

Authority Paper

Committee:	HFEA
Meeting Date:	May 12, 2004
Agenda Item:	10
Paper Number:	HFEA (12/05/04) 153
Paper Title:	Ethics & Law Committee – Summary of Current Work
Author:	Peter Mills
For Information or Decision?	Information
Resource Implications:	Various – see individual project plans
Recommendation to the Committee:	The Committee is invited to note the items of work with which the Ethics & Law Committee is currently involved.

Project work

A number of major policy projects are reporting to the Ethics & Law Committee (ELC). Advisory/steering groups involving members and Executive staff have been established to progress each project.

Project 1 – PGD/HLA typing review

Review of HFEA policy on selection of embryos for non-medical reasons (e.g. HLA typing to produce sibling tissue donors).

- Various strands of research are underway, including:
 - Commissioned market research into public opinion formation on embryo selection for tissue donation
 - Evidence on safety of embryo biopsy to be reviewed (reviewed inconclusively by SCAG in April)
 - The development of the debate through opinions expressed by other ethical and advisory bodies to be reviewed
 - Case law relating to consent/authorisation for procedures involving non-Gillick-competent donors (should bone marrow donation be indicated) to be reviewed
 - Evidence from paediatricians/ family psychologists regarding experience of families and children in sibling bone marrow donation
 - Evidence from paediatricians/ haematologists regarding state of the art in stem cell therapy/ prognosis for cord blood-derived stem cell grafts
 - Additional contextual factors will also be reviewed, including:
 - Law and regulation in other jurisdictions
 - Development and accessibility of cord blood banks (e.g. Eurocord), and bone marrow registers (e.g. Anthony Nolan Trust)
 - Availability and state of the art of treatment alternatives (with mismatched HLA loci / multiple cord allogeneic transplants, PBSC expansion/stem cell culture, therapeutic cloning, etc.)

- Available findings of the review to be considered by the Authority in June 2004.

Project 2 – Sperm, Egg and Embryo Donation Review (SEED Review)

Comprehensive review of sperm, egg and embryo donation, taking into account the views of clinics, recipients, donors and donor-conceived people.

- Stage 1 – survey of clinics (sent out April 30, to be returned by May 28).
- Stage 2 – review of the evidence base supporting existing HFEA policies/legislation. The review will address, *inter alia*:
 - Age limits for gamete donors
 - Limit of live births per donor
 - Statutory storage periods
 - Information about donors/recipients
 - Laboratory screening of gamete and embryo donors
 - Discursive screening of gamete and embryo donors
 - Remuneration and incentivisation of gamete donors
 - Transfer and distribution of gametes/embryos between UK clinics
 - Importation of gametes from abroad
 - Advances in reproductive technology affecting donor treatment
 - Welfare of the child
 - Recruitment of gamete donors
 - Effect of HFEA policies on unlicensed treatments
 - Implications of the EU Tissues and Cells Directive

Reports on significant issues arising from this research will be addressed jointly by SCAG and ELC in June 2004.
- Stage 3 – consultation (with RIA based on evidence gathered in stage 1) and report, to be agreed early 2005.

Project 3 – Welfare of the Child

Comprehensive review of welfare of the child guidance and assessment to ensure appropriateness, fairness and consistency of procedures in clinics.

- A project plan for the review was agreed at the last ELC meeting in May. An advisory group has been established.
- The review will in the first instance focus on the use of the child welfare assessment in clinical practice. Data from inspection reports and licence committees will be analysed to identify inconsistencies and problems with the child welfare principle in practice. In addition to that, HFEA will invite centres to report their experience with child welfare assessments, problems they regularly encounter and ways they would like to see guidance from the HFEA improved.
- Different policy options will then be discussed with all the relevant stakeholders, ideally at a major conference towards the end of 2004.
- The major output of this review will be revised guidance to clinics (Part 3 of the Code of Practice) on the conduct of child welfare assessments, in order to achieve greater consistency, acceptability amongst practitioners (including GPs) and patients, and compliance.

- It is hoped that ultimately this work will also be useful to clarify the Authority's thinking on child welfare issues, including our input into the Department of Health's review of the 1990 Act in 2005.

Other issues

In addition to project work identified in the business plan, the ELC is currently addressing or anticipating other policy issues arising from regulatory activity or other developments (e.g. donor codes, s.31 regulations) and conducting work to improve the HFEA's own processes (e.g. horizon scanning).

Issue 1 – Donor Codes

- Previous advice has been that donor codes (generally, alphanumeric codes assigned to individual donors by recruiting centres) may not be disclosed to recipients and/or donor-conceived people born as a result. The HFEA has, however, never produced formal guidance on this issue.
- Legal opinion obtained (April 2004) – policy options and implications to be considered by ELC in September prior to consideration by Authority in November. Guidance to centres to be issued thereafter.

Issue 2 – s.31 applications

- Addressing issues relating to the management of section 31 applications (following work by dedicated advisory group).
- Considerable work needs to be done to ensure that an appropriate mechanism for managing s.31 applications is in place, and that appropriate advice (including information leaflets) is provided to licensees, donors, recipients and potential recipients, and donor-conceived people.

Issue 3 – Horizon scanning

- Development of horizon scanning processes.
- Creation and involvement of an informal panel of advisors.

Issue 3 – Artificial Creation of gametes

- Work on ethical aspects of artificial gamete creation to follow advice from SCAG on this issue.