among patients without a fresh pregnancy are truly add-ons to the fresh rate and should be so recorded. This matter has been discussed previously (Jones et al., 1995)

The net result of all this is that programmes or clinics with cryopreservation are penalized by HFEA by expressing their live birth rate (the information most asked for according to Deech, 1996) as if a frozen–thaw was just another cycle rather than an augmentation. Furthermore, programmes without cryopreservation very likely have an especially good fresh pregnancy rate by virtue of deselection and discard of all pre-embryos that were not used for the three which were transferred fresh according to the current law. It would be unreasonable to think that the three transferred were not considered to be the best available ones from the cohort.

There is another generic concern HFEA has been issuing licenses to some programmes and, presumably, has not issued licenses to others. HFEA, therefore, has made a judgement as to which programmes are satisfactory for the public use and which are not.

Now HFEA seems to be saying (in spite of many disclaimers to the contrary) that some licensed clinics may, in fact, be better than others, and that it is up to the consumers to identify which clinic is best for them, giving consideration to all factors, but also to data supplied by HFEA which, in my view, are misleading. Could this passing of the responsibility for selection to the consumer be a matter of encouraging consumers to rush in where experts fear to tread?

As indicated in the first paragraph, I have long been an admirer of HFEA and its preceding organizations. It is furthermore stated by Deech (1996) that refinements can be made in the model. I hope all concerned will understand that the above comments are intended to offer ideas on which refinements might be made, or better still, lead to a discussion which might conclude that HFEA is in the best possible position to assume the responsibility for evaluating for the public, and therefore, discontinue ‘The patients’ guide to donor insemination and IVF clinics’, at least until such time as a level playing field can be constructed.

Reference

ART regulation: the Australian viewpoint

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From an Australian viewpoint the advent of ‘The Patients’ Guide to Donor Insemination and IVF Clinics’ is welcome. Welcome because it represents a further step in the maturity of assisted reproductive technology (ART). The guide is a public reflection of ART regulation and encompasses unique national data. Real data, not a publication in the Journal of Positive Results, not even a meta-analysis but holistic data pertaining to the whole activity of in-vitro fertilization (IVF), fetal embryo transfer and donor insemination in the UK; it lacks data on gamete intra-Fallopian transfer (GIFT) and intrauterine insemination (IUI) programmes. What other discipline of medicine displays its results so openly? Perhaps this is a harbinger of how medicine will appear in the next century. The Human Fertilisation and Embryology Act in the UK binds units to exceptionally detailed data keeping and, from the patient’s point of view, it is difficult to argue against seeing the data since the couple are vulnerable people spending their resources in an uncomfortable exercise with mostly disappointment to look forward to. In general terms the data differs from that from Australia, which are complete but not detailed cycle by cycle. In comparison, ART ‘regulation’ in Australia has largely developed on non-legislative, voluntary and anonymous lines. Perhaps the most innovative initiative of the Fertility Society of Australia (FSA) was the creation of the Reproductive Technology Accreditation Committee (RTAC) in 1987. This body, which incorporated a consumer place from the beginning, has commanded great respect and some trepidation from reproductive units seeking accreditation. All units proffering ART have voluntarily sought accreditation without coercion and, in recent years, some individual states have adopted incorporation of RTAC accreditation as part of their state licensing system. Such states nominate their own representatives to join the accreditation team. Whilst there will always be a need for continued improvement towards total professionalism in the accreditation process, it has been outstandingly successful as an example of self-regulation.

From an ethical standpoint, RTAC has incorporated National Health and Medical Research Council (NH & MRC) guidelines (currently under revision) relating to ART (Supplementary Note 4). Part of the accreditation process is the compilation of data independently by the Australian Institute of Health and Welfare National Perinatal Statistics Unit of The University of Sydney and this has been in the forefront of national data collection in world terms. However, in the absence of individual cycle data, it remains vulnerable to criticism and any publication of ‘league tables’ would require negotiation with the FSA. In addition, RTAC reports are not public documents and there is probably need for change for this to occur in the future. However, what Australia has is a credible and inexpensive system of accreditation (~£5 per cycle), largely due to the voluntary contributions of dedicated senior persons. This is not unimportant when in the end the couple has to pay.

The controversial aspect of the ‘Patients’ Guide’ is not particularly the overall data, but the ‘league tables’. It could be seen as an instrument for praising the winners and admonishing the losers. Overall, is it fair?

Well, it’s certainly pretty tough; live birth rates per commenced cycle is less fair perhaps than live birth rates per oocyte recovery (when patients are committed to the procedure) or live birth rates for embryo transfer (when couples have a real chance of pregnancy). Additionally, a small percentage of
couples will lose their babies through obstetric failures. One could make some further criticism of the tables. The statistical model used to calculate adjusted live birth rates is not public but it must be pretty sophisticated (which could be a worry). It seems of limited appropriateness to report a mixture of stimulated, unstimulated and frozen embryo transfer cycles to calculate the live birth rate/adjusted live birth rate when clearly there are differences in the expectation of pregnancy from each of these programmes. Is it really appropriate to claim comparison of four clinics, when of the three clinics reporting over 1000 ART cycles, two report 98% of their profile as fresh embryo transfer cycles (with considerable variation between clinic results) and the third only 71% relating to fresh cycle transfers. The expectation of live births from frozen embryo cycles is lower than fresh transfer in most studies. A similar argument applies to the proportion of natural cycles in the mix, although not as influential to the overall figures. It would certainly be interesting to see the gold standard here, fetal viability on early ultrasound per individual embryo transferred. The Patients’ Guide compares apples with apples, but some may be Granny Smiths and some Cox’s Pippins. Perhaps we need to have more confidence in the statistical weighting before being comfortable.

Maybe we are seeing a ‘Choice’ magazine, which is valuable not so much for selecting the very cheapest product, or even the best value, but identifying what issues are important to consider in choosing the product; not to be particularly useful to select the best facility, but to reassure couples that their nearest and most convenient clinic has a profile not deviating from the mean.

**Comparing the British and American approaches to regulating ART programmes**

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The article by Deech (1996) describing the role of the Human Fertilisation and Embryology Authority (HFEA) and its method of reporting assisted reproductive technology (ART) outcomes reinforces the idea that we desperately need to raise the level of accountability in our field. It would seem that the UK and US exist in parallel universes, as they each try to cope with the issue of accountability in their own way. We would like to compare and contrast the ways in which our two countries have set about regulating ART through legislation. Also, we feel it worthwhile to discuss the reporting system described by Deech (1996) in the wake of our recently published article describing our in-vitro fertilization (IVF) audit (Feinman, 1996).

The American equivalent to British legislation involved with ART is the Fertility Clinic Success Rate and Certification Act of 1992 sponsored by Representative Wyden of Oregon. This Act establishes guidelines for the practice of ART. However, ART programmes are not required to undergo certification; only the ART laboratories are expected to do so. Accreditation is left to the individual states, each of which is approaching the situation differently. Thus, there are 50 possible systems of certifying ART laboratories in the US.

In California, for instance, there is no licensing or regulatory board that deals with ART laboratories; they fall under the jurisdiction of the federal Clinical Laboratory Inspection Act (CLIA). The State Department of Health Services is establishing its own laboratory inspection programme that will closely mirror CLIA. ART laboratories will be held to the same standards as other clinical laboratories that perform diagnostic tests, without consideration of the unique aspect of the IVF process. ART programmes also fall under the jurisdiction of the California Tissue Bank and the national Uniform Organ Donor Act, both of which seek to limit the spread of infectious diseases, but fail to recognize the difference between cohabiting couples trying to conceive and organ transplant recipients. It is safe to say that while there are a number of agencies claiming to regulate ART, none of those agencies specifically deal with the unique aspects of ART itself.

Mr. Wyden’s Act also requires the Secretary of Health and Human Services to organize a reporting system at the Center for Diseases Control (CDC). To date, Congress has not provided funding for this purpose, thus encouraging some degree of self-regulation and self-reporting. The Society for Assisted Reproductive Technology (SART) happily approves of this policy, since the organization has also pressed for self-regulation.

SART is trying to assume the responsibilities of auditing and regulating ART laboratories. It is doing so through its annual SART report and by creating a voluntary laboratory accreditation process in cooperation with the College of American Pathologists (CAP). The SART report continues to suffer from the problems inherent in an unaudited self-reporting system. The results from only a few programmes are actually audited, but the data collection system itself makes a true audit almost impossible. As a result, the most recent report was held up for many months due to an inability of the auditors to reconcile the reported results of some clinics with what they found in the records.

To date, only a few programmes have gone through the accreditation process as pilot attempts. The voluntary nature of the accreditation system allows for the continuation of the status quo ART programmes can continue to function and prosper, without either reporting to SART, or undergoing an ART-specific accreditation process.

Thus, in contrast to the British system described by Deech (1996), the American approach seems less organized and less committed to enforcing minimal standards of care. Yet, the British system imposes some restrictions on the practice of ART that may have sounded reasonable to legislators, but may not be medically reasonable. For instance, British IVF programmes are restricted to transferring only three embryos to the uterus of the prospective mother, regardless of age. While the intent of this rule is meant to limit multiple births,