

AGENDA ITEM 4**Emerging Science and Bioethics Advisory Committee****Focus Group on Dementia****Proposal to ESBAC****INTRODUCTION**

1. At the second ESBAC meeting, the Committee decided to set up four Focus Groups each to consider one of the four topics selected for possible work. These Groups met twice with the aim of scoping the feasibility of these areas of work.
2. Discussions from the Dementia Focus Group are reflected in this paper which proposes to ESBAC that the issue of *emerging technologies for early detection/diagnosis of dementia and the impact this may have on the individual, family, clinical profession and society* should be included in ESBAC's workplan.
3. The reasoning behind this proposal is outlined below with reference to ESBAC's topic selection criteria, together with initial scoping information on the proposed approach including potential stakeholders, delivery mechanisms and deliverables. This is in line with Annex E of ESBAC's Code of Practice. The Membership of the Focus Group is included at Annex A.
4. Dementia is an area that tests a wide range of fundamental ethical issues and questions standard approaches to bioethics. If taken forward, it would be a high profile piece of work that would also help both test and develop ESBAC's ways of working.
5. ESBAC is invited to comment on this proposal and collectively agree whether the Committee is supportive of the proposal progressing.

PROPOSED APPROACH

6. Diagnosing dementia is a complex task and as yet there is no single accurate test. Currently GPs, and later specialists, use a process of exclusion and a series of cognitive tests over time to reach a diagnosis¹.

¹ Page 157. <http://www.alzheimers.org.uk/site/scripts/download.php?fileID=1401>

7. The advancement of emerging technologies such as blood tests, spinal fluid tests and improving the use of brain scanning techniques for the early detection or predisposition for dementia would be beneficial to researchers allowing them to test interventions earlier in disease progression.
8. As technology develops², earlier and earlier detection and diagnosis of dementia may eventually become possible even when symptoms are almost negligible. For example, it is recognised that changes in the brain can occur up to 15 years before the occurrence of overt symptoms of Alzheimer's and this will focus attention on the discovery of biomarkers that are able to identify individuals at the very earliest stages of disease.
9. However, earlier diagnosis could potentially raise a number of ethical issues for patients and their families, as well as for scientists, clinicians, healthcare funders and society more widely.
10. As part of this work, the current status of the emerging technologies for early diagnosis would necessarily need to be identified and considered, in particular their likelihood of success, the likely degree of accuracy, timeframe and further implications (e.g. cost, type of test). This would be with a view to assessing the emerging technology and the associated ethical, legal, social and economic implications.
11. If taken forward, this work on dementia could be further developed to explore commonalities with early diagnosis of other chronic or life-threatening conditions.

TOPIC SELECTION CRITERIA

12. The case for how this topic fulfils ESBAC's remit is summarised below:
 - ✓ **Relevant:** Emerging technologies may enable people to be diagnosed with dementia at a much earlier stage of the condition, raising the potential for any number of ethical, legal, social and economic implications. Dementia presents a growing global disease burden and is very much in the public eye. There are an estimated 820,000 people in the UK with dementia (diagnosed and undiagnosed) and one estimate puts the likely number of people with dementia at one million by 2021³. A 2012 YouGov survey⁴ found that 63% of people are worried about dementia in some way.

² In terms of emerging technologies to diagnose people with dementia, there are a number of avenues currently in research, including blood tests and spinal fluid tests, as well as improving the use of brain scanning techniques. Currently, most of the biomarker related tests that are in development relate to Alzheimer's disease, and not other forms of dementia.

³ http://www.smf.co.uk/files/3413/5539/6734/325SMF_ALZHEIMERS_13.12.12_COMPLETE_web.pdf

⁴ <http://research.yougov.co.uk/news/2012/05/22/are-you-worried-about-dementia/>

Taking dementia as a case of early and widespread diagnosis is also relevant in a broad way to a future where increasingly we have more and more medical and predictive information

- ✓ **Applicable to policy:** The clear policy link is the PM's Challenge on Dementia (which builds on the achievements of the existing National Dementia Strategy) which recognises that dementia is one of the biggest challenges facing society. The PM's Challenge emphasises research and contains a clear commitment to increase diagnosis rates.
- ✓ **Timely:** It would be appropriate to think through the social and ethical issues *now* of potential early detection/diagnosis, even if the science is not quite there yet, and hence to feed into the current debate and policy development. The percentage of early diagnosis is on the increase, and is expected to rise with the numerous initiatives on dementia. It would be timely for ESBAC to raise the implications for the individual, their families, and society and suggest mitigation tools.
- ✓ **Realistic:** A critical assessment of the emerging technology for early detection and implications is one possible output that should be realistic to achieve in collaboration with key stakeholders. The proposed work could inform the debate and policy deliberations on the impact of scientific developments that are currently being promoted as part of the Government's commitments on dementia.
- ✓ **Unique:** It is proposed to follow on from the work of the Nuffield Council on Bioethics and their 2009 report (Dementia: ethical issues⁵) which focused on care, rather than emerging technologies. ESBAC could contribute in a way that it is uniquely positioned to address - the impact of the emerging diagnostics, when symptoms may be almost negligible on the individual, family, clinical profession and society.

TOPIC FRAMING ISSUES

Scoping:

13. The scope of the work covers dementia in general, although in some aspects, in particular research, may focus more on Alzheimer's Disease where research is more advanced.
14. A focussed and self-contained piece of work is proposed to concentrate on the emerging technologies around the early detection/diagnosis of dementia that would seek to capture the 'state of the art' in this area. This would include identifying what

⁵ <http://www.nuffieldbioethics.org/dementia>

diagnostic developments and products are in the pipeline, the governance mechanisms for evaluating the technologies (e.g. diagnostic reliability/accuracy issues) and understanding what technologies could actually offer. It would also identify if there are new ethical, legal, social or economic issues arising from the emerging technologies.

15. In parallel the work would consider the potential implications of early diagnosis on the individual, their families, and society, including for example:
 - People's attitudes to diagnosis and what it would mean for them and their families.
 - Support and resource issues post-diagnosis.
 - Whether early diagnosis will result in better outcomes or whether such interventions might create a community of 'worried well'.
16. This work also proposes to look at the types of testing for different conditions, for example, genetic testing for predisposition to Huntington's, and the associated ethical implications.
17. Some questions that will be explored if this work is taken forward include:
 - Why should you do early testing?
 - What are the anticipated advantages/disadvantages, costs/benefits of early testing?
 - Will early testing for dementia raise new and important questions to other forms of pre-clinical screening or testing for other conditions?
 - How/when emerging technology could be/should be used in this area?

Stakeholders:

18. The initial identification of stakeholders includes:
 - Age UK
 - Alzheimer's Society
 - Alzheimer's Research UK
 - BIVDA (British In Vitro Diagnostics Association)
 - Dementia Action Alliance
 - DeNDRoN (Dementias & Neurodegenerative Diseases Research Network)
 - DH policy colleagues (research, Dementia policy and long term conditions policy)
 - European Federation of Neurological Associations
 - Industry representatives
 - NICE Diagnostics Advisory Committee

- Patient Groups
- Research
- SAGA
- Sciencewise
- Other experts in the area
- Those who responded substantively with respect to early/earlier diagnosis, screening to the Nuffield Council on Bioethics' dementia consultation

Delivery Mechanism:

19. A collaborative approach to the work is proposed, engaging with relevant stakeholders as appropriate to maximise resources available and ensure expert input.
 - Co-ordinate a piece of work identifying and pulling together the current state of the art in emerging technologies for the early detection/diagnosis of dementia (for example, drawing together the existing literature and rapid knowledge capture at a workshop with experts).
 - Having established the status of the emerging technologies undertake a critical assessment of them and the potential associated ethical, legal, social and economic implications. This work would be informed by a (necessarily brief) meta analysis of the ethical issues raised by testing and screening more generally.
 - In parallel, draw from the Nuffield Council on Bioethics' report on Dementia (2009) to consider the implications of diagnosis, in the early stages of the disease, on the individual, their family and on society. Work to identify those who might act as enablers of safe introduction of new technologies and those who might seek to oppose such developments so that both groups can be directly addressed.

Deliverables:

- The tangible output could be a report or framework to be placed in the public domain that considers the ethical implications (not necessarily with recommendations) to feed into the current debate and policy considerations. It should be possible to include a critical assessment of the status of the emerging technology in this area.
- Any workshop would be a deliverable in itself.
- There is the possibility that this work, using dementia as a good case study, could be further developed to apply to other conditions where relevant advances are identified.

- Furthermore, the collaborative working model proposed – particularly with the Nuffield Council represented (and drawing on the Council’s earlier work) and the major charities – could stand as a pilot for working arrangements in future projects.

Cross cutting themes:

20. Overarching themes of particular relevance to this topic that would need to be given consideration if work was taken forward include the impact of regulation, consumer protection/safeguarding patients, governance and good practice, translation and societal impact.

QUESTIONS for ESBAC:

ESBAC is asked to comment on the proposal with a view to recommending whether or not this work should be taken forwards.

If ESBAC recommends that this work should be taken forwards, then it will wish to comment on the remit, scope and deliverables.

However, if ESBAC considers that this work should not be taken forward at this stage, the Committee will wish to record its reasons for its decision.

Annex A

Dementia Focus Group

Members

Professor Bobbie Farsides (Champion)

Dr Stuart Hogarth

Ms Diana Sternfeld

Professor Neil Scolding

Professor Nicholas Lemoine

Dr Paula Boddington

Dr Jonathan Mill

Ms Katharine Wright (Nuffield Council on Bioethics)

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Dr Mark Bale

Mr Jerry Bird (DH Policy)

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