EXPERT ADVISORY GROUP ON AIDS

Providing expert scientific advice on HIV

ANNUAL REPORT 2009

Introduction

1. This report from the Expert Advisory Group on AIDS (EAGA) covers the period 1 January 2009 to 31 December 2009.

Role of EAGA

2. The Expert Advisory Group on AIDS (EAGA) is an advisory non-departmental public body which is non-statutory. It was established in 1985 with the following terms of reference:

"To provide advice on such matters relating to HIV/AIDS as may be referred to it by the Chief Medical Officers of the Health Departments of the United Kingdom".

EAGA Membership

- 3. EAGA membership comprises experts in a range of relevant medical and scientific specialties and disciplines (e.g. epidemiology, genitourinary medicine, general practice, infectious diseases, perinatal HIV, occupational medicine, public health and virology) and also includes members from the HIV voluntary and community sectors. A list of members who served during 2009 is attached at **Annex A**.
- 4. Three new members were appointed in 2009. There were no re-appointments.

EAGA Observers

- 5. The Government Departments and Agencies listed below have Observer status at EAGA.
 - Department of Health
 - > Department of Health, Social Services and Public Safety, Northern Ireland
 - Department for International Development
 - Health Protection Agency
 - Medicines and Healthcare Products Regulatory Agency
 - Ministry of Defence
 - Scottish Government
 - Welsh Assembly Government
 - > UK Blood Services

Code of practice and register of members' interests

6. EAGA works to a code of practice based on the Government Office for Science's <u>Code of Practice for Scientific Advisory Committees</u> (December 2007) and the Cabinet Office's <u>Model Code of Practice for Board Members of Advisory Non-Departmental Public Bodies</u> (October 2004). The code covers issues such as the seven principles of public life set out by the Committee on Standards in Public Life, the role of the chair and members, the handling of EAGA papers and declarations of members' interests. EAGA's code can be found at: http://www.dh.gov.uk/ab/EAGA/DH_095303. The register of members' interests is attached at **Annex B**.

Epidemiology of HIV/AIDS

- 7. EAGA receives regular updates on the UK's HIV epidemic from the Health Protection Agency (HPA) and its collaborators (e.g. Health Protection Scotland) including copies of published reports. Regularly updated and detailed information from surveillance systems is published on the HPA's website: <u>http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/HIVAndSTIs/Surve</u> <u>illanceSystemsHIVAndSTIs/</u>
- 8. The key findings from surveillance in 2008¹ were presented to EAGA at their 84th meeting, as follows:
 - The number of people living with HIV in the UK continues to rise, with an estimated 83,000 infected at the end of 2008, of whom over a quarter (27%) were unaware of their infection.
 - During 2008, there were 7,298 new diagnoses of HIV in the UK. This represents a slight decline on previous years, predominantly due to fewer diagnoses among black African women who acquired their infection abroad.
 - New diagnoses among men who have sex with men remained high in 2008, and four out of every five probably acquired their infection in the UK.
 - New HIV diagnoses among those who acquired their infection heterosexually within the UK have risen, from an estimated 740 in 2004 to 1,130 in 2008.
 - Over half of patients were diagnosed with a CD4 cell count <350 per mm³ within three months of diagnosis in 2008, the threshold at which treatment is recommended to begin.
 - Preliminary data for the first six months of 2009 indicate that one in five men who have sex with men, and one in ten heterosexuals newly diagnosed with HIV were likely to have acquired their infection within the last six months.
 - Uptake of HIV testing in antenatal and genitourinary medicine clinics continued to improve in 2008, reaching 95% and 93%, respectively.
 - 43 English Local Authorities (35 Primary Care Trusts) had a prevalence of diagnosed HIV > 2 per 1,000 population in 2008, at which threshold it has been recommended to expand HIV testing in the local population.
 - Preventing the 3,550 HIV infections that were probably acquired in the UK, and subsequently diagnosed in 2008, would have reduced future HIV-related costs by more than £1.1 billion.

¹ From *HIV in the United Kingdom: 2009 Report*. Available from: http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1259151891830

Main items of business

9. EAGA met twice during the period of this report - on 25 February 2009 (83rd meeting) and 21 October 2009 (84th meeting). The substantive items discussed and their outcomes are summarised below. The annual Work Plan can be found at **Annex C**.

83rd meeting, February 2009

 <u>Focus on HIV prevention</u>: The results of recent surveys conducted among the two key population groups at greatest risk of acquiring and transmitting HIV infection – men who have sex with men (MSM) (Gay Men's Sex Survey) and people from African communities (BASS Line survey) – were presented and their implications for future prevention work discussed.

Certain subgroups within these populations had greater need for accurate and relevant information about HIV and how to prevent it. Among Africans, African men who had sex with both men and women, those who were younger, had lower educational attainment and who were diagnosed with HIV had the highest information needs. Similarly, younger MSM, less educated MSM and those with diagnosed HIV had higher information needs. Other demographic and risk behaviours associated with need among MSM included black ethnicity, higher numbers of sexual partners and problems with drugs or alcohol.

Some important facts emerged. MSM had unrealistic expectations about HIV infection and its impact on lives due to lack of first-hand knowledge of anyone they knew to be living with HIV – an outcome of the success of antiretroviral treatment. Strategies for avoiding infection were flawed by the assumption that HIV-infected men would disclose their status before sexual encounters when, in reality, disclosure was uncommon because of continuing stigma.

Combination prevention – the application of behaviour change interventions alongside biomedical interventions such as male circumcision, vaccines, microbicides and pre-exposure prophylaxis – had gained acceptance as a strategy more likely to be effective than any one intervention used in isolation.

Measures of reduction in HIV-related sexual risk behaviour would include increased condom usage, decreased frequency of unprotected sex, fewer sexual partners and fewer STIs. Translating these effects into cases averted remained challenging. Studies found effectiveness of interventions depended on how they were delivered (individual versus group versus community) and showed varying degrees of sustainability.

EAGA concluded that, based on the available evidence, the clinical setting was the right place to deliver behavioural interventions and it was a matter of finding the time, space and opportunity to make this a reality. It would require better collaboration between clinical and community services. Interventions integrated with routine clinic visits might be a practical solution for HIV-diagnosed individuals. However, with an estimated 50-70% of transmissions originating from the undiagnosed, earlier identification of infections remained critical. It was necessary, but not sufficient, to raise awareness and understanding of HIV among groups at greatest risk.

 <u>Surveillance of UK HIV drug resistance</u>: A database of sequences from resistance tests performed as part of routine clinical care of UK patients had been established in 2001 and provided a rich source of information, particularly through linkage with clinical databases. Evidence from the database of transmitted drug resistance had led to the recommendation that all HIV patients should have a resistance test before commencing treatment, in order to guide the choice of drugs and minimise the clinical impact. Routine pre-treatment resistance testing had made the database more representative of the population of HIV-diagnosed individuals.

Stratifying patients according to whether they had received antiretroviral treatment or not revealed that transmitted drug resistance had declined from a peak of around 12% in 2002 to around 8% in 2007. Transmitted resistance levels were lower in patients with non-B subtypes compared with subtype B virus; this was expected as non-B subtypes are associated with heterosexual infections acquired in sub-Saharan Africa, where access to HIV treatment has been more limited.

While the origin of transmitted resistance must once have been an individual on treatment, there was growing evidence that transmission of resistance was from the untreated population. Such a reservoir of resistance posed a threat to the long-term efficacy of antiretroviral therapy, could limit the decline in transmitted drug resistance and highlighted a potential role for earlier antiretroviral therapy to stop the spread of resistant virus. Resistance-associated mutations present in individuals at HIV diagnosis had been shown to persist over many years in the absence of drug selection pressure.

Resistance among treated patients had also declined, reflecting improvements in treating patients with HIV. It would remain important to keep monitoring both the levels and patterns of drug resistance, for example to guide regimen choices for pre-exposure prophylaxis.

 <u>HIV post-exposure prophylaxis (PEP) guidance</u>: EAGA discussed a number of practical issues around implementation and interpretation of its updated guidance. The first concerned the shelf-life of PEP starter packs containing Truvada (tenofovir/emtricitabine). Some Trusts had only been able to obtain packs with a 30-day expiry, which would lead to high wastage where PEP use was infrequent. The Secretariat had compiled and distributed a list of licensed NHS manufacturing units that were able to supply packs with a 12-month expiry.

Secondly, EAGA reiterated the importance of taking a proper medical history, including sexual history, as part of the risk assessment for healthcare workers presenting following possible occupational exposure to HIV. Neither a sexual health screen nor a baseline HIV test were considered necessary on a routine basis² and might deter healthcare workers from reporting exposures. This aspect

² These would be part of the protocol for an individual seeking PEP following sexual exposure.

of EAGA's guidance was clarified in a brief article in the British Association for Sexual Health and HIV's April 2009 newsletter.

84th meeting, October 2009

 <u>Current treatment issues</u>: Feedback from the International AIDS Society Meeting held in Cape Town in July 2009 highlighted a number of developments in antiretroviral treatment of general interest, together with those that might impact on EAGA's recommended PEP regimen (currently Truvada [tenofovir/emtricitabine] plus Kaletra [lopinavir/ritonavir]) or on interpretation of surveillance data.

An apparent increased cardiovascular risk with abacavir use had been attributed to its selective use in patients with renal disease for whom tenofovir was contraindicated. Long-term use of Kaletra (lopinavir/ritonavir) resulted in poorer lipid profiles than use of newer boosted protease inhibitors. However, this was not of immediate concern in the context of PEP because of the short course (28 days) of treatment.

The results of several studies demonstrated potential for cost savings. For example, switching patients with stably suppressed viral loads to protease inhibitor monotherapy was not inferior to a conventional triple combination and could reduce regimen costs substantially. A comparison of daily highly active antiretroviral therapy (HAART) with a treatment schedule of 5 days on and 2 days off showed undetectable viral load could be maintained but with increased viral load blipping, which could be detrimental in the long term. It was reassuring that missing a couple of doses was unlikely to be harmful, but intermittent therapy was not recommended as a long-term strategy.

- <u>Breastfeeding transmission risk reduction trials</u>: Data from a number of African breastfeeding transmission risk reduction trials were discussed. Substantial reductions in transmission risk were achieved. Transmission rates of between 1 and 3% were attained by giving HAART to the mother, starting as soon as practicable to maximise viral load undetectability at delivery, or by giving nevirapine to the infant. Good adherence to treatment by mothers was critical to sustain an undetectable viral load throughout the breastfeeding period. As the transmission risk was not reduced to zero, breastfeeding was still unacceptable for the majority of HIV-infected women in the UK. The policy on breastfeeding avoidance would be kept under review.
- <u>HIV vaccine</u>: EAGA reviewed the results of a Phase III HIV vaccine trial (RV144) that were reported in 2009. The trial involved over 16,000 low-risk volunteers and combined two vaccines that had failed to provide protection when used singly. A modest protective effect against HIV infection of ~30% compared with placebo was reported. Whilst still far from being an effective vaccine, there was a small chance that studying the immune responses of vaccine recipients would provide insights to assist future vaccine design and rejuvenate vaccine efforts.
- <u>Testing incapacitated source patients for blood-borne viruses</u>: Under the Mental Capacity Act 2005, it was not permitted to test source patients who lacked capacity to consent for blood-borne viruses (BBVs), unless it was in their best

interests (i.e. not for the benefit of another person). Previous guidance from the General Medical Council (GMC) on *Serious Communicable Diseases* had been permissive of such testing under certain limited circumstances. EAGA's interest in this issue stemmed from the implications for healthcare workers who suffered a potential exposure to BBVs through a needlestick injury, where the source was unconscious or otherwise incapacitated. Lack of information on the source's infection status would hamper the risk assessment, probably resulting in more healthcare workers taking PEP unnecessarily, with a consequent increase in staff absences and economic costs.

EAGA agreed to work with the GMC which was considering developing practical guidance for use in situations in where the source patient for a blood exposure incident was incapacitated.

For further details of EAGA's discussions, see the agendas and minutes of these and earlier EAGA meetings, which can be found at: <u>http://www.dh.gov.uk/ab/EAGA/DH_094969</u>

Consultations

EAGA submitted formal responses to the consultations listed below in 2009. Full details can be found on the website at: <u>http://www.dh.gov.uk/ab/EAGA/DH_094975</u>

- June 2009: UK National Screening Committee consultation on repeat screening for HIV in pregnancy
- September 2009: Department of Health consultation on Health Protection Regulations
- October 2009: NICE Public Health Intervention Guidance (draft scope): Preventing and reducing HIV transmission among men who have sex with men: interventions to increase the uptake of HIV testing.
- October 2009: NICE Public Health Intervention Guidance (draft scope): Preventing and reducing HIV transmission among black African communities living in England: interventions to increase the uptake of HIV testing.

EAGA Subgroups

- 10. There were no subgroup meetings in 2009. EAGA members participated in the Tripartite Working Group in March 2009 which met to review guidance on the management of healthcare workers infected with blood-borne viruses.
- Contact: Dr Linda Lazarus EAGA Secretariat Health Protection Agency Centre for Infections 61 Colindale Avenue London NW9 5EQ

e-mail: EAGA@hpa.org.uk

Prepared by EAGA Secretariat: March 2010

MEMBERSHIP OF THE EXPERT ADVISORY GROUP ON AIDS IN 2009

Name			Term of appointment	
Chair				
Professor Brian Gazzard	Professor of HIV Medicine/Director of Clinical Research, Chelsea & Westminster Hospital, London	N/A	Appointed 1 July 2005; re-appointed 1 July 2008	
Members				
Dr Christopher Conlon	Consultant in Infectious Diseases, John Radcliffe Hospital, Oxford	Infectious disease	Appointed 14 February 2007	
Mr David Crundwell	Communications Consultant	Lay member	Appointed 1 July 2005; re-appointed 1 July 2008	
Dr Matthew Donati	Consultant Medical Virologist, Health Protection Agency Regional Laboratory, Bristol		Appointed 2 February 2009	
Ms Ceri Evans	Senior Sexual Health Adviser, West London Centre for Sexual Health, Charing Cross Hospital	Sexual Health Advice	Appointed 1 April 2006; re-appointed 1 July 2008	
Professor Geoffrey Garnett	Professor of Microparasite Epidemiology, Department of Infectious Disease Epidemiology, Imperial College, London	Epidemiology	Appointed 1 April 2006; re-appointed 1 July 2008	
Dr John Green	Chief Clinical Psychologist, Central & North West London NHS Foundation Trust and St Mary's Hospital, London	Clinical psychology	Appointed 1 April 2006; re-appointed 1 July 2008	
Dr Jeremy Hawker	Head of Public Health Development, Health Protection Agency	Public health	First appointed 1 March 2001; re-appointed 1 January 2007	
Professor Clifford Leen	Consultant Physician, Regional Infection Unit, Western General Hospital, Edinburgh	Infectious disease	Appointed 14 February 2007	

MEMBERSHIP OF THE EXPERT ADVISORY GROUP ON AIDS IN 2009 (cont.)

Name	Position		Term of appointment	
Ms Ruth Lowbury	Chief Executive, Medical Foundation for Voluntary set AIDS & Sexual Health (MedFASH)		Appointed 1 July 2005; re-appointed 1 July 2008	
Dr Helen McIlveen	Clinical Manager Sexual Health and HIV for Newcastle and North Tyneside Community Health Services	HIV/GUM nurse consultant	Appointed 2 February 2009	
Ms Beatrice Osoro	Case Worker, Positively Women, London	BME groups affected by HIV	Appointed 2 February 2009	
Sir Nick Partridge	Chief Executive, Terrence Higgins Trust, London	Voluntary sector	First Appointed 1 March 2001; re-appointed 1 January 2007. Elected Vice Chair 10 October 2005	
Professor Deenan Pillay	Professor of Virology ,University College London and Head of HIV and Antivirals, Virus Reference Department ,Centre for Infections, Health Protection Agency	Virology	Appointed 1 July 2005; re-appointed 1 July 2008	
Dr Anton Pozniak	Consultant Physician in GUM/HIV, Chelsea & Westminster Hospital, London	HIV medicine	Appointed 1 July 2005; re-appointed 1 July 2008	
Dr Keith Radcliffe	Consultant in HIV/GUM, Whittall Street Clinic, Birmingham	HIV/GUM	Appointed 14 February 2007	
Dr Alison Rimmer	Consultant Occupational Physician, Sheffield Occupational Health Service, Northern General Hospital, Sheffield	Occupational medicine	First Appointed 1 March 2001; re-appointed 1 January 2007	
Miss Susan Sellers	Consultant Obstetrician, St Michael's Hospital, Bristol	Perinatal HIV	Appointed 1 April 2006; re-appointed 1 July 2008	
Dr Ewen Stewart	General Practitioner, Edinburgh	General practice	Appointed 1 July 2005; re-appointed 1 July 2008	

Annex B

EXPERT ADVISORY GROUP ON AIDS (EAGA): REGISTER OF MEMBERS' INTERESTS 2009

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS		OTHER INTERESTS	
	Name of organisation	Nature of interest	Name of organisation	Nature of interest	Name of organisation	Nature of interest
Professor Brian Gazzard	Gilead, Pfizer, GlaxoSmithKline, Bristol-Myers Squibb	Consultant (ad hoc)	Gilead, Pfizer, GlaxoSmithKline, Bristol-Myers Squibb	Research and educational grants		None
Dr Christopher Conlon		None		None		None
Mr David Crundwell		None		None		Magistrate
Dr Matthew Donati		None		None		None
Ms Ceri Evans		None		None		None
Professor Geoffrey Garnett	GlaxoSmithKline, Merck, Sanofi Pasteur, Sanofi Pasteur MSD	Consultant	GlaxoSmithKline	Research grants		None
Dr John Green		None		None		None
Dr Jeremy Hawker		None		None	Health Protection Agency	Employee (Management)
Professor Clifford Leen	Boehringer Ingelheim, Bristol- Myers Squibb, Abbott, Gilead, Merck, Pfizer, Tibotec	Consultant (ad hoc)	Bristol-Myers Squibb, Merck Pfizer, Gilead, MRC	Travel grants Research grants	BHIVA Hepatitis Working Group Executive BHIVA Education and Scientific Sub- committee	Secretary Chair Member
					MRC College of Experts	
Ms Ruth Lowbury		None	Pharmaceutical companies	MedFASH (employer) receives a number of unrestricted educational grants and occasional financial support for specific events		None

EXPERT ADVISORY GROUP ON AIDS (EAGA): REGISTER OF MEMBERS' INTERESTS 2009 (cont.)

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS		OTHER INTERESTS	
	Name of organisation	Nature of interest	Name of organisation	Nature of interest	Name of organisation	Nature of interest
Dr Helen McIlveen		None		None	Blue Sky Trust Newcastle (HIV charity)	Chair
Ms Beatrice Osoro		None		None	Positively Women	Staff member
Sir Nick Partridge		None		None	THT	Chief Executive
Professor Deenan Pillay	GlaxoSmithKline, Gilead, Boerhinger Ingelheim, Bristol- Myers Squibb	Consultant	GlaxoSmithKline, Gilead, Boerhinger Ingelheim, Bristol-Myers Squibb, Pfizer, Monogram Biosciences	Consultancy fees paid to Department		None
Dr Anton Pozniak	Delphic Europe UK; GlaxoSmithKline, Bristol-Myers Squibb, Boehringer Ingelheim, Tibotec, Pfizer, Roche, Gilead; LEPRA and St Stephens AIDS Trust	Non-executive Director; Consultant; Board Member (charities)	Delphic Europe UK, GlaxoSmithKline, Bristol-Myers Squibb, Boehringer Ingelheim, Tibotec, Pfizer, Roche, Gilead	Consultancy fees paid to Department		None
Dr Keith Radcliffe	Bristol-Myers Squibb	Consultant	GlaxoSmithKline	Travel grants	BASHH IUSTI	Vice-President & Trustee Regional Director (Europe) & Trustee
Dr Alison Rimmer		None		None		None
Dr Susan Sellers	Medical Protection Society	Member of Claims Advisory Group		None		None
Dr Ewen Stewart	Abbott	Teaching fee		None		None

BASHH - British Association for Sexual Health and HIV; BHIVA - British HIV Association; IUSTI - International Union Against Sexually Transmitted Infections; LEPRA – the British Leprosy Relief Association; MedFASH – Medical Foundation for AIDS and Sexual Health; MRC – Medical Research Council; NAT - National AIDS Trust; THT – Terrence Higgins Trust

Annex C

EXPERT ADVISORY GROUP ON AIDS WORKPLAN 2009-10

Topic		Lead	Timescale	
	Continuing work on reviewing policy on restricting practice of blood-borne virus infected healthcare workers and development of advice for consideration by the tripartite group	Joint work with UKAP and AGH. UKAP to lead	Tripartite group met March 2009. Work ongoing via scientific subgroup.	
•	Review and update guidance on HIV and Infant Feeding (2004) as an adjunct to BHIVA/CHIVA guidance on the management of HIV infection in pregnant women	BHIVA/CHIVA to lead with EAGA input	Guidance in preparation for publication in April 2010	
A	Contribute to DH's review of consent to testing incapacitated source patients following occupational injuries to health care workers	Alison Rimmer to represent EAGA	Work ongoing by General Medical Council	
~	Contribute to public consultation on three sets of health protection regulations arising from the Health and Social Care Act 2008	David Crundwell and John Green	September 2009	
•	Consider the need to update <i>Guidance</i> for clinical healthcare workers: protection against infection with blood-borne viruses (1998) in light of other sources of advice	Chair plus Alison Rimmer	October 2009	
>	Ongoing review of surveillance data	HPA	October 2009	
À	 Oversight of expansion of HIV testing Near-patient testing technologies and implementation European approach to reducing undiagnosed infections 	Alan McOwan Chair	February 2010	
~	Behavioural interventions: action research as an alternative to randomised controlled trial evidence	Derek Bell	February 2010	
•	Examination of relationship between other STIs and HIV transmission	Chris Conlon	June 2010	
•	Horizon scanning for emerging HIV issues	ALL	ongoing	