregablin - an anticonvulsant drug used for neuropathic pain and as an adjunct therapy for partial seizures with or without secondary generalization in adults - improved pain, no better than placebo.

Comment: two injections per day for somebody with neuropathy is of concern.

Q: Did BMS sponsored a study on K-pak? (mouse study on nerves)
A: There is a need to sponsor a long term study on de/regeneration of nerves.

Cardiovascular Risk (CV Risk)

This was a CV Risk in ddI study of 74k patient years and results showed prolonged treatment with ddI (didanosine, *Videx*) is the sole factor significantly associated with the development of Noncirrhotic Portal Hyperpertenstion (NCPH) in HIV-positive individuals. An important finding of this study is that long-term toxicity of antiretroviral drugs might emerge only after decades. As persons with HIV infection in industrialized countries live longer and ART exposure is prolonged, we need to be alert for novel clinical manifestations attributable to drug-related adverse events.

Q: Is NCPH reversible?
A: No medical data available, but maybe not, there have been some mortalities.

Q: If you are on ddI for more than 5 years, how do you know if you developed NCPH? What about children?
A: Liver enzyme tests should be able to monitor this. Its not known in children, will check, most likely in adults.

Q: How much ddI is being sold in the UK?
A: No much, will find out and feedback. It's a second-line dosing in the rest of the world.

Q: Stavudine use in the UK?
A: Very little, physicians have become more aware of the lypo issues.

Q: Is there an ethical issue about people coming from low-income countries where there are no other options? What happens to those who come off a study to adverse effects?
A: BMS continues to supply the drug to the people in the study, if they stop the study then they may have to be managed by the physician's choice.

C: Would it be ethical for countries with no access to drugs e.g children's trials, it's the only way they can continue to access treatment.

903E Study: The Safety and Efficacy of Tenofovir DF (TDF) in Combination with Lamivudine (3TC) and Efavirenz (EFV) in Antiretroviral-naïve Patients Through 7 Years

Study conclusions**:**

- Sustained, durable antiretroviral efficacy
- Continued CD4 cell count increases
- No discontinuations due to renal adverse events
- No evidence of clinically relevant bone effects
- Significant increases in limb fat from years 2 through 7

Q: How ill would these people have been?
A: will check and advise.

Q: What were the CNS side effects such as sleep disturbance over a long period – 7yrs?
A: will feedback after checking

Q: Where there other discontinuations due to other adverse effects?
A: CNS seems to be a bigger issue on EFV, fantastic when it over but has some horrible effects on others. Difficult to measure CNS adverse effects, 6% discontinuation from study results.

Comment: American studies need to explain the source of participants as most of them do not have health insurance and therefore not much choice.

Comment: EFV levels in Africans are usually higher, patients experienced more symptoms such as dizziness, sleep disorders.

Q: Is it normal to take 800mg of EFV?
A: This would be specific for drug interaction with TB drugs, ask your physician.

Q: Could you lower the EFV dose to manage the side effects? This is a formal request from UK CAB. At what stage did you pick the problem of EFV side effects?
A: Consider the patient, drug and virus in each instance, they all to be considered when looking at what caused resistance? Safety data is collected and submitted every 6 months to the regulatory body (MHRA).

Q: Is only physicians who can report adverse events?
A: Anyone can, yellow card scheme can also be used.

Q: Is there great concern of CNS toxicity?
A: Data doesn't exist at present, we are looking at the literature at the moment. Data is mixed; how much drug is going into the CNS, balance out on whether drugs suppresses virus and causes neurological toxicity.

Q: Can you tell me the symptoms of toxicity?
A: You feel a bit high, dizziness, light headed, lack of energy, happiness, liver malfunction.

Comment: Also a small percentage of people can get extreme agitation, anxiety and paranoia.

Q: Can TDM test and reduced dosage continue to suppress the virus?
A: Need a dose that suppresses 50% of the virus depends on other factors such as liver disease, etc.

Q: Is BMS going to sponsor DAD study long-term?
A: Will find out and feedback.

Comment: BMS is re-introducing 100mg EFV paed formulation, there is some some currently available if patients require it. You can take credit for making noise!

Conference Feedback
Simon Collins

DART study
The most important study results presented at the 5th IAS conference were from the DART (Development of AntiRetrovial Treatment in Africa) trial. Sponsored by the UK's Medical Research Council and University College London, DART randomised over 3300 treatment-naive patients in Uganda and Zimbabwe to be managed by either routine three-monthly CD4 count and laboratory monitoring (LCM group), or by clinically driven monitoring (CDM). Laboratory monitoring was also performed for this group, but results were only given to the treating doctor when a grade-4 toxicity was identified. Viral load was not monitored in either arm.

The rationale behind DART was to determine whether ARVs could be used effectively without routine monitoring, in order to broaden access to treatment in settings where CD4 and laboratory monitoring are either no available or where they are difficult to access. The top line results were both impressive and challenged common assumptions. Both arms showed a remarkable and similar 5-year survival rate - 90% vs. 87% in the lab and clinical arms respectively - separated only by a small percentage difference that only occurred after the first two years on study. This compared to an historical 5-year survival rate prior to HAART of only 8%. Clinic attendance was >98% with high reported adherence and only 7% patients lost to follow-up over five years.

Other studies:
Prevention – treatment as prevention, MTCT exclusive breastfeeding, less that 1% of children got HIV.

Circumcision works:
Q: What is the benefit for women?
A: Less STI transmission. Men not protected from HIV, essential to wait 3-6 months after circumcision for the healing process.

Comment: In Uganda children are now circumcised at birth, older people also getting circumscised, including government ministers.

ABC and heart disease – several varying studies suggest CVD findings links to abacavir maybe complicated by patients with renal disease.

New drugs: GlaxoSmithKline's S/GSK1349572, or GSK-572

- second-generation integrase inhibitor demonstrated very good anti-HIV activity in a 10-day monotherapy study.

Other ARV studies

- ARTEN study nevarapin v atazanavir/r: to directly compare the efficacy and safety of nevirapine and ritonavir-boosted atazanavir (ATV/r) when combined with TDF/FTC, a modern backbone therapy commonly used with both nevirapine and ATV/r in clinical practice.

- LPV/r once daily - Lopinavir/ritonavir (*Kaletra*) taken once-daily as part of a combination antiretroviral regimen worked as well as the approved twice-daily dose in previously treated patients but led to better adherence.

- Raltegravir (*Isentress*) three year study results have resulted in a key step being taken towards approval for use in first-line HIV therapy in Europe. Currently its European licence restricts its use to treatment-experienced patients. This recommendation came after presentationof trial data about the safety and efficacy of the drug in treatment-naive patients. Interim three-year results from an ongoing study showed that raltegravir was as effective as efavirenz as part of antiretroviral therapy for patients starting HIV treatment. Raltegravir is very expensive, not available in London clinics.

- Routine monitoring – changed drug on clinical symptoms rather than data, not available in developing countries, hence restricting access to treatment. 500 people a year die of HIV complications in the UK.

Comment: NHS should decide on what it is NOT doing in terms of funding for HIV.

AOB - BHIVA Audit information to be discussed on the forum

Next meeting: 23 October 2009
Topic: Aging and HIV