

**EMERGING SCIENCE AND BIOETHICS ADVISORY
COMMITTEE (ESBAC)**

MINUTES OF THE 3rd MEETING

29 January 2013

Skipton House, London

Present

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

Apologies

Professor Duncan McHale	Ms Katherine Littler
Professor Sir John Savill	Dr Michael McBride
Dr Julie Maxton	Professor Peter Littlejohns

Secretariat

Dr Simona Origgi
Ms Melanie Pepper
Ms Catherine Simpson
Mr Nathaniel Dahan

1. Chair's Welcome

- 1.1 The Chair welcomed Members to the third ESBAC meeting. Two new Members (representing the ABPI and the Scottish Government's Health and Social Care Directorate) who were attending for the first time were invited to introduce themselves.
- 1.2 Apologies were noted and the Chair reminded those present to declare any new conflicts of interest.
- 1.3 The Chair asked if Members were content with the minutes of the previous meeting. All present indicated they were.
- 1.4 The Secretariat provided an update on the actions from the previous meeting.
- 1.5 Members were reminded that any outstanding declarations of interest were needed as a matter of urgency for publication on the forthcoming ESBAC webpage. Member biographies and meeting minutes would also be published on the website.

2. Ways of Working

- 2.1 Dr Origgi introduced the Code of Practice (ESBAC 03(02)(01)) and invited Members to make any final comments. It was agreed that 'The Royal Academies' would be removed from paragraph 6, and subject to this final amendment the Code of Practice was formally signed-off.

3. Members' Updates

- 3.1 Dr Bale provided an update on the House of Lords Science and Technology Committee Regenerative Medicine inquiry. The Committee will meet on 26 February for their final evidence session. A range of individuals, including the Chief Medical Officer, had given evidence in front of the Committee. Transcripts from the sessions are available online.
- 3.2 Clinical Trials Directive: The Chair updated Members on the European Commission's proposed revision to the Clinical Trials Directive with reference to the House of Commons Science and Technology Committee's call for written evidence as part of their Inquiry into clinical trials and the disclosure of data. The Chair intended to forward a personal submission to the Inquiry but welcomed any comments from Members.

- 3.3 Caldicott Review: Professor Martin Severs attended the meeting to provide an update on the information governance review concerning the appropriate balance between the protection of personal information and the use and sharing of information to improve care. Professor Severs indicated the review was progressing well and would report to the Secretary of State shortly.
- 3.4 Nanotechnology: Dr Bale provided an update on the provisional report on Nanotechnology from the Bioethics sub-Committee of the Council of Europe Committee on Human Rights. The draft report had been circulated to Members before Christmas and Dr Bale invited Members to submit any further comments to him, indicating the Bioethics sub-Committee would be discussing it again in June.
- 3.5 Announcement on Genomics: On 10 December, the Prime Minister announced the plan to sequence the genomes of 100,000 patients over the next three to five years. The CMO has set up three working groups on: Science (Chaired by Professor David Lomas); Data (Chaired by Professor Janet Thornton); and Consent and Ethics (Chaired by Professor Mike Parker) to develop thinking and report advice to the CMO by the end of March. The NHS Commissioning Board will lead on implementation in terms of procuring the high throughput sequencing capacity and capability. As a result of this development the work of the ESBAC Genomics Focus Group has temporarily been put on hold to avoid any potential duplication of effort and resources.
- 3.6 Nuffield report on Emerging biotechnologies: Members were updated on the report, which explores the ethical issues and challenges raised by emerging biotechnologies and describes a framework of 'public ethics'.
- 3.7 Other updates included:
- The joint MHRA, AMS and ABPI workshop on 30 October on Regenerative Medicine where the need for more harmonisation of guidelines was discussed. A report is forthcoming.
 - The European Commission has announced that it is to set up an expert group on the development and implications of patent law in the field of biotechnology and genetic engineering (following the Brustle case).
 - The European Medicines Agency (EMA) has set up five working groups looking at the publication of clinical-trial data and are due to report in April.

4. Proposals from the Focus Groups

- 4.1 Dr Origgi recapped the background to the four focus groups being set-up. The Regulations, Technologies to Optimise Treatment and Dementia Focus Groups had met twice since the last ESBAC meeting,

and had each produced proposals to present to ESBAC. As previously mentioned, the Genomics Focus Group had been put on hold and therefore had not produced a proposal for the meeting.

4.2 *Regulations*

- 4.2.1 The Regulations Focus Group Champion provided an update on the discussions of the Regulations Focus Group and presented the Group's paper (ESBAC 03(04)(01) which proposed that governance related issues in the context of the regulation of emerging technologies should be included in ESBAC's workplan. In particular, Annex B was outlined which recognised that different issues might arise depending on whether the impact of technology is disruptive or incremental. It included examples of questions policy makers might face that could be translated into a governance framework consisting of policy guidelines.
- 4.2.2 Members were supportive of this work, but some concerns were raised about the scope of what was intended and that it was perhaps too ambitious and would require significant resources. It was considered important that the work outlined in the proposal should build on the report from the Nuffield Council on Bioethics ('Emerging biotechnologies'). It was also noted that the collective expertise of and varied contributions from ESBAC Members should provide good capacity for taking the work forward.
- 4.2.3 It was agreed the work should be taken forward and managed appropriately to allay concerns around scope and resources. The Focus Group would reconvene to consider next steps and a tentative timetable. MHRA would be engaged.

4.3 *Technologies to Optimise Treatment*

- 4.3.1 The Focus Group Champion introduced the paper from the Technologies to Optimise Treatment Focus Group (ESBAC 03(04)(03)) which proposed a piece of work to explore using emerging technology to assist and improve patient adherence as a technique to improve healthcare.
- 4.3.2 The ethical issues that may be raised were described, including consent to treatment, responsibility and blame, social inclusion and the patient/healthcare professional relationship. Some additional areas, not yet considered by the Focus Group, were outlined by the Chair which could broaden the scope to include conditions where new technologies were being utilised by patients themselves (e.g. in the management of diabetes, hypertension).
- 4.3.3 There was some discussion on how much technology is emerging in this area and how much is established, and whether there had been any survey done to date of the technology. It was suggested the bullet points on page 5 – identifying and pulling together what the state of the

art is in emerging technologies in this area, and exploring the ethical aspects of this technology might be good starting points.

- 4.3.4 It was agreed this was an area of work to take forward, but for the Focus Group to reconvene to firm up the proposal and ensure it dovetails with existing work, including the medicines optimisation agenda.

4.4 *Dementia*

- 4.4.1 The Focus Group Champion introduced the paper from the Dementia Focus Group (ESBAC 03(04)(03)) that proposed a piece of work on emerging technologies for early detection/diagnosis of dementia and the impact this may have on the individual, family, clinical profession and society, outlining how the topic fits with ESBAC's selection criteria.

- 4.4.2 Gillian Ayling, Deputy Director - Older People and Dementia in the Department of Health attended this part of the meeting and updated the Committee on the Prime Minister's Challenge on Dementia, which builds on the 2009 Dementia Strategy.

- 4.4.3 Mrs Ayling made reference to work being carried out to see how research into dementia can be improved and how countries can collaborate better to approach the issue internationally. The Alcove report is being published next month, which is a joint action between European Union Member States and the European Commission. It aims to both improve knowledge and improve knowledge on dementia and its consequences and promote the exchange of information to preserve health, quality of life, autonomy and dignity of people living with dementia and their carers in EU Member States. The UK is leading on early diagnosis as part of the report. As part of the Dementia Challenge a £1 million 'Innovation to challenge' award had been announced for ways to increase diagnosis.

- 4.4.4 Members discussed how best ESBAC could contribute to this priority area. It was noted that science is advancing rapidly and it was thought to be inevitable that biomarkers would be found in a few years and a test would emerge, perhaps similar to a genetic test for Huntington's. One Member conveyed the view that in terms of the inevitability that pre-diagnostics testing will emerge it would seem sensible to get ahead of the curve now.

- 4.4.5 It was agreed that this was an area of work to take forward and that the Focus Group would reconvene to consider the points made and develop a more pointed work programme, seeking the input and support of Gillian Ayling and colleagues via the Secretariat to ensure the proposal aligned with existing work.

- 4.5 Given the Genomics Focus Group had been put on hold, Members of this Group were invited to join one of the other three Focus Groups.

5. Horizon scanning

- 5.1 Dr Claire Packer from the National Institute for Health Research Horizon Scanning Centre joined the meeting to give a presentation on Horizon Scanning and 'Futures' Methodology. The Centre provides advance notice to the Department of Health and health service policy making-bodies of significant new and emerging technologies. Its remit includes pharmaceuticals, devices, diagnostic tests and procedures, surgical and other interventions, rehabilitation, public health and health promotion activities.
- 5.2 Dr Origgi introduced the paper (ESBAC 03(05)(01)) from the Horizon Scanning Steering Group (HSSG) and referred Members to the HSSG terms of reference at Annex A. Members were asked to comment on the draft pro-forma (Annex D) devised as a tool for capturing information on emerging issues from existing horizon scanning centres, Members and stakeholders.
- 5.3 There was some discussion around what was achievable in terms of horizon scanning, and whether the pro-forma would work in terms of others' willingness to complete returns. The Chair summarised the key questions for ESBAC's horizon scanning activity as how to collect intelligence and how to assess it. Dr Packer indicated that her horizon scanning centre would be amenable to providing input where appropriate. It was suggested that the Intellectual Property Office be approached as a possible source of help, and it was reiterated that all Members themselves are horizon scanners.
- 5.4 It was agreed that the pro-forma should be tried and tested and that it was important to be active in seeking input from others and give them an opportunity to contribute. Accompanying the pro-forma with a letter from the Chair and targeted at an appropriate level in organisations from where information is sought might elicit a greater response.
- 5.5 It would also be important to ensure that there was clarity around what was being asked of submitting organisations and what they were expected to fill in. A Member of the HSSG agreed to draft a short instruction note on completing the pro-forma. A 'bioethical risk assessment' element would be incorporated in the pro-forma. The pro-forma would initially be tested by all ESBAC Members before sharing with a wider audience.

6. ESBAC Forum

- 6.1 Dr Origgi introduced the ESBAC Forum paper (ESBAC 03(06)(01)). It is expected that the forum will take place in April or May, depending on availability of the Chair and the CMO. Members were asked for their comments on the outline agenda, proposed content and format. Views on who should be invited were also sought. It was discussed that

targeted invitations should be sent, as well as advertising on targeted websites. It was proposed that ESBAC would meet again before the Forum.

7. Agenda items for next meeting

- 7.1 Members were asked to continue to hold the 26 March for a possible meeting.

8. AOB

- 8.1 It was clarified that *ex-officio* Members could share Committee papers with relevant colleagues within their organisations on the basis that these would be treated as restricted until such times as papers were published on the website.