

# Debate concluded

## Guide to donor insemination and IVF clinics

### A patient's guide or a government league table?

H.S.Jacobs<sup>1,3</sup> and H.I.Abdalla<sup>2</sup>

<sup>1</sup>Department of Endocrinology, UCL Medical School, The Middlesex Hospital, Mortimer Street, London W1N 8AA and <sup>2</sup>Fertility and Endocrinology Centre, IVF Unit, The Lister Hospital, Chelsea Bridge Road, London SW1 8RH, UK

<sup>3</sup>To whom correspondence should be addressed

Last September the Human Fertilisation and Embryology Authority (HFEA) published a glossy magazine (*The Patient's Guide to DI and IVF Clinics*) which contained some information on the outcome of donor insemination (DI) and in-vitro fertilization (IVF) calculated from data given to it by the clinics it had licensed to undertake these treatments. Publication was preceded by a certain amount of consultation. The British Fertility Society (BFS), of which one of us was then Chairman, voiced a number of concerns and there were both informal and formal meetings at which these concerns and those of others were raised.

We all accepted that the HFEA had embarked on a difficult enterprise but on reflection the most striking impression left was that its determination to go ahead with publication in spite of so many problems was matched only by its haste in getting the Guide into print. At the time this haste was puzzling. So too was the HFEA's willingness to dismiss so many of the concerns of professionals working in the field, who, it may be added, had supplied the HFEA with all the data to be processed through 'the model' and who, of course, had so much to gain by publication of an accurate and understandable account of the outcome of licensed fertility treatment.

Some technical issues first: since the data had been collected for one reason (to ensure clinics were practising according to the requirements of their licence) there was no reason to suppose it would automatically be suitable for a quite separate one. For a start, there was disagreement about defining a cycle of treatment and therefore, of course, of the definition of an abandoned cycle. Is a cycle defined by the commencement of hormone treatment or by the procedure of egg collection? The BFS has been (re)consulted over this issue as recently as December 1995 (e.g. after publication of the Patient's Guide). At present the HFEA enters into its 'model' all cycles in which hormone treatment has been started. An abandoned cycle has of course 0% chance of conception; in the ranking of results, clinics with the same rates of conception after egg collection but lower cancellation rates according to the HFEA definition achieve higher scores, final 'success' rates then being determined solely by cycle cancellation rates. This must

surely be an encouragement to abandon treatment in fewer cycles than before, a practice that cannot be in the patient's interests. Needless to say, the HFEA received advice from several sources to define an abandoned cycle as one in which no attempt had been made at egg recovery. After all, the HFEA has accurate knowledge of this event because this is when patients become liable for its fee, all clinics have accurate records of the procedure and incidentally this is when the patient feels most trauma, physically, mentally and financially. The advice was ignored.

In this year's publication, the HFEA report results also related to egg collection and to embryo transfer. This is, however, of no real value since they still put all the emphasis on treatment cycle started which remains the only figure considered by both patients and media.

The results published in the Patient's Guide do not distinguish cycles in which donated spermatozoa are used to treat male factor infertility. Thus, in the calculation of the adjusted live birth rate, cycles in which the indication for IVF is impaired male fertility are combined with cycles in which donor sperm is used to overcome the male factor. Clearly the proportion of cases in which donor semen is used will profoundly affect a clinic's results. Although stated in the preamble to the Guide, results of treatment by intracytoplasmic sperm injection (ICSI) are not included. Readers of this journal will not need persuading that to omit information on the results of the most important advance since the invention of IVF itself hardly constitutes a help to patients seeking information on the likelihood of a successful outcome of their fertility treatment.

The impact of factors such as age and duration of infertility, so familiar to infertility practitioners, is supposed to be accommodated by the HFEA's statistical model. In the UK, some 11% of cycles of treatment by IVF are, apparently, performed in women over the age of 40. But it has been stated publicly by one of the spokesmen of the HFEA that the adjustment to the pregnancy rate produced by the model would have the effect of correcting downwards by 2% the results of a clinic in which 1% of the patients were over the age of 40; it would correct upwards by 2% the results of a clinic in which as many as 23% of the patients were over the age of 40. It is difficult to understand the point of such small corrections.

The important question therefore arises whether a single measure of 'success' can usefully reflect a patient's prospect of a happy conclusion to her infertility treatment. Is the single figure derived by the model useful both to a woman of 20 and to one of 40? Infertility is often multifactorial, its treatment requires skill and experience, not to say compassion and wisdom. It is not uncommonly the case that its resolution can only be achieved by accepting one's predicament, a position that may sometimes only be attained by trying even when the

odds are stacked against success. With the concentration on success rates by the Guide, there will be an understandable tendency to dismiss such patients from treatment. We doubt whether the complexities of management of all the patients a clinic treats can be adequately summarised by a single measure of outcome but this is exactly what The Patients Guide attempts to do.

Sadly our scepticism has not been allayed by inspection of the HFEA's presentation of its analyses. For example, the adjusted live birth rate for treatment by donor insemination at one clinic is recorded as  $9.6 \pm 25\%$ . Whatever can that mean? This type of result (and there are other examples) does make one wonder whether parametric tests have been used to analyse data that are not normally distributed. Whatever the explanation, it must be admitted that the result is strange enough to confuse anyone. It also raises the question of whether differences in the results between clinics could have arisen by chance rather than because of the expertise of the clinic personnel. No test of statistical significance has been applied to the data and indeed the concept of testing the validity of apparent differences is not even hinted at in the Guide. Inspection of the data published by the HFEA certainly suggests there is no statistically significant difference among the top 10 clinics or among the bottom 15, although with the little information available in the Guide there is no way to judge reliably.

Clearly the HFEA has had a battle to reduce complex information to a single figure. It has produced numbers that are vulnerable to errors arising from misclassification and from omission of important features of infertility treatment. Some of the numbers in the Guide are strange and frankly defy understanding. As the HFEA was told repeatedly would happen, their publication was rapidly transformed into a treatment league table (see, for example, *The Times* of October 12, 1995 and *The Times* of July 23, 1996) which ranks clinics according to the adjusted live birth rate but which gives no hint of the statistical validity of any differences identified. Publication of the Guide went ahead despite anticipation of these problems by infertility professionals who had not hesitated to share their concerns and advice with the HFEA. There is already evidence that the need to score well in the league table is influencing clinical practice—and not necessarily to the benefit of patients. For example, some centres are abandoning treatment by gamete intra-Fallopian transfer (GIFT) in favour of IVF because a successful outcome of GIFT does not feature in the Guide's statistics.

So the question arises: if there were so many problems, why the haste? Particularly as most of the problems could be overcome by collection of specific information or by refinement of the statistical model. The answer must lie in political ideology, the populist notion that difficult and complex areas can be reduced to a single figure which free agents (in this case, supposedly patients with infertility problems) can use to make up their own minds. One of the features of the present regime in the UK is a tendency to rely less on the advice of professionals (judges, teachers, doctors come easily to mind) more on simplistic assessments of what seems right. And what

better than a league table which ranks the subtleties of clinical activity on the basis of a single figure.

The only feature that has seemed surprising in political terms is that league tables published by quangos usually relate to areas of public expenditure, and in the UK the National Health Service (NHS) has traditionally eschewed the purchase of IVF. Perhaps the most optimistic feature of the rushed publication of the HFEA's league table is that it may herald increasing purchase of IVF by NHS purchasers. And actually there is evidence now that just such an increase is occurring. If this continues and becomes substantial a league table may have to be seen as the necessary price to pay.

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