DEBATE

Guide to donor insemination and IVF clinics

A patient's guide to donor insemination and in-vitro fertilization clinics

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Over the past 5 or 10 years providers of public services have increasingly, by reason of administrative decree or public demand, been required to provide information about the services they provide in terms of quality, cost and performance. In transport and education, and in many other services, we, as users, have come to expect accountability and responsiveness, both of which can only be achieved on the basis of public information about performance and outcome measures. We expect to be able to exercise choice based on good quality information, and we expect services which are failing to meet proper standards to change accordingly.

Health services have been subjected to this kind of scrutiny through medical audit and through the pressures brought to bear by purchasing authorities. But they are also increasingly under pressure from patients themselves who wish to take a more active role in their own medical care than perhaps they did in the past. This has been particularly the case in assisted conception where, because much of the treatment is sought privately, there is the added consideration for patients of value for their often large sums of money. We should welcome, and not discourage, this patient involvement.

Parliament, in preparing the Human Fertilisation and Embryology Act 1990 (HFE Act), recognized the need for patients to have good information and realistic expectations. Licensed in-vitro fertilization (IVF) and donor insemination (DI) clinics therefore have a statutory duty, before offering treatment, to provide relevant information to patients [HFE Act, section 13(6)]. The Human Fertilisation and Embryology Authority (HFEA), in its Code of Practice, has always said that this should include 'the limitations and possible outcomes of the treatment proposed' [Code of Practice (second revision, paragraph 4.4)] and has required clinics to provide patients with their live birth rates. The HFEA itself also has a duty to 'provide... advice and information for persons... who are receiving treatment services... or who may wish to do so' [HFE Act, section 8(c)].

One of the problems that patients frequently approach the HFEA about is the great difficulty they have in using the data given to them by clinics in making their decision about which clinic to attend. The information is presented in different formats; some is more recent than others; some are broken down into sub-groups where others are not; some quote only pregnancy and not live birth rates; some highlight data for a specific, and particularly successful, form of treatment. The same problems arise in clinics' success rates quoted in the press. Claims of success are sometimes made which are plainly far in excess of what most couples could possibly expect from any clinic. It is not surprising that thousands of people contact the HFEA to seek independent information about clinics. The information that most ask for is live birth rates.

The HFEA spent some considerable time in deciding whether to publish these figures. There were many questions to address: Did we have the information? Yes. Was it reasonable that people should ask for it? Yes. Were we capable of providing it? Yes. Should we provide it? The Act requires us to provide information, though precisely what information we should provide is not specified. Certainly it was what was wanted. We decided that it would be wrong in principle to withhold information unless it could be shown that it would be harmful to patients or unfair to clinics. The question then was whether we could provide it in a way which met these requirements.

Almost all of the clinics who expressed a view about this agreed that raw live birth rates can be misleading. They disguise the many factors which affect outcomes, such as for IVF: age of patients treated; whether fresh or frozen embryos are used; and whether donor eggs are used. There was also a consensus that information about pregnancy or birth rates should not become the sole basis on which decisions about which clinic to attend should be made.

In September 1995, after lengthy consultation with clinics, professional organizations, patient groups and individuals, the Authority published 'The Patients' Guide to Donor Insemination and IVF Clinics'. This provides advice for patients who are considering treatment. It briefly describes donor insemination and IVF treatment; it informs people about what they should expect to happen, what they should ask and what they will need to consider before making any decisions. It gives statistically adjusted live birth rates for all DI and IVF clinics, but stresses that these should be considered only in the context of other relevant factors such as location, cost, specialisms, waiting times, counselling services, etc.

The live birth rates themselves take account of the actual patients treated by each clinic by using a statistical model which adjusts the live birth rate to account for: the woman's age; whether there is male subfertility in IVF patients; duration of infertility; whether the couple have had previous pregnancies; whether the couple have had previous live births, number of previous treatment cycles; whether cycles were stimulated or unstimulated; number of embryos transferred; and whether frozen or fresh embryos were transferred.

Cycles using donated eggs or embryos are excluded from the adjusted data.

The HFEA collects information about every donor insemination and IVF cycle performed. We therefore have a database...
which now extends to over 80,000 IVF and 90,000 donor insemination cycles. Using this database we can reliably determine for each major factor in IVF or donor insemination treatment what likely effect it has on live birth outcome. We can apply this to each clinic’s actual caseload, adjusting the overall live birth rate to account for the expected outcomes using a common, national standard, and thereby producing live birth rates which better reflect the clinic’s own performance rather than simply the characteristics of its patients.

It has been said that the model is faulty because some determinants of outcome are not collected by the HFEA and are not therefore included in the model. These are factors such as weight and baseline concentrations of luteinizing hormone (LH). We will continue to look at these and welcome research that will illuminate the issues. However, the absence from the model of factors which have a very marginal effect on live birth rates, and factors which are experienced in fairly equal proportions by all clinics, will not significantly affect the value of a statistical model which accounts for what are generally agreed to be the main influences on outcome.

The value of the model is that it provides validated information in a common format. It gives patients more confidence that the information properly reflects the performance of the clinic. The value of the Patients’ Guide is that it places this data in the context of other relevant factors and helps people determine their own priorities and thereby make decisions which are right for them.

The Patients’ Guide does not claim to give rates that are applicable to individuals. Couples are encouraged to discuss this with their specialist. It does not claim that each clinic’s rates will be repeated. It gives an indication of likely variance and states that rates will change from year to year. While it provides the most recent possible validated live birth rates, it does not claim to reflect what is currently happening in clinics. Patients are encouraged to discuss with clinics their most recent (raw) live birth and pregnancy rates.

There are, for coming years, refinements that can be made to the model. There are improvements that can be made to the text. We are looking at all this with professional and patient groups. But what the Patients’ Guide already does, is to give to patients more manageable, more meaningful, and more consistent information than they have had hitherto. Many patients have welcomed this—so, too, have many clinics.

HFEA’s patient guidelines penalize the value of embryo preservation

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In view of remarks to be made below, it may be of some importance to point out that I have long been an admirer of the Human Fertilisation and Embryology Authority (HFEA) and its predecessor organizations, the Interim Licensing Authority (ILA) and the Voluntary Licensing Authority (VLA). In fact, I was privileged to be invited to a special meeting on the subject of surveillance at the Royal Society of Obstetricians and Gynaecologists early on, and later was privileged to be in the visitors’ gallery at the House of Commons on the occasion of the first-ever debate on the Warnock Report.

It is, therefore, with some reluctance that it seems necessary to point out that, in my opinion, the publication of the ‘The patient’s guide to donor insemination and IVF clinics’ was a mis-step, or at least a premature step on the part of HFEA, for the simple reason that the clinic-specific data as published are, simply put, misleading, in fact very misleading. This is because of unaccounted-for variables, the treatment of accounted-for variables, as well as for other reasons which will be mentioned below.

Among the variables accounted for are such items as size of the clinic (large clinics usually have better pregnancy rates than small ones), the criteria for the entry selection of patients and rejection rates, the influence of the number of abandoned cycles (although the number of abandoned cycles is stated), the normality of the uterus, and the importance of the role of deselection and discard of oocytes and/or pre-embryos.

To be sure, the live birth rates have been adjusted to account for nine stated variables. However, the details of the derivation of the statistical model for such adjusting is not revealed. To save time and space, this discussion will be confined to only one of these variables, but a similar analysis could be done for several others. It is stated that there is an adjustment to account for the use of cryopreservation, but the adjustment could scarcely be realistic.

It seems to be the current HFEA policy to count a thaw transfer as a cycle. No table in the 1995 annual report or in the Patients’ Guide allows one to distinguish between the birth rates from fresh and from frozen transfers. Thus, the presumption is that they must be more or less the same, or they could scarcely be commingled in the way they are. However, the Patients’ Guide (p. 8) states, ‘The live birth rate from frozen embryos is usually lower than from fresh embryo transfers’.

Be the differential rates as they may be, the main point about cryopreservation is that its purpose is to supplement, that is, augment the fresh rate by having an opportunity to use transfers from the same egg harvest subsequent to the fresh transfer. Such an evaluation can be made only by expressing the cryopreservation rate as additive to the fresh rate. This is, to be sure, really not a simple calculation. In order to do this, it is necessary to be sure that pregnancies attributed to cryopreservation are calculated to account for the fact that such pregnancies can occur in patients who already have had a fresh pregnancy. If this happens, it is my opinion that such pregnancies should not be double-counted, but care should be taken to count only pregnancies which occur from cryopreservations which occur in patients who did not have a pregnancy from a fresh transfer. The point is that patients with cryopreservation pregnancies who have fresh pregnancies really are having multiple pregnancies from the same harvest, just as they could have multiple pregnancies fresh, or for that matter, from cryopreservation. By the same token, frozen–thaw pregnancies