Tracing the impacts of public dialogue projects supported by Sciencewise:

Animals Containing Human Material

March 2016

Animals Containing Human Material

Key facts

Date
January 2010 – October 2010 (10 months)

Costs
- Total cost of project: £239,250
- Sciencewise funding: £129,250

Commissioned by
Academy of Medical Sciences, Department of Health

Delivery
Ipsos MORI-led consortium

Evaluation
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Introduction

The public dialogue was part of a major study by the Academy of Medical Sciences (2009 – 2011)[1] to examine the scientific, social, ethical, safety and regulatory aspects of research involving animals containing human materials (ACHM), and to make recommendations for action. The policy impacts of the dialogue were apparent relatively quickly, and continued over several years, up to and including February 2016.

The dialogue project in summary

Context
In 2007, to support the revision of UK legislation that was underway at that time, the Academy of Medical Sciences convened a working group to examine the use of embryos combining human and animal material in medical research. The UK Human Fertilisation and Embryology Act (2008) (the HFE Act) provided the legislative framework for research involving *human* embryos (including human admixed embryos), but it was noted that the regulatory and ethical challenges of the '*animal* end of the spectrum of human-animal mixture' (which was the responsibility of the Home Office) had received relatively little consideration or public attention. The Academy's 2007 report drew attention to the need to review the regulatory environment for research involving Animals Containing Human Material (ACHM).

In that 2007 report, the Academy committed to undertake further work in this area, and recognised the importance of public values and judgements in informing the continuing development of law and policy in relation to ACHM. It warned of a gulf between current and future scientific practices, and public awareness of them. The strength of public opinion around the creation of mixed human-animal entities was evident throughout parliamentary debates around the HFE Act (2008) and in associated media coverage. At that time, public values and concerns were explored in a wide public dialogue and consultation also supported by Sciencewise and undertaken by the Human Fertilisation and Embryology Authority (HFEA) on the creation and use of human-animal (hybrid and chimera) embryos for research[2].

The Academy's study on the use of ACHM in biomedical research was launched in autumn 2009. The scope of the study was to examine the scientific, social, ethical, safety and regulatory aspects of research involving non-human embryos and ACHM, and to draw conclusions and make recommendations for action. A programme of public dialogue was commissioned during 2010 to inform the study.

> *"One of the major questions in going into this is what would be the level of public resistance and although we all had our own views, the reality is that it just hasn't been in the papers, it's not an issue that's been formulated in quite this way and we really didn't know." (Oversight Group member; evaluation report page 31)*

Main dialogue project activities
- Initial literature review to identify existing public opinion research on the topic.
- Extensive stakeholder engagement to agree the aims and questions for the dialogue, bringing together different stakeholder perspectives. An Oversight group of diverse stakeholders was established for the dialogue. In total, 19 experts / stakeholders, plus the Academy Working Group of 16 members, were involved. The breadth and level of engagement of the Oversight Group was seen to be one of the strengths of the project.

[1] http://www.acmedsci.ac.uk/policy/policy-projects/animals-containing-human-material/
[2] HFEA project page: http://www.hfea.gov.uk/519.html. Dialogue report: http://www.hfea.gov.uk/docs/Hybrids_Report.pdf. Evaluation reports seem to be only on our webpage at:http://www.sciencewise-erc.org.uk/cms/hybrids-and-chimeras/

- A stakeholder workshop on 22 April 2010 to develop materials for the workshops with the public, at which key questions and case studies for the dialogue were identified. The workshop was attended by the Oversight Group and representatives from NGOs, industry, religious organisations and animal welfare organisations.

- 70 public participants took part in deliberative workshops, recruited face to face to ensure a broadly demographically mixed group. Two deliberative workshops, each involving 21-22 people public participants meeting for a full day on two occasions, were held in London and Newcastle. Two scientists attended each workshop to provide professional expertise. Between the two workshops, a homework task involving discussion with friends and family and personal reflection was completed by participants.

- Three shorter discussions held with special interest groups: people with experience of serious health problems (patients and carers); those with concerns about animal welfare; and those for whom religious belief was important.

- 20 in depth follow up interviews conducted with public participants to explore issues further.

- Issues from the deliberative workshops were used to inform the questions in a separate opinion poll conducted through a face-to-face omnibus survey which had 1,046 public respondents.

- Data analysis was conducted using feedback that was collected in various ways including direct feedback from participants (e.g. homework tasks, posters produced during workshops), transcribed notes from the workshops, facilitators' notes and flipcharts, notes from an observational researcher.

- The use of a range of different methods of working with the public (deliberative workshops, focus groups, polls etc) allowed the results to be seen as particularly robust by the AMS Working Group.

The key findings[3] from the dialogue showed:

- Overall, public participants in the dialogue accepted and were supportive of ACHM research on the condition that such research was conducted to improve human health or to combat disease. A minority of participants did not find ACHM research acceptable even to address human health problems.

- Most of the stakeholders involved were surprised by how relaxed the public were about animals containing human material, and how interested they were in the science.

  "*Probably [the main finding was] (and this was quite surprising) ... most members of the public were much more accepting of this type of research than we thought. There was less of the 'yuck' factor and once they had talked through the issues and heard from scientists they were much more accepting ... participants were able to have a fairly sophisticated discussion. They were much more positive than expected.*" (AMS)

- The majority of participants decided how acceptable they found ACHM research by 'trading off' their view of the purpose of the research against concerns about the process it involved. The benefits of ACHM research were considered highly persuasive because of the perceived benefits to human health. This view was strengthened further if the health problem being addressed was seen as serious (terminal, debilitating or intractable).

- Changes involving animal and human reproductive systems were felt to be furthest away from current boundaries of acceptability. Key concerns included that entities produced in this way might genuinely 'cross the boundary' between human and animal, raising moral and practical difficulties.

- Public participants had more concern around experiments 'in vivo' (on living animals) rather than 'in vitro' experiments (e.g. in test tubes), involving changes to external rather than internal tissues where they changed an animal's appearance (in part because the results could be more easily visualised) and on changing the brain of an animal where it might affect an animal's cognition.

- There were also concerns about risk, particularly of experiments that might cause 'cross-contamination' or genetic mutations outside the laboratory. Participants worried that these could threaten humans, animals and the ecosystem as a whole. They were also worried that sanctioning some ACHM research now would eventually lead to more unacceptable research in future – the 'slippery slope' argument.

- For many participants, animal welfare was important. Participants often transferred general concerns about the welfare of animals used in research directly onto the subject of ACHM. Some participants expressed concerns that certain ACHM research might cause greater animal distress – this would be seen as less acceptable (e.g. if animals' limbs or external organs were modified to be more human, or if animals had their cognition enhanced).

[3] Text on key findings from Sciencewise case study

- A further important dimension for participants was about who would benefit from the research. Many participants were concerned that medical benefits should be distributed fairly and equitably.

- In terms of research regulation, the two main factors for participants were the need for transparency and independent supervision. In addition, participants wanted to see regulation that focused on animal welfare, minimised risk, and that reflected their views on the kind of animal that is created and the tissues and organ types involved.

Dissemination of dialogue results

- The dialogue report was published and launched on 15 September 2010 at an event at the British Science Festival titled 'Beyond the yuck factor: just how 'human' should laboratory animals become?'. The two-hour event involved four speakers from the Academy's Working Group, and one of the presentations provided the results of the dialogue. Over 50 people attended the event.

- A press conference was also held on the same day, prior to the event, and generated press coverage in The Financial Times and Daily Telegraph, as well as specialist journals. Further press coverage was generated when the main Academy report was published in July 2011. The evaluation report was published in November 2010.[4]

- A summary of the dialogue results was sent to all participants, with a postcard for them to return with their further feedback on the process.

Impacts on policy

- **In July 2011**, the Academy's final report was published and included recommendations for the national and international regulation of future research using ACHM, with direct quotations from the results of the public dialogue. This report identified the key areas of public concern (especially ACHM research involving the brain, reproductive tissues and the external appearance of animals), which the Academy recommended should be given specialist scrutiny in the future.

- The AMS view was that there were no negative responses from religious organisations to the launch of their ACHM proposals because of the widely publicised input from the public as well as scientists. The dialogue meant the AMS could have more confidence in their conclusions and recommendations.

  "*The fact that we could more concretely make recommendations knowing it had public support was great*" (AMS)

- **In August 2011**, the Academy used their report findings to respond formally to the Home Office consultation on options for transposing the European Directive on the protection of animals used for scientific purposes (2010/63/EU). The UK law was updated in December 2012, and the Government stated that it would take account of the recommendations of the ACHM report when agreeing the functions of the new national committee which would take over from the previous Animal Procedures Committee as the new advisory body on matters relating to the Animals Scientific Procedure Act 1986 (as amended) in early 2013. The AMS recommendations included the need for the new national committee to be actively involved in public engagement and consultation to ensure that scientific work in this area proceeds with reasonable public understanding and support. It highlighted that the public dialogue indicated that the UK public would be receptive to such an approach.

- **I January 2013**. A new committee, the Animals in Science Committee (ASC), was then established by the Home Office as recommended in the Academy report and the public dialogue. The Committee was established on 1 January 2013 and held its first meeting on 27 June 2013. A letter from Lord Taylor (the Lords Minister at the Home Office) set out the duties of the ASC (under the Animals (Scientific Procedures) Act 1986 (ASPA) as amended by the transposed European Directive on animal research. The letter from Lord Taylor specifically asked the Committee to consider the public dialogue findings in the guidelines and in the consideration of specific cases of human admixed embryos in terms of: which were uncontentious, which required greater scrutiny and which should currently not be licensed.

  "*People make a fairly clear distinction between different kinds of experiments - some they are comfortable with and some they felt went too far ... It was very helpful and reassuring ... Both me and my organisation felt more secure having the views of specialists and non-specialists involved ... The dialogue gave it a political weight it wouldn't have had otherwise*" (Oversight Group member)

[4] ACHM study report: http://www.acmedsci.ac.uk/download.php?f=file&i=13666.
Dialogue report : http://www.acmedsci.ac.uk/download.php?f=file&i=15882.
Evaluation report http://www.acmedsci.ac.uk/download.php?f=file&i=15883

The new committee is an independent non-departmental public body sponsored by the Home Office and is responsible for providing impartial, balanced and objective advice to the Secretary of State (Home Office) and to animal welfare and ethical review bodies on issues relating to the Animals (Scientific Procedures) Act 1986 (ASPA) and the use of animals in scientific procedures. Applications for project licences under ASPA which raise novel or contentious issues, or are likely to give rise to serious societal concerns, are referred automatically to the Animals in Science Committee for advice.

The Committee is expected to work in the public interest, and includes members with wide-ranging expertise. As well as members with expertise in the welfare of animals, veterinary science and neuroscience research, the Committee also includes lay members with an interest in the ethical issues arising from the use of animals in scientific research. Two NGOs are represented – People for the Ethical Treatment of Animals (PETA) and the RSPCA.

The dialogue results were that the majority of participants would support research involving animals containing human material if it was undertaken to improve human health and disease and was carried out within carefully considered boundaries and robust regulation. Boundaries and regulation became a key focus for the AMS Working Group report in 2011. The press release from the AMS on the Home Office Guidance (15 February 2016) explicitly places the dialogue results within their timeline for developing recommendations and final report[5].

The two main factors for the public dialogue participants were the need for transparency and independent supervision. Participants wanted to see regulation that focused on animal welfare, minimised risk and that reflected their views on the kind of animal that is created and the tissues and organ types involved. Animal welfare was important for many participants, especially concerns that some ACHM research might cause particular animal distress.

The Animals in Science Committee is described in the 2016 Home Office Guidance (see below) as "*the national expert body envisaged by the AMS*" (page 16). The Committee includes specific members concerned with animal welfare; it scrutinises the categories of research identified as priorities within the dialogue; it is independent and makes transparency a priority – with minutes of meetings published online.

- **2013 - 2014**. The Academy report led to the development of guidance on the regulations that investigators should consider when applying for authority to conduct animal experiments using human material. This guidance was being led by the Home Office in liaison with the Department of Health and the HFEA. The draft guidance highlighted the different categories of experiments involving ACHM, including those that require additional specialist scrutiny and those that should not, at present, be licensed. These categories were the same as those identified by the public dialogue.

- **11 February 2016**. The Home Office published new Guidance on the use of human material in animals[6]. The guidance includes (as Part B) a summary of the Academy of Medical Sciences report, published in 2011, and states "*The Home Office, HFEA and Department of Health have accepted the recommendations set out in the AMS report*". That AMS report draws directly on the results of the public dialogue project in 2010 on Animals Containing Human Material (supported by Sciencewise).

  The new guidance uses the AMS report to identify three categories of experiments involving animals containing human materials:
  - Category 1 covers experiments that do not present issues beyond those of the general use of animals in research.
  - Category 2 experiments require additional specialist scrutiny by a national expert body and covers experiments involving substantial modifications of an animal's brain, experiments that may lead to the generation or propagation of functional human germ cells in animals, experiments that could be expected to significantly alter the appearance or behaviour or animals, and experiments involving non-human primates.
  - Category 3 experiments should not, for now, be licensed. At present, these include allowing the development of an embryo beyond 14 days of development; transplantation of human derived neural cells into a non-human primate which is likely to substantially modify the brain; breeding animals that may have or may develop human derived germ cells which could lead to the production of human embryos or true hybrid embryos within an animal.

  The public dialogue identified the types of changes that were least acceptable to participants – those which changed an animal's appearance, those that changed the brain of an animal where it might affect the animal's cognition, and those that involved animal and human reproductive systems. Experiments involving these types of changes are clearly shown in Category 2 and 3 above as now requiring greater scrutiny.

[5] http://www.acmedsci.ac.uk/more/news/government-adopts-academy-recommendations/
[6] '*Guidance on the use of Human Material in Animals*' (Home Office Advice Note 01/16), dated January 2016. https://www.gov.uk/government/publications/guidance-on-the-use-of-human-material-in-animals

Press coverage around the launch of the new guidelines included mentions of the Academy's 2011 report and highlighted that the recommendations that had been accepted were informed by the programme of public dialogue. For example, an item on the BBC Radio 4 Today programme on 8th February 2016 included an interview with Professor Martin Bobrow, Chair of the Academy Working Group, who referred specifically to the public dialogue and how the results had informed the Academy report. (http://www.bbc.co.uk/programmes/b06zqn0r; about 2.34 mins in).

Impacts on the Academy of Medical Sciences

- **In 2012**, the Academy's five year strategy made a commitment to encourage input from, and dialogue with the public, to ensure the hopes and concerns of wider society help shape its advice and choice of projects in future.

  The ACHM dialogue was the second major piece of public dialogue undertaken by the Academy with support from Sciencewise: the first was the Drugsfutures dialogue. In between these two projects completed with Sciencewise support, the Academy had run another dialogue themselves. Both dialogue projects have helped encourage a positive perception of the benefits of public engagement within the Academy.

  "There has been a shift in expectations of AMS Fellows, and more of them would expect to hear some kind of public views that five years ago … the aim is to have some public dialogue in all policy projects " (Academy 20)

- **February 2016**, the Academy planned a new public dialogue project: 'Evidence for all: how do we weigh up the benefits and harms of medicines?' The overall aim of the project is to engage members of the public, patients, researchers and healthcare professionals in dialogue to explore how they access, interpret and use evidence to judge the potential benefits and harms of medicines.

  The dialogue will identify: how evidence can best be communicated and used by different societies; what the role of professionals such as GPs and journalists are in this process; how individuals' views of evidence are influenced by health beliefs; and what forms of evidence influence the decision to take or use medicines.

  It is expected that the recommendations that result from the work on the communication, trustworthiness and utility of evidence will inform Government departments including the Department of Health and the Department for Business, Innovation and Skills (BIS), research funders such as the Medical Research Council and the National Institute for Health Research, and healthcare providers in the NHS and beyond.

  Using the success of previous projects, the Academy were able to secure funds for this new project independently of Sciencewise. However, some support from a Sciencewise Dialogue and Engagement Specialist (DES) was provided to the project. Although not required to do so (as no funding was provided), the AMS tender for the delivery of the dialogue states that "*The Academy supports the guiding principles for public dialogue on science and technology related issues identified by the Sciencewise programme. As such any applicants should accord with these principles in their tender proposals*." The tender also provides a direct link to the Sciencewise guiding principles.

Impacts on wider policy

- In 2013, the Japanese government cited the final dialogue report in their work to draft new guidelines on the use of admixed embryos in research (e.g. insulin production in pigs). The draft guidelines directly used the three categories recommended by the AMS, based on the conclusions of the public dialogue. (Academy 34)

- The dialogue provided "*a positive case study from the AMS to the development of the Concordat on openness on animal research, and enabled AMS to confidently sign up to that process*" and thus strengthen that Concordat (Academy 20). The Concordat on Openness on Animal Research was published in May 2014. There was a separate public dialogue (supported by Sciencewise) on the Concordat (http://www.sciencewise-erc.org.uk/cms/openness-in-animal-research-dialogue/)

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