

AGENDA
OF THE EXTRAORDINARY MEETING OF THE
HFEA ETHICS COMMITTEE
ON APRIL 25, 2003,
AT PAXTON HOUSE

1. Apologies
2. Access to the HFEA Register for Research — paper [EC \(04/03\) 01](#)
3. Sex Selection: Options for Regulation (Draft report on HFEA sex selection consultation) — paper [EC \(04/03\) 02](#)

MINUTES OF THE EXTRAORDINARY MEETING OF THE HFEA ETHICS COMMITTEE HELD AT 2.30 ON 25 APRIL 2003 AT PAXTON HOUSE

PRESENT:

Members:

Tom Baldwin – Chair
Ivor Brecker
Suzi Leather
Sara Nathan

Executive:

Peter Mills
Chris O'Toole
Kerri Treston
Rupert Walder

1. Apologies

- 1.1 Apologies were received from Bishop Michael, Simon Jenkins, Walter Merricks, Andrew Grubb and Chris Barratt.

2. Access to the HFEA Register for Research – EC (04/03)01

- 2.1 Chris O'Toole presented this paper, confirming the view taken at the March Authority meeting that there was no consistent policy on allowing access to the Authority's database for research purposes and that clear criteria and procedures for such access needed to be agreed.
- 2.2 The Ethics Committee was asked to consider the proposed procedure for access to the register by researchers. Specifically the Committee was asked to take into account the accuracy of the data held on the database; the legality of the Authority disclosing information held on the register in relation to the HF&E Act 1990; intellectual property rights to any research based on the database; potential conflict of interest in allowing access to the HFEA database; and how the Authority could ensure appropriate and robust governance arrangements.
- 2.3 The Committee discussed the possibility of maximising the use of the database and whether, in principle, the Authority should make data available retrospectively or prospectively. The Committee agreed that it should not limit itself to only providing prospective data, as researchers would find the information held on the database extremely valuable, although the Authority would need to ensure the accuracy of the data.
- 2.4 It was noted that there was an approximate 2% error rate on the database and this was largely due to lost follow-up outcomes. It was suggested that such a small percentage error rate on the database would not be significant enough to effect conclusions drawn from research.
- 2.5 It was noted by the Executive that under section 33(3)c of the HF&E Act 1990 the Authority does have the discretion to provide the data on the register externally for research purposes, providing the data is

anonymous and cannot identify an individual to whom the data applies. However, it was noted that if an in-house researcher was enlisted to overcome legal restrictions, as an employee of the Authority may have access to identifying information held on the register, the conclusions from the research could be seen as biased, flawed and not autonomous. It was noted that similarly Professor Allan Templeton, a former member of the Authority, was affected by this situation when his research findings on the 2vs3 embryo transfer were considered not to be independent due to his connection with the HFEA.

- 2.6 It was noted that the role of the in-house researcher was envisaged to look at the data on the HFEA register and provide statistics for the Scientific and Clinical Advances Group and the Ethics and Law Committee. It was also envisaged that the researcher would have access with other registers such as the NRCT and see if conclusions could be drawn, for example, on the incidence of childhood cancer associated with assisted reproductive technologies.
- 2.7 It was noted that legal advice is currently being sought as to whether the statutory functions in section 8 of the Act could be extended to include linking the HFEA register with those of other organisations. It was suggested that for the HFEA to carry out this function primary legislation may need to be introduced to be less restrictive than the 1990 Act.
- 2.8 It was noted that previous advice had been sought in relation to research but not from this perspective.
- 2.9 The Committee discussed ways for which this function could be carried out to ensure anonymity under the current Act. Suggestions included:
 - using a numeric system to anonymise retrospective data and to use NHS numbers for prospective anonymous data; and
 - that an HFEA employee could link the data with other registers, then before allowing other researchers to have access to the data, the HFEA employee could withdraw the identifying information. It was agreed that this particular suggestion was brought to Morgan Cole Solicitors' attention for consideration and to take into account the Data Protection Act, which may further complicate the issue of access to data.
- 2.10 Due to the nature of the data held on the HFEA database the Committee discussed the issue of obtaining consents from patients to allow the use of their data in research, as a matter of good practice. The Committee came to the conclusion that if consents were obtained in this way this would affect the data collected and the studies carried out rendering them partial.

- 2.11 The Committee further discussed the possibility of identifying patients through non-identifying data during longitudinal studies. People involved with treatment could be identified through the jig saw identification process, for example, if a offspring involved in the study had a rare imprinting disorder as a result of ART, they may be easily identified due to the small number of reported cases.
- 2.12 The Committee noted that the Authority should be aware that anyone could bring legal action against the HFEA for contravening the HF&E Act 1990, more specifically, identifying individuals covered by the Act. It was therefore agreed that it would be advisable, before making any decisions in relation to the presented paper, to await legal advice from Morgan Cole to ensure that any action would be taken within the remit of the Act.
- 2.13 The Committee noted that if research of this nature would be permitted within the legal framework of the 1990 Act should the Authority collaborate with foreign bodies who may be interested in adding to the evidence base?
- 2.14 The Committee went on to discuss intellectual property rights. It was noted that data kept on the register was a statutory function and that it exists for the public good and that it would not be appropriate for the Authority to charge researchers for using the data nor to have property rights over studies that used the data register as an evidence base. The Committee was aware that the Authority would not want to endorse all conclusions resulting from research carried out on the data. It was noted that commercial companies would use the data to support the use of their products such as IVF media or equipment.
- 2.15 The Committee agreed that the executive should obtain case precedents on intellectual property rights to ensure that the Authority would be aware of when it should be appropriately acknowledged for providing the data to research studies.
- 2.16 The Committee agreed that a process should be established to allow research licence committees to consider research applications.
- 2.17 Specifically in answer to the questions raised in the paper the Committee agreed the following:
- Public Health – it was noted the database is a valuable research tool to monitor the ongoing health status of children born as a result of ART. Members agreed that it would not be ethical to deny access to such a valuable database to researchers whose studies might be able to provide better informed consent to future generations of couples with fertility problems;
 - Allowing researchers access to anonymised data from the HFEA Register – the Committee agreed that it should await legal advice

before commenting on where it would be legal to provide access to confidential information to researchers which could potentially identify individuals without their knowledge or consent.

- Linking the HFEA Register to other Registers – it was noted a proposal was received by the Childhood Cancer Research Group to carry out a project looking at incidence in children born through assisted reproductive technology by linking the HFEA Register with that of the NRCT. The Committee agreed that it would like, if possible, for the Authority to employ a researcher for the purpose outlined above. A legal opinion is currently being sought to ascertain whether the law on confidentiality (either under the 1990 Act or on Common Law principles) permit a researcher to access and use such confidential information in the manner proposed.
- Partnership – It was noted that the MRC/HFEA initiative provides a framework encouraged by Government to establish embryology research priorities and to commission studies. It was noted that progress had been slow, however, the Committee agreed that the executive should meet with Catherine Peckham following approval of this research paper at an Authority meeting.
- Intellectual Property Rights – it was noted that precedents should be collected on good practice relating to establishing intellectual property rights and responsibilities of researchers and their funders before a decision is made on what if any share of IP rights the HFEA should own to any research based on the HFEA database.
- Conflict of Interest – the Authority has several members who are active researchers in the field and may wish to apply for access to information held on the Register. It was agreed that adequate and transparent systems should be in place for the Authority to address potential conflicts of interest in allowing access to the HFEA database. It was agreed that this should be referred to the Authority to take a view.
- Data and research quality - the Members agreed that research applications requiring funding would be peer reviewed by the MRC or the Wellcome Institute and would therefore not need to be reviewed by the Authority. In order for the Authority to assure the quality of research studies proposed and which pieces of information, if any, are of sufficient quality to underpin robust research conclusions, evidence of peer review should be presented to the Authority at a time when it would consider approving projects.

3. Sex Selection: Options for Regulation (Draft report on HFEA sex selection consultation) – EC (04/03)02

- 3.1 Peter Mills presented this paper. Members were asked to approve the overall structure of the report, to comment on the presentation of options for regulation in Part Four of the report; to approve the

recommendations in Part Five of the report; and to suggest further modifications to the report.

- 3.2 The original letter from the Minister inviting the HFEA to conduct a review of sex selection, comments on the draft report from Walter Merricks and Simon Jenkins, and suggested amendments to the draft sex selection report from Tom Baldwin were tabled for members' information.
- 3.3 Members' initial responses to the draft document were:
 - that reference to the invitation from the Minister should be included at the beginning of the document, as this explains the purpose of the consultation. This should be given context by citing section 8 of the HFE Act 1990 which would clearly indicate the Authority's terms of reference;
 - that the results of the MORI and Counterpoint research should be included in the report;
 - that responses had highlighted ambiguities in the questions posed in the consultation questionnaire; and
 - that evidence on safety of the flow cytometry was found to be inconclusive. Members agreed that this evidence should be included in the report and that the HFEA should seek further opinion from the US FDA. It was also suggested that the British Consulate in Boston should be contacted to verify how many people use sperm sorting in the USA.
- 3.4 In relation to the structure of the report, Members agreed that the information pertaining to national practices of sex selection techniques should be supported by a table such as that on page 8 of the consultation for the sake of clarity.
- 3.5 The Committee noted that a decision should be made as to whether the Counterpoint findings from the ethnic minority groups be presented in the report. The Committee agreed that it was important to distinguish the results from the ethnic minority groups as the conclusion could be seen as suggestive.
- 3.6 The Committee agreed that the report should have a summarising paragraph at the end of each Part.
- 3.7 The Committee went through the report and suggested a number of amendments.
- 3.8 In summary the following amendments were agreed to Part 3 of the report:

- The report should note that the MORI research was commissioned following the original tender process.
- Paragraph 33, 36, 37, the last line of paragraph 46, the last line of paragraph 50 and paragraph 51 should be removed as the information was felt to be unnecessary.
- Reference to the USA in paragraph 38 was also felt to be irrelevant and should therefore be removed.
- In paragraph 42 the Members noted that some interest groups responded individually as well as collectively, perhaps to add weight to their views. The Members felt that this paragraph should not be treated in a quantitative way and that this explanation should be included in the text.
- Members asked that the proportion of respondents should be clarified in the comments raised about each of the 8 individual questions from the questionnaire.
- Members also agreed that any evaluative descriptions of conclusions from the questionnaire should be removed, e.g. 'surprising' and 'overwhelming'.
- Members agreed that under General Statements on page 16 of the report examples of individual responses from key stakeholders (e.g. from BFS, RCOG, BICA, CORE, SPUC) should be inserted.
- The Members asked that the penultimate sentence in paragraph 55 should be removed: 'but none confronted... take it outside the sphere of personal freedom'.

3.9 Concerns were raised regarding Part Four of the report. It was noted that the Minister of Health, in inviting the HFEA to carry out the sex selection consultation, had not specifically asked the Authority to make recommendations. The Committee agreed that Part 4 of the report should be put to one side due to division of opinion among Members on including the section. It was noted, however, that if the Authority's views were not included the conclusion would stand that sperm sorting should be prohibited, and members felt that the contrary view of the Committee, that the technique should not be categorically prohibited to allow potential health benefits, should be included. Two versions of the Part Four of the report should be drafted putting forward alternative views for the Committee's consideration.

3.10 The Committee agreed that the Executive should contact the Department of Health to clarify the level of recommendations that the Minister's letter had sought.

- 3.11 The Committee discussed Part 5 of the Report which it was agreed should be reinstated as Part 4 and renumbered, and include consideration of the option of preserving the scope of regulation as it was at present.
- 3.12 The Committee suggested that the views of the HFEA should be included under Options for Regulation. This would demonstrate that the Authority had considered the benefits of using sperm sorting for medical reasons in the future, when supporting evidence on the safety and efficacy of the technique were forthcoming.
- 3.13 Some Members raised concerns that if the Authority were to endorse the use of sperm sorting subject to the safety of the technique being proven, the Authority could be seen as agreeing with sex selection for non-medical reasons. It was suggested that the report should specifically detail the Authority's policy position on sex selection by quoting the Code of Practice, so that any comments made by the Authority would not be misinterpreted or taken out of context.
- 3.14 The Committee noted that 65% of respondents in the MORI research agreed with sex selection through sperm sorting for medical reasons.
- 3.15 Some Members of the Committee continued to have concerns in relation to the safety of the sperm sorting technique and suggested that the Committee's anxieties should be relayed to Chris Barratt for information and that he should be asked if he was aware of any further data which could be included in the report. It was also suggested that the executive contact Lars Björndahl, a researcher within this field, to clarify his views on the safety of sperm sorting.
- 3.16 The Committee did agree that its policy should be that it would allow the sperm sorting technique to be used for X-linked disorders as it offers greater potential for creating embryos of the intended sex than PGD, is less invasive than that of PGD and women would not be faced with the risks associated with IVF treatment. The Committee would be against the technique of sperm sorting for any non-medical reasons.
- 3.17 It was agreed that the Executive should draft a process for licensing sperm sorting if this were to be regulated.
- 3.18 The Committee agreed that the following amendments should be made to Part 5:
- that the criminal reference in paragraph 76 should be removed;
 - that reference to CHI in paragraph 82 should be removed; and
 - that paragraph 92 should be removed.

3.19 It was agreed that the amended report should be presented to the next Ethics Committee on the 15th May for detailed discussion in order to inform the Authority's consideration of the report later that day.

4. Date of Next Meeting

4.1.1 The next meeting will be the first meeting of the Ethics and Law Committee to be held on 15th May at 10 a.m.

HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

ETHICS AND LAW COMMITTEE

ACCESS TO THE HFEA REGISTER FOR RESEARCHERS

1. Members are asked to consider the access to the HFEA Register for researchers paper EC (04/03) 01.

Issues to consider

2. Members are asked to consider the issues raised and suggest any corrections, additions and how best to make recommendations to the full Authority.

Chris O'Toole
HFEA Executive
April 2003

HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

ETHICS AND LAW COMMITTEE

ACCESS TO THE HFEA REGISTER FOR RESEARCHERS

Introduction

1. This paper follows up discussion at the Authority meetings in February, when wider research issues were discussed, and in March when a specific proposal for an outside researcher to access the HFEA database was considered.
2. It became clear at the March meeting that the Authority did not have a consistent policy on allowing access to its database for research purposes and that clear criteria and procedures for such access needed to be agreed. The Ethics and Law Committee is asked to consider the proposals in this paper before the matter is referred back to the full Authority for its May meeting.

Background

3. Only limited access has been made available to the HFEA database in the past. Concern has been expressed in some quarters about perceived “favouritism” in allowing access to such a potentially valuable resource.
4. For the best part of a year the HFEA and MRC have been meeting in a working group (with HFEA Member involvement) to consider
 - Priorities for embryology research generally, with particular focus on stem cells; and
 - Access to the HFEA database to mount epidemiological studies on the long-term effects of IVF and ICSI on offspring.
5. Progress on this work has not been as rapid as had been hoped. The Chair of the Working Group, Professor Catherine Peckham has been invited to an Authority meeting to discuss this work.
6. Recent studies have suggested that the imprinting disorder Beckwith-Weideman syndrome appears to be more common in children born as a result of ART. Animal studies of the related “large offspring” syndrome have also suggested links with ART. In another small-scale study it has been

suggested that there is a possible link between ART and the rare ocular tumour in children, retinoblastoma.

7. There has been an extensive audit of the database held by the Registry, but concerns remain about the accuracy of data, especially for the period 1999-2002.
8. Would it be lawful for the Authority to disclose information held on its register for the purpose of research?

The Human Fertilisation and Embryology Act 1990

9. The Authority has a statutory obligation to collect and store information on licensed infertility treatments. Section 31 of the Human Fertilisation and Embryology Act 1990 details the information that shall be held by the Authority, namely:

*“(a) the provision of treatment services for any identifiable individual, or
(b) the keeping or use of the gametes of any identifiable individual or of an embryo taken from any identifiable woman,
or if it shows that any identifiable individual was, or may have been, born in consequence of treatment services.”*

10. The disclosure of information held on the HFEA Register is regulated through the Human Fertilisation and Embryology Act 1990. Section 33 of the HF&E Act 1990 states that:

“No person who is or has been a member or employee of the Authority shall disclose.....

- (a) any information contained or required to be contained in the register*
- (b) any other information obtained by any member or employee of the Authority on terms or in circumstances requiring it to be held in confidence.”*

11. Therefore, the Authority is restricted in its ability to disclose information contained or required to be contained in its Register unless such disclosure is made to Members or employees of the Authority or to persons to whom a licence applies for the purpose of their functions as such. The only exception to this restriction is if no individual to whom the information relates can be identified.

Purpose of keeping a Register of Information

12. The HFEA Register contains information about donors, patients and treatments. This Register was set up on 1st August 1991 and therefore

contains information concerning children conceived from licensed treatment from that date onwards. Section 31 of the 1990 Act requires the Authority to give access to certain statutory information in the case of a person who has reached the age of 18. The applicant is entitled to be informed by the HFEA that they were, or might be, born as a result of licensed assisted conception treatment and whether this was a result of using donated gametes or an embryo. An applicant contemplating marriage may also discover whether they are related to the person they propose to marry.

Discussion

13. It might be helpful to distinguish between issues of principle, which should shape any policy the Authority might adopt from practical issues which could be addressed in a protocol or procedure.

Public Health

14. The HFEA database is unique and a potentially very valuable research tool to monitor the ongoing health status of children born as a result of ART. Given that Louise Brown is not yet 30 it will be important to continue to monitor offspring. Where there may be chromosomal abnormalities, such as in the case of Down's syndrome there are often other health problems which develop in middle age such as very early onset dementia, chronic respiratory failure and heart disease. ***Is it ethical to deny access to such a valuable database to researchers whose studies might be able to provide better informed consent to future generations of couples with fertility problems?***

Allowing researchers access to anonymised data from the HFEA Register

15. As stated above the HFEA can disclose information held in accordance with Section 31 (2) of the 1990 Act if "*no individual to whom the information relates can be identified*" [Section 33 (3)(c) of the 1990 Act]. However, it may be appropriate to inform patients that the information submitted to the HFEA may be disclosed to researchers for the purpose of epidemiological studies. Furthermore, it may well be that any consents given to the keeping of information may not cover the use of the database for epidemiological studies. It is understood that this has been a problem in other epidemiological studies such as the proposed West London Life House which tried to use GP information for another purpose. It is worth noting that in the case of rare disorders such as retinoblastoma it would be possible to identify individuals even without personal identifiers because the numbers concerned are so small. Thus use of aggregate data would not necessarily guarantee anonymity. Policy is currently taking legal advice on the interpretation of Sections 31-33 of the HFE Act.
Is it legal to provide access to confidential information to researchers, which can potentially identify individuals without their knowledge or consent?

Linking the HFEA Register to other Registers

16. The HFEA recently received a proposal by the Childhood Cancer Research Group (CCRG) to carry out a project looking at incidence in children born through assisted reproductive technology. The CCRG proposed linking the HFEA register with the NRCT (a population based registry which includes records of children diagnosed with cancer). As part of the proposal submitted to the Authority, at its meeting in March 2003, was that an employee of the Authority would access the HFEA Register and have access to information held on the NRCT and thus would be able determine the incidence of childhood cancer associated with assisted reproductive technologies. There are two issues:
- a) *Is it ultra vires the 1990 Act for the Authority to employ a researcher for the purpose outlined above?*
 - b) *Irrespective of the answer to a), does the law on confidentiality (either under the 1990 Act or on Common Law principles) permit a researcher to access and use such confidential information in the manner proposed?*

Policy is currently seeking legal opinion on this especially as to whether the statutory functions in Section 8 of the 1990 Act can be read as extending to this function.

Further Issues to Note

Partnership

17. The MRC/HFEA initiative provides a framework encouraged by Government to establish embryology research priorities and to commission studies. ***Is it appropriate to allow access the HFEA database without these arrangements, even if progress has been slow?***

Intellectual Property

18. It is good practice to establish from the outset the intellectual property rights (and responsibilities) of researchers and their funders. Research based on the HFEA register will be potentially very valuable. It could be argued that the HFEA should own at least a share of any IP rights deriving from studies on its own database. ***Who should own the intellectual property rights to any research based on the HFEA database?***

Conflict of Interest

19. The Authority contains several members who are active researchers in the field and thus may wish to apply for access to information held the Register. If there are inadequate systems and insufficient transparency in deciding whether or not access is granted to researchers who are known to members, then a perceived conflict of interest could arise. ***How best can the Authority address potential conflicts of interest in allowing access to the HFEA database?*** [Note: The HF&E Act permits the disclosure of

information held on the register to “a person as a member...of the Authority.” However, this exemption does not apply to the disclosure of information to members for the purpose of carrying research.]

Data and research quality

20. Not all research is good quality. It may be that it is flawed in terms of science and methodology. However it can also be adversely affected if the quality of the data used is poor. It is understood for instance that up to 15% of live birth outcome information is missing from the Register. There is a danger that wrong conclusions can be drawn, reputations can be damaged and the public may be alarmed by “false positives” and “false negatives”. We are aware of certain data problems. We need to determine whether all pieces of information are equally affected and ensure that researchers are aware of the limitations. Current data capture is much improved. Would it be sensible, if all other issues were addressed, to consider prospective studies but not retrospective studies? If that were the case then it may be possible to address consent issues at the same time.

How best can the Authority assure the quality of research studies proposed (? via Peer review) and which pieces of information, if any, are of sufficient quality to underpin robust research conclusions?

Governance

21. What is the role of the Authority, its various sub-committees and the Executive in framing policy and procedures, and for considering individual applications? In particular what are the roles of the Ethics and Law Committee and the Scientific and Clinical Advisory Group in advising the wider Authority? In the NHS there is a research governance framework, which covers all NHS organisations. It may be worth adopting and adapting this framework for use in the HFEA.

How might the Authority ensure that the governance arrangements in this regard are appropriate and robust?

Proposed Protocol or Procedure

- i. As a first step is necessary for the Authority to determine whether and, if so, under what circumstances it has powers to disclose any patient related information to researchers. Legal advice should be sought. Policy is already doing this in relation to the HFEA Act and other relevant legislation.
- ii. It is necessary to determine how robust the information held in the Register is before disclosing it to any third parties.
- iii. If 1 and 2 were satisfied, it would be sensible to agree respective roles and responsibilities with the MRC for assessing and approving access.

- iv. Within the HFEA, it is suggested that SCAG consider the scientific and clinical aspects of any studies, seeking peer reviews as appropriate and supported by the Executive. Any conflicts of interest would have to be declared and appropriate action taken.
- v. It is suggested that the Ethics and Law Committee act as the mandatory research ethics committee for the purpose of assessing ethical issues on any applications regarded by SCAG as scientifically robust. Conflicts of interest should be declared and appropriate action taken. Intellectual Property rights could be determined at this stage.
- vi. Given the sensitivities involved it would probably be sensible for the Authority to sign off approval.
- vii. If necessary, researchers would have to be given a contract of employment with the Authority to conform to Disclosure of Information legislation.
- viii. There would have to be arrangements for monitoring and feedback possibly based on the model the HFEA uses for progress reports in relation to research licences.

Conclusions

The Ethics and Law Committee is invited to consider the issues of principle and suggested procedure as outlined above and suggest any corrections, additions and how best to make recommendations to the full Authority.

**Chris O'Toole and Ian Hammond
April 2003**

HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

ETHICS COMMITTEE

SEX SELECTION: OPTIONS FOR REGULATION

(DRAFT REPORT ON THE HFEA SEX SELECTION CONSULTATION)

Introduction

1. At the previous meeting members reviewed the quantitative findings from the responses to the consultation *Sex selection: choice and responsibility in human reproduction*.
2. The HFEA has agreed to present a report of the consultation exercise to ministers, including any options for regulation, as requested by the Minister for Public Health in her letter of August 14, 2001.
3. The report, including the results of all the research conducted, will be published following presentation of the report to ministers.
4. This paper presents a first draft of the report.

Timing

5. It is intended that a final draft will be presented to the Authority for approval at its May meeting.
6. The HFEA has previously indicated that it intends to publish a report on the sex selection review during Spring 2003.

Conclusion

7. Members are asked:
 - To approve the overall structure of the report;
 - To comment on the presentation of options for regulation in Part Four of the report.
 - To approve the recommendations in Part Five of the report.
 - To suggest further modifications to the report.

Annexes

A – Draft report on the sex selection consultation.

B – Spreadsheet of responses to the consultation document.

Peter Mills

[→ [AGENDA](#)]