# UK-CAB 69: Sex, sexuality and self-image

**Saturday 3 August 2019**
**Duncan Catterall Seminar Room, Mortimer Market Centre**
**Capper Street, Bloomsbury London WC1E 6JB**

# Meeting Report

| Morning session | |
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| **Company meeting: Janssen** | Janssen are part of Johnson & Johnson, one of the key areas they work is infectious diseases and vaccines. We were joined by their new Patient Engagement and Advocacy Lead, Diana Ribeiro.<br><br>Janssen's work in HIV falls under their Infectious Diseases Clinical Development programme. Working globally they respond to differences in health systems, the varying success of the HIV treatment cascade (UNAIDS 90-90-90 targets) including the new developments around quality of life or the '4th 90'. Their current UK product list can be found here: https://www.janssen.com/uk/products<br><br>Janssen's well known products include darunavir and rilpivirine. One of their newer drugs is Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) which has been approved for use in Europe since September 2017.<br><br>Current research and development at Janssen is focused on vaccines:<br>• Prophylactic HIV vaccine (to stop people getting HIV)<br>• Therapeutic HIV vaccine (used after infection, to induce anti-viral immunity<br><br>Janssen have a number of recent collaborations with ViiV Healthcare, including the first licenced two-drug regime, branded Juluca it is a fixed-dose combination of dolutegravir and rilpivirine.<br><br>Janssen have been working with ViiV on a long-acting injectable using rilpivirine and cabotegravir. Studies including ATLAS and FLAIR have been presented at CAB meetings before, and further data was presented at IAS. The marketing and promotion of this drug will be led by ViiV.<br><br>The half-life of rilpivirine is shorter than cabotegravir. Half-life does not mean the drug is active in the body, just that it can be traced, therefore, resistance concerns aren't as big an issue as you might be concerned about.<br><br>The formulation uses slow release molecules, interactions are the same as the oral formulations, although the ant-acid issues with rilpivirine are circumvented as it now avoids the stomach. Otherwise the drug is processed the same and there are no expected renal issues.<br><br>It is administered as two separate injections (one of each drug). The CAB were advised we would need to speak to ViiV about how they intend to 'package' the drug.<br><br>Janssen are working on other deliverables, e.g. an implant. They're also exploring six-month formulations, currently licencing for long-acting injectable products has been one month, but two/three is feasible but not enough published data on this yet. All licences are based on adults only at the moment. |

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| | Members asked why Janssen had so many collaborations with ViiV Healthcare. They were advised that partnerships mean that both companies can bring drugs to market that work effectively for people. It's a commercial decision and usual based on whether or not the other company already has similar drugs in their pipeline they could already use in combination therapy.<br><br>Janssen's current focus is on vaccines. They were questioned on whether they are yet exploring bNABs (broadly neutralizing antibodies) against HIV, the meeting was advised this is a very new, innovative space. Members asked to be kept updated on this area.<br><br>There is only one vaccine which is close to showing sufficient efficacy (~30%). Results in macaques found 91% prevention of 6 of them exposed 6 times. The aim of the vaccine is to drive T and B cell response. Macaques appear to have a much higher response to SIV infection than we do to HIV. It is anticipated any vaccine would have to be administered every five years. Mosaic trial will be looking at parts of HIV rather than full virus. Aiming to have safety data by 2022/23.<br><br>The Imokodo study in southern Africa is looking at women aged 18-35 years old. It was fully recruited earlier this year. PrEP is not being offered and CAB members raised the ethical issue of this, we were advised that PrEP can't be administered as it would not show whether that or the vaccine was preventing HIV. CAB members also questioned what support is made available to people who do become infected during trials.<br><br>AT IAS 2019 it was announced that Mosaic would look at gay and bisexual men and transgender women. The UK is not involved in this trial due to our issues with access to PrEP.<br><br>Development of a therapeutic vaccine is on-going with an aim to achieve long-term remission of HIV. In pre-clinical data three out of nine animals suppressed the virus after treatment interruption.<br><br>CAB members also asked for updates around Janssen's work in TB and Hepatitis B (HBV). Janssen has a TB drug which works against multi-resistant strains of the infection, standard therapy is 48 weeks but they're studying 24-week therapy. This drug also works against other bacterial infections and further trials are being explored.<br><br>Janssen's work in HBV is currently investigating a therapeutic vaccine to 'kick start' then clear out the infection. They are also researching RNA interference (RNAi). This research is important as whilst currently anyone taking TDF can suppress HBV it reactivates if you stop treatment.<br><br>When asked about preparations for a 'No deal Brexit' CAB members were advised Janssen were already prepared for March 2019. Consideration has also been made for 13 people who are currently still being administered long-acting injectable formulation post-trial due to how that needs to be prepared, transported and stored (refrigeration etc.)<br><br>Throughout the meeting members expressed concern of the numbers/percentages of women involved in clinical trials compared to men. Whilst clinicians can't influence who is recruited there were discussions about interventions that could do more to support the inclusion of women, for example providing funding for child-care, different clinic times and ensuring that women are given information about the benefits of taking part in trials. |
| **IAS feedback: Simon Collins** | The 10th IAS Conference on HIV Science (IAS 2019) in Mexico City was held from 21 – 24 July 2019. |

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| | IAS 2019 provided an update on a number of studies on existing and new drugs, in particular there was a large focus on long-acting formulations. Simon presented back some highlights from the conference.<br><br>IAS 2019 shared results from trials looking at two-drug regimens. One example was the results from GEMINI-1 and GEMINI-2 which evaluated dolutegravir and lamivudine against dolutegravir and TDF/emtricitabine. The studies were conducted in treatment naïve people. The trials found that the two-drug regimen was non-inferior regarding efficacy. Safety and tolerability was comparable between both groups and there was a lower risk of drug-related adverse events with the two-drug regimen. Renal and bone biomarkers significantly favour the two-drug regimen. The TANGO study also found that this combination was non-inferior to continuing a TAF-based regimen to maintain virological suppression.<br><br>Results were published on new drug Islatravir (formerly MK-8591) which could have potential to be used in a twelve month PrEP implant. Studies looking at the drug in combination with doravirine found adults with HIV maintained viral suppression, the potency of this drug is high with only a small dose required, with trials presenting a preferred dose of 0.75mg.<br><br>Results from the first in-human trial of MK-8591-eluting implants demonstrated concentrations suitable for PrEP for at least one year. The implant is 4cm long by 2mm and uses the same polymer as the Impanon/Nexplanon implant design.<br><br>A number of studies on long-acting formulations of ART were presented. A comprehensive list can be found via the **i-base Pipeline report (2019):** http://i-base.info/htb/36278<br><br>The issue of dolutegravir in pregnant women was revisited at the conference, the latest research presented showed a small potential risk of neural tube defects compared to the large projected benefits of the drug. However, more surveillance is required in pregnant women and the number of the defects recorded recently has gone down.<br><br>Another study on dolutegravir looked at weight gain. Greater weight gain was observed in the ADVANCE study, as it has with other research looking at integrase inhibitors. Weight gain was higher in women and people who had lower CD4 counts and higher viral loads. Interestingly the weight gain was higher in combinations containing TAF. The ADVANCE study is continuing to 96 weeks and further analysis is underway.<br><br>Results from DISCOVER, looking at using TAF rather than TDF for PrEP were presented. This found that TAF had a longer duration after the last dose compared to TDF. There is also some anecdotal evidence that the smaller pill size is preferred.<br><br>For more information see the meeting slides.<br><br>**i-base First reports from IAS 2019:** http://i-base.info/first-reports-from-ias-2019/<br><br>**IAS 2019 news from NAM:** http://www.aidsmap.com/conference/ias-2019<br><br>**IAS 2019 official site:** https://www.ias2019.org/ |
| **Afternoon session** | |

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| **Sex, sexuality and self-care: Personal stories and Q&A panel** | The meeting welcomed George and Becky who shared their personal stories relating to their diagnosis followed by a group discussion which largely focused on the sexual transmission of HIV.<br><br>Members discussed that public knowledge of 'U=U' was increasing but people continue to face obstacles and stigma. Many agreed that the science is believed and trusted, but this doesn't necessarily translate to sexual partners believing an individual had an undetectable viral load or that they would be adhering to their medication.<br><br>Members spoke of their experiences of their consultants or those who provide their HIV care talking to them about HIV transmission risk. It was largely felt that most consultants are talking to patients, but concern was raised from results of a survey conducted by BHIVA which was presented at their conference in April. It was strongly felt that any clinician who 'selects' which people should know about 'u=u' should be challenged and that this was something that all people living with HIV should be aware of.<br><br>It was felt that amongst gay and bisexual men trust in 'u=u' was higher because many negative people within this population take PrEP and therefore understand the science behind the drugs. Members from other communities felt more needed to be done to help educate other groups about PrEP, many new projects were cited.<br><br>Language around transmission was discussed, including the complexity of 'undetectable equals untransmittable', especially for non-English speakers and when translating into other languages. Other terms raised during the meeting included the use of 'mother to child', which can infer blame on a mother for passing HIV on to their child rather than 'vertical transmission'.<br><br>**Video of the BHIVA survey results:** https://www.bhiva.org/190402-1<br><br>**New AAF 'PrEP and Prejudice' programme:** https://www.prepandprejudice.org.uk/ |
| **Members Updates** | 1. Roy presented the MRC CTU PPI slides. MRC has a new PPI coordinator, Kate Sturgeon whose is piloting the PPI standard operating practice (SOP) and associated documents. She is the formal point of contact and support for PPI representatives and activities. She will also offer advisory service for PPI.<br>2. The PRISM pain study poster was also shared by Roy.<br>3. Alex is hosting a PrEP dosing webinar in August, information to follow.<br>4. Jo Josh informed the meeting that she is part of the Global HIV Pain Task Force. The task force will look at chronic pain in PLWH. It was established at AIDS Impact conference in July 2019; as a 4th 90 on QoL.<br><br>**AOB**<br>1. Following the meeting with Janssen, the meeting discussed the need for a training meeting bNAbs.<br>2. Memory reported that it is challenging to invite professionals to meetings on a Saturday. UK-CAB meetings will revert back to Fridays.<br>3. One out of London Saturday meeting will be yearly. This will be held following the April BHIVA Spring Conference. |
| **Next meeting** | 15 November 2019<br>Topic: Ageing, polypharmacy and POPPY study community feedback |