Report on Rectal Microbicides Workshop

Date: 17 Sept 2014 18:00 – 20:30

Location: Terrence Higgins Trust (THT), Gray's Inn Rd

Presenter: Jim Pickett, Chair IRMA; Director of Prevention Advocacy & Gay Men's Health - Aids Foundation of Chicago (AFC)

Facilitator: Justin Harbottle, THT

Topic: The bottom line on HIV prevention

Audience: Approximately 22 people (excluding presenter and facilitator) of whom approximately 8 to 10 were advocates or working in the field of HIV.

Presentation (see attached powerpoint)

Jim presented a short video – The Rectal Revolution Is Here – an international video introducing the concepts of HIV prevention research and rectal microbicides (RMs) and then provided an overview of rectal microbicide research. The video can be viewed at tinyurl.com/rectalvid.

Participants were introduced to International Rectal Microbicide Advocates (IRMA) – a coalition of over 1200 advocates, scientists, funders and policymakers from 6 continents. The mission of IRMA is to support the development of safe, effective, acceptable, and accessible RMs for all that need them. IRMA operates through advocacy and education; by engaging with science and community and with clinical research; by funding civil society support; by promoting anal health; and by improving lubricant access and safety. IRMA operationalises its work via its moderated listserv; a website; social media including You Tube, Twitter and Face book; global teleconferences; and through materials, presentations and videos. IRMA's work includes the support of Project ARM – Africa for Rectal Microbicides.

Recent developments in RM research were presented – specifically with regard to study MTN-017. This is a Phase 2 randomized sequence open label expanded safety and acceptability study of oral Truvada (emtricitabine/tenofovir disoproxil fumarate) and rectally-applied tenofovir reduced-glycerin 1% gel. The trial has recruited 192 gay/men who have sex with men and transgender women in eight study sites in 4 countries (USA, Thailand, South Africa and Peru). Participants follow each of the study regimes for eight weeks, followed by a week in between each regime when no product is used. The order in which participants receive each regime is randomised. The regimes are: rectal tenofovir gel used daily; rectal tenofovir gel used before and after sex; and Truvada tablets taken daily. All participants receive standard HIV prevention packages and monitoring of product use takes place including using SMS messaging, product returns and computer assisted self- interview. Participants also provide blood samples which are tested to determine drug levels. This information is fed back to the participants in "real time" by trial staff as another means of assessing product use and adherence.

Jim highlighted some of the issues with oral PrEP roll-out in the USA following FDA approval of PrEP in 2012. Some of the challenges include provider problems – with medical staff being unaware of PrEP or being unwilling to provide it; payer problems – with insurance companies making PrEP coverage confusing and/or by requiring high levels of cost-sharing; misinformation – including information about the science, side effects or payment being made; and resistance to PrEP – including well-resourced misinformation campaigns from the Los Angeles-based Aids Healthcare

Foundation dissuading PrEP use and a small handful of old-school activists describing PrEP users as 'cowardly' or 'lazy'.

PrEP awareness interventions are increasingly being seen and developed – especially in the USA – including New York City's "Share the Night, Not HIV" social marketing campaign on PrEP and PEP and AFC's My PrEP Experience website (www.myprepexperience.org).

Jim's presentation concluded with an update on the PROUD study, noting that recruitment closed in April 2104 with 545 gay and other MSM enrolled. A funding application has been made to enrol an additional 1200 men – with the outcome of the funding application to be expected early 2015.

For more details visit the IRMA website: rectalmicrobicides.org or email Jim Pickett at: jpickett@aidschicago.org

Following Jim's presentation a number of discussion points were raised. These focused on:

- Insurance – and whether insurance companies might be willing to pay for PrEP now, knowing that future costs of paying for HIV medications if someone became infected with HIV, would be averted. There was a sense that US health insurance tended to focus on short-term savings rather than longer-term gains. Even when insurance companies are paying for PrEP now, barriers are being erected, which is indicative of a system built on profit.
- Efficacy – the extent to which MSM might prefer oral PrEP to RMs, given current data on the efficacy of oral PrEP and that there is currently NO data on RM efficacy.
- Social health systems – and the extent to which the UK or other places with more social health systems (such as Canada) might be more or less willing to provide PrEP.
- Patent issues – and whether there is a sense that changes in patent status of currently used drugs in PrEP would impact on availability of PrEP in a UK basis.
- Gel application and blood measures – how application of gel rectally would be detectable in blood measures.
- PrEP advocacy – the need to be advocating not only for future research but on-going and future PrEP availability. It was noted that a PrEP Policy Development sub-group of the HIV Clinical Reference Group was being formed to assist in developing future English PrEP prescribing.
- Ethical issues – and whether it is ethical to continue to use placebo drugs and/or deferred arms in trials.

Breakout discussions

In four break out groups the following three questions were discussed:

1. What are your thoughts on rectal microbicides – are they needed, who would they be useful for, what are the pros and cons?
2. What are your thoughts on PrEP – are they needed, who would they be useful for, what are the pros and cons?
3. What are the key research questions that you would want to be addressed?

Feedback from groups covered the following areas (not necessarily in direct relation to the questions above):

- Oral PrEP was seen as more favourable by many participants than RMs. There were many questions about using RMs in practice including spontaneity, how they might interfere with sex (taste, smell, ingestion), toxicity and potential side effects. Further discussion centred

around the protection that oral PrEP gives to men regardless of whether they are insertive or receptive during anal intercourse, yet RMs would be protective for men having receptive anal intercourse. This also raised issues and discussion around informed consent – for example, issues around an active partner inserting RM into a receptive partner's body without his consent.

- Advocacy around the need for continued availability of oral PrEP for current PROUD participants was raised – especially from men who were now used to using PrEP and who were concerned about its lack of future availability.
- The logistics of using RM was raised – including the practicalities of carrying RM around, and the size of the applicators.
- Concerns were raised about community or social issues around all PrEP use including 'slut shaming', or PrEP being seen to undermine two decades of HIV prevention work.
- The practicalities of self-application of RM were discussed – including concerns if men would get the right amount of RM in to the right place. Some discussants felt that being in control of one's own HIV prevention was an important issue and self-application of RM was one way to do this, whilst others felt that pills or injections gave a more reliable way of ensuring the right dose of PrEP was being used.
- Questions focused on whether RM might be more acceptable if they included a combined prevention against Hepatitis C. Attendees generally felt that this would not make RM more acceptable, especially as attempting to prevent Hep C through a RM would not be protective against the other common ways of Hep C being transmitted such as through injection drug use.
- A number of participants thought that RM would be attractive when used in addition to condoms as additional protection.
- Outreach workers who attended the session felt that there is the need for more on-the-street narrative, terminology and discussions about all types of PrEP to enable men to be better equipped at discussing the options.
- Finally, there were two clear overriding reminders from the small group discussion. The first, that comparing RM to oral PrEP is comparing a pipeline technology with one that is currently available (if on a limited basis) and being used. The second, it is important for users of prevention technologies to be in control of their prevention and that different users will have different preferences. As such, moving the debate to oral pills **and** RM (and other pipeline options), rather than casting them as either/or choices is an important way forward.

Report prepared by: Will Nutland 22nd September 2014