EMERGING SCIENCE AND BIOETHICS ADVISORY COMMITTEE (ESBAC)

MINUTES OF THE 1ST MEETING

17th July 2012

Avonmouth House, London

Present

Prof Sir Alasdair Breckenridge (Chair)	
Prof Andrew Baker	Mr Julian Hitchcock
Prof Angus Clarke	Ms Katherine Littler
Prof Bobbie Farsides	Dr Wendy Ewart
Mr David Townend	Ms Madeleine Colvin
Dr Dipti Amin	Dr Michael McBride
Dr Helen Munn	Dr Neil Scolding
Mr Hugh Whittall	Prof Nicholas Lemoine
Dr Bella Starling	Dr Paula Boddington
Mr James Peach	Prof Peter Littlejohns
Dr John Brown	Dr Stuart Hogarth
Dr Jonathan Mill	Dr Mark Bale
Prof Joyce Tait	

Apologies

Dr Julie Maxton	Mr Stephen Whitehead
Ms Diana Sternfeld	Dr Louise Leong (deputy to Mr Stephen Whitehead)
Professor Duncan McHale	Professor Andrew Morris
Professor Sir John Saville (deputy Dr Wendy Ewart)	Dr Rachel Quinn (deputy Dr Helen Munn)

Secretariat

Dr Simona Origgi
Ms Melanie Peffer
Mr Emyr Harries
Miss Beccy Cummings

1. Chair's Welcome

1.1 The Chair welcomed Members to the first meeting of the newly constituted Emerging Science and Bioethics Advisory Committee (ESBAC), adding that he was very pleased to be a part of ESBAC as it presents an exciting opportunity. The aim of the first meeting was to enable Members to get to know one another, to start to establish the identity of ESBAC and to clarify its role.

1.2 By the end of the meeting the Committee should move forward on four areas:

i. take forward the scope and ways of working,
ii. start defining the framework around how ESBAC would select topics,
iii. start identifying a list of topics to help shape the workplan,
iv. discuss the approach to horizon scanning.

1.3 The Chair expressed the view that ESBAC should focus on what it was uniquely qualified to address. The projects that the Committee does get involved with should be in the public interest and in areas where implementation of ESBAC's contribution would be possible. The Committee's work should also have relevance to the priorities of the Department of Health, as the sponsoring Department and the other UK Health Departments to which it also provides advice.

2. Round Table Introductions

2.1 Members were invited to introduce themselves and indicate what expectations they had for ESBAC. Expectations and general comments included the following points, in no particular order:

ESBAC role and function

i. The opportunity presented by having a blank sheet and being able to contribute was noted. It is advantageous that the Committee will be able to have a distinctive role and it is important to focus to find a niche given the potentially broad scope of the Committee. There is a lot ESBAC could achieve.

ii. ESBAC should concentrate on where it can add value, how it will take advice, the shape it will take to help inform policy making and the basis on which more fundamental core issues are dealt with. ESBAC should forge its own way but also pick up some of the issues raised by the Human Genetics Commission (HGC).

iii. It will be important to make full use of existing connections (e.g. Medical Research Council/ National Institute for Health Research)

and their associated links into the broader regulatory and ethical framework.

iv. It was suggested that ESBAC should contribute to bringing innovative technologies to the public in a timely and optimum way. ESBAC's role should include interfacing science and policy and being able to bring communities together, encourage public dialogue and to make a useful contribution to the development of policy. It will be critical to ensure that ESBAC is clear on what its deliverables/outputs will be as well as how it engages with its stakeholders.

Topical areas

v. It is important that the legal and ethical frameworks keep up with advances in technology and their application. A smarter approach to regulation of new therapies that takes small businesses into account is needed.

vi. Getting the fundamental questions in ethics right. Too many innovations stumble because the ethical basis is not resolved early on; this is an example of where ESBAC could help. It is essential that research funding is performed in a regulatory environment which is ethical and sound.

vii. A suggestion was made for potential for work around benefit and risk in assessing new technologies.

2.2 Several further themes emerged from the round table introductions both in terms of the areas of work Members were involved in or had knowledge of and in highlighting expectations for ESBAC. This included stem cells, regenerative medicine and stratified medicine and particular issues around the regulatory approach, bioethics and communication. Discussions continued under agenda item 5.

3. Sponsoring Department Presentation

3.1 Dr Mark Bale gave a presentation that began by outlining the characteristics and strategic objectives of the 'future' Department of Health (DH) as it undergoes transformation alongside changes in the wider health and care system.

3.2 The presentation went on to cover the structure of ESBAC, which is made up of a broad membership encompassing biosciences and biotechnology, law, social sciences, humanities and economics, science in society and representative organisations. It was emphasised that all Members have equivalent status, whether *ex-officio* or appointed via the Appointments Commission.

3.3 Dr Bale emphasised that a key element of the Committee will be the networking opportunities it presents and an important output will be the

discussions the Committee engages in to identify what issues are important.

3.4 Dr Bale clarified that the focus of ESBAC is not solely on bioethics, but it also included the social, legal and economic aspects and implications of emerging science.

3.5 It is likely that some aspects of ESBAC's work will be of interest to other Government departments and the Council for Science and Technology, which advises the Prime Minister on strategic issues that cut across the responsibilities of individual government departments. Each government department has its own Chief Scientific Adviser (CSA). The Chief Medical Officer, Sally Davies, undertakes the CSA role in DH providing the link with other CSAs as appropriate, including the Government's Chief Scientific Adviser.

3.6 In terms of the flow of information and reporting lines, information and requests to ESBAC may come down from Ministers or the CMO in addition to information being fed upwards from ESBAC via the CMO.

3.7 Dr Bale clarified that resources to support ESBAC consisted of a small Secretariat based within DH and funds to run up to three meetings per year. Whilst it may be possible to bid for funds to support specific areas of work, the emphasis will need to be on working together and to join forces with other work areas where possible, helping to marshal disparate strands of work through the creation of working groups.

4. Ways of Working

4.1 This agenda item consisted of two parts – the scope of ESBAC and its working practices. Dr Simona Origgi introduced the paper and explained that the covering note (ESBAC 01(04)(01)) summarised the questions included in the main paper (ESBAC 01(04)(02)) and the aim of the paper and discussion was to clarify ESBAC's remit, role and working practices.

4.2 The Secretariat wanted to ensure that the paper was detailed enough to ensure a common understanding and transparency from the outset, both amongst Members, and wider stakeholders. However, it left key issues open for Members to discuss and shape ESBAC.

4.3 With respect to ESBAC's role, it was noted that there was a tendency to focus on the impact of science on society, without adequately considering that society also has an impact on science. A two-way, more circular approach was thought be an important principle for ESBAC.

4.4 There was a suggestion that the name of the Committee did not reflect its work sufficiently. Dr Bale explained that the name had to be short to

be manageable and that it would be problematic to change the name at this stage. However, the finalised role statement would ensure clarity.

4.5 Dr Origgi introduced and summarised the terms of reference (ToR) and invited comments from Members, including whether it would be helpful to spell out the organisations that are also actively engaged in bioethics to clarify the remit.

4.6 On the ToR, a number of points were raised. In summary:

i. It was agreed to clarify the 'out of scope' section as there was concern voiced about excluding ESBAC from discussions in any prescribed way. The original intention of 'out of scope' was that it would apply to long running debates unless there was something new or emerging in these areas, they would remain out of scope for ESBAC.

ii. The list of organisations covering potentially overlapping issues was not intended to be exhaustive but was intended to clarify roles. It was agreed to remove Nuffield Council of Bioethics given it is an independent organisation and the others currently listed are statutory.

iii. It was agreed that the ToR should reflect not only debate and engagement, but be a two-way involvement to reflect the extent to which ESBAC will have a role in public engagement and debate. The point was made that networking would be an output in itself.

iv. It was noted that it was difficult to separate out regulation and policy roles, given some organisations, such as the Medicines and Healthcare products Regulatory Agency (MHRA) have a dual role.

v. It was noted that any potential for overlap between the work of the Nuffield Council on Bioethics and ESBAC could be resolved at the onset by working closely together. The Nuffield maintained a list of potential topics and would be willing to share this with the Committee, in particular if they fell outside their remit. There would be concerns if ESBAC took on the role of a national ethics advisory body.

vi. The Chair confirmed that ESBAC would be able to include recommendations as part of the advice it would provide, including for example, advising Ministers on issues or barriers that have an impact in this area. It was suggested that inviting CMO to meetings would be beneficial and that this would be explored after the first couple of meetings once the ways of working are finalised.

4.7 Paragraph 14, outlining what is expected of the Chair and Members, was agreed.

4.8 Most members agreed that appropriate observers should be invited to meetings, depending on the particular topic being discussed. As

indicated in the draft Scope and Working Practices paper, these observers may include other Government Department representatives and Members/Secretariats of other Committees.

4.9 Members discussed options on the format of ESBAC's meetings. Many Members advocated open meetings as an important principle but not necessarily helpful in practice. A hybrid model that was part open/closed was considered a worse option as it only provided partial information. Hybrid models could also raise issues around who is invited and in what capacity.

4.10 It was suggested that perhaps the best solution to achieve the correct balance was to explore holding one open meeting a year that would aim to promote engagement with the public and to inform the public on ESBAC and its work, maintaining transparency. This open meeting could also be a useful forum for finding out about new developments.

4.11 On whether ESBAC should have an open call for topics on its website, it was agreed that this could generate a huge amount of work, without the resource to manage it, and that it would be difficult to manage expectations. Members agreed that it would be better to publish the list of topics ESBAC decides to discuss and then invite comment on these specific areas.

4.12 The section on requesting and reporting advice was accepted. With respect to relationships with other Committees, ESBAC may need to assess evidence or seek expert advice from external sources or other committees and conversely, other committees may seek ESBAC's expertise.

4.13 The Chair indicated that as ESBAC's programme of work became clearer it would network with other bodies such as the European Medicines Agency and the Department for Business, Innovation and Skills (BIS). In terms of the mechanisms for engagement with other bodies the Chair said that relationships had to be carefully and sensibly managed as events work out.

4.14 Members were content to comment and finalise the minutes of ESBAC's meetings electronically out of Committee. Minutes will reflect comments and will not be attributed to individuals. Papers will be made publicly available on ESBAC's website, to be set up shortly.

4.15 The Chair ran through the remaining sections on media relations, declarations of interest at meetings, terms of appointment, accountability, diversity and equality of opportunity and recruitment. No further comments were made on these sections. The declarations of interest would be published on the ESBAC website.

4.16 Concluding the discussion on paper ESBAC 01(04)(02) the Chair thanked Members for their helpful comments.

Action point: The Secretariat would consider the points raised by Members, incorporate changes and circulate an updated draft of the Scope and Working Practices paper for further comments.

5. Workplan

5.1 Dr Origgi introduced the covering paper on ESBAC's framework and topics for ESBAC's consideration (ESBAC 01(05)(01)) and explained that the framework consisted of a broad selection of criteria to assess topics followed by considerations to help frame issues. Some changes were discussed.

5.2 It was suggested that debates can become politicised very quickly around certain ethical issues and there is perhaps the need for a dispassionate look at the fundamental issues of disagreement. ESBAC could provide an authoritative view to help the debate get back to the core issues. It was noted that the preferred timeline for policy implementation may not run with the need to have a thorough discussion of the policy issues.

5.3 In conclusion, the Chair suggested to include the words "authoritative, objective and timely" to the proposed criteria.

5.4 Dr Origgi outlined the framing issues, explaining that the list was not intended to be exhaustive but to include points for consideration.

5.5 A question was raised about putting ESBAC's work in the public domain. If ESBAC was giving advice to CMO and Ministers, at what stage would ESBAC put it into the public domain and would it present a conflict. Dr Origgi said it would not create a conflict if managed appropriately. The minutes will be published but any sensitive information (e.g. around the current development of a sensitive policy area) may be excluded if it was exempt under the Freedom of Information Act.

5.6 Dr Bale added that this would depend on how ESBAC decides to operate. One mechanism that might be used is to peer review a number of other activities and produce a position paper or authoritative statement of a helpful nature that indicates progress and is put in the public domain. For other reports this might not work and ESBAC's advice would be published alongside other information as part of a policy document.

5.7 The discussion moved on to topics for ESBAC's consideration (ESBAC 01(05)(02)) and Dr Origgi explained the structure of the paper. Members who had suggested topics for inclusion in the paper were invited to talk through their contributions.

5.8 The first part of the discussion focused on the core issues section of the paper and the following remarks and observations were made:

i. The need to explore the core ethical issues, which often get overlooked. One Member raised that central to these core values is the division and balance between the role of the individual and solidarity in a patient-led world.

ii. Several hypothetical questions were raised in the context of ethics in government and risk management. These included issues of privacy, solidarity, free choice, welfare/wellbeing implications, responsibility in health. This could be ESBAC's opportunity to find its distinctive bioethics voice.

5.9 Discussions continued on obstacles to translating science into clinical applications and technologies. The following points were made:

i. Regulatory frameworks are mechanisms for bringing to bear social values about safety, effectiveness, efficacy and cost effectiveness in the development of technologies. ESBAC is an opportunity to think more broadly about emerging technology and how this is shaped. ESBAC should think about this as an interactive process of technology assessment and construction.

ii. The view was expressed that to separate the regulatory process from the health technology assessment seemed like a false division and that there is a need to bring these together in a logical sequence.

iii. There was a discussion on the extent to which regulation and other factors raise obstacles to the translation from basic science to useful innovative developments, for example by discouraging commercial investment from venture capitalists.

iv. ESBAC should help the NHS pull through technologies and developments and help the DH make the NHS more innovative. Consideration also needs to be given to the escalators and the impact: picking out ideas, developments and technologies that would make a difference.

v. ESBAC's approach to tackling topics was discussed. ESBAC could either view an issue from the perspective of the emerging technology, or follow a route that questions what the economic drivers, are or follow a route based around solidarity. If the entry point is technology itself then wider issues need to be considered, including justice, equity, environmental concerns, inter-generational issues. In each case, it is necessary to start examining an issue in context before being able to see precisely what concerns or principles are important.

vi. From this part of the discussion, the Chair highlighted two potential areas that should go on the topics list - the concept of benefit and risk

(especially the communication of benefits and risk and incorporating value) and how to simplify health technology assessment and regulation to make the pathway more straightforward.

5.10 Discussions progressed to the specific topics suggested by Members, with the aim of producing a list of topics ESBAC would consider further.

- Genomics and related genetic topics

  i. The need to map out current and ongoing work in this area was mentioned, to inform decisions as to where ESBAC could contribute. Examples include following up the Human Genomics Strategy Group's January report[1], and a policy framework relating to the forthcoming regulation from the European Commission in the Autumn.

  ii. Concerns were raised as to how genetic testing data is reported and on the quality control procedures applied to these tests. Members agreed to include genomic testing and regulation as a possible topic to be refined in more detail following up these issues and previous recommendations made by the Human Genetics Commission.

  iii. The Human Fertilisation and Embryology Authority are currently covering the issue of germline therapies, so it was decided that ESBAC would keep a watching brief over this topic.

  iv. Gender differences were not discussed in any detail and was not put forward for future discussion.

  v. It was thought that epigenetics could be linked to other projects. Given the long timescale that this work will require, it was considered premature to include it on a shortlist at the moment.

- Stem cells

Research

  i. The MHRA, Academy of Medical Sciences and Association of the British Pharmaceutical Industry are holding a workshop in the Autumn and there is significant work going on in this area. ESBAC should have this topic on its list and look at what aspects are not being covered elsewhere, which would be of value.

  ii. A Court of Justice of the European Union (CJEU) case was referenced (Brustle v Greenpeace judgement) for its effect on the potentially very broad denial of patentability, and the impact this would have on research in terms of investment. A Member thought that the claim for the removal of the financial argument was not true,

[1] Building on our inheritance: Genomic technology in healthcare: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_132382.pdf

however the argument had found traction at the European level and was reported to have an impact on Horizon 2020 discussions. In terms of ESBAC being able to make a contribution it was concluded that this did not fall within the additional criteria which ESBAC discussed on whether topics should be selected for further consideration.

iii. A wider issue of the morality clause in European Patent Law was touched upon, how it impacts in this area and one Member suggested that there was the need for an authoritative view on how the clause should be applied.

iv. Reference was made to the HGC report on the impact of DNA patents on diagnostic innovation that called for further work in this area. ESBAC might want to consider a piece of work that was not technology specific but that looked more broadly at the role of IPR in biomedical innovation.

v. The House of Lords Science and Technology Committee inquiry into regenerative medicine was mentioned as the issues Members have raised are likely to come up during the inquiry.

vi. Members agreed that stem cell research is high on the agenda and should be included as a topic to be considered further in more detail.

Medical tourism

vii. The example provided was the NHS establishing an international cell therapy centre alongside a commercial partner to subsidise advanced therapies under the NHS by means of (benign) stem cell tourism. This topic did not receive support from Members at this stage to be shortlisted as a main topic for further discussion.

Stratified medicine

viii. This topic was already discussed under other headings. Economic issues around stratified medicine and whether it is affordable were discussed briefly. It was agreed stratified medicine had to be on ESBAC's future agenda.

- Consent, patient data and evidence

i. Members considered patient data to be an important area, particularly with the advent of the routine re-use of data in the NHS. The breadth of existing ongoing work was acknowledged and it would be good to marshal the arguments in a more robust way. ESBAC could consider the implications of different versions of consent.

ii. There was the suggestion that ESBAC could possibly gather the latest developments on the issue of patient data. This might be a

good example of ESBAC being able to bring together the key issues, review and discuss existing work and add value where it can. There are consultations forthcoming in this area and perhaps ESBAC could input collectively and provide an authoritative, balanced view. Issues are solidarity versus the individual were raised again in the sense that patients' view of how their information is used can be different to the public view. It was decided to add patient data to the list of topics.

iii. Members also acknowledged the interest and importance of evidence and clinical trials issues and included these for further discussion.

iv. However, it was decided that the topic regarding increasing the use of generic consent for analysis of tissue samples and patient data records would be best addressed as part of other topics areas and was not put forwards as a topic by itself.

Intellectual property rights (IPR)

v. This issue includes some handover from the Human Genetics Commission (report on a workshop). It was decided that this may fit better within some other areas of work as appropriate (e.g. broader stream of work on stratified medicine) rather than being a topic for discussion in itself.

- Regulatory challenges of emerging areas of science

i. It was noted that the Nuffield Council on Bioethics is already doing a piece of work on emerging biotechnologies (report due later this year). It was noted that uncertainty is what characterises emerging science.

ii. The point was made that some of the discussions had focused on products, but there are many stages before that and the pathways are not always clear and linear. There was an understanding that the decision points in terms of providing an environment to enable beneficial developments to occur are complex and difficult and do not necessarily sit on clear regulatory pathways.

iii. Major initiatives from UK research councils have pioneered anticipatory approaches to enable citizen participation in decisions about the funding of basic research ('upstream engagement'), and more recently regulation. These initiatives raise challenging questions for social science methodology and also for innovation and governance processes and would benefit from balanced scrutiny.

iv. Members agreed to add regulatory challenges to the list of issues for further discussion.

v. Members acknowledged the importance of the use and availability of publicly funded research, but thought that it was more a policy issue

rather than emerging science. No new issues were raised under this topic and elements had been picked up elsewhere.

- Innovation

How innovation is governed in the NHS was thought particularly pertinent because of reforms to the health and care system. Sir David Nicholson's report on uptake of innovation was mentioned[2]. However, it was questioned whether this was a topic for ESBAC and it was decided not to add this topic.

- Synthetic biology

  i. The Technology Strategy Board (TSB) and others are currently promoting synthetic biology and so require appropriate guidelines and ethical principles to be established. It was recognised that synthetic biology is a very broad description. Perhaps one useful function ESBAC could provide through its forum, is to find a way of breaking the topics under synthetic biology down into areas that might need to be addressed by health departments and those for attention at a later date. It was decided to add this topic to future discussion.

- Dementia

  i. There was discussion on dementia as a topic, given its status as health priority. Early detection of dementia appears to be a key area for research development, which does bring into question its value to individuals and society. This could be an early test case where new molecular markers bring into question whether the governance of screening is adequate. The development of biomarkers was also touched upon.

  ii. Three areas of dementia were described to help separate out the topic to make it more manageable – diagnostic, potential for cure/treatment and caring for increasing numbers of people with dementia.

  iii. Dementia is an area that tests a lot of fundamental ethical issues and questions standard approaches to bioethics and Members agreed to watch developments and add dementia to the list for scoping.

- Other issues raised

  i. ICT including assisted living was discussed in relation to existing activity around data storage, but was not selected for inclusion in a shortlist at this stage

[2] http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_134597.pdf

ii. Members noted that other groups were already carrying out work on the topic of animals containing human material and it was therefore not considered a priority for ESBAC.

iii. Members recognised the interest and potential issues regarding human enhancement and considered that ESBAC could gather and discuss what has been done and add value where it can.

iv. Members showed interest in the topic of nicotine vaccination and the wider vaccine debate (e.g. as an example of issues around responsibility and health) but considered that other topics already discussed would take priority.

5.11 The current and future work of the Nuffield Council on Bioethics was summarised. A long list of potential future topics is being compiled by Nuffield and it will be shared with ESBAC towards the end of the summer.

5.12 The letter from the Former Acting Chair of the Human Genetics Commission to Dr Bale was raised and would be kept in mind in terms of governance and in drafting future workplans.

Action point: The Secretariat would consider Members' views and draft a proposal for a workplan for discussion.

6. Horizon scanning

6.1 Dr Origgi introduced the paper on horizon scanning (ESBAC 01(06)(01)). Given that there are no specific resources for horizon scanning the Secretariat would be looking to Members to collaborate and help to establish what horizon scanning could look like and how to make it work. The paper included existing horizon scanning activities and described a multi-prong approach including literature searches, events, conferences, reports and utilising existing horizon scanning available.

6.2 Accompanying the horizon scanning paper was a list of stakeholders (ESBAC 01(06)(02)) which indicated links between ESBAC Members and other organisations. Members were asked to highlight any further links and select topics for horizon scanning.

6.3 Dr Origgi suggested Members may want to have a broader definition of horizon scanning topics with the view of developing another list where ESBAC knows there is work ongoing but where it would be helpful to keep a watching brief.

6.4 The Chair asked whether the suggestion was to undertake horizon scanning for each of the topics that will be included in ESBAC's agreed workplan. Once ESBAC has decided on the areas it can usefully contribute to, part of the approach for addressing these areas, would

be to engage in horizon scanning alongside information that ESBAC knows about its stakeholders.

6.5 The importance of the charity sector was noted and further suggestions for stakeholders were made.

6.6 It was clarified that horizon scanning was intended to have an international dimension and this would include regulatory aspects. There is some trans-national cooperation on regulation (e.g. in stratified medicine the European Medicines Agency works closely with the US Food and Drug Administration (FDA)) but this information does not necessarily reach individual Member States.

6.7 It was suggested that each ESBAC Member is a horizon scanner and the question is whether there are any areas (e.g. European regulation) ESBAC is missing where the Committee needs to ask the opinions of others.

7. Agenda items for next meeting

7.1 A revision of the scope and working practices with tracked changes will be circulated for further comment out of Committee before the next meeting, with the view of being signed off at the next meeting. The horizon scanning activities will be further defined and further thought will be given to how horizon scanning might work in practice. Further refinement of the workplan will also be undertaken to move towards agreement on the priority topics.

7.2 The process for and timing of ESBAC Members getting involved in allocated topics was queried. The Secretariat had envisaged the next step would be to seek final comments on the papers to be signed off at the next meeting. The list of topics forming the workplan clearly needs to be refined. It was suggested that at the September meeting Members might also want to consider what happens with the topics not included in the workplan, how to move other areas forward and consider whether ESBAC needs to go out to wider stakeholders at the outset with some particular issues. The Secretariat suggested a workshop in January to further refine the questions around the particular topics being taken forward.

8. AOB

8.1 The Chair brought the meeting to a close thanking Members for attending and for the interesting discussions, and thanked Dr Origgi for all her work.