UK-CAB
HIV treatment advocates network

UK-CAB 44: Generics and drug development

19 October 2012

Contents:

Presentations are all available to download for the October meeting at:
http://www.ukcab.net/2012/10/cab44-generics-and-drug-development/

Programme

Chair: Robert James **Timekeeper:** Jeff Ukiri	
09:30 – 09:50	Registration, refreshments and expenses
09:50 – 10:00	Welcome, introductions, UKCAB updates
10:00 – 11:00	**Drug development process, an introduction –** Rebecca McDowall, HIV i-Base **Drug development in relation to PrEP and the PROUD studies** – David Dolling, MRC
11:00 – 11.15	**Break**
11:15 – 12.30	**Generic HIV drugs** – Katy Athersuch, MSF Geneva **Stop AIDS Campaign** – Lotti Rutter, UK Consortium on AIDS & International Development
12:30 - 14:00	**Lunch –** Strada Restaurant
Chair: Mark Platt **Timekeeper**: Virginia Cucchi	
14:00 - 15:30	**Conferences feedback by UKCAB members:** Silvia Petretti/Angelina Namiba – Women/advocacy and Option B+ Robert James – AIDS2012 - History and Hepatitis Roger – IAS, BHIVA Chris O'Connor – Washington Snapshot Damian Kelly - WAC Feedback; Living2012, 2015 Pledge
15.30 - 15.35	**Break**
15:35 – 16:00	**UKCAB AOB**
16.00	Close

Members attending and apologies:

No	Name	Organisation	Destination
1	Angelina Namiba	Positively UK	London
2	Ben Cromarty	North Yorkshire AIDS Action	Yorkshire
3	Beverly Marshall	Brent Community Services	London
4	Chris O'Connor	Baseline magazine	London
5	Damian Kelly	George House Trust	Manchester
6	Fabiola Bayavuge	Black Health Agency	Manchester
7	Jackie Ayugi-De Masi	NAM	London
8	Jacqueline Maycock-Cato	Brent Community Services	London
9	Jeff Ukiri	Personal	Manchester
10	Lotti Rutter	UK Consortium on AIDS	London
11	Mark Platt	Personal	London
12	Memory Sachikonye	UKCAB	London
13	Michael Marr	Waverley Care	Edinburgh
14	Mike Mpofu	George House Trust	Manchester
15	Miurgen Stack	HIV i-Base	London
16	Paul Clift	Kings College/Forum Link	London
17	Phyllis Okai	CMH – PPE	London
18	Rebecca McDowall	HIV i-Base	London
19	Robert James	Brighton Clinic	Brighton
20	Roger Pebody	NAM	London
22	Silvia Petretti	Positively UK	London
22	Tendai Ndanga	AHPN-Ffena	London
23	Tsepo Young	NHS Dumfries and Galloway	Stranraer
24	Virginia Cucchi	Bloomsbury Pt Network	London
25	Yusef Azad	NAT	London

Apologies:

1. Glenda Gibbs
2. Robert Fieldhouse
3. David Rowlands
4. Patrick Dzwekesu
5. Angelina Dzwekesu
6. Febby Chisha
7. Alastair Hudson
8. Simon Collins

The Drug Development process – Rebecca McDowall

Rebecca is a treatment advocate at HIV i-Base. She gave an introduction to the drug development process. Drug development is a process which takes a drug from initial discovery to the pharmacy shelves. Very few pharmaceutical products actually make it all the way through drug development, and sometimes the process can be an extremely costly and frustrating. Only in 10,000 compounds ever make to a licensed drug.

The first stage of drug development is to identify the target. These are proteins in the body or microorganisms that are associated with a disease. HIV most commonly uses CCR5 and/or CXCR4 as a co-receptor to enter its target cells. Several receptors can function as viral co-receptors, but CCR5 is likely the most important co-receptor during natural infection.

Once the targets are identified screening tools and computer databases are used to identify chemical compounds that could bind to the identified target. When a compound binds to the target it may alter its function. If a compound is found that affects the target in a way that could alter the disease it is then monitored to improve safety and effectiveness, eventually becoming a drug candidate. Once a drug candidate is identified there are still several stages before it can enter human studies.

Pre-clinical studies:
Just because a compund is found to have promising activity against the 'drug targets' this doesn't automatically mean it will be suitable to be made into a treatment. Little may be known about its safety, toxicity, pharmacokinetics and metabolism in humans. Pre-clinical trials must assess all of these parameters prior to human clinical trials. These studies take an average of one to two years before a 'phase 1' trial can begin.

Cell studies are carried out to look at the activity and toxicity of the drug. This can tell us a lot about how we would expect the drug to act in the human body. But some of these pre-clinical tests need to be conducted using animals to get a clearer image of toxicity to certain organs, and to look at how long a drug will remain in the body. Different animals used for different types of studies and different types of drug. At this stage many promising drugs are often shelved based on rat or dog toxicity.

At this stage there is also research into early formulations to see whether the drug candidate can be used to form a tablet, capsule or injection. The information gathered from this pre-clinical testing, as well as information on Chemistry and Manufacturing Controls (CMC), and is submitted to regulatory authorities (in the US, to the FDA), as an Investigational New Drug application or IND. If the IND is approved, development moves to the clinical phase.

Phase 1 studies are the first human studies and usually enrol 'healthy' HIV negative people. Phase 1a trials include single-dose studies with a small group of participants (5-10) taking one single dose and are carefully monitored. 1-2 patients usually get a placebo. At this stage they're just testing for safety- that the compound is not a poison.

Phase 1b trials include short-term multi-dose studies for 1-2 weeks with 10-20 participants who are also carefully monitored. This is generally spread out over time, rather than giving all patients the dose at the same time. The danger of simultaneous dosing was shown in 2006 when the trial of a drug at Northwick Park in London resulted in six study participants becoming seriously ill. This had not been picked up in pre-clinical trials.

Phase II studies are usually the first studies look at whether the investigational compound is actually active. Unlike phase 1 these trials are run in HIV-positive people. These can last one day, a week or two or several months. Phase IIa studies usually enrol 20-50 people. Phase IIb studies also look at different doses of a drug called 'dose finding' studies. In which case they may enrol 200-300 people.

Phase III studies are the large randomised, double-blinded (where neither doctor or patient knows which treatment is being given), sometimes placebo controlled trials and have 800-1500 participants for HIV drugs. An independent drug safety monitoring board (DSMB) monitors the safety of these studies. These studies collect main efficacy and safety data and determine whether regulatory agencies like the EMA in Europe or the FDA in the U.S. will approve a new drug or new indication.

If the same people from the Phase II study, the study is sometimes called Phase II/III 'roll-over' study. More advanced formulations and manufacturing scale up to meet larger demands for larger studies.

Phase IV studies are usually referred to as 'post-marketing' studies. They involve longer follow-up of patients looking at side effects and other safety concerns. Sometimes a rare side effect, or a side effect that takes years to develop, may not be seen in a Phase III or earlier study. They are usually recommended by regulatory agencies at the same time that a drug is approved.

Although, in the past, the European regulatory agency had very little power to make sure companies followed through on these commitments, recent legislation has strengthened their authority. Phase IV studies are now compulsory and the EMEA can withdraw a medication if safety commitments are not followed.

Q: At what stage in the drug development process is compound patented?
A: This is during drug discovery. If the pharmaceutical company believes at this stage of the drug development process that it may have a useful compound, it can start to file paperwork with regulatory agencies, identifying and naming the compound so that the agencies can start reviewing it

Comment: A patent is for 20 years - this is where the company will make its profit.

Q: What the mechanism for collecting the data in phase IV studies?
A: Data is collected by the companies in phase IV studies. Yellow Card scheme in the UK is an alternative for collecting information.

Q: Why was vicriviroc withdrawn?
A: Due to lack of efficacy in phase III studies

Q: What is the transparency in clinical trials?
A: Not all information is published; you have to dig deep to get answers.

Q: At what stage do patients get expanded access to pipeline drugs?
A: Depends on company. Regulatory bodies have established rules that enable companies to provide drugs prior to their approval to patients who exhausted available treatment options and cannot meet clinical trials criteria. Usually this is not until the phase III studies are fully reported and often not until submissions to the FDA/EMA.

Q: How are paediatric formulations made during drug development?
A: The US government in 1997 and the EU in 2006, approved laws creating incentives for companies to drug research in children at the same time as adult studies. For the most part, these laws have been successful in generating new scientific data in the appropriate usage of medications in children.

Drug development in relation to PrEP and the PROUD study – David Dolling

David Dolling is a medical statistician in the HIV Group at the MRC Clinical Trials Unit. After completing his Masters in Biometry at Reading in 2010 he began working on the UK HIV Drug Resistance Database, a central repository for resistance tests performed as part of routine clinical care throughout the UK. His current research interests include antiretroviral drug resistance, the use of laboratory markers to monitor HIV infection and HIV prevention. He is currently helping to design and run PROUD, an open label evaluation of pre-exposure prophylaxis in HIV negative men in the UK which aims to start recruiting in the UK in November 2012.

David's introduction complimented Rebecca's presentation on drug development. He explained that Pre-exposure Prophylaxis (PrEP) is a strategy that uses ART to reduce the risk of HIV infection in HIV negative people.

Why is PrEP needed?
Whilst new diagnoses have been declining since 2005 the continued success of HAART has transformed HIV from a fatal illness to a chronic infection and has led to an overall increase in the number of individuals diagnosed and on therapy. 91,500 people estimated to be living with HIV at the end of 2010 (25% are undiagnosed). HPA predict that the number of people living with HIV will reach 100,00 in 2012 - more people are diagnosed with HIV each year especially in MSM. 3,000 new diagnoses of HIV in MSM in 2010; 81% thought to be UK acquired. It is expensive for the health system to treat HIV positive people. Lifetime cost of treatment per person is £280,000-360,000. PrEP will reduce infections and therefore reduce lifetime costs. The PROUD study will use Truvada (TDF/FTC), approved by the FDA in 2004 as an ARV and approved in 2012 for PrEP.

PrEP timeline – Truvada
Phase 0: 1995 early work evaluating efficacy, already knew PK for Truvada and so needed to demonstrate efficacy in PrEP in macaque studies. Controls got infected after 1.5 weeks and others after about 6weeks. The weaknesses of the study was that in was not in humans, the virus was SHIV not HIV. There was small number of monkeys that were injected with 5x virus vs. actual virus in semen. In 2006 Truvada demonstrated partial prevention using tenofovir on SHIV in macaques.

Some Truvada studies at different phases:

- Phase I: MTN-007 study with 1% tenofovir rectal gel microbicide study which did not demonstrate efficacy.

- Phase II studies: 2005-2010, e.g. the West African study where two people on TDF seroconverted and 6 more in the placebo arm. Study closed in other sites due to controversy and logistic issues.

- Phase IIb - The VOICE trial of high-risk women in eastern and southern Africa looked a 5 treatment groups: daily oral tenofovir, oral Truvada, oral placebo, tenofovir vaginal gel, and vaginal placebo. The trial was discontinued in the oral tenofovir group because of a lack of likelihood of effectiveness.

- Phase III: 2009 – FEM-PrEP, double blind, randomized, placebo-controlled trial enrolled HIV-negative women from 4 sites in 3 countries (Kenya, Tanzania, South Africa). The study's purpose was to investigate the safety and effectiveness of a once-daily Truvada pill (compared with placebo) in preventing HIV among HIV-negative women at risk of becoming infected through sexual intercourse. Study closed in April 2011as the investigators concluded that even if it continued for its originally planned duration, the FEM-PrEP trial was highly unlikely to show a significant protective effect of Truvada against HIV infection in this population.

  iPrEX enrolled 2499 gay and transgender men, but had more infections in the placebo arm (n=29). It showed 44% efficacy in the primary endpoint across the whole study, but >90% efficacy in people with active drug levels (i.e. who were taking the drug).

Q: What is the ethics for people not knowing whether they are on a real drug or placebo?
A: This is to generate evidence and measure the actual effect of the drug being tested.

Q: Are there any PrEP studies targeting women in high prevalence areas?
A: The VOICE study enrolled 5,029 sexually active, HIV-negative women aged 18 to 45 into the clinical trial, which is taking place at 15 sites in South Africa, Uganda and Zimbabwe.

- Partners PrEP enrolled 4758 heterosexual partners in Kenya and Uganda and followed for 36 months. Study was stopped as it showed that transmission was reduced by 73% for participants in the Truvada arm.

- Phase IV studies: 2012-20xx, e.g. PROUD. FDA approved Truvada for reducing the risk of acquiring HIV infection in July 2012

Q: Why was Truvada chosen for PrEP?
A: It is all do with PK *(absorption and distribution of an administered drug)*; it has *a long half-life. When a person misses some doses, they can still be protected, it is a well-tolerated drug. Each drug has a different PK profile values with different absorption rates in different compartments such as the brain and genital tract.*

Q: Why was N-9 in MTN-007 study arm used when it was known to be unsafe?
A: I am not sure, but early hope that N-9 might be effective against HIV proved to be false. When scientists first began looking for vaginal microbicides, they decided to first evaluate whether any existing products might work for this purpose. They began testing existing spermicides containing N-9 to see if they prevented HIV transmission when used in the vagina. After a long and complicated history of testing, scientists have concluded that products containing N-9 do not offer protection against HIV. N-9 containing products increase risk of HIV transmission by causing small disruptions in the vaginal cell wall which may increase a woman's risk of acquiring HIV.

Q: What was the proportion of gender of the participants in this study?
A: One-third were women.

PROUD study
PRe-exposure Option for reducing HIV in the UK: an open-label randomisation to immediate or Deferred daily Truvada for HIV negative gay men who have unprotected anal intercourse (UAI) with men. This is a pilot study to determine the feasibility of a larger trial assessing the clinical and cost-effectiveness of including anti-retroviral pre-exposure prophylaxis (PrEP) in the HIV risk reduction package for men who have sex with men who are at risk of acquiring HIV in the UK. The pilot study is in 500 people and is funded by Gilead. It is not large enough to show efficacy. The full study (2000-3000 people has not received UK funding.

The two-year study will recruit volunteers across England, who will be placed at random into one of two groups. One group will use PrEP from the start of the study, and the other group will receive PrEP after 12 months. Both groups will receive support to remain HIV negative throughout the study. Participants are asked to keep a short daily diary, fill out a monthly questionnaire and attend a clinic appointment every three months.

This study is looking at a new way to reduce the risk of getting HIV. It will look at the impact of taking PrEP on how often men have sex; how often they use condoms; and whether they get other sexually transmitted infections. The aim of the study is to find out whether a daily tablet, Truvada, can safely reduce the risk of gay men catching HIV, researchers need to do a large trial in which half the men do not receive Truvada for one year. They do not know if gay men at risk of HIV are interested in taking Truvada, and if they are, whether they would be willing to wait a year before they can take it.

The reason it may not be safe, is that taking Truvada-PrEP may lead to an increase in risk behaviour. This could mean there was more chance of catching HIV and other infections.

As well as finding out if a large trial would be possible, this study will looks at other factors including:
- Whether people using PrEP change the number of partners they have sex with.
- Whether people using PrEP change how often they use condoms.
- Whether PrEP leads to higher rates of other sexually transmitted infections (STIs).

This information on changes in sexual activity over time is one of the most important aspects of the study, because no one has ever collected this before in the UK. This means researchers don't know what happens to people's sexual activity without PrEP!

Exclusion criteria:
- An acute viral illness that could be due to HIV seroconversion.
- Any contraindications to Truvada according to the current package insert.
- Treatment for hepatitis B infection indicated or ongoing.
- Unlikely, in the opinion of the clinician, to comply with the randomised allocation.

Other outcomes include HIV infection between randomization and month 12, adherence cost-effectiveness of prevention. Follow-up will include psychological support.
Safety:
- Serious adverse reactions attributable to Truvada.
- Adverse events that lead to interruption or cessation of Truvada
- Renal function estimated using serum creatinine at 12months.
- Frequency of viral resistance in men who acquire HIV.

More information and how to volunteer in the study is at:
http://www.proud.mrc.ac.uk/default.aspx

Q: What is point of randomising participants?
A: To avoid any possibility of selection bias in a trial. It also demonstrates that if participants have knowledge of which drug they are, it will change their behaviour.

Q: How much does the Truvada used in the study cost per patient per year?
A: It is estimated at £7,000 a year, but will be donated by Giled for this study.

Q: How long before or after exposure should PrEP be taken?
A: It takes a while for Truvada to build up to levels in the body that can protect people from HIV infection. We don't yet know exactly how long this takes, but it likely takes at least a few days. Additional studies are exploring this topic and testing alternative dosing schedules, such as four and two times a week. It is recommended that people take PrEP once a day, as this was how it was tested in previous PrEP studies. It is also important to have some amount of medication use after exposure.

Médecins Sans Frontières/Doctors Without Borders (MSF) Access Campaign – Katy Athersuch

Katy Athersuch is the Innovation and Access Adviser for the Campaign for Access to Essential Medicines of Médecins Sans Frontières/Doctors Without Borders (MSF) based in Geneva, Switzerland. Katy studied International relations and Development Studies at the University of Sussex in the UK. Before joining MSF in 2009, she was the Coordinator of the Stop AIDS Campaign in the UK; a coalition of over 80 UK based NGOs working on HIV and International Development. Her interest is in the problems of access to medicines and the lack of innovation for diseases that primarily affect people in poor countries.

Access Campaign was set up in 1999 by doctors and nurses frustrated at not being able to treat patients because medicines and diagnostic tools were:

- Unavailable - many medicines are too expensive for patients or governments in developing countries to afford – newer treatments used for HIV are an illustration of this. One reason is that the growth in patent protection in developing countries has pushed up prices and restricted competition, as a patent can give the originator company a market monopoly for 20 years.
- Unaffordable - research and development is not geared towards the needs of people in poor countries. Drugs and diagnostic tests are being developed on the basis of their future market potential rather than on patients' needs. Only 1.3% of the drugs that have come to the market in the past 30 years were developed for tropical diseases or tuberculosis. These diseases represent 11.4% of the global disease burden. The existing drugs for these diseases are often toxic and are becoming less and less effective due to resistance. There has been a decrease in drug cost over the last 10years; though not on favourable regiments!
- Unsuitable - even when better medicines and tests become available, there are other barriers to be overcome. For example, one key problem delaying the further rollout of HIV treatment is the chronic shortage of health staff, particularly in Southern Africa. MSF is working also to provide field research that will support the development of more simplified models of care to deliver treatment and that will benefit both patient and health care workers. MSF closely follows the developments in the world of access to medicines, vaccines and diagnostics.

MSF Access Campaign and many other actors have worked and brought about significant advances over the last few years although important problems persist. Large-scale treatment of HIV with ARVs has become a reality and an international priority. This became possible thanks to massive price reductions triggered by generic competition for the first generations of ARVs that MSF promoted. Treatments that cost more than US$10,000 per patient per year are now less than $70. MSF also called for WHO to assess the quality of these medicines which WHO does today through the WHO pre-qualification system. However, urgently needed newer HIV medicines remain much more expensive and large-scale expansion of treatment will rely on the continuing flow of quality, affordable medicines.

Currently:

- 6.6 million people now are on treatment in poor countries and AIDS deaths have fallen by 20%. In 2001 there were 100 000 people on treatment.
- Access to treatment will prevent deaths as well as transmission.

Game changing – need for investing in access to treatment to save lives and can result in a decline of new HIV transmissions. This can be done by:

- Accelerating treatment, i.e. starting treatment at a higher CD4 count – 350 or higher.
- Initiating immediate treatment for people with active TB.
- Treatment in sero-different couples (treatment as prevention).
- Lifelong treatment for pregnant and breastfeeding mothers regardless of CD4 count.

Challenges: 9 million people in the world still need treatment. There is need to bridge the standard of care in wealthy countries and that in the developing world. The tools available for this are better drugs, access to viral load monitoring and access to TB diagnostics.

The Trade Related Aspects of Intellectual Property Rights (TRIPs) treaty sets rules for the purpose of avoiding trade frictions and securing free trade. TRIPS gave 20 year monopolies on drugs from 2005, medicines became patentable everywhere, biggest threat is that India has started patenting all its dugs resulting in no price reduction. TRIPS can also guarantee drug efficacy and safety. There is a prequalification by WHO to generic manufacturers and ARVS do have this protection for quality.

Katy showed a diagram of ARV patent landscape – all patented drugs and when the patents expire and this led to an interactive discussion:

Q: There is recent evidence from Uganda on a drug that was returned because it was fake, how could it have passed through quality control?
A: It could be fake drugs that may their way through the procurement pipeline, investigations can trace the source, sometimes its corruption in a country's system.

Q: Where does funding for quality checks come from?
A: The companies have to pay to be checked against safety standards set by PEPFAR and WHO.

Comment: Gilead has a price-tier system on TDF-based first line regiments and the generic competition has resulted in a lowered price. Would like to see a process where we do not pay for R&D.

Q: Will the generic drug companies fund support for patients as the big companies have been doing?
A: Not sure about that, but we will need however to advocate for the savings by the government by using generics for support services.

Comment: Abbott does not license their drugs to generic companies; they guard their monopoly while Gilead licenses their drugs to generic companies and gets paid royalties.

Q: How far lower could the prices of generics prices go?
A: It's all about cost-efficiency.

Q: How much government pressure will influence branded pharma to lower their drugs?
A: Government has a role; they will not buy high priced drugs. It is different in the US as most people are on insurance. For example the Controller of Patents in India granted the first-ever compulsory licence to Natco to make sorofenib tosylate, a generic version of Bayer's high-priced anti-cancer drug Nexavar. Indian patent law allows grant of a compulsory licence to an applicant if the patented drug is not available to the public at a reasonable price.

Comment: As a community we need to start preparing ourselves for generics. There is full list from the Medicines Patent Pool with list of drugs on/off patent. More information at:
http://www.medicinespatentpool.org/

Q: There was a presentation at IAS on the rates of resistance to generic drugs in Sub-Sahara Africa, should we be worried?
A: There is no difference in quality on WHO quality assured compounds. There is need for more adherence support in such cases and at least an annual viral load monitoring, which is not easily accessible for most patients. There is new viral load monitoring diagnostics in the pipeline, but price has to be affordable. This is beneficial in long term for earlier intervention.

Comment: There are suggestions that savings from generics in the UK will fund earlier treatment.

Recommended reading: Untangling the Web of ARV Price Reductions
http://utw.msfaccess.org/

STOP AIDS Campaign – Lotti Rutter

Lotti Rutter is the Activism & Campaign Officer at Stop AIDS Campaign. Stop AIDS Campaign is an unprecedented initiative of the UK Consortium on AIDS and International Development, bringing together more than 60 of the UK's leading development organisations, trade unions and HIV and AIDS organisations. Launched on World AIDS Day 2001, the campaign works to raise awareness in the UK about global HIV/AIDS epidemic and to campaign for urgently scaled up international action.

Stop AIDS Campaign are campaigning for comprehensive universal access to prevention, treatment, care and support with no one left behind. We are striving for a world in which peoples' human rights are respected. Discrimination that prevents certain groups of people from accessing services is stopped and the rights of people living with HIV and AIDS are fully respected.

In 2005 world leaders promised to provide Universal Access to HIV prevention, treatment care and support by 2010. Yet, thousands of people are still dying every day of AIDS-related illnesses, unable to access the essential services they need to stay alive.

Stop AIDS Campaign share in the UNAIDS vision of zero discrimination, zero new infections and zero AIDS related deaths. However, due to a lack of financial and political support this dream could easily slipping away. They need help from UKCAB advocates so they can build the foundations of a world without AIDS.

AIDS activists from across the UK recently staged a protest outside the gates of a UK Novartis plant, demanding the Swiss pharmaceutical giant drops a court case which campaigners say could strangle the supply of affordable medicines from India to the developing world.

Novartis has been locked in an ongoing battle with the Indian government for the last six years following the rejection of a patent on a cancer drug. This case is about a cancer drug, but the result will have a much wider impact on the health of poor people all around the world. If they win, the change will make it easier for drug companies to get unjustifiable extensions to their monopolies, and make it more difficult for generic companies to produce and sell the affordable generic medicines health care providers across the developing world rely on.

The case fundamentally threatens the supply of affordable medicines from India to the developing world. The Stop AIDS Campaign, as part of a global movement of activists and civil society organisations, has been campaigning for Novartis to drop the case.

Currently they are targeting Johnson & Johnson (Janssen) to encourage them to join the Medicines Patent Pool. J&J part own a crucial, life-saving HIV/AIDS drug so as activists we really need them to join the Patent Pool. As the other half of the patent is already in the pool, they are effectively blocking cheaper production of this drug, which would save millions of lives.

UKCAB members can also ask J&J to join the Patent Pool here:
http://stopaidscampaign.org/poolparty/

International AIDS Conference feedback by UKCAB members - personal views:

History and Hepatitis – Robert James
Robert was unhappy with the following things about the IAC:

- Title of turning the tide; tides turn naturally, so title didn't quite match.
- Welcome to all – some people with convictions and sexual workers not allowed into the US.
- Programme had good things happening at the same time.
- Overflow rooms were too small.

History
A couple of activist films on fighting AIDS were screened: *Fight Back, Fight AIDS: 15 years of ACT UP* and *A history of ACT-UP New York.* These show that demonstrations/activism has been happening since the epidemic began.

What will take to turn the tide? It will take government to realise value for money, doing things right – e.g. Brazil buying generic drugs early from India.

Hepatitis: HCV saliva test not effective, the pin prick rapid blood test to be rolled out. Surprised at the no mention of co-infection in China in labour camps where there is no treatment! The new HCV drugs now have names, though nothing new about drugs was presented.

The good thing is that we are looking at future 12 week once a day oral treatment for HCV. Hopefully this will get companies working together in co-formulations. Robert's favourite poster showed that HIV patients with a CD4 over 200 for over 11 years on moderate alcohol consumption (3 units a day) evidence of protection against coronary and other arterial diseases.

Washington Snapshot - Chris O'Connor

HPTN 065 trial on assessing a new approach to encourage newly diagnosed HIV positive people to seek care and adhere to HIV treatment. Study participants are given a coupon ($25) for a gift card to claim after they complete clinic visits and laboratory tests.

As a journalist, HIV is not new at the moment. There were over 1,000 media/journalists at the conference, with 2 mainstream reporters from the UK. Why all this attention for HIV, why not TB, Malaria? Should journalists be activists? Mia Malan (*Mail & Guardian* paper) yes, in South Africa that's the decision they made. No - says John Cohen (*Science* and *Nature* magazines), Bird Flu is more interesting at the moment. The exciting news however is that AIDS cure is imminent; how soon is imminent? Maybe in 10 years time.

HIV can be perceived as huge investment and threatened aid for other diseases, lots of evidence that it is 'lifting all boats' in health care systems such as family planning, diabetes, heart disease etc. Would like to see an integration of HIV services into other disease areas.

Many faith-based groups had a presence at Washington 2012. They were challenged on stands and at sessions on the Church's role in stigmatising people living with HIV. Sex workers called for change in US policy to promote best practice. There are calls for the repeal of the PEPFAR anti Prostitution Loyalty Oath. The US clinical guidelines should omit sex workers when talking of at risk groups.

Make women count – Silvia Petretti and Angelina Namiba
Silvia was pleased that Hilary Clinton made big commitment to continue funding the Global Fund. The Women's Networking Zone in the global village with workshops and other advocacy activities. Anna Sango, a 23-year-old woman from Zimbabwe openly living with HIV spoke at the opening ceremony on the challenges faced by women living with HIV.

Over 50% of people living with HIV globally are women. AIDS still the leading cause of death for women of childbearing age. There are high levels of human rights violations in health care settings including forced sterilisation. Women's organisations underfunded and still lack of meaningful involvement of women living with HIV. Women still make up < 15% in many clinical studies.

4.8 million young people aged 15 – 24 years are living with HIV which is 3 million (two out of every three) are girls. Dr Rao Gupta, Deputy CEO UNICEF recommended to have national plans in all countries to ensure girls are protected and empowered and have strategies in place to ensure girls are educated and remain in school. Adolescents must be visible in monitoring and routine data systems and engaged as partners in this process, for they "are experts in their own reality."

Only one woman Linda Scruggs spoke in the plenary activist Linda Scruggs spoke about the need to address gender inequality if we want to turn the tide on transmission to women.

Women's networks met with Michel Sidibe of UNAIDS on involvement of women with HIV; asked for meaningful GIPA. There is a video on want women need on the Internet which is a global coalition. This meeting demonstrated that when you approach the right people and you can get something done.

TASP – Malawi has implemented Option B+ - maternal ART for life. Silvia sought thoughts from the room:

- What's the alternative to this?
- Partners not accessing treatment – problem.
- Women should have the choice to opt out.
- No 2nd line treatment if resistance develops.
- No one has looked at Option B+ in the long term.
- There was no community involvement in this.

Comment: A new study - WAVES will be women only study and Margaret Johnson will be the UK PI.

Did you know what women living with HIV want? – Video link:
http://hivpolicyspeakup.wordpress.com/2012/10/26/did-you-know-what-women-living-with-hiv-want/

WAC feedback – Damian Kelly

Living2012 leadership summit – highlights:
The issue of "excluded" people from the USA was highlighted via video by those affected by the ban. Prevention, treatment, care and support was discussed and the issues of increasing access to ARVs. Treatment as prevention, discussion showed different understandings in the community. What does TasP mean? A worldwide definition is needed.

Recommended that advocacy to include young people as new advocates, young people engage better with their age mates.
Towards a cure – there was a lot of information and expect more at forthcoming Glasgow conference.

Great speakers like Hilary Clinton, Michele Sibide and Dr Jim Yong Kim all stressed that money was an issue in ensuring access to those needing treatment in the world and current services. We have to change our ways of working and stressed the need for Robin Hood Tax!

Human rights - criminalisation, travel restrictions, sexual and reproductive rights, stigma and discrimination, treatment must be treatment and accessible worldwide.

There is need to involve PLWH in policy and service deliver, community mobilization and activism is needed. There was a call for zero generation; no child to be born with HIV by 2015.

Posters – two stood out for Damian:

- Transplants – HIV should not be a barrier to transplants if stable etc with optimal time, levels etc to avoid rejection and complications
- Testing - Car mechanics trained to take blood!!! Tested over 2000 men and picked up over 50 positive men. They gave out gave out safe sex messages.

Amongst other sessions, Damian also attended the INSIGHT investigator meeting at the conference.

Conference feedback - Roger Pebody
The US and UK analyses showed that black MSM are eight times more likely to be HIV positive vs. black populations worldwide. They are twice more likely to be HIV positive vs. general populations.

Risk behavior does not explain HIV the great differences in UK or US black MSM, and late ART access for black MSM in both countries. Disparities greatest for structural, clinical, network variables associated with HIV infection. Future interventions must focus here.

Criminalisation of homosexual activity is associated with a two-fold increase in HIV prevalence among black MSM across African and Caribbean countries.

Both reviews establish similar patterns in greater risk for HIV infection among black MSM across countries. Addressing structural barriers is essential to eliminating disparities and achieving health equity for black MSM at higher risk for HIV infection worldwide and should be targeted for HIV prevention and care efforts.

- Use of a rapid HIV home test to screen potential sexual partners prevents HIV exposure in a high-risk sample of MSM - each study participant received 16 rapid HIV home-testing kits for optional use with sex partners over a three-month period. At the end of that time, the men were interviewed about their use or non-use of the kits. Study participants collectively reported having a total of approximately 150 partners. They used rapid HIV home-testing kits with 101 partners. Another 23 partners were asked to undergo testing but refused. The researchers concluded that the rapid home HIV test is highly acceptable among high-risk MSM, and that it may also encourage beneficial modifications in risk behaviour.

    - Criminalizing Condoms - how policing practices put sex workers and HIV services at risk in Kenya, Namibia, Russia, South Africa, the United States, and Zimbabwe. Police confiscate and destroy sex workers' condoms. Police use condoms as evidence to detain or arrest sex workers. Sex workers are afraid to carry condoms and are more likely to have unprotected sex

    - Why is a cure important? - The answers of Steven Deeks:
        - Life expectancy
        - Long term side effects
        - Financial reasons

A survey (n=453-458) of the opinion of people living with HIV on the disadvantages of having HIV was mainly the worry about ART side effects and other health problems in future. The most desirability of cure scenarios showed that:

- 95% that they could never get HIV again and no longer have to take ART.
- 41% that they no longer take ART, do not transmit but could potentially get HIV again.
- 24% that they still have HIV, no ART, but can transmit.
- 19% where they seem to be completely cured but doctors are not 100% sure and still go for tests every six months for life. Patient is not sure if virus would come back and whether they can transmit.

Next meeting:

Topic: HIV Cure research
Date: 18 January 2013 (changed from 25 January 2013)