

# EMERGING SCIENCE AND BIOETHICS ADVISORY COMMITTEE (ESBAC)

## MINUTES OF THE 4th MEETING

30 September 2013

Skipton House, London

### Present

Professor Sir Alasdair Breckenridge (Chair)	
Dr Aileen Keel	Dr Jonathan Mill
Professor Andrew Baker	Professor Joyce Tait
Dr Bella Starling	Mr Julian Hitchcock
Dr Bina Riwal	Ms Madeleine Colvin
Professor Bobbie Farsides	Dr Mark Bale
Dr David Townend	Dr Neil Scolding
Ms Diana Sternfeld	Professor Nicholas Lemoine
Professor Duncan McHale	Dr Paula Boddington
Mr Hugh Whittall	Professor Peter Littlejohns
Mr James Peach	Dr Rachel Quinn
Dr John Brown	

### Apologies

Professor Angus Clarke	Dr Dipti Amin
Dr Julie Maxton	Professor Sir John Savill
Dr Katherine Littler	Dr Michael McBride
Dr Stuart Hogarth	

### DH

Dr Dorian Kennedy  
Mr Emyr Harries (for agenda item 3)

### Secretariat

Ms Melanie Pepper  
Ms Viona Pereria-Marron  
Mr Robin Herbert

### Genomics England Limited

Ms Laura Riley (for agenda item 2)

## 1. Chair's Welcome

- 1.1 The Chair welcomed Members to the fourth ESBAC meeting. Apologies were noted and the Chair reminded those present to declare any new conflicts of interest.

## 2. Genomics England update

- 2.1 The Chair introduced Laura Riley (Ethics Advisor and Programme Manager, Genomics England Limited) who was attending on behalf of Mike Parker to give an update on the ethics programme of work being set up to support Genomics England. The 100k Genomes project had been announced by the Prime Minister in December 2012. Genomics England Limited (GEL), a small company wholly owned by the Department of Health, was launched in July as the vehicle for managing the programme including the contracts for sequencing.
- 2.2 An Ethics Advisory Group, chaired by Mike Parker, was in the process of being appointed to advise GEL on issues such as consent and feedback of findings. Terms of reference for the Group would be agreed and a framework developed for deliberations going forward.
- 2.3 Dr Bale explained that GEL's focus would initially be on cancer, rare disease and infectious disease. There are currently two pilots about to start with the expectation that the project would be scaled up over the next year. Dr Bale mentioned that GEL would be holding its first stakeholder events on 3 October.
- 2.4 The Chair asked what this meant for ESBAC's Genomics Focus Group that had previously been put on hold. Dr Bale said that, as previously suggested by a Member at the ESBAC Forum, there may be merit in ESBAC (as a whole) discussing 'omics' (e.g. proteomics) more broadly and consider what other technologies might be important. Dr Bale said he would be guided by advice from the Committee in terms of recommended action regarding the Genomics Focus Group, but suggested work should perhaps get underway first by Mike Parker and colleagues before perhaps bringing specific issues back to ESBAC for discussion.
- 2.5 A Member asked whether someone from ESBAC could attend meetings of the Ethics Advisory Group as an observer. Action: Laura Riley agreed to discuss this suggestion with Mike Parker.
- 2.6 A helpful link with ESBAC was noted in that Mike Parker was also a member of the Nuffield Council on Bioethics working group for their current 'Biological and health data project' that was looking at the ethical issues around the collection, linking, use and exploitation of biological and health data.

### 3. DH Update

3.1 Regenerative Medicine: Emyr Harries reported that the Government Response to the House of Lords Science and Technology Committee Inquiry into Regenerative Medicine would be published tomorrow, Tuesday 1 October.

3.2 Dr Bale provided an update on a number of other areas from within DH including:

- Reviewing human tissue legislation: following the Government's acceptance of the recommendation in the McCracken Report to review human tissue legislation, DH is currently developing this work and plan to publish a consultation policy document by the end of 2013/2014. The Human Fertilisation & Embryology Authority and the Human Tissue Authority will be retained as separate statutory bodies.
- Mitochondria donation: it is intended to consult on new draft regulations later this year.
- Organ donation: a new organ donation and transplantation strategy was published on 11 July 2013.
- Rare diseases: the first UK Strategy for Rare Diseases is due to be published by the end of the year and will aim to improve the management, treatment and care of those suffering from rare diseases.
- Antimicrobial resistance: the UK Five Year Antimicrobial Resistance Strategy was published on 10 September. It responds to the challenges described by the CMO in her annual report for 2011. It proposes an integrated approach to tackle the issue which increases the scale, scope and pace of action at a national and international level.
- Data governance: on 12 September, the DH published its response to the Caldicott information governance review - the independent review of how information about individuals is shared across the health and care system.

3.3 Dr Bale reported on Council of Europe work on the ethical issues of emerging and converging technologies. A study on emerging and converging technologies was being undertaken by the Rathenau Institute in the Netherlands and a meeting was being organised in October to discuss the initial findings. Dr Bale and the ESBAC Chair were due to attend.

3.4 Members were invited to send the Secretariat comments on the 'Future Vision of UNESCO's Bioethics Programme'.

## Focus group updates

### *Innovative Governance Focus Group*

- 4.1 The Champion for the Innovative Governance Focus Group provided a progress report. The starting point for the work was the draft governance framework and the use of test case analyses to look at opportunities to rationalise the governance landscape. It was proposed to hold three workshops to consider cell therapies, stratified medicine and synthetic biology. The offer was made that the Cell Therapy Catapult could host the first workshop on cell therapies. The deliverables would be workshop reports that would feed into the framework, the development of which would be the overall output.
- 4.2 There was some discussion around if and how clinical trials should be included in this work and reference was made to the recent clinical trials report from the House of Commons Science and Technology Committee. It was suggested clinical trials could be considered in due course and perhaps after the European Medicines Agency (EMA) had published its final policy on the publication and access to clinical trial data at the end of the year.

### *Technologies to Optimise Treatment*

- 4.3 The Champion for the Technologies to Optimise Treatment Focus Group provided a progress report. After consideration of various topics this group had decided to concentrate on patient adherence to medicines. When the group last met it agreed to engage with interested parties (including the Faculty of Pharmaceutical Medicine who held a symposium on patient adherence in November 2012 and the Academy of Medical Sciences) and a meeting was arranged for October.

### *Dementia Focus Group*

- 4.4 The Champion for the Dementia Focus Group provided a progress report. The focus for this group was on developments in dementia testing and treatment and an ethical framework for discussing the introduction of earlier testing and new treatment regimes. After preliminary work on those two areas was completed the intention was to hold an expert workshop to refine the framework.
- 4.5 It was recognised that dementia is an area attracting much interest and activity, including the forthcoming G8 summit on dementia on 11 December. Dr Bale offered to raise the proposed Dementia Focus Group workshop with DH colleagues to seek advice on timing and direction. The Medical Research Council Member referred to the Council's call for expressions of interest from UK cross-disciplinary teams to create a UK Dementias Research Platform.

#### **4. Horizon Scanning Steering Group update**

- 5.1 The Chair of the Horizon Scanning Steering Group (HSSG) reminded Members that the approach to horizon scanning was based on a referral system of emerging issues from existing horizon scanning centres as well as ESBAC Members themselves.
- 5.2 The first call to organisations went out in August and there had been three returns to date. Two were referrals from Public Health England covering high throughput sequencing of the genome and antibiotic resistance in *Helicobacter Pylori*. The third was from the HFEA sharing information about their horizon scanning activities. The HSSG Chair emphasised that the pro-forma was a backstop and that focus should be on the collective wisdom of Members as horizon scanners.

#### **5. Taking stock and forward look**

##### **6.1 Members' updates included:**

- An update on Nuffield Council on Bioethics activities (including reports on: novel neurotechnologies - looking at the ethical issues raised by technologies that intervene in the brain; donor conception). Current projects include: children and clinical research and biological and health data. A new piece of work is planned on research culture and the demands that take place in the research environment.
- The Academy of Medical Sciences had published its report, Realising the potential of stratified medicine in July.
- The Technology Strategy Board was planning two new catapults – diagnostics for stratified medicines and energy systems
- The Royal Society had held a recent symposium 'Drug Discovery, Regulation and the Law: Is the patient getting the best deal?'

6.2 The original topics ESBAC had identified at an earlier meeting for potential inclusion in its workplan were reviewed. Given the GEL programme of work, Dr Bale suggested a watching brief should be maintained on genomics, but that it might be helpful to unpack what aspects of genomics could fit with the work of the other focus groups.

6.3 The Chair raised the suggestion that ESBAC should consider developing an 'annual report'. There followed some discussion on the purpose of and audience for such a report and it was agreed the timing was perhaps not right.

6.4 Some Members expressed the view that there had been little feedback to ESBAC from DH, in terms of ESBAC being asked to address specific questions and whether the Committee to date had met the Department's

expectations. The Chair noted that the Committee had generated most of its work. A Member raised the question of the direction of ESBAC as the landscape had changed since ESBAC was first established. These points were noted and further consideration would be given to the future role of the Committee.

**6. Agenda items for next meeting (January 2014)**

- 7.1 The next meeting would be held in January, date to be confirmed.  
Suggested agenda items should be sent to the Secretariat.

**7. AOB**

- 8.1 None.