MINUTES OF THE 95th MEETING OF THE EXPERT ADVISORY GROUP ON AIDS 23 October 2013

Chair: Professor Brian Gazzard

Secretariat: Dr Linda Lazarus (PHE)

Members:
Prof Jackie Cassell
Dr Chris Conlon
Mr David Crundwell
Dr Annemiek De Ruiter (co-opted)
Dr Matthew Donati
Ms Ceri Evans
Dr John Green
Ms Deborah Jack
Ms Ruth Lowbury
Dr Helen McIlveen
Prof Andrew Phillips (co-opted)
Dr Anton Pozniak
Dr Keith Radcliffe
Dr Alison Rimmer (co-opted)
Dr Ewen Stewart
Mr Paul Ward

Observers:
Dr Su Brailsford (UK Blood Services/PHE)
Dr Alison Brown (PHE)
Dr Naresh Chada (DHSSPS Northern Ireland)
Dr Valerie Delpech (PHE)
Lt Col Ngozi Dufty (MoD)
Ms Andrea Duncan (DH)
Professor Noel Gill (PHE)
Dr Andrew Riley (WAG)
Dr Nicola Steedman (Scottish Government)

Apologies:
Mrs Moji Ajeneye (MHRA)
Prof Dame Anne Johnson
Ms Kay Orton (DH)
Ms Beatrice Osoro

Invited:
Dr Fortune Ncube (PHE)
Dr Katy Sinka (PHE)
Dr Daniel Webster (Royal Free Hospital)

Agenda item 1 Welcome, introductions, apologies and announcements

1. The Chair welcomed everyone to the meeting and announced that Professor Deenan Pillay had resigned from EAGA to take up a new post as Director of the Wellcome Trust's Africa Centre for Health and Population Studies based in South Africa. The Chair acknowledged his significant contribution to EAGA during the 8 years of his membership and wished him success in his new role on behalf of the committee.

2. A number of people had been invited to EAGA for specific agenda items. Dr Daniel Webster, Consultant Clinical Virologist from the Royal Free Hospital and Drs Fortune Ncube and Katy Sinka from PHE.

Agenda item 2 Minutes of the last meeting (19 June 2013)

3. The minutes were accepted as an accurate record without amendment.

Agenda item 3 Matters arising

Agenda item 3.1 *Report from the Secretariat* *Paper EAGA(95)1*

4. The Secretariat reported that, since the last meeting, the DH sponsorhip from EAGA had transferred to Kay Orton in the Sexual Health Policy team.

Agenda item 3.2 Feedback from TasP PrEP Evidence Summit, September 2013

5. Members and Observers who attended shared some of their reflections on the meeting and related issues, as follows:
   - Not much new data had emerged since last year's meeting and nothing to inform health economic case. Of the UK's HIV-diagnosed cohort of 73,430 in 2011, 10,510 not on treatment had a CD4>350 (83% of untreated) and would be potentially eligible for TasP, representing a significant cost pressure for the health service. The HIV Clinical Reference Group had been tasked with addressing TasP to inform national commissioning.
   - If the benefits of early treatment demonstrated by the NA-ACCORD study were universally applicable, rather than particular to the North American healthcare model, it would have been unethical to continue with the START trial. The outcome from that ongoing study was likely to influence future UK policy.
   - The US clinicians at the summit were strongly supportive of earlier treatment to reduce incidence. The treatment coverage rates in the US (38%) were lagging behind those in the UK where an estimated 58% of people living with HIV (diagnosed and undiagnosed) are virally suppressed. 'Obamacare' could help address the health inequalities in the current system, but it could take a decade to catch up.
   - Some interesting insights were shared on the driving factors behind the latest WHO treatment guidelines[1] recommending HIV treatment initiation regardless of CD4 count for certain populations (including pregnant women and HIV-positive partners in serodiscordant couples) and a general CD4 threshold of 500 cells/mm^3. Rather than being linked to individual patient outcomes, the prohibitive cost of CD4 count monitoring in developing countries, coupled with high loss to follow-up of patients not immediately put on treatment, meant it is arguably more cost-effective to adopt a test and treat approach, at least in some settings. The modified strategy for HIV-positive pregnant and lactating women (Option B+) being trialled in Malawi found that treating all pregnant women with ART and keeping them on therapy for life instead of stopping ART after cessation of breastfeeding had improved rates ART initiation and retention in care.
   - In the UK setting, those seeking TasP were more likely to be motivated by personal interests such as for the benefit of loved ones or to enjoy greater sexual freedom (free from fear of infecting others), rather than the public health benefits of curbing the epidemic.
   - The summit also addressed PrEP and examples of demonstration projects in the US were presented. The UK's GUM clinic network potentially provides better opportunities to deliver PrEP than the US, making it important to persevere with the PROUD trial.

Agenda item 3.3 Feedback from 14th European AIDS Conference, October 2013

6. A number of advances in treatment options were highlighted. For example, combinations including the integrase inhibitor dolutegravir demonstrated superior rates of virological suppression when compared with current standard of care. This would present NHS England with a potential dilemma – whether to pay a premium for dolutegravir or favour

[1] WHO (2013). Consolidated guidelines on general HIV care and the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach. Available from: http://www.who.int/hiv/pub/guidelines/arv2013/download/en/

generic efavirenz for which evidence of central nervous system side effects was mounting (e.g. three-fold higher occurrence of suicidal ideation).

7. Long-acting injectable formulations of antiretrovirals (e.g. a new form of rilpivarine) were also in the pipeline. These present the possibility of single monthly or quarterly injections for maintenance therapy, or even pre-exposure prophylaxis, and patient acceptability was high. Such drugs would present new patient management issues, but were a potentially exciting development.

8. Other researchers were examining regimen simplification (reduction in the number of drugs) with some promising preliminary results.

9. Finally, the European Centre for Disease Control was examining the impact of austerity on health. In the HIV field, this may be manifesting as marked differences in antiretroviral coverage levels across Europe. The HIV in Europe project is promoting HIV testing and access to care.

Agenda item 4 HIV post-exposure prophylaxis: review of US versus UK advice following exposure to sources with undetectable viral load (SP1)

10. EAGA had last considered its advice on this topic in relation to the new policy on HIV-infected healthcare workers (HCWs), where the concern was specifically about the management of patients following exposure to a HCW's blood during an invasive surgical procedure. EAGA advised:

> Neither PEP nor HIV testing at 3-month follow-up was recommended for HCWs or patients exposed to a source with undetectable HIV viral load. Where the viral load was detectable (>200 copies/ml for consistency with proposed policy for EPP workers), an assessment of the infectious dose was needed to determine the infectivity risk. In most cases, the risk of transmission would be lower than the psychological harm from informing the patient of a possible exposure.

11. Subsequently, the US Public Health Service had published updated guidelines for the management of occupational exposures (SP1), in which they stated:

> Exposure to a source patient with an undetectable serum viral load does not eliminate the possibility of HIV transmission or the need for PEP and follow-up testing. While the risk of transmission from an occupational exposure to a source patient with an undetectable serum viral load is thought to be very low, PEP should still be offered. Plasma viral load (e.g. HIV RNA) reflects only the level of cell-free virus in the peripheral blood; persistence of HIV in latently infected cells, despite patient treatment with antiretroviral drugs, has been demonstrated, and such cells might transmit infection even in the absence of viremia. HIV transmission from exposure to a source person who had an undetectable viral load has been described in cases of sexual and mother-to-child transmissions.

12. Dr Webster had been invited to help EAGA reconsider its recommendation in light of the discordance with the US guideline, by reviewing the evidence cited in the US guideline and other data sources addressing the transmission potential of cell-free and cell-associated virus.

13. The risk of HIV transmission associated with percutaneous exposure had been estimated at 0.3%. Factors increasing the risk, such as – deep injury, visible blood on the device, advanced HIV disease in the source – were all surrogates for the size of the viral inoculum. While PEP monotherapy with zidovudine was found to decrease the risk of percutaneous HIV transmission in a case-control study, there were no data on triple therapy and it would be unethical to conduct such a trial.

14. The US guidelines cited two pivotal studies on persistence of HIV in the absence of viral RNA in plasma. Infected cells harbour HIV as integrated proviral DNA within the host's chromosome and also episomally as circular viral DNA within the cell nucleus. The latter is a marker of active replication and is reduced by treatment with antiretroviral therapy (ART). However, if ART is interrupted, viral load rebound occurs, with new virus generated from the integrated proviral DNA.

15. The examples of transmission from undetectable sources related to sexual and mother-to-child transmission rather than occupational. The potential inoculum sizes were also much bigger than in the case of a needlestick injury. It was possible that in the single case reported by Stürmer *et al*. of sexual transmission from an undetectable partner, virus may have been present in the semen but absent from plasma or the plasma viral load may not have been optimally suppressed throughout the exposure risk period. [By contrast, in cases of occupational exposure, the viral load at the exact time of the incident can be checked.] No further cases have been reported in the literature, so this remains a rare phenomenon that has not been fully explained.

16. Animal studies had demonstrated efficient transmission of simian immunodeficiency virus, in cell-associated form, by means of intravenous inoculation, with as few as two infected cells resulting in transmission. *In vitro* studies of infection of human colonic mucosa found that cell-associated HIV was better than cell-free virus at establishing productive infection at lower concentrations, presumably due to better binding to, and penetration of, mucosal cells.

17. Discordant heterosexual couple studies (e.g. HPTN 052) had demonstrated no transmissions from partners with undetectable viral load (<50 copies/ml) in plasma but no threshold has been established at which the risk disappears entirely.

18. The latest (2011) BASHH guidelines for PEP following sexual exposure to HIV do not recommend prescribing PEP in the vast majority of scenarios where the source has undetectable viral load. The single exception to this is for the highest risk sexual activity – unprotected receptive anal intercourse.

19. In breastfeeding populations, mother-to-child transmission rates for HIV are around 30-40%, reduced substantially (UK rates of ~1% or less) by suppressing maternal viral load and not breastfeeding. In a French cohort study, factors associated with 19 cases of transmission despite suppression of maternal viral load at birth to <500 copies/ml included not being on HAART at conception and delayed attainment of viral load <500 copies/ml, highlighting the importance of early HAART and sustained virological suppression. The risk of post-partum transmission was predicted by the level of cell-associated virus in breast milk; this was a more important predictor of early transmission (by 6 weeks) than cell-free virus levels.

20. What does undetectable viral load mean? Data show that having a previously suppressed viral load makes it more likely that the next measurement will also be undetectable. Viral load blips between measurements are possible and intercurrent illness can exacerbate blipping. In the occupational setting, there is a reasonable expectation that the source will have another medical condition that could make them more susceptible to blips.

21. Viral dynamics after initiating HAART result in undetectable viral load within 3 months (first and second phases), followed by a prolonged 'third phase' in which circulating virus can be detected at levels of 1-10 copies/ml using sensitive assays. The origins of these circulating viruses are unclear and may represent ongoing replication in cells or emergence from reservoirs of latently infected cells. Viral evolution is absent, but the virus can be isolated and replicated in culture. Patients exhibiting this low-level viraemia are more likely to experience virological rebound, so this is an important marker.

22. In summary, single genome analysis of acute infections has revealed that the majority of HIV infections have evidence of productive clinical infection by only a single virus and cell-associated DNA can also be responsible for transmission. It is not possible to state that there is zero risk of occupational transmission from a source patient with undetectable plasma viraemia, but it will be extremely low. No data were presented on the ability of cell-associated virus to cause transmission in the presence of antiretroviral agents (i.e. assumed to be active in the source patient's blood), which would mimic the circumstances of occupational exposure.

23. Data from the National Study of HIV in Pregnancy and Childhood indicate a handful of cases where babies became HIV infected despite undetectable maternal viral load at birth, where transmission was not thought to have occurred *in utero*, and was most likely to have occurred around the time of birth: 4 such cases have been reported in over 6000 mother-child-pairs. Post-natal transmission has also been reported in studies from Botswana of HIV-infected mothers on antiretroviral therapy with undetectable viral load and no detectable RNA in their breast milk[2].

24. The review of current literature established that the objective risk of transmission from cell-associated HIV in the context of mother-to-child and sexual transmission is not zero, but is it acceptably low? Taking PEP is not without risk e.g. drug side effects that may require time off work, the psychological morbidity of waiting for the 'all clear'. PHE's surveillance of occupational exposures to blood-borne viruses monitors PEP usage, and analysis of PEP uptake according to the viral load of the source may be feasible to assess practice.

25. In conclusion, there was good evidence that cell-associated transmission of HIV was possible, but less data on occurrence in the presence of antiretrovirals in the source. None of the evidence for transmission from an undetectable source comes directly from occupational exposures, but is extrapolated from the single case of sexual transmission (Stürmer *et al*.) and more extensive data from breastfeeding and mother-to-child transmission. For those exposed to a source with undetectable viral load, the balance of risks should be discussed. PEP should be offered to those who are anxious about the risk, but not recommended. There has been no new significant data to change EAGA's advice, but EAGA will continue to keep the evidence under review. The advice is based on there being a theoretical transmission risk, without any direct evidence; intervention (i.e. PEP) is not encouraged for an extremely low risk.

[2] Shapiro RL et al. Antiretroviral regimens in pregnancy and breast-feeding in Botswana. NEJM 2010; 362:2282-94.

26. A member commented that EAGA's advice about PEP following occupational exposure to an undetectable source had not reached all clinicians with responsibility for needlestick management. It had been posted on the members section of the Association of National Health Occupational Physicians (ANHOPS) website in February 2012 for cascading. In addition to updating the statement for ANHOPS, further mechanisms for disseminating the advice (e.g. via BASHH and MEDFASH newsletters) would be explored. The new integrated guidance for blood-borne virus infected healthcare workers would also contain the up-to-date advice.

27. It was also noted that the US guidelines recommend raltegravir (an integrase inhibitor) in combination with Truvada as PEP for occupational exposures because of its tolerability, potency and convenient administration. EAGA undertook to review its recommended PEP regimen, taking account of relevant new data, but cautioned against changing established practice without considering all the implications.

Agenda item 5 The window period debate: defining the window period for a range of scenarios (POCT, PEP, routine screen) – latest evidence

28. The HIV 'window' or seroconversion period is defined as the time taken from infection to detection of the virus or the immune response to it, i.e. HIV antibody. The infection timecourse starts with the eclipse period (when nothing is detectable), is followed by the nucleic acid then antigen detection window and finally by the antibody/seroconversion window.

29. The antibody window was set at 3 months from the earliest days of the epidemic (in the 1980s), with little inclination to change it, despite significant improvements in assays. Early, first-generation, assays typically detected antibody 35-45 days post infection. This has been reduced to 15-20 days with fourth-generation (4G) antibody/antigen assays and 10-15 days with RNA detection by NAT.

30. To be clinically useful, the window period should reflect the upper limit rather than the average or quickest interval from exposure to detectable infection. Antibody is typically detected in 4 weeks and p24 antigen in 2 weeks[3]. Rare cases of delayed seroconversion (6 months plus) can be found in the literature, but these were mostly based on antibody detection and may have been antigen positive earlier, if this had been tested for.

31. Shortening the window period would be beneficial in reducing patient anxiety – having to wait 3 months can deter patients from re-attending – but what data are available to inform such a decision? Animal models are a key source, but equivalence cannot be assumed. Human examples are limited to cases where the last exposure date is known with certainty (e.g. transfusion, needlestick), but these are atypical transmission scenarios. Mother-to-child transmission can provide useful data, although not directly comparable to sexual transmission, and unrecognised breastfeeding can occur. More data might come from better collection of information on date of last known risk or, less likely, by intensive follow-up of a cohort of high-risk individuals with very regular testing. Host responses are not uniform – elite controllers and rapid progressors exemplify the extremes.

[3] Branson BM and Stekler JD. Detection of acute HIV infection: we can't close the window. J Infect Dis 2012; 205:521-4.

32. The most recent window-period guidance came from BASHH (March 2010), who stated that a negative 4G test at 4 weeks post exposure was highly likely to exclude infection, but still recommended re-testing at 12 weeks. EAGA felt it needed to re-examine the evidence because variations in practice between clinics would reflect badly on healthcare professionals and was confusing for patients. A consistent approach would offer certainty to patients and ensure appropriate clinical management. However, there were no new data to inform the decision, beyond improvements in testing technology. Ultimately, it was an issue of balancing the risks of missing a delayed seroconversion versus offering reassurance to the majority.

33. EAGA reached the preliminary view that the 3-month window period should be shortened, but would need to consider further how to express this advice to promote consistent practice. The original window period had been defined arbitrarily and did not reflect the superior sensitivity and accuracy of current tests. There was no consensus from the literature, but there was a tendency to imply, based on comparative test performance, that the majority of individuals would seroconvert within 6 weeks of acquiring HIV infection (4G assays may detect reactivity as early as 3 weeks after the infecting event). Thus, a negative test at 6 weeks post exposure with a 4G test provides high reassurance of freedom from infection. This shortened seroconversion window period was applicable to non-high risk individuals, but not to those at repeated risk of exposure.

34. Other circumstances when reducing the window period might not be appropriate were detailed, as follows:

- For those taking PEP following occupational exposure: current EAGA guidance recommends testing at 12 weeks post-exposure, or 12 weeks after cessation of PEP, if taken. This was to allow for possible delay of seroconversion by the antiretroviral medication. Harmonising follow-up to 6 weeks post exposure, regardless of PEP, was considered and dismissed. [Subsequently, a case report of prophylaxis failure, in which seroconversion occurred 6 weeks after occupational PEP discontinuation, was brought to the Secretariat's attention[4]. It supports the need for continued caution, and possibly for extended follow-up, after PEP.]
- The current testing schedule for infants born to HIV-positive mothers - proviral DNA at birth, 6 weeks and 3 months - should be unchanged, as evidence of infection has been found to emerge between 6 weeks and 3 months, although undisclosed breastfeeding cannot be ruled out in such cases.
- When NATs are being used to detect RNA, a shorter window period may be appropriate. Some private clinics were offering a day-10 test for HIV and hepatitis C RNA. Despite their potential for earlier detection, NATs are not used routinely for HIV diagnosis because of issues of cost, possible low-level false positives and potential subtype detection problems not associated with serological testing.
- EAGA did not address what window period should apply when using point-of-care tests (POCTs). It had previously discussed the limitations in performance of 4G POCTs 'in the field' (see EAGA 94 minutes), and concerns about ability to detect acute infections. The window period used by Trusts for POCTs should therefore be consistent with any claims for detection made by the manufacturers. There are no data to support a reduction in the window period from 12 weeks for POCT.

[4] Li H et al. Molecular mechanisms of HIV type 1 prophylaxis failure revealed by single-genome sequencing. J Infect Dis, 2013; 208:1598-603.

Agenda item 6 Integrated guidance for healthcare workers infected with blood-borne viruses: progress and issues (SP2) Papers EAGA(95)2&3

35. EAGA was asked to discuss two aspects of follow-up work stemming from the publication, in August 2013, of the Department of Health's response to the consultation on the management of HIV-infected healthcare workers (HCWs) (see SP2).

36. In the first paper, EAGA(95)2, advice was sought on defining some of the decision rules to be built into the confidential register being established to monitor compliance with the new policy allowing HIV-infected HCWs to perform exposure-prone procedures on treatment. The questions and EAGA's recommendations are set out below:

    1) What is the definition of "at least 3 months apart" as it applies to demonstrating initial clearance to perform EPPs and sustained response to treatment?
       12-16 weeks

    2) What is the definition of "every 3 months" for regular follow-up monitoring?
       12±2 weeks (allowing flexibility for holidays or other absences)

    3) For HCWs currently restricted from EPPs who are on cART with undetectable viral load (UDVL), is one identified, validated sample (IVS) at least 3 months since last UDVL sufficient proof on which to grant clearance for EPPs?
       Yes, for those already on cART

    4) Who should nominate the panel of expert clinicians to whom complex cases can be referred?
       EAGA will nominate and contact the clinicians, selected on the basis of geographical coverage and familiarity with treating infected HCWs. It was not felt necessary to replicate the model used for hepatitis cases, of paired occupational health physicians and hepatologists in each region, as the numbers affected were much smaller.

    5) Does EAGA think it is necessary/important for the register to collect clinical detail on cART regimens and, if yes, what is the justification?
       EAGA recommended collection of this information to assist with monitoring the policy (rather than the HCW). For example, viral load blipping is known to occur more frequently with regimens including boosted protease inhibitors. It was not perceived as difficult to collect – adequate to base on self-report by the HCW – and full collection should be encouraged routinely using a simple drop-down menu, such as the one developed for the HIV and AIDS Reporting System.

37. There was concern that a disproportionate burden of cases would fall to NHS Occupational Physicians, as private sector occupational health services generally lack the consultant-grade provision needed to manage these complex cases.

38. The second paper, EAGA(95)3, provided an outline of the combined guidance for health clearance and management of blood-borne virus (BBV) infected HCWs that was in preparation by PHE and Health Protection Scotland. The layout aimed to capture the commonality between BBVs and highlight the differences. It was anticipated that a draft would be available for review by the beginning of December 2013.

Agenda item 7 Expanded testing through HIV self-sampling

39. The preliminary results and learning from two HIV home sampling services – provided by a THT/PHE collaboration and Dean Street GUM clinic – were presented. A shared goal was to expand access to HIV testing for individuals at high risk of HIV infection who were not accessing traditional clinic-based services. Self-sampling followed by laboratory-based testing protected privacy and autonomy whilst giving access to the most sensitive tests available (i.e. fourth generation antibody/antigen assays).

40. HIV Prevention England had previously demonstrated the effectiveness of digital platforms/social marketing to engage high-risk men who have sex with men (MSM) who were not attending sexual health services. A survey found 26% of high-risk MSM had not used a GUM service in the past 2 years.

41. Between the two services, nearly 15,000 self-sampling kits were supplied, via internet ordering, of which 60-62% were returned for analysis. THT/PHE found the return rate increased with duration of the pilot. High positivity rates were achieved – 1.8-2.3% among MSM and 3.6% in Africans. The marketing strategy proved highly flexible, with the ability to be switched "on" and "off" to control demand and boost orders from the African community by appropriate targeting. The geographical spread of orders received by THT/PHE was split 50:50 between London+South and the rest of England whilst Dean Street's catchment was predominantly Londoners.

42. Another critical indicator of success of the services was confirmed linkage to care for those testing positive. The THT/PHE service achieved 76% but this was expected to improve in the final analysis. Dean Street achieved 100% referral. There were also opportunities to engage those testing negative in broader prevention work, opportunities that would be lost with home testing. Both studies were being written up for publication.

43. A further analysis proposed to evaluate the services included mapping the geographical spread of service users by proximity to clinical services to assess whether self-sampling was a substitute for clinic-based testing or was the only accessible service. Cost per kit returned was around £20, with cost per diagnosed case ~£350. There were a small number of repeat testers identified.

44. Some other positive messages from the analysis to date: many thousands of individuals found it acceptable to provide a dried blood spot sample. Appropriate targeting could achieve high demand. There were opportunities to operate alongside local GU clinics e.g. to recall high-risk MSM for regular HIV testing. In a second phase, THT would be working with Dean Street in support HIV testing week in November, ensuring messages were co-ordinated, with THT targeting African communities and Dean Street focussing on MSM. An important outcome to demonstrate was that the service was being accessed by 'hard to reach' groups. Further initiatives that could build on this included establishing a recall service for high-risk negatives and linkage to 'stay negative' programmes.

45. PHE was looking to develop a nationally-branded sustainable service model, along the lines of the chlamydia self-sampling service, paid for by Local Authorities from their HIV prevention budgets.

Agenda item 8 HIV testing in abortion services: current guidance and preliminary audit results Paper EAGA(95)4

46. A substantial proportion of abortion services in England, although commissioned and paid for by the NHS, are provided by the independent sector. Unlinked anonymous surveys conducted in a sample of termination of pregnancy (TOP) clinics in London found a prevalence of HIV infection of 1.19% (latest data, 2004), compared with 0.57% in corresponding antenatal clinics. While there may be some bias in the TOP sample – it cannot be ruled out that some women were seeking terminations because they had received a positive HIV diagnosis – this 2-fold difference indicated an unmet need. Subsequently, HIV infection among heterosexuals had diffused outwards from its London-centric focus, but prevalence was expected to remain consistently higher among those seeking TOP, making them a legitimate 'target' for tackling undiagnosed infections.

47. The 2008 UK National HIV testing guidelines, endorsed by the 2011 NICE guidelines, recommended a universal offer of HIV testing in TOP services. PHE conducted an audit of practice and policies relating to HIV testing in a randomly selected sample of TOP services in England. The results had been presented in a poster [EAGA(95)4, Annex 1] at PHE's annual conference in September 2013. The audit clearly demonstrated that protocols and guidelines around HIV testing were not being followed.

48. For comparative purposes, the experience of introducing a standard around provision of contraception for all women seeking pregnancy termination was described. This had proved challenging and implementation remained patchy in some places. A termination of pregnancy service specification required the provision of contraception in abortion services and recommended that service users should be offered an HIV test. However, this specification expired on 31 March 2013 and a new version has not been published.

49. Following transition, Clinical Commissioning Groups (CCGs) were now responsible for commissioning abortion services. They inherited some contracts from PCTs, which varied in their expectations about contraception and STI testing. Responses from non-NHS providers to the audit indicated that routine HIV testing was not specified in the service contract and, therefore, was not delivered. It was clear that responsibility for commissioning, and therefore paying for, HIV testing rested with CCGs as part of the package of care for women seeking termination.

50. EAGA agreed the following steps should be taken to promote HIV testing in TOP services.

- Enter into dialogue with the two largest non-NHS organisations providing TOP services – Marie Stopes International and the British Pregnancy Advisory Service (BPAS) – to raise inclusion of HIV testing in discussions with their local commissioners.
- Engage NHS England in the debate in their 'duty of leadership' capacity – e.g. via their representative on the Sexual Health Forum
- Encourage the Care Quality Commission to include in their assessment visits
- Identify examples of best practice from services where testing is routine and promote local action as part of expanding HIV testing agenda and reducing late HIV diagnoses
- Compile evidence of effectiveness to present to the Royal College of Obstetricians and Gynaecologists (RCOG) to inform a change to their guidance (The care of women requesting induced abortion) from risk-based to universal HIV test offer.

51. One caveat was to avoid linking action to local prevalence as this would provide an excuse for inaction. It was argued that because HIV testing was routine in antenatal services, it should also be in TOP services because all pregnant women have had unprotected sex. Furthermore, a high proportion of women seeking termination go on to have further pregnancies.

Agenda item 9 Annual review of surveillance data

52. Ahead of publication of 'HIV in the United Kingdom: 2013 Report', scheduled for the end of November, some of the key findings were presented to EAGA. Some data related to 2011 rather than 2012, as the latest figures were still being finalised.

- While the overall number of new HIV diagnoses was plateauing, underlying this was a rise in new diagnoses in MSM, particularly in London, and declining new diagnoses in heterosexuals nationally.
- New diagnoses in MSM rose 10% between 2011 and 2012, a combined effect of an increase in HIV testing (by 13%) and ongoing high rates of transmission.
- The proportion of individuals newly diagnosed at age 50 and over has grown steadily, accounting for 1 in 6 adults in 2012.
- Analysis of new diagnoses by country of birth shows that the proportion in the UK-born population is rising, surpassing those born abroad in 2009. This reflects changing migration patterns, particularly for infections acquired heterosexually in Africa.
- The importance of CD4 count data was demonstrated by its multiple uses: to analyse late diagnoses; as a proxy measure for linkage to care; as part of the algorithm for assigning country of infection and for use in back-calculating incidence. Its use is being promoted Europe-wide. A CD4 count of 350 cells/mm^3 indicates that serocvonversion took place ~4 years previously, although there is a big range around this figure.
- Among the 77,610 persons receiving HIV care in 2012, 1 in 8 are now aged over 50 years due to increasing diagnoses in older people and an ageing cohort. It is predicted that 3000 (4%) will not be seen for care in 2013, of whom 30% will have been newly diagnosed.
- The proportion of HIV patients with CD4 <350 cells/mm^3 on antiretroviral therapy was 89% in 2012 and showed no significant variation across demographic groups. Overall numbers accessing care outside London are higher now than inside London (since 2007).
- Latest data on HIV incidence in MSM shows it to be stable at around 2300-2500 cases per annum, with the estimated number of undiagnosed MSM consistently in the region of 8-9000. This indicates that the number of new diagnoses in MSM is being matched by the number of incident cases. 1 in 3 MSM continue to present late, so it remains a challenge to ensure those infected in the last year test more often.
- Quality of care indicators remained impressive with, for example, little variation in the proportion of patients achieving viral suppression within 12 months of initiating therapy. A by-product of the introduction of the HIV specialised service quality dashboard across England had been improved data quality (e.g. linkage of clinical and laboratory data), as Trusts sought to maximise their 'scores'. Currently, the dashboard presented outcomes compared to a national mean, but the aim was to move towards measurement methods that would promote high standards.
- Late HIV diagnosis is the most important predictor of morbidity and 1-year mortality and is a key indicator in the Public Health Outcomes Framework. Late diagnosis varies by age, sex and ethnicity and was 47% overall in 2012. By contrast, linkage to HIV care

shows little variation by demographic characteristics and 85% were retained in care between 2010 and 2011. The BHIVA audit of non-retention in care (presented at EAGA94) provided valuable insights into the predictors of retention in care.

- It was also noted that 92% of individuals diagnosed late in 2010, and by definition recommended to be on ART, were receiving ART by the end of 2011. Treatment coverage was higher in older versus younger age groups. The 1-year mortality rate for those aged over 50 at diagnosis and diagnosed late was >1%. Death rates among MSM have reduced to background levels, with the exception of those diagnosed late. The majority of deaths in the over 50s were due to AIDS-defining illnesses.
- New development: Positive Voices: the national survey of people living with HIV, would begin in 2014 to collect information on patient experiences and healthcare needs.

53. Between 1 in 4 and 1 in 5 people living with HIV remained undiagnosed. What accounted for the increasing diagnoses in older ages? This was attributed to a combination of better case ascertainment (more testing e.g. in general medical admissions) and diagnosing long-standing infections. New diagnoses had risen among MSM in all age groups, but were most marked in the youngest and oldest age groups and 19% were recent infections (within the last 6 months). Among MSM, 20% had a concurrent STI at HIV diagnosis. Anecdotal evidence suggested a substantial fraction of new diagnosis in MSM may be linked to use of club drugs. A detailed questionnaire has been developed to obtain information on risk factors for HIV infection in those recently infected.

54. A general point was made about the need for greater awareness among clinicians of cultural factors, such as recreational drug use among MSM, and the need to provide tailored services, separate from those for people who inject drugs. The London Councils had done some work to address this.

55. Despite the observed increase in HIV testing, it was not having the desired impact on public health and HIV transmission. Almost half of MSM newly diagnosed with HIV between 2010 and 2012 were diagnosed at their first test at that clinic, indicating that many MSM who require an HIV test have yet to seek one.

56. The Chair queried what impact starting treatment at CD4 500 cells/mm^3 (as per the 2013 WHO treatment guidelines) would have in the UK. This would mean 5% extra of the diagnosed population (~4000) would be eligible for treatment, but as the analysis by Brown *et al*. (IP3) showed, the impact on the epidemic would be modest.

Agenda item 10 HIV aspects of the 100,000 genomes programme Paper EAGA(95)5

57. This short briefing paper had been prepared to keep EAGA informed of the HIV-related work proposed under the 100,000 genomes project. It was not discussed. Further updates would be commissioned as the work progressed.

Agenda item 11 DH policy update (SP3)

58. A Framework for Sexual Health Improvement in England: The framework document was published in March 2013. DH officials met with PHE colleagues during the summer to develop an implementation action plan and a national indicator set to support monitoring of progress.

59. Transition arrangements for sexual health commissioning: A number of documents have been produced to support commissioners including: a service specification for integrated sexual health services for Local Authorities; guidance on cross-charging (for open-access GUM services); and guidance on clinical governance. [All accessible from the following link: https://www.gov.uk/government/publications/public-health-services-non-mandatory-contracts-and-guidance-published]

60. NHS (Venereal Diseases) Regulations 1974 and the NHS Trusts and PCTs (Sexually Transmitted Diseases) Directions 2000: When the Health and Social Care Act 2012 is fully implemented, these Directions and Regulations will lapse. A new statutory Code of Practice (CoP) on sharing patient identifiable information is being prepared by DH with the Health and Social Care Information Centre. It is intended to produce separate guidance on confidentiality and disclosure of information on sexual health as part of the CoP that will apply to all providers of health and social care services but be more flexible than the existing arrangements.

61. Repeal of HIV testing kits and services regulations: As EAGA was already aware, DH analysts have been developing an impact assessment to address the potential commercial market for HIV home-testing kits. DH officials had met with Orasure, the manufacturer of the OraQuick kit, which was approved for sale in the US last year by the Food and Drug Administration. It was not guaranteed that the product would meet the EU Directive requirements for marketing in Europe. In the US, some Public Health Departments had been making the OraQuick kits available to facilitate partner testing. There was some opposition in Europe to home-testing kits because of concerns about possible coercion and use by employers to screen their workforce.

62. Child sexual exploitation: DH has commissioned BASHH to develop a new screening proforma for use in sexual health services to help identify young people at risk of sexual exploitation. It was expected to be available for use from April 2014.

Agenda item 12 EAGA Workplan 2013/14: for review and sign-off

Paper EAGA(95)6

63. An expansion was proposed to the workplan item on medical indications for HIV testing to cover consideration of the pilot interferon gamma-release assay (IGRA)-based screening programmes taking place in parts of England[5]. The roll-out of IGRA screening to migrants had the potential to boost screening of relevant populations (i.e. from sub-Saharan Africa) for HIV, as a prerequisite to interpreting the IGRA result. An HIV prevalence of >3% had been demonstrated by the HIDES I study[6], among patients with mononucleosis-like illness.

64. Other revisions to the workplan included: addition of an item (for 2014-15) on results of the African Health and Sex Survey 2013 (formerly BASS Line); review of proposed changes and scientific basis for re-provision of HIV services in London. Expressions of interest from individual members to contribute to existing workplan items were also noted.

[5] Zenner D et al. Reversing the tide of the UK tuberculosis epidemic. Lancet 2013; 382:1311-2.
[6] Sullivan AK et al. Feasibility and effectiveness of indicator condition-guided testing for HIV: results from HIDES I (HIV Indicator Diseases across Europe Study). PLoS ONE 8(1): e52845. doi:10.1371/journal.pone.0052845.

Agenda item 13 Any other business

Agenda item 13.1 *NICE consultation on future public health quality standard topics* *Paper EAGA(95)7*

65. In light of the earlier discussion around availability of HIV testing in termination of pregnancy services (Agenda item 8), EAGA welcomed the fact that both 'HIV testing: encouraging uptake' and 'Provision of termination of pregnancy services' were already on the list of proposed topics.

66. An important public health consideration was ensuring appropriate provision of STI care for HIV-positive individuals in view of the high incidence of STIs in this group and the separation of commissioning responsibilities. Standards to address this would be helpful.

67. Self-sampling/self-testing for HIV might be addressed under the HIV testing topic. However, there was concern that waiting for formal cost-effectiveness studies could delay implementation of an activity that pilot studies had shown to be effective for case finding. If Local Authorities, en masse, demonstrated reluctance to purchase a self-sampling service, a NICE evaluation might then be beneficial.

68. HIV prevention was not identified as a separate topic, but there were clearly other topics where integration of HIV testing was warranted, such as the standards for TB, termination of pregnancy services, hepatitis B and hepatitis C.

Agenda item 13.2 *BASHH/MEDFASH consultation on revised and updated 'Standards for the management of STIs'* *Paper EAGA(95)8*

69. EAGA agreed to submit a response to this consultation. It was noted that the format had changed significantly, giving greater prominence to the quality measures. STI care for HIV-positive individuals was a topic EAGA was keen to see addressed comprehensively. [The revised Standards for the management of STIs were published in January 2014.]

70. 'Tissues and Cells: MSM Donor Selection Review': EAGA was informed that this report from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) had recently been published. As a result of the review, some of the restrictions on donations of tissues and cells from men who have had sex with men had been relaxed. The report is available from: https://www.gov.uk/government/publications/donor-selection-criteria-for-men-who-have-had-sex-with-men

Agenda item 14 Dates of the 2014 meetings

71. The dates for meetings in 2014 are as follows: 19 February, 18 June and 8 October 2014. Timings to be advised nearer the date.