

Authority Paper

Committee:	Authority Meeting
Meeting Date:	12 May 2004
Agenda Item:	12
Paper Number:	HFEA (12/05/04) 155
Paper Title:	MDS Update
Author:	Clare Keates
For Information or Decision?	Information
Resource Implications:	
Recommendation to the Committee:	

Paper:

Future/Minimum Future Data Sets

The consultation process has continued (since Version V20042) and further changes have been made. The forms will be introduced alongside Electronic Data Interchange (EDI) at the Centres, with the exception of the Donor form which will need to be introduced earlier (July).

Some comments on outstanding issues are given below. We would welcome any further comments you may have on the forms and any of the unresolved issues. The manual will be updated to deal with any changes and provide extra guidance where required.

Some comments on Draft V2004-6.

Patient & Partner Registration.

1). Surname at birth for both the patient and the partner has been included, but forenames at birth have not. There has been a suggestion that all surnames/forenames be collected for an individual, but there is no room on the form.

2). Addresses have not been collected for either the patient or partner. NHS Numbers have been collected for both where they are UK residents, and the Passport Number & Issuing County has been collected where they are not. The assumption is that all follow-up studies involving patients must go through the centres until the HFE Act is suitably changed.

3). Patient ethnic groupings are in-line with NHS standards (though there is concern over the development of a limited "other" list/category).

4). As agreed at a previous Authority meeting, ethnicity is not being collected for the partner.

- 5). Patient obstetric history has been changed (and simplified) significantly.
- 6). Cause of infertility has been changed (and simplified) significantly.
- 7). There is concern over the posthumous use of sperm.
- 8). Detailed medical histories/backgrounds for the patient/partner have not been included.

Donor Information

- 1). There has been a suggestion that **all** surnames/forenames be collected for the donor.
- 2). The box for number and ages of girls & boys born to the donor may be confusing so require guidance.
- 3). The date that the gametes are first used (or supplied for use) in treatment may not be known in all cases.
- 4). Ethnic groupings are in-line with NHS standards (though there is concern over the development of a limited “other” list/category).
- 5). There are concerns over how the limit to the number of Live Birth Events will work in practice in all cases.
- 6). Guidance may be required for the centres on how to complete the known illnesses section of the form.
- 7). There is concern over the list of screening items – is it comprehensive?
- 8). There is a suggestion that the last page of the form (which should be completed by the donor) should be available in numerous languages.
- 9). There is a suggestion that the donor is able to flag their intention to become identifiable at the point when the new regulations come into force. However, DH have confirmed that legally, the donor can only flag their intention after the new regulations come into force. This option has therefore not been included.
- 10). There is no reference as to whether the donor is known to the recipient of the gametes – such as a friend or relative. This has only recently been questioned.

Treatment Forms

- 1). Details of treatment practice such as freezing protocols, culture media, sperm preparation, etc. will not be collected on the new forms.

2). Stimulation drug details (other than date, anti-oestrogen/gonadotrophins) will not be collected on the new forms.

3). The categorisation of the reasons for collecting/storing eggs has been reduced to a small list. This list has been questioned and an alternative suggestion for a list made. This list includes: OHSS, cancer Treatment, Fertility Preservation.

Outcome Forms

1). Because of the difficulty in identifying and/or correctly categorising congenital abnormalities, this option has been removed from the forms and three options supplied which are – no anomaly observed, possible anomaly observed (unsure), anomaly observed. This was decided upon after much debate and as in line with the NHS NORCAT project definitions.

An issue has been raised as to whether anomalies should be categorised into major and minor, or whether a list should be issued to select from for a congenital abnormality.

