HIV vaccines: good news or bad? Elisabeth Pisani. http://www.wisdomofwhores.com/2009/10/28/hiv-vaccines-good-news-or-bad/ The paper reviewed on the preceding page has received much media attention, and has featured in Elisabeth Pisani’s blog, ‘Sex and Science’. I felt it could be helpful to Journal readers if I also reviewed some recent comments about the HIV vaccine paper that were detailed in that blog.

Dr Pisani’s blog focuses mainly on specific aspects of the HIV vaccine trial paper approaches taken to statistical analysis, observed variation in vaccine efficacy (VE) in some subgroups (such as high-risk individuals), and the public health perspective.

Three analyses undertaken in the paper are termed Real World [Intention to Treat (ITT)], Ideal World (per protocol) and Tiedid-up World (modified ITT). Dr Pisani states that the Real World analysis is most useful to public health policymakers, which is usually correct. However, in this case it would mean witting acceptance of a misleading estimate of VE, because in this analysis the two groups compared included unequal numbers of individuals who had already become infected before vaccination commenced, and for whom infection could not be prevented. That said, this is one example of a divergence in med-or-filler – the estimates obtained by the three analyses are strikingly similar, a VE of around 26% to 31%.

Would a vaccine of such efficacy be of clinical use? It depends on the wide confidence intervals (CIs) around the estimates of VE. This is an important point and, as has been commented above, it would have benefited from some discussion. However, this is perhaps over-laboured. In all trial papers the point estimate reported is likely to be accompanied by an interval estimate, which argues for a more circumspect assessment of plausible possibilities for true effect, and often some of these possibilities are clinically trivial. While it is true that this trial has turned out to be underpowered, and hence provides very imprecise estimates of effect, we still need to give the point estimate due consideration.

Having disparaged, on account of their wide CIs, the overall effect estimates from the two planned and one modified analysis approaches, Dr Pisani then focuses on the effect estimate for the high-risk subgroup, and laments the VE estimate of only 4% to +46% in the high-risk group. He says that “the group most likely to be exposed to the virus”. However, this subgroup involves only 23% of all study participants, and more crucially involves only 34% of events (n=45), compared to 100% and 65% of events in the planned analyses, and 95% in the modified ITT. This partly explains the width of the 95% CI reported for VE for the high-risk group, which is –73% to +46% (the upper limit of the 95% CI). There is evidence for the safe use of Depo-Provera in different client groups, followed by workshops to lead a specialist service. Further training would be required to lead a specialist service. Accreditation: FSRH accredited, 13 hours CME. Information: Mike Gray (see 11–12 March 2010 entry).

MEETINGS AND COURSES

BLOG REVIEW

Meeting: TAVEG Investigators. Vaccination with ALVAC and AIDSVAX to prevent HIV-1 infection in Thailand. Vaccine. 2007; 25: 4505–4511. E-mail: info@crescetis.com. Website: www.crescetis.co.uk. This course is practical and interactive in design, based on the workshop style of the FSRH Diploma course. It is aimed at doctors but would equally be suitable for specialist nurses who work regularly to provide women’s health advice and management. It intends to equip the clinician to work within a menopause clinic or primary care environment. Further training would be required to lead a specialist service. Accreditation: FSRH accredited, 13 hours CME. Information: Mike Gray (see 11–12 March 2010 entry).

25–26 November 2010

Meeting: BMS – FSRH Menopause Special Skills Module. Venue: Holiday Inn, Southampton, UK. Details: This course is practical and interactive in design, based on the workshop style of the FSRH Diploma course. It is aimed at doctors but would equally be suitable for specialist nurses who work regularly to provide women’s health advice and management. It intends to equip the clinician to work within a menopause clinic or primary care environment. Further training would be required to lead a specialist service. Accreditation: FSRH accredited, 13 hours CME. Information: Mike Gray (see 11–12 March 2010 entry).