Legislation on the Practice of Assisted Reproduction in Western Australia

INTRODUCTION

Those practitioners in Western Australia undertaking assisted reproductive techniques, such as in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), and donor insemination (DI), are obliged to conform to regulatory requirements laid down at both a state and a national level. The varied beginnings of each regulatory body has meant much overlap and duplication of oversight, leading to a considerable increase in the beaurocratic workload of the individual clinics and laboratories. These early days in the administration of the various regulatory bodies require much work and cooperation among all concerned, and it is hoped that, in time, a unified system will be available to minimize the documentation and avoid inconsistencies in decision making.

STATE LEGISLATION

Several states in Australia, such as Victoria and South Australia, now have legislation in place to regulate reproductive technology. This means that a uniform national law will not be applied and that practitioners and patients in different parts of Australia will have to abide by different regulations.

Background

A brief insight into the evolution of the State legislation in Western Australia can be obtained by tracing the various groups employed by the Western Australian Government in obtaining information on IVF activity in Western Australia and then drafting the legislation.

IVF Ethics Committee of Western Australia. A ministerial committee was appointed by the State Government in June 1983. The brief of this curiously named IVF Ethics Committee of Western Australia was to report on the social, ethical, and legal issues surrounding IVF, to advise on the relevance of recommendations from similar committees in Australia and overseas, and to assume a supervisory role in the practice of IVF in Western Australia. The committee made a final report to the Minister of Health in September 1986, containing 23 recommendations pertaining to the ethical conduct and supervision of reproductive technology services. A final report on an independent demographic, clinical, and economic evaluation of IVF followed in April 1988.

Reproductive Technology Working Party. In a move toward the drafting of legislation, the Minister for Health announced in July 1988 the formation of a 16-member Reproductive Technology Working Party. The Working Party was responsible for making specific legislative recommendations to the Minister on the basis of the two reports mentioned above and the Reproductive Technology Act 1988 of South Australia. The specific terms of reference of the Party were

(i) to advise on specific legislative proposals that would establish a Western Australian Council on Reproductive Technology,
(ii) to recommend the basis on which the council should formulate and enforce a code of ethics for reproductive technology, and
(iii) to advise on specific legislative proposals in relation to surrogate pregnancy.

A final report was then submitted by the Working Party to the Minister in August 1988, in which it was recommended that two acts be implemented, the Reproductive Technology Act and the Surrogacy Act. The latter has yet to appear. The specific recommendations for the Reproductive Technology Act included those regarding the following.

(a) The formation of the Reproductive Technology Council
  - It should be a 10 member Council.

- There should be equal numbers of men and women.
- The appointment to the Council of any person licensed under the Reproductive Technology Act, or anyone with a direct or indirect pecuniary interest in reproductive technology, would be prohibited.

(b) The prohibition of certain practices
- Mixing of multiple sources of gametes so as to render impossible the biological parents of any resulting embryo or child.
- Sale or purchase of human reproductive material.
- Mixing of human and animal reproductive material.
- Culture of human embryos in vitro beyond 14 days.
- Generation of human embryos solely for the purposes of experimental research.
- Any procedures involving the cloning of a human embryo.

Western Australia Legislative Assembly Select Committee. In November 1988, it was moved by the Western Australian Government that a multi party Select Committee of five members of the legislative assembly be appointed to consider the report of the Reproductive Technology Working Party in order

(a) to form a view on the desirability or otherwise of each of the specific legislative recommendations,
(b) to make alternative legislative recommendations which may either diminish or expand the scope of the original report in areas where the Select Committee had a view which differed from that embodied in the report, and
(c) to make its own report to Parliament.

The Select Committee considered submissions from the general public, patient groups, and medical practitioners. In their final report of December 1988, it was noted that all practitioners who spoke to the Committee's hearings expressed a view that legislation was not necessary with self-regulation being the regulatory method of choice, but the Committee thought that legislation was required to guide the progress of reproductive technology. The guiding principles of the Working Party's report were endorsed, particularly the introduction of the Reproductive Technology Act. However, the recommendations of the Select Committee relating to that Act did differ in some ways, including additional considerations that

(i) the welfare of the child should be of paramount importance in the administration of the Act,
(ii) potential clients should be adequately assessed as to the appropriateness of any licensed procedure,
(iii) the Council could have a maximum of one member with a direct pecuniary interest in IVF, and
(iv) the Reproductive Technology Act should be reviewed after 5 years.

Human Reproductive Technology Act of 1991

Following the Select Committee's report, draft legislation was produced and public consultation undertaken. The final bill of the Human Reproductive Technology Act passed through the Western Australian Houses of Parliament by August 1991 and the Act came into effect on 8 April 1993. In the Act, reproductive technology is said to mean (a) artificial fertilization procedures (i.e., artificial insemination or IVF), (b) the keeping or use of gametes intended for use in an artificial fertilization procedure, eggs in the process of fertilization, or embryos, or (c) other procedures or matters incidental thereto. In practice, it is considered to relate specifically to IVF, GIFT, and donor insemination.

The Act established the Reproductive Technology Council, a body with 10 nominated members chosen to represent all the relevent interests in the community. However, the Human Reproductive Technology Act is now administered by the Commissioner of Health, subject to the Minister for Health. The Commissioner alone acts as the Licensing Authority and grants licenses for the practice of reproductive technology and the storage of human eggs, sperm, and embryos. These licenses are granted on the recommendation of the Reproductive Technology Council, who also have the responsibility for advising the Minister on general matters and drawing up the Code of Practice. Among a host of regulations, there are several which have significant effects upon the day-to-day workings of an assisted conception unit. Important ones which have come to light thus far include the following.

(a) A maximum storage period of 3 years for frozen embryos and 15 years for frozen sperm. This period is not extendable, and at

the end of this period, the frozen material becomes the property of the Licensing Authority, namely the Commissioner for Health. Embryos and sperm frozen before the introduction of the Act can be stored only for a maximum of 3 years from the date the Act came into being (i.e., until 7 April 1996).

(b) The number of donee families per semen donor is restricted to five, including those interstate and overseas. This allows for second babies for women conceiving following donor insemination.

(c) The mixing of human and animal gametes is prohibited, thereby preventing the use of hamster oocytes in the zona-free hamster oocyte penetration test (although hamsters are forbidden in Australia) or mouse oocytes for assessment of the usefulness of ICSI with patient sperm.

The cost to each center per annum is a flat fee of Aus$350. For each treatment cycle of IVF, six forms have to be completed (plus one extra if donor sperm are used), whereas a DI treatment cycle needs only one form.

NATIONAL REGULATION

Regulation within Australia at a national level is through accreditation. Diagnostic laboratories are accredited through the National Association of Testing Authorities (NATA), whereas clinics are accredited through the Reproductive Technology Accreditation Committee.

National Association of Testing Authorities

Formed in 1947, the National Association of Testing Authorities (NATA) is the national authority for the accreditation of laboratories performing tests, measurements, calibrations, and related standards, although it excludes those laboratories producing pharmaceutical and biological products for therapeutic use.

The procedures for the registration of medical testing laboratories include initial contact with the laboratory, application for registration, assessment of the laboratory by NATA representatives, and then the granting of accreditation by the NATA Council based upon the recommendation of the Medical Testing Advisory Committee.

Application for accreditation incurs a fee of Aus$1300.

Reproductive Technology Accreditation Committee

From its inception in 1982, the Fertility Society of Australia (FSA) concerned itself with the idea of voluntary regulation for the emerging IVF units in Australia (and also later in New Zealand). At that time the media projection of IVF procedures was mostly favorable, holding the technology in awe. However, the early signs of public concern were present following the very visual medical presentation of high-order multiple pregnancies delivering at a markedly preterm stage. Other concerns from some members of the public indicated that there was an undercurrent of fear that the clinical and scientific staff involved with IVF were keen to show the miraculous aspects of human reproduction and may not be concerned with the best interests of society or the offspring. These fears led to the first legislation in Australia following the Wallace Committee report (Victoria, 1984). However, the FSA felt that by concerning itself with quality control, ethical control, voluntary accreditation, and insistence upon adherence to the NH&MRC guidelines, that Regulation would satisfy the Australian public and prevail over Legislation—the latter being more likely to satisfy only the opponents of IVF and probably act as an inhibitory influence over further research in IVF.

In 1986, the FSA drafted a series of standards as a guide to the code of practice of IVF and related technologies. Then, in 1987, the Society recommended the formation of a Reproductive Technology Committee whose responsibilities included the

(a) review of applications and reapplications for accreditation to perform IVF, donor insemination, and related techniques,

(b) invitation of new units to seek accreditation,

(c) monitoring of compliance with the guidelines,

(d) conduction of site visits at regular intervals, and

(e) publication of lists of accredited units.

The Council of the FSA decided upon the composition of the RTAC, being the Chairman (nominated by the FSA), a medical practioner with knowledge of IVF (nominated by the Royal Australian College of Obstetricians & Gynaecologists), a medical scientist with a knowledge of reproductive biology

(nominated by the Australian Society for Medical Research), a patient representative (nominated by the Infertility Federation of Australasia), and a biomedical ethicist (nominated by the National Health & Medical Research Council). The committee met for the first time in March 1988.

The Code of Practice issued by the RTAC is more concerned with the day-to-day running of the unit, and makes specific recommendations regarding staff and resources, patient services that are available, information and consent forms, issues relating to treatment methods, record keeping, ethics and research, and quality control. The Code states that every IVF Unit must practice within the guidelines published by the National Health and Medical Research Council (NH&MRC), yet another set of regulations. These state in Supplementary Note 4 that all aspects of the unit must be approved by the local Institutional Ethics Committee, yet another regulating body at a local level.

The cost associated with accreditation is a flat fee of Aus$500 per annum, plus a levy of Aus$4 per IVF treatment cycle. One form is completed per cycle, the data being supplied to the National Perinatal Statistics Unit of the FSA.

SUMMARY

The practice of IVF in Western Australia is subject to several layers of oversight. At a local level, each unit has to be monitored by the Institutional Ethics Committee, as well as abide by the Reproductive Technology Act and satisfy the associated body, the Reproductive Technology Council. In addition, accreditation is bestowed at a national level, with diagnostic laboratories being accredited by the NATA and clinics by the Reproductive Technology Accreditation Committee.

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