

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

**MINUTES OF THE 2<sup>nd</sup> MEETING**

**24 September 2012**

**Wellington House, London**

**Present**

Prof Sir Alasdair Breckenridge (Chair)	
Professor Andrew Baker	Professor Joyce Tait
Professor Angus Clarke	Mr Julian Hitchcock
Dr Bernadette Hannigan	Ms Katherine Littler
Professor Bobbie Farsides	Dr Louise Leong
Mr David Townend	Ms Madeleine Colvin
Ms Diana Sternfeld	Dr Neil Scolding
Dr Dipti Amin	Professor Nicholas Lemoine
Prof Duncan McHale	Dr Paula Boddington
Mr Hugh Whittall	Peter Cotgreave
Dr Bella Starling	Professor Peter Littlejohns
Mr James Peach	Dr Rachel Quinn
Dr John Brown	Dr Stuart Hogarth
Dr Jonathan Mill	Dr Mark Bale

**Apologies**

Professor Andrew Morris	Dr Michael McBride (deputy attending - Dr Hannigan)
Professor Sir John Savill (deputy Dr Ewart)	Mr Stephen Whitehead (deputy attending – Dr Leong)
Dr Julie Maxton (deputy attending - Dr Cotgreave)	

**Secretariat**

Dr Simona Origgi  
Ms Melanie Pepper  
Miss Beccy Cummings

## **1. Chair's Welcome**

- 1.1 The Chair welcomed Members and deputies to the second ESBAC meeting. Those Members who were attending for the first time were invited to introduce themselves.
- 1.2 Apologies were noted and Members reminded to declare any new conflict of interest.
- 1.3 The Chair congratulated John Brown on his appointment as Chairman of the Cell Therapy Catapult Centre and James Peach on his forthcoming appointment to the Wellcome Trust's new healthcare investment fund. The Chair also congratulated David Townend on being awarded a doctorate *cum laude*.
- 1.4 A couple of minor changes were agreed to the draft minutes of the first meeting.
- 1.5 The Chair outlined the five areas to be covered at the meeting:
  - finalising the Code of Practice and Webpage material
  - agreeing how best to undertake horizon scanning
  - agreeing which topics ESBAC should begin to engage with
  - discussing the ESBAC Forum/Workshop proposal
  - presentation from TSB on synthetic biology

## **2. Ways of Working**

- 2.1 Dr Origgi introduced the highlighted changes to the Code of Practice (ESBAC 02(02)(01)) for Members to review. It was agreed that 'educational' in paragraph 18 (page 4) should be changed to 'informing and engaging'. It was suggested that the previously agreed intention to limit open meetings to one a year should be reflected in paragraph 18.
- 2.2 Dr Origgi indicated that Annex E (ESBAC Framework) had been updated to reflect discussions at the previous meeting. Some minor changes were agreed: the wording under the criteria 'unique' (page 16) should incorporate 'not fall wholly within' and under 'Scoping' (page 17) it was suggested that both technologies and issues might be applicable depending on the context and therefore the wording should not be limited to 'or'.
- 2.3 Dr Origgi confirmed that the other annexes remained the same, and reminded Members that Annex J contained the expenses claim form and that Members needed to ensure that claims were submitted to the Department within three months of the claim date, and that the Department's guidance on expenses had to be adhered to.
- 2.4 The Chair asked Members to feed any further comments on the Code of Practice to the Secretariat after the meeting.

- 2.5 Dr Origgi reminded Members that the ESBAC web presence would be a page off of the DH website that had a standard look and feel. Members were asked to inform the Secretariat if, when submitting material, it could not be published on the website.
- 2.6 The Chair asked Members to review their biographies and send any revised text and/or photos to the Secretariat after the meeting.

### **3. Members' Updates**

- 3.1 The purpose of this agenda item, which was envisaged as a standing agenda item, was to seek updates from Members that would be useful to share with the Committee that may have a direct bearing on ESBAC's work, including recent or forthcoming events and meetings, and work Members were involved in.
- 3.2 Various forthcoming meetings and events were referred to, including:
- Joint MHRA, AMS and ABPI workshop on 30 October on regenerative medicine.
  - AMS Fellows discussion dinner on 15 October - 'Stem cell research: past, present and future'. Speaker - Dr Robin Lovell-Badge.
  - Conference on 12 November in Paris – 'The Evolving Promise of the Life Sciences' - Genomics Forum Symposium in collaboration with OECD.
  - Council of Europe Committee on Bioethics (DH-BIO) meeting on 18-19 October in Paris (Dr Bale attending).
  - Wellcome Trust workshop on dementia on 22-23 October.
  - Health Technology Assessment international (HTAi) 10<sup>th</sup> annual meeting on 15-19 June 2013 in Seoul.
  - European Medicines Agency (EMA) pharmacogenomics workshop on 8-9 October.
  - The Global Summit of National Bioethics Advisory Bodies – meeting at the end of September.
  - International Cancer Genome Consortium (ICGC) annual meeting.

### **4. Horizon Scanning**

- 4.1 The Chair introduced this item, which would focus on how horizon scanning might best be carried out by ESBAC. Dr Origgi took Members through the paper on the horizon scanning proposal (ESBAC 02(04)(01)).
- 4.2 At the outset, Dr Origgi reminded Members that there were no dedicated resources for horizon scanning and that as agreed at the last meeting, Members themselves are horizon scanners. Dr Origgi had shared the proposal with both the National Institute for Health Research Horizon Scanning Centre and Foresight, and had been reassured by their positive responses.
- 4.3 Horizon scanning needs to serve ESBAC's requirements and the 'purpose' of horizon scanning. Suggestions made in the paper will need to be further considered by the Horizon Scanning Group once set up. This will need to include clear criteria to guide the horizon scanning process (e.g. in deciding what is and is not important), and utilise decision-making tools as appropriate.
- 4.4 It was agreed the focus should not just be technology driven but include cross cutting issues in order to achieve a balanced approach. Threats and opportunities would be considered on a case-by-case basis.
- 4.5 Dr Origgi described the broad outline of the structure and mechanism to collect information as depicted in the diagram in Annex A. It was anticipated that traditional literature searching and current awareness alerts, whilst useful and not to be overlooked, would only make a small contribution and instead the most valuable source of information and intelligence was expected to come from Members themselves via their own expertise and networks of contacts and associations.
- 4.6 There was some discussion about Members' experience of horizon scanning, timescales for scanning, different players having different timescales and pathways, and connections between investment and regulation. Foresighting technology that is already beginning to be applied is perhaps easier than genuinely emerging technology where the regulation is uncertain. It was suggested a 5-10 year timescale needs to be used for therapeutics but that for pharma and diagnostics 5 years is relatively short.
- 4.7 The Nuffield Council on Bioethics report on emerging biotechnologies due at the end of the year would be helpful and the Wellcome Trust offered to provide to the Committee a list of the current bioethics funding grants from the Trust.
- 4.8 It was noted that bioethical reflections on issues were sometimes ahead of the science so it would be helpful to be aware of what is being discussed in the bioethics research literature.

- 4.9 Other potential sources include the implications of legal judgements (e.g. in diagnostics and genetics cases in the US) and an awareness of what is being funded, which is perhaps a good test of what technologies might appear. The Technology Strategy Board (TSB) work would prove useful here, although it is biased towards new technical opportunities. It was noted that TSB should be added to the diagram in Annex A.
- 4.10 Members were invited to:
- add to the list in Annex B that attempted to capture details of committees and organisations that Members have an association with, connection to or active role in.
  - share any horizon scanning mechanisms and relevant literature searches undertaken with the Secretariat.
- 4.11 It was agreed to set-up a horizon scanning group that would then decide and propose a way forward and report back to ESBAC. Peter Littlejohns agreed to chair the group and other Members were invited to volunteer. James Peach agreed to join and the ESBAC Chair indicated his willingness to be involved too. External input would be sought from the NIHR Horizon Scanning Centre, Foresight. The Nuffield Council on Bioethics agreed to identify someone to take part.
- 4.12 Dr Origgi said she would reshape the horizon scanning proposal into what the group might look like. It was proposed that the horizon scanning group would work out of Committee and meet before the next Committee meeting.
- 4.13 With reference to the Stakeholder List (ESBAC 02(04)(02)) it was suggested that some of the headings could be refined further and perhaps include a hierarchy, although this will depend on the issue being discussed. Members suggested adding the following organisations to the list, and were invited to submit further suggestions to the Secretariat after the meeting:
- Health Technology Assessment (HTA)
  - Arts and Humanities Research Council (AHRC)
  - HeLEX (Centre for Health, Law and Emerging Technologies)
  - British In Vitro Diagnostics Association (BIVDA)
  - Advanced Technologies Committee (ATC)
  - Faculty of Pharmaceutical Medicine
  - Royal Society of Edinburgh
- 4.14 The Chair reiterated that horizon scanning would be an essential part of ESBAC's work, and the horizon scanning group would look to appoint appropriate members, tapping in to other horizon scanning activities, to lead this work on behalf of the Committee.

- 4.15 The Chair for the Horizon Scanning Steering Group would discuss membership and next steps with the Secretariat.

## **5. Workplan**

- 5.1 Dr Origgi indicated that the draft Workplan (ESBAC 02(05)(02)) was intended to be a live document summarising the topics ESBAC will engage with. It is the intention that the Workplan will be a standing agenda item at ESBAC meetings.
- 5.2 The draft Workplan summary made recommendations as to which topics could be *in progress for scoping*, which ones ESBAC might want to keep a *watching brief* on (e.g. issues of interests but perhaps other work is ongoing that ESBAC needs to wait for) and those topics that would benefit from *horizon scanning*.
- 5.3 Dr Origgi indicated that the recommendations were not set in stone, and Members were invited to comment on the draft Workplan.
- 5.4 In months to come it would be used as a document summarising topics identified. Particular topics for discussion would have specific papers developed to update members.
- 5.5 The Chair moved discussion on to the list of topics, consisting of the topics identified at the last meeting and some suggested later. The areas discussed under different topics are summarised below, although topics were not discussed in isolation and tended to cross reference one another:

### **Direct-to-consumer genetic testing**

- I. It was noted that what is not included in this topic is what specifically the NHS should be worried about, what harm is this going to cause and what good is this going to generate. It was suggested that might be a useful angle to add to the debate.
- II. One Member suggested that to limit this topic to direct-to-consumer testing is too constraining and that it could be broadened. Many companies also sell kits through clinics, some of which are not of good quality, and this is a cause for concern. In addition, there was thought to be implications for who has access to this data and how it is interpreted.
- III. It was observed that years ago direct-to-consumer used to be a marker for a fault line for tests that were clearly no good. Now direct-to-consumer testing does include tests that could be very good and are also being developed in research centres and beginning to come into the NHS.

- IV. As there was an overlap with the genomics topic, it was agreed to subsume direct-to-consumer under the general genomic issues topic.
- V. The Chair reminded the Committee that it should consider what is relevant to the DH and where can ESBAC contribute. Dr Bale referred to the phrase – ‘recreational genomics’ (i.e. non-health related) and there perhaps being some negatives around how this genetic testing technology is used, outside of health. This might be an area of work to keep an eye on and pick up the other issues under the genomics heading.

### **Genomics**

- I. ‘Genomics issues’ as a topic was considered to be very broad and it would be helpful to identify what the different aspects are. The Chair indicated the way of working he anticipated was for ESBAC to pick out several topics, set up working groups and leave it to the experts within the groups to specify the areas that fulfil the criteria and are relevant and then report back to ESBAC.
- II. Use of data, and who has access to data were considered key issues. It depends how the Committee maps the work and identifies the crosscutting issues that may be relevant to all groups. Early and frequent matching across groups may be helpful to ensure consistency across themes.
- III. It was suggested that a timely and relevant piece of work would be for ESBAC to feed into the work MHRA will be undertaking to formulate the UK’s position in response to the European Commission’s draft proposal on the regulation of in-vitro diagnostics. A Member volunteered to draft a briefing for the next ESBAC meeting for Members to consider how ESBAC might input to MHRA.
- IV. It was noted that there was an element of consumer protection as a potential overarching theme.

### **Regenerative medicine and stem cells**

- I. A few Members noted the concern around commercial stem cell therapy clinics selling direct to often very vulnerable people, raising unrealistic expectations, and what potential topic this might sit under.
- II. It was noted that there are groups (e.g. Scottish Stem Cell Network) counselling against the practice and publishing helpful advice about not taking up these therapies. Members were not aware that any malpractice had been found in the UK.
- III. Views were expressed that the uncertainty of regulation in this area has a negative influence on commercial and other progress being made. It can also prevent people even proposing innovative ideas

to the point of self-censoring. Regulations concern what is envisaged at the time but medicines regulations do not altogether work in this area, and neither do *bona fide* attempts to legislate into the future. Ethical considerations could arise if it is perceived that regulation impedes access to treatment. A Member considered whether the new Health Research Authority should have an enabling role in pulling new technologies through as opposed to just the regulator.

- IV. There are issues of breadth and transparency in stem cells, including awareness of regulations and definitions of stem cell therapy. The five-year roadmap needs reviewing, and has been considered too complicated, although it was noted that the online toolkit is a helpful resource. Problems of European legislation and the translation processes between different states was also noted from an economic perspective, in terms of the more efficiently a country can translate the greater the economic benefit.
- V. The observation was made that the draft workplan seems to have two types of topics listed - those that concern more robust issues, and those more general issues that will likely come up regularly, described as consumer protection/safeguarding patients, data management, research ethics and governance, regulation, risk/cost benefit analysis. It was suggested these sorts of issues come off the list as standalone topics to be thought of instead as crosscutting issues to be considered alongside every topic. The workplan should perhaps be viewed as a topic list with crosscutting issues that could apply to each topic.

### **Stratified medicine**

- I. The Academy of Medical Sciences has four subgroups running (research/clinical infrastructure involving patients, a regulatory strand and two economic strands - one from the perspective of companies and the other from healthcare providers).
- II. The Chair suggested stratified medicine remains on ESBAC's draft workplan but how the Committee addresses it may well be better defined after the AMS meeting.
- III. A TSB/Sciencewise public dialogue on stratified medicine is due to start and will report back and potentially highlight some interesting issues.
- IV. Of the four issues discussed under this topic the first (whether the current medical research model could actually sustain a personalised medicine approach) was not considered by one member as an area ESBAC would be best placed to answer, or add anything new to existing debates.



- V. The second issue under this topic was whether there was a need to provide a continued incentive for companies to invest and is this financially sustainable. This was thought to be a useful question framed in terms of what the DH could do to stimulate activity in this area.
- VI. The third issue on access to diagnostics tests was considered fairly uncomplicated and not discussed further.
- VII. Another issue previously raised was the increasing use of diagnostics to stratify people out of treatment. Creating the evidence base to stratify people out of treatment would be very expensive without commercial funding. This will need to be done with sound evidence from clinical trials or it may develop into a grey ethical area that ESBAC might usefully be able to comment on.
- VIII. Notwithstanding what the AMS is doing on the regulation strand, it was suggested there are some very interesting issues about the regulatory framework and in particular the relationship between the European Medicines Agency and the individual regulatory agencies within member states.
- IX. In relation to the new in-vitro diagnostic devices regulations, they will include a definition of a companion diagnostic and there will be a lot of discussion about how to define a companion diagnostic (how narrow or broad). It was thought that ESBAC could input to MHRA's consultation and make a significant contribution.
- X. Liability in stratified medicine was also suggested as a potential issue.

### **Dementia**

- I. Dr Origgi introduced this topic, indicating that detection of early signs of dementia was as a possible route into this topic. What are the implications of telling people they may be likely to develop dementia, given once diagnosed there is no cure.
- II. Dementia is a health priority and following the publication of the PM's challenge on dementia there is a clear commitment to increase diagnosis rates, to make additional investment in brain scanning and to increase the number of patients in clinical trials to 10%. It would therefore seem timely and topical to explore what bioethical issues should be considered in the early detection or screening for dementia.
- III. Dr Origgi indicated that from short preliminary conversations with prominent experts in the area there was support for this work.
- IV. It was suggested that dementia was an important area to start with. Ethical issues around the management of dementia raised included

managing loss of autonomy and capacity to decide, interventions and monitoring people with dementia. Another issue raised was the current governance arrangements for evaluating and introducing new screening programmes and the degree to which they are robust enough.

- V. This work would also complement the Nuffield Council on Bioethics report published in 2009 on ethical issues in dementia ([Dementia: ethical issues](#)). The areas that were left open that Nuffield identified were early detection as well as how useful it was to provide early detection when there was no support or therapy that could be offered.
- VI. There was support for dementia to be included as a topic for scoping.

#### **Patient data/research data**

- I. It was agreed that this was a 'watching brief' topic pending other work currently in progress, including the Caldicott Review, and forthcoming consultation on the NHS Constitution. In addition, the Nuffield Council on Bioethics would likely start a piece of work on biodata next year (including databases, data sharing, data linkage, and the implications for confidentiality and privacy).
  - II. However, ESBAC could be called upon to input to ongoing work in this area where required and appropriate, and should actively signal that it is willing to do so (e.g., genomics work as part of the HGC legacy). Balancing individual good versus the collective good was raised as an important issue in this area to keep a watch over.
- 5.6 Synthetic biology was not discussed in the light of the later presentation.
  - 5.7 Taking stock of discussions so far which had identified links, overlaps and common themes across topics, the Chair asked whether Members wanted any of the remaining topics on the list to be considered as standalone topics.
  - 5.8 It was agreed fraud in scientific discovery and in medicinal supply was an emerging problem rather than an emerging science and not within ESBAC's remit.
  - 5.9 It was suggested patient adherence/compliance and condition of treatment could be subsumed into a topic broadly described by the Chair as health related behaviours. To this was added active monitoring (e.g. tools to do so) and other potentially related aspects were touched upon, including the role of doctors as behavioural motivators, 'nudging' people to change behaviour and the ethics around changing behaviour, including treatment being administered if people agree to remote monitoring technology.

- 5.10 Dr Bale suggested decisions behind topic selections had to be justified including checking others were content to be seen as a more relevant lead on those topics where ESBAC had decided not to pursue.
- 5.11 The Chair indicated that the earlier comment from the Member suggesting that certain issues were common to all topics had been very helpful and should be taken forward and considered against each topic selected. This draft list of common issues, which could be refined and developed, was summed up as follows:
- Safeguarding patients / consumer protection
  - Data management
  - Research ethics, governance, integrity and fraud
  - Principles of regulation
  - Translation
  - Overarching cost/benefit analysis (which would look at the economic, scientific and social)
- 5.12 The Chair recapped from the discussions the selection of specific topics to be scoped further. The emerging topics were as follows:
- **Regulation** – of stem cells and personalised medicine (and how this is not understood and a commercial barrier to taking things forward), genetic testing, what is important to regulators may not be important to health technology assessors, adaptive licensing, future proofing legislation
  - **Dementia** (e.g. early diagnosis and what to do encompassing tools around detection, governance of introducing screening tests, what to do following screening, how screening fits with DH policy)
  - **Health related behaviours** (e.g. patient adherence/compliance, condition of treatment, new active monitoring tools and ethical issues of using them)
  - **Genomic issues** (e.g. marketing, quality assurance of tests and reporting, genetic testing, consent, databases and research).
- 5.13 In discussion, it was agreed the four topics above would be considered further by focus groups and for each consideration would be given to the type of crosscutting issues identified in paragraph 5.11.
- 5.14 Dr Bale reminded the Committee that resources to support the topic groups would be limited, and that a matrix approach considering the topics against the cross cutting issues might be a helpful way of marshalling information to establish what areas had been covered elsewhere and unique areas where ESBAC could contribute. A pragmatic approach might be to have a major and a minor issue in addition to a horizon-scanning element. Dr Bale indicated that any work on regenerative medicine would need to wait until the House of Lords Inquiry had been completed. Similarly, MHRA has ongoing work on

regulation and would need to be consulted and advised if ESBAC was considering work in this area.

- 5.15 Dr Bale suggested there was no pressure to establish full working groups now, but to come up with topics and scope unique inputs ESBAC could contribute. It was thought genomics would be an easier group to set up and scope, but that health related behaviour would need proper scoping to establish its viability.
- 5.16 One Member mentioned that it was important to remember that ESBAC's work would be guided by what DH needs advice on.
- 5.17 Volunteers were recruited at the meeting for each topic focus group. The Secretariat agreed to set up meetings for these groups and draft a short paper on each topic with questions to help tease out if there is potential scope (with reference to ESBAC's remit and framework), and what the output from these initial exploratory meetings should be. The crosscutting list of issues would be incorporated into the ESBAC framework (Annex E of the Code of Practice).

## **6. Workshop Proposal**

- 6.1 Dr Origgi introduced the Workshop proposal paper (ESBAC 02(06)(01)) and outlined the suggested objectives for ESBAC's proposed inaugural open event, the intention being one open event would be held each year.
- 6.2 Members had mixed views as to whether it would be preferable to hold the open event earlier (e.g. to set the scene and test out ESBAC's emerging thinking on its workplan and horizon scanning arrangements) or later and announce the areas of ESBAC's work.
- 6.3 It was suggested that care should be taken not to pitch the event as simply a 'bioethics' event, to the exclusion of scientific development. This was particularly relevant to international stakeholders. Consideration would also need to be given to potential media engagement.
- 6.4 Following discussion on the Workplan it was thought that the focus groups could generate some output on scoping that could be presented to stakeholders at an open Forum, the proviso being that the focus groups would need to have firstly reported back to the main Committee for approval before sharing at an open event.
- 6.5 It was agreed that the Secretariat would revise the proposal and circulate to Members out of Committee for comment.

## **7. Synthetic Biology**

- 7.1 The Chair welcomed and introduced Paul Mason, Head of Development at TSB, who gave a presentation on TSB's call for synthetic biology proposals and the provisional ethical framework TSB had developed ('Ethical, Societal and Regulatory (ESR) Framework for Responsible Innovation'). Members had no significant comments to make on the proposed ESR Framework.
- 7.2 Mr Mason also updated the Committee on TSB's plans for public engagement on personalised medicine.

## **8. Agenda items for next meeting**

- 8.1 To be agreed, depending on whether it was decided out of Committee to hold the proposed open event on the same day as the next ESBAC meeting (29 January 2013).

## **9. AOB**

- 9.1 A Member raised an issue on behalf of the Gene Therapy Advisory Committee (GTAC) regarding a change to its function as follows.
- GTAC was to be dis-established and the scientific function taken to MHRA as an expert advisory group and the ethics function as a standard REC. Concerns were raised due to the multifunctional role of GTAC to the community that would be lost, together with concerns about loss of the unique functioning of GTAC in clinical trials regulation and that this has served gene therapy very well. This is especially important when stem cell therapy using pluripotent cells is in its infancy.
- 9.2 Dr Bale was tasked with reporting from a meeting that was being held to discuss GTAC with MHRA and HRA.