

Authority Paper

Committee	Authority Meeting
Meeting Date	20 October 2004
Agenda Item	12
Paper Number	HFEA(20/10/04)195
Paper Title	Advisory Group on Safety and New Technologies (SANT)
Author	Jenny Dimond (Policy Manager)
For Information or decision?	Information
Resource Implications	None
Recommendation to the Committee	The Committee is invited to note the establishment of SANT and the proposed work plan for the group

Background

1. The Executive has established an Advisory Group on Safety and New Technologies (SANT). This follows on from the Risk Matrix Group, recommendations from the TOFT report, and analysis of reported incidents. It also relates to requirements under the EU Tissue Directive on labelling, coding, and traceability.

2. Membership of the Group:

Maybeth Jamieson (Chair)	Steve Troup
Paul Ashford	Angela McNab
Sue Avery	Tim Whitaker
Andy Glew	Trish Davies
Neva Haites	David Tellis
Simon Fishel	Stephanie Sullivan
Charles Kingsland	Charles Lister
David Morroll	Jenny Dimond (Secretary)
Allan Pacey	

3. It is envisaged that the Group will meet around four times a year and the future of the group will be reviewed at the end of 2005. Please refer to Terms of Reference below.

Aims

4. The Group will advise the Executive on ways of improving safety in assisted conception clinics, including the use of technologies that are new to the ART sector. Outputs from the Group will be used by the Executive in developing policies for consideration by the Authority. The Group will not endorse any particular technology/product.

5. The main tasks of the Advisory Group are to:
 - a. Consider the role of new technologies and their application to IVF clinics, taking account of the requirements of the EU Tissues and Cells Directive;
 - b. Consider ways of reducing the risks of mismatching;
 - c. Develop guidance for clinics on risk assessment, clinical governance and handling communication around risk, safety and adverse incidents
 - d. Look at methods of root cause analysis and associated training needs;
 - e. Advise on the development of an evidence base to support good practice solutions
 - f. Investigate support required for pre-registered and newly registered embryologists, and andrologists.

Initial meeting – 29th September 2004

6. At its initial meeting the Group agreed to focus on reducing the risk of miss-matching material in the laboratory and to explore how 'new' technologies might affect HFEA policy on double witnessing. Also to consider solutions in the wake of the labelling, coding and traceability requirements of the Tissue Directive.
7. The Group is in the process of collating information on products and devising a strategy for their evaluation in terms of whether they satisfy HFEA requirements. A specification will be prepared that centres might eventually use when looking into purchasing/devising products.
8. In preparing minimum specifications members of the Group are process mapping laboratory procedures and performing a gap analysis to identify areas where solutions will be needed, taking into account products that are currently on the market.
9. The Group is concerned about the possible effects that the frequency of light and radio waves involved in the products might have on gametes and embryos. The Group has referred this issue to SCAG.
10. The Group will meet again in December 2004/January 2005.

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY
ADVISORY GROUP ON SAFETY AND NEW TECHNOLOGIES
(SANT)

Terms of Reference

Introduction

1. The Advisory Group has been established to advise the HFEA Executive on ways of improving safety in assisted conception clinics, including the use of new technologies. The outputs from the Group will be used by the Executive in developing policies for consideration by the Authority.

Aims

2. The main tasks of the Advisory Group are to:
- Consider the role of new technologies and their application to IVF clinics, taking account of the requirements of the EU Tissues and Cells Directive;
 - Consider ways of reducing the risks of mismatching;
 - Develop guidance for clinics on risk assessment, clinical governance and handling communication around risk, safety and adverse incidents
 - Look at methods of root cause analysis and associated training needs;
 - Advise on the development of an evidence base to support good practice solutions;
 - Investigate support required for pre-registered and newly registered embryologists, and andrologists.

Priorities for Consideration

3. The first priority for consideration by the Group will be the availability and possible application of new technologies to reduce risks associated with gamete matching and to improve the tracking of gametes from donor to recipient.

4. Other priorities are to be determined by the Group in a formal work plan.

Membership

5. The Advisory Group consists of Authority Members, Executive and external stakeholders, Members are:

- Maybeth Jamison (Chair)
- Paul Ashford
- Sue Avery
- Andy Glew
- Neva Haites
- Simon Fishel
- Charles Kingsland
- David Morroll
- Alan Pacey
- Steve Troup
- Angela McNab
- Tim Whitaker
- Trish Davies
- David Tellis
- Stephanie Sullivan
- Charles Lister
- Jenny Dimond (Secretary)

6. The Group may decide to co-opt members with specific expertise as the work proceeds.

Management of Meetings

7. The Group will meet around 4 times a year.

8. The aim is to produce recommendations for the HFEA Executive to a timetable to be agreed with Members. It is expected that the work of the Group will be completed by 31st December 2005. The future of the Advisory Group will be reviewed at this stage.