



Human Fertilisation and Embryology Bill: Confidentiality & Disclosure of Information Provisions

House of Commons, May 2008

Those involved in the provision of care for the infertile would now regard licensed treatment (in vitro fertilisation and related options) as integral to the progressive pathway of care for their patients.

It has always seemed anomalous to clinics as well as to the majority of patients that specific consent to disclose details of their treatment to others has been a requirement. Indeed explaining the issue to patients is often greeted with surprise given that they have been used, in the preliminary assessments of their infertility and in the provision of first line treatment, to normal lines of communication between those who are involved in their care, for the most part hospital clinicians and general practitioners, being established without their permission being sought.

One might understand certain sensitivities in the context of gamete donation, but even where routine IVF treatment takes place without the use of donated eggs, sperm or embryos, the restrictions on communication can and does raise problems.

The current section within the Code of Practice allowing for disclosure of information is shown:

10.4.1 Disclosure of information: general

Information held by the centre that relates to:

- a. the keeping or use of gametes or any identifiable person; or
- b. the provision of treatment services for any identifiable woman; or
- c. the keeping or use of an embryo taken from any identifiable woman; or
- d. the birth of a child as a result of treatment services

should, in general, be disclosed only to the HFEA or to another licensed clinic which needs to know for the purpose of continuing care. This includes not only information that directly concerns the matters set out above but also any information held by the centre that could connect them with a person whose identity is known.

10.4.2 Disclosure of information: exceptions

Exceptions to this general rule may apply in certain cases where the information is disclosed:

- a. to the person to whom the information relates (or their partner, if the information relates to their treatment together); or
- b. with the consent of the person or persons to whom the information relates; or
- c. in connection with certain proceedings, including any formal procedure for dealing with complaints; or
- d. incidentally, where this is unavoidable when making a permitted disclosure; or
- e. in an emergency, where disclosure is necessary to avert imminent danger to the health of a person to whom the information relates and it is not reasonably practicable to obtain the consent of that person; or
- f. by order of a Court in certain specified circumstances; or
- g. in certain circumstances and subject to certain specified safeguards, about a person who has died.

Examples of clinical problems which could be in breach of the law:

Confidentiality May 08.doc

1. Gynaecological referral

I receive a referral from a general practitioner or other clinician seeking further investigation of a gynaecological problem. The referral alludes to previous IVF treatment which is of relevance to the presenting complaint. If I record in the hospital notes the details of previous treatment I am in breach of the law, unless I obtain written permission from the patient, in so far as the information is being recorded in an unrestricted file (i.e. not the infertility file). An example might be a referral for laparoscopic investigation of pelvic pain.

2. Communication with other health professionals

Clinicians sometimes require to correspond with another specialist in the ongoing management of a patient with a complex clinical problem, possibly but not necessarily related to infertility. The patient will often have had licensed treatment under my care in the past, knowledge of which may be of help to the advising specialist. Unless one has written permission from the patient it would be a breach of the law to give any details of their past treatment. An example might be the advice of haematologist in someone who had a history of thrombosis in association with past IVF treatment, who now needs a surgical procedure in dealing with continued pelvic pain.

3. Admission with complications after IVF treatment

Infertility notes are usually kept in clinics, separate from general hospital files. A patient who has received IVF may require hospital admission if she has problems in the aftermath of treatment. On occasions this may be pregnancy associated e.g. ovarian hyperstimulation syndrome, threatened miscarriage, ectopic pregnancy. It is usually the case that care is provided in a general hospital setting with information recorded in the general hospital notes. Unless one had previously obtained written permission from the patient to disclose the nature of their treatment one would be in breach of the law unless it can be shown that the situation is an emergency where the "disclosure is necessary to avert imminent danger to the health of a person to whom the information relates and it is not reasonably practicable to obtain the consent of that person". In other words unless the patient is in extremis I am obliged to obtain their written permission.

4. Antenatal care

I am in breach of the law if I refer a patient for antenatal care without their written permission. Providing details of assisted conception procedures is of great importance in determining gestation accurately, a fundamental element of decision making in many specifics of care e.g. timing of investigations including screening tests, interpreting growth scans of the developing fetus, the timing of delivery.

5. Referral for screening

Screening tests are integral to the delivery of antenatal care. Included amongst these is blood sampling for measurement of proteins such as maternal serum alpha-feto protein for estimating risk of Down syndrome. Such information is frequently of importance for patients in determining the need for further invasive testing such as amniocentesis to make a diagnosis of a genetic abnormality. Knowledge of maternal age, as well as gestational age, is important in accurately assessing this risk. In a situation of egg donation adjustment to maternal age in making the request to the reference laboratory is essential. Without written permission this is not possible.

Some reference laboratories include a specification in the sample referral form allowing indication that the sample has been derived from an IVF associated pregnancy, suggesting that reference ranges of results may differ in this subset of patients. A clinician filling in such a form is in breach of the Act if permission had not been obtained from the patient to include such information in the form.

6. Neonatal care

It is frequently of value to neonatal colleagues, in dealing with parents, to know whether a child admitted to a neonatal unit has been derived from IVF treatment. Gamete donation information is also of importance in situations of suspected genetic disease.

There is also an unfortunate tendency through a lack of information being passed on a routine basis to our colleagues to assume that all conceptions arising through fertility treatment are a product of IVF. Often this is not the case and a culture of impaired communication does not lend itself well to prospects for informed audit of outcome of fertility treatment associated conceptions.

7. Clinical care in later life

There may be a request for assistance from a clinician dealing with a new health problem in the later life of either male or female partner. Without the written permission of the patient concerned this would not be possible.

8. Joint notes

Infertility files are unusual in so far as they contain information about two individuals sometimes more, where offspring are concerned. One might sometimes be asked to provide details of past treatment relevant to ongoing care in another, perhaps unlicensed centre. If this is done without the written permission of both parties this is a breach of the Act.

The culture in which medical practice flourishes and provides the best care possible for patients is one where open communication is encouraged. Legislative restriction on communication, even in relation to donated gametes, acts against this principle, provides unnecessary impediments in delivery of care and acts against the best interests of our patients.

All working in the sector would prefer a system which allowed the routine nature of IVF treatment to be acknowledged with the ability of clinical staff to communicate in a routine fashion, without fear of prosecution, with clinical colleagues. In other areas of medical practice of a sensitive nature e.g. mental illness, HIV, abortion, confidentiality issues do not seem to require the same degree of legislative imposition.

Required Amendment (Section 33)

The BFS would support an amendment which allowed rules on medical confidentiality to be applied, similar to those applied in other fields of medical practice.

A proposal of an opt-in process, which allows for a couple or patient to request that clinical information on their case be kept confidential i.e. separate from other "routine" hospital data, is attractive. In other words, the default position would be one where there was no restriction on the passage of information unless specific instruction to that effect had been given.

Such a system could be easily operated allowing patients to indicate their wishes at the outset of care by active signing of a restricted communication form. In the absence of such instruction from patients, then the usual boundaries of health care communication would apply.

PROPOSAL

Amendment to 1990 Act –

Section 33 (1)

no person who is or has been a member or employee of the authority shall disclose any information mention in subsection (2) **against the explicit wishes of the patient**, and

Section 33 (5)

no person who is or has been a person to whom a licence applies, and no person to whom directions have been given, shall disclose **against the explicit wishes of the patient** information within section 31 (2) who he holds or has held as such a person.

BFS
May 2008

Restricted Communication Form

It is usual practice in medicine for professionals to provide information on treatment services provided for patients to other health professionals in facilitating ongoing care. In usual circumstances such communication takes place without formal consent being required from patients.

In vitro fertilisation is now an integral part of the management of infertility. In the past it has been a requirement that specific consent should be taken from patients to communicate details of their treatment to others. It is now felt that the routine nature of such treatment should not require an explicit consent process to allow such communication to take place.

For some individuals, however, particularly where sperm, egg and embryo donation is planned, the sensitive nature of their treatment may be something that they wish to keep private.

This form provides the opportunity for individuals who are undertaking licensed treatment to place restrictions on communication on their care. Unless specific instruction to restrict communication is given then, where required, as occurs in other fields of medical practice, usual communication arrangements will prevail.

Please tick boxes as they apply to you and sign this form if you wish restricted communication arrangements to apply in your case.

FEMALE RECEIVING TREATMENT

I wish **all** information about my treatment kept private and only communicated to others on a need to know basis in a clinical emergency.

I wish **only** the fact that donated sperm/eggs/embryos (delete as required) were used in my treatment kept private and communicated to others only on a need to know basis in a clinical emergency, otherwise standard communication is acceptable to me.

Signature:

**Witness signature on behalf
of licensed centre:**

Date:

Date:

PARTNER RECEIVING TREATMENT

I wish **all** information about my treatment kept private and only communicated to others on a need to know basis in a clinical emergency.

I wish **only** the fact that donated sperm/eggs/embryos (delete as required) were used in my treatment kept private and communicated to others only on a need to know basis in a clinical emergency, otherwise standard communication is acceptable to me.

Signature:

**Witness signature on behalf
of licensed centre:**

Date:

Date:
