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Case Study

Animals containing human material

A public dialogue on attitudes to research

Vital statistics

Sponsoring department: Department of Health

Commissioning body: Academy of Medical Sciences (the Academy)

Duration of process: 10 months: January 2010 – October 2010

Number of public participants: Dialogue workshops = 70
Omnibus survey = 1,046

Number of experts/stakeholders involved: Experts/stakeholders = 19
Academy working group = 16 members

Cost of Academy working group study: £239,250 total, Sciencewise-ERC funding = £129,250 (and contributions from the Department of Health, Medical Research Council, Wellcome Trust and the Academy of Medical Sciences)

The use of animals containing human material (ACHM) has a long-standing history in biomedical research, although little public consideration of this area has previously taken place. This public dialogue was part of a major study by a working group of the Academy of Medical Sciences to examine the scientific, social, ethical, safety and regulatory aspects of research involving animals containing human material, and to make recommendations for action. The dialogue aimed to provide insight into public values, concerns and aspirations around these issues, and input to Government considerations of how this research should be regulated in the UK.

Key messages from the public

- Overall, public participants in the dialogue accepted and were supportive of ACHM research on the condition that such research is 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
- 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 involves. 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)
- 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.

Background

In 2007, to support the revision of UK legislation that was underway at that time, the Academy convened a working group to examine the use of embryos combining human and animal material in medical research. While the UK Human Fertilisation and Embryology Act (2008) (the HFE Act) ultimately provided a contemporary legislative framework for research involving human embryos (including human admixed embryos), it was noted that the regulatory and ethical challenges of the 'animal end of the spectrum of human-animal mixture' had received relatively little consideration or public attention. Therefore, the Academy's 2007 report drew attention to the need to review the regulatory environment for research involving ACHM[1].

In its 2007 report, the Academy committed to undertake further work in this area. It took the view that, as researchers seek to create more effective research models and evaluate potentially important medical interventions, there is a need to ensure a comprehensive system for the regulation of research involving ACHM that protects animal welfare, maintains the highest standards of safety and ethics and keeps the issues of public acceptability of research to the forefront.

The Academy's 2007 report recognised the importance of public values and judgements in informing the continuing development of law and policy in relation to ACHM. However, 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. During that time, public values and concerns were explored in a wide public dialogue and consultation also supported by Sciencewise-ERC and undertaken by the Human Fertilisation and and Embryology Authority (HFEA) on the creation and use of human-animal 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 to inform the study.

Policy influence

- The dialogue informed the Academy's working group study on ACHM[3] and was an important source of evidence for the study. The Academy's final report made recommendations for national and international regulation of future research using ACHM, and included direct quotations from the public dialogue report and from participants. Key areas of public concern (especially ACHM research involving the brain, reproductive tissues and the external appearance of animals) were included in the types of research that the Academy recommended should be given specialist scrutiny in future

- The audience for the Academy's report includes policy makers in UK Government, regulatory bodies, biomedical scientists, research funders, academic philosophers, social scientists, bioethicists, professional organisations and their international equivalents. The report is particularly intended for the Government bodies that regulate ACHM in the UK (principally the Home Office, Department of Health, and the Human Fertilisation and Embryology Authority) and the groups and advisory bodies that provide guidance to researchers (including the Steering Committee of the National Stem Cell Bank and research funders including the Medical Research Council).

- One input based on the Academy's report was to the Home Office consultation on options for transposing an EU directive on the protection of animals used for scientific purposes. The Home Office response states they will take account of the Academy of Medical Sciences recommendations on authorisation of projects on ACHM. (http://bit.ly/MqJALX)

[1] Academy of Medical Sciences (2007) ***Inter-species embryos*** (http://bit.ly/AqjKkg)

[2] Human Fertilisation and Embryology Authority (2007). Hybrids and Chimeras. A report on the findings of the consultation. HFEA, London (http://bit.ly/w2l54O)

[3] Academy of Medical Sciences (2011) ***Animals containing human material*** (http://bit.ly/pSK4Tc)

Dialogue activities

The aim of the dialogue was to engage members of the public on the issues raised by the current and future use of ACHM in research. The specific objectives of the project were to:

- Provide opportunities for members of the public to discuss and explore their aspirations and concerns relating to the scientific, social, ethical, safety or regulatory aspects of research involving ACHM
- Identify areas of consensus, disagreement or uncertainty on a broad range of issues raised by current and possible future scientific developments, and explore initial views and changes in opinion
- Inform the final recommendations made by the Academy for public policy and research needs
- Enable the Academy and the wider science community to build on previous experience in public dialogue, to pioneer innovative approaches in public engagement, and to develop knowledge and understanding of public dialogue and its potential for future applications.

The dialogue programme included qualitative and quantitative research, stakeholder engagement and opportunities for in-depth deliberative discussions among members of the public.

- An initial literature review was undertaken to identify existing public opinion research
- Stakeholder engagement was undertaken to agree the detailed aims for the dialogue, identify the themes and questions to cover with the public participants, and help develop information materials to support the public's discussions. Stakeholders included representatives from industry, non-government, religious and animal welfare organisations. An Oversight Group for the dialogue was also set up that included the project sponsors, members of the Academy working group and representatives from organisations with an interest in the subject
- The deliberative phase of the programme brought together 70 members of the public with six experts in a series of workshops, discussion groups and interviews. Two deliberative workshops, each involving 21-22 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. Three shorter discussions were also held with special interest groups: people with personal experience of serious health problems, such as patients and carers; those for whom animal welfare was important; and those for whom religious belief was important. Twenty, in-depth, follow-up, telephone interviews were conducted with participants in these events to explore some issues in further detail
- Public participants were recruited face to face for the deliberative events to ensure that a mixed and broadly demographically representative group attended. Participants were screened in terms of their views, primarily to allocate those with strong existing views into special interest groups. In line with standard practice, participants were paid a cash incentive of between £40 and £145 depending on the time commitment expected of them
- The findings of the deliberative sessions were used to develop questions that informed a nationally representative survey of 1,046 respondents.

Summary of good practice and innovation

- The public dialogue was fully integrated into the Academy's study on ACHM. The timing of the programme allowed the dialogue to inform and influence the Academy's expert working group considerations, alongside scientific and other evidence, at an early stage of the study. In addition, the different stages of the dialogue worked well in sequence
- Evidence from the different elements of the dialogue (i.e. from the workshops, discussions with specialist groups and public-opinion survey) was seen as consistent and coherent. This gave increased credibility and confidence in the dialogue findings
- Feedback from participants indicated that the range of ways in which the science was communicated to them was excellent; participants felt the materials were accessible and not patronising
- The series of two, full-day workshops with each group in this dialogue was effective and made efficient use of participants' and contractors' time
- Participants particularly valued the scientists' input because they were able to answer specific questions in depth. The participants did not feel that the scientists allowed their personal views to influence the dialogue and felt they were careful to give only factual information
- Participants were positive about the open discussions in small groups, where people with different views were able to come together to listen and share ideas
- A synopsis of the Academy's report was produced to provide an accessible summary for a broader public audience. This was sent to all dialogue participants, together with a summary of press coverage from the report's publication and pre-paid cards to provide an opportunity for participants to provide further feedback.

Lessons for future practice include:

- Dialogue is an intense process and required a great deal of time and commitment from the Academy staff and the Oversight Group. Being realistic in anticipating and allocating this time commitment helps to ensure the process runs smoothly and delivers a credible outcome
- Some of the expert scientists were concerned that they may have introduced bias at the groups simply by being present and felt unsure about whether their contribution had been appropriate. Some scientists reflected that additional support and information would have been useful in helping them to prepare for the events
- It is valuable to balance the seniority of the experts involved in any Oversight Group and the deliberative events with their ability to commit time, and to build capacity in those with more limited experience or understanding of public dialogue
- Public participants were very interested in how the dialogue worked, but could not confidently explain what it was supposed to achieve, even though the Academy and the contractors explained it at the start. It is important that public participants are clear about what their involvement is expected to achieve and, therefore, what is expected of them.

> We welcome the valuable contribution of this study to the understanding of the complex ethical, scientific and animal welfare issues involved in this area of research. We will consider the recommendations carefully.

Home Office Minister, Lynne Featherstone MP

> I think it's allowed the working group to focus clearly on issues of communication and public acceptability... there's now something hard to chew on which now that we've got it done is going to allow us to move much more confidently on policy areas and to spend much less time trying to imagine what we think people think.

Oversight Group member

> The dialogue opened my mind to science and what's going on. It's made me feel like I'd go again, no matter what was being talked about. It felt nice to be invited.

Public participant

> More science communication stuff could be done that's actually reaching people that don't realise they want to know about it until they're told about it. I think it's difficult but I think that was a good aspect of it that came out ... that people want to know more.

Scientist stakeholder

Impacts

Policy impacts are covered on the second page of this summary. This section examines the impacts on participants in the process.

Impacts on public participants

- Public participants enjoyed the workshops and described them as interesting, informative and thought-provoking. All the participants said that they had learned something new as a result of their involvement
- Over half of participants said that the workshop had changed their views. The mechanisms for this change appeared to be the provision of new information and listening to the views of other people
- All those interviewed for the evaluation said that they would like to be involved in dialogue again. For some, this was because they enjoyed the process of learning and debating. For others, it was important to be 'making a difference'.

Impacts on scientists/experts and other stakeholders

- The dialogue report led some stakeholders to reflect on their own opinions and see the issue from a different perspective
- Scientists and experts were surprised at how accepting members of the public were of ACHM research if it was seen to be for medical benefit
- The experts were inspired to do more science communication after realising the level of public interest in science and the impact that it can have. Some particularly valued this opportunity for insight into a dialogue process.

Overall impacts

The launch of the Academy's study in July 2011 received considerable coverage in the UK and internationally through broadcast and print media, and online. Responses from a wide range of stakeholders demonstrate the likely wider and longer term impacts of the study.

Contacts and links

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The Department of Health

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Full project and evaluation reports available from the Sciencewise-ERC website (**www.sciencewise-erc.org.uk/cms/animals-containing-human-material/**)

Additional details on the Academy working group study available at **www.acmedsci.ac.uk/p47prid77.html**