THE MEDICO-LEGAL AND ETHICAL ISSUES SURROUNDING THE CREATION OF A HUMAN EMBRYO

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CHAPTER 1

1.1.INTRODUCTION

It has been estimated that 10-20% of all married couples are infertile[1]. Infertility is generally defined as the inability to conceive after 12 months of unprotected intercourse[2]. The definition of infertility may also include "infecundity, meaning the inability to conceive or impregnate, and pregnancy wastage, meaning failure to carry a pregnancy to term through spontaneous abortion and stillbirth. Infertility includes primary infertility, where a couple has never achieved conception, and secondary infertility, where at least one conception has occurred but the couple is currently unable to achieve pregnancy"[3]. Natural conception has many disadvantages according to Wood[4]. He submits its' success is unpredictable, ranging from one month to several years. It places stress on couples that are anxious to conceive which results in a reduction in sexual enjoyment, which in turn reduces the chances of live sperm reaching the cervix, and in the male may cause impotence or reduced sperm quality, resulting from incomplete ejaculation[5]. Natural conception allows the implantation of genetically abnormal embryos, resulting in therapeutic abortion if the defect if detected, or the birth of mentally or physically defective children if not detected, or if abortion is not considered ethical by the parents[6]. Sexually transmitted diseases may occur at the time of conception and may adversely

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1 D.Giesen *International Medical Malpractice Law* (1988) para 1343 page 628
2 J.Yeh and M.Uline-Yeh *Legal Aspects of Infertility* (1991) 1
3 B.Dickens *Reproductive Law and Medical Consent* (1985)35 U. Tor. L.J. 255
4 C.Wood 'Future Trends in Human Reproduction' (2000) 40 No.2 *Australian and New Zealand Journal of Obstetrics and Gynecology*127-132
5 Ibid
6 Ibid

affect the mother or the child[7]. Paternity is not guaranteed as 3-7% of offspring result from a father outside the marriage or de facto relationship[8].

Assisted reproductive technologies (ART's) are making it possible for these couples to have their 'own 'children as opposed to adopting a child[9]. It is preferable for women with unwanted pregnancies to abort the pregnancy than to have the child and to put it up for adoption. It is also possible for these children to have up to five parents (genetic mother, genetic father, rearing mother, rearing father and surrogate mother)[10]. Assisted reproduction has increased women's reproductive choices and liberty. But, it is also possible that these reproductive technologies may further oppress women according to Schenker and Eisenberg[11]. They submit that assisted reproductive techniques may lead to pressure on women to undergo several cycles of treatment; for which prenatal sex testing might lead to pressure to abort, while prenatal genetic testing makes a woman responsible for having a handicapped offspring if she rejects amniocentesis, when previously she would have been seen as 'a victim of the natural lottery[12]'. Women may be treated as a reproductive vessel to produce or serve the interests of males and the state in achieving healthy offspring[13]. Women are known to undergo hazardous reproductive procedures when the reason for the infertility is the male factor[14].

There are various methods of ART's including:

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[7] Ibid
[8] Ibid
[9] Giesen op cit 629
[10] M.A.Dada and D.J.McQuoid -Mason eds *Introduction to Medico-Legal Practice* (2001) 67
[11] J.G.Schenker and V.H.Eisenberg 'Ethical Issues relating to Reproduction Control and Women's Health' (1997) 58 *International Journal of Gynecology and Obstetrics* 167-176
[12] Ibid
[13] Ibid
[14] Ibid

- AID[15] : A donor sperm is introduced into the vagina by a syringe or similar means.
- AIH[16] : The husband's sperm is introduced into the vagina by a syringe or similar means.
- GIFT[17] : Eggs are collected and together with sperm from the husband or donor are put directly into the woman's fallopian tube (the tubes through which the egg in the normal course descends into the uterus[18]).
- POST[19] : Eggs and sperm are collected and placed into the peritoneum.
- VISPER[20] : Only sperm is transferred directly into the woman's peritoneal cavity.

But these methods do not confront society with the many issues that arise from the creation of the extra-corporeal human embryo when utilizing *in vitro* fertilization and embryo transfer (IVF-ET). IVF-ET[21] begins with the extraction of a ripe human egg from the ovary, before it would have been released naturally. The retrieval of the eggs is guided by ultrasound. The egg is then mixed with the sperm of the husband, partner or donor, so that fertilization can occur. The fertilized egg (embryo), once it has started to divide, is then transferred back to the mother's uterus. (See Figure 1.)[22]

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[15] Artificial insemination donor (AID) M.L.Lupton "Medico-Legal Aspects" in I.D.Schafer (ed) *Family Law Service* 46 J109

[16] Artificial insemination husband (AIH)- See Lupton op cit J107

[17] Gamete intra fallopian transfer (GIFT)- See Lupton op cit J107 (d)

[18] S.A.Strauss *Doctor, Patient and the Law* (1991)187

[19] Peritoneal oocyte and sperm transfer (POST)- See Lupton op cit J107 (c)

[20] Vaginal intro-peritoneal sperm transfer (VISPER)- See Lupton op cit J107 (e)

[21] In vitro fertilization-embryo transfer (IVF-ET)- See Kennedy and Grubb The Warnock Report para 5.2 633

[22] B.Dale and K.Elder *In Vitro Fertilization* (1997) 69

- ICSI[23] : A single sperm is injected directly into the egg.
- SZI[24] : Several sperms are inserted into the perivitelline space.
- PZD[25] : A mechanical technique involving making a hole in the zona pellucida with a sharp glass micropipette and subsequently placing the dissected egg into a suspension of sperm on the assumption that sperm entry is facilitated by the slit.
- ZD[26] : A mechanical technique involving making a hole in the zona pellucida with a sharp micropipette and then placing the egg in a suspension of sperm.
- Cloning[27] : A biological mechanism of reproduction by which one or more genetically identical cells are derived from a single parent.
- Twinning[28] : The splitting and implanting of embryo cells that are totipotent[29] to obtain multiple embryos from one sperm and egg that are genetically the same.

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[23] Intra cytoplasmic sperm injection (ICSI)-See S.H.Aitee 'A Simple Approach to Intracytoplasmic Sperm Injection' (1995) 63 No.3 *Fertility and Sterility* 652-655

[24] Sub zonal sperm injection (SZI)- See B.Dale. and K.Elder *In Vitro Fertilization (*1997) 67

[25] Partial zona dissection (PZD)- See Dale and Elder 67

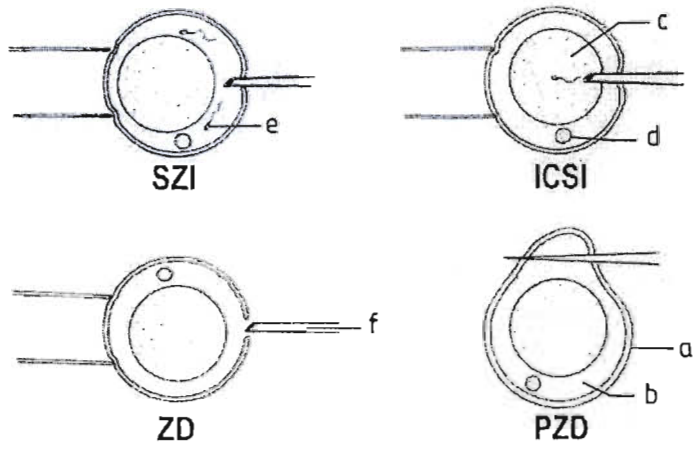
[26] Dale and Elder op cit 177

[27] S.J.Fasouliotis and J.G.Schenker. 'Ethics and Assisted Reproduction' (2000) 90 *European Journal of Obstetrics and Gynecology and Reproductive Biology* 171-180

[28] Dada and McQuoid-Mason op cit 66

[29] Totipotent means the ability of a cell to develop into any type of cell-Dorland's *Illustrated Medical Dictionary*

Figure 1. Some methods of Artificial Reproductive Technology



a-zona pellucida | c-egg cytoplasm | e-sperm

b-perivitelline space | d-polar body | f-micropipette

The aim of this project is to identify the many problems that arise during the creation of the embryo- from the initial selection of donors, their gametes and the recipients, through to the conception, post-conception and finally the issues that concern the rights to, over and of, embryo's that are spare and not used or cryopreserved[30].

1.2.CONCLUSION

There are many assisted reproductive technologies available that allow a person to have their own child. It is submitted that before a specific technique is decided upon, the

[30] The maintaining of the viability of excised tissue or organs by storing at very low temperatures – Dorland's *Illustrated Medical Dictionary*

recipient must have all the information available to her so that a fully informed decision can be made. Each person needs to be able to weigh the risks attached to each technique and balance it against the benefits.

CHAPTER 2

PRE-CONCEPTION

2.1.INTRODUCTION

In South Africa, artificial fertilization is governed by the Human Tissue Act[1] (HTA) and the regulations[2] promulgated in terms of the Act[3]. There are also proposed new Regulations that have yet to be implemented[4]. In terms of the HTA, artificial fertilization of a person means the introduction by other than a natural means of a male gamete or gametes into the internal reproductive organs of a female person for the purpose of human reproduction, including the bringing together outside the human body of a male and female gamete or gametes with a view to placing the product of a union of such gametes in the womb of a female person; or the placing of the product of a union of a male and female gamete or gametes which have been brought together outside the human body, in the womb of a female person, for such purpose. These regulations promulgated are not applicable[5] to the:

- Removal or withdrawal of a gamete from the body of a married man for the purposes of the artificial insemination of his wife.
- The artificial insemination of a married woman where only a gamete removed or withdrawn from her husband is involved.

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1 Act 65 of 1983
2 Government Notice R1182 of June 1986 (Government Gazette 10283)
3 Section 37
4 Government Notice No.433 of 17 May 1991 (Government Gazette 13228)
5 Regulation 2

In terms of the HTA, gamete is defined as either of the two generative cells essential for human reproduction[6].

2.2.SELECTION OF THE DONOR

The use of donor sperm to treat an infertile couple can be traced back to the 19th century[7]. In 1884, Dr. Pancoast, a professor at Jefferson Medical College in Philadelphia, examined an infertile patient. She was a Quaker and the wife of a merchant. Her name was never recorded. Dr. Pancoast had examined her on numerous occasions and finally discovered that she was fertile and that the husband had the fertility problem. He asked her to come in for one more examination. The woman lay on the table as she had been told to do. Dr. Pancoast's six medical students (all young men) stood around her body. He anaesthetized the woman with chloroform and subsequently inseminated her using a hard rubber syringe with semen that Dr. Pancoast's medical student had masturbated in. The semen was inserted into her uterus and the cervix was then plugged with gauze. When the woman awoke, the doctor did not tell her what he had done. This was clearly unethical. The doctor was paternalistic and did what he thought was best for the woman without asking her consent. The doctor did not respect the patient's autonomy for decision-making. Nine months later the woman bore a son. This was the first reported case of human artificial insemination.

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[6] Act 65 of 1983

[7] http://fubini.swarthmore.edu/ W530/W530F1998/nrosado3.html

The primary reason for the use of donor sperm is to treat the infertile couple when abnormal semen findings exist in the husband and the wife is potentially fertile[8]. The causes for male infertility include if the husband is permanently sterile because of irreversible azoospermia[9]; the husband is sterile after a vasectomy and does not want a surgical correction or the correction was unsuccessful; the husband has a known genetic disorder, and if the husband has other semen abnormalities that cannot be treated[10].

The right procreate is entrenched in the Bill of Rights[11] giving everyone the right to bodily and psychological integrity, which includes the right to make decisions concerning reproduction. The single person may feel the same desire to have a child as a married person and should therefore be granted the same right as a married couple. The single woman who wants a child might therefore choose to be artificially inseminated with donor sperm and a single man may choose to inseminate donated eggs and allow a surrogate mother to bear his child. However, the Warnock[12] Committee recommends that as a general rule it is better for children to be born into a two-parent family. The British Human Fertilization and Embryology Act[13], states that a woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need for that child for a father), and of any other child who may be affected by the birth.

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[8] Ethics Committee of the American Fertility Society 'Ethical Considerations of the New Reproductive Technologies' (1990) 53 No.6 *Fertility and Sterility* 43S

[9] Azoospermia is the absence of spermatozoa in the semen or failure of formation of spermatozoa-Dorland's *Illustrated Medical Dictionary*

[10] Ethics Committee of the American Fertility Society op cit

[11] Constitution of South Africa Act108 of 1996 Section 12. (2)

[12] HM Stationery Office.Report of the Committee of Inquiry into Human Fertilization and Embryology (1984) Section 2.11

[13] Act 1990 Section 13(5)

A donor egg can also offer the possibility of children for couples when the woman is not able to provide her own eggs. Specific instances when donor eggs would be necessary are if the patient's ovaries are absent, in ovarian failure (egg exhaustion), if the patient has a genetic defect and even if the methods for harvesting the eggs are inadequate to retrieve eggs from ovaries that seem to be functioning normally[14]. Donor eggs may be obtained from patients undergoing *in vitro* fertilization[15] (excess eggs retrieved), or voluntary donation by women undergoing tubal ligation[16] or other abdominal surgery. A relative or friend or a person unknown to the recipient may also specifically donate donor eggs[17].

It has also been suggested by some researchers[18] that eggs from foetuses might eventually be used in egg donation programs. The eggs may be removed from the ovaries of aborted foetuses, matured *in vitro* and then used in egg donation programs, or the ovaries may be removed from aborted foetuses and transplanted into women who lack ovarian function so that the transplanted tissue will eventually contribute to the woman's normal reproductive cycle[19]. In England, the Human Fertilization and Embryology Act[20], states that no person shall, for the purpose of providing fertility services for any woman, use female germ cells taken or derived from an embryo or a foetus or use embryos created by using such cells. In this section, female germ cells means cells of the female germ line and includes such cells at any stage of maturity, and accordingly includes eggs; and

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[14] Ethics Committee of the American Fertility Society op cit 48S

[15] In vitro fertilization (IVF) means fertilizing in a laboratory dish (*in vitro* literally means 'in glass') S.A.Strauss *Doctor, Patient and the Law* 3rd ed. (1991) 187

[16] R.Frydman, H.Letur-Konirsh, D. de Ziegler, M.Bydlowski, A.Raoul-Duval and J. Selva 'Anonymous Exchange of Donated Eggs' (1990) 53 *Fertility and Sterility* 666-672

[17] Ethics Committee op cit 48S

[18] A. Shoshone and J.G. Schenker 'The Use of Oocytes Obtained from Aborted Fetuses in Egg Donation programs' (1992) 62 *Fertility and Sterility* 449-51

[19] Ethics Committee of the American Fertility Society for Reproductive Medicine 'The Use of Fetal Oocytes on Assisted Reproduction' (1997) 67 No.5 *Fertility and Sterility*

[20] Act 1990 Section 3A

fertility services means medical, surgical or obstetric services provided for the purpose of assisting women to carry children. It must be noted that the present use of foetal eggs is both hypothetical and speculative[21].

In South Africa prior to the removing or taking of gametes the donor must sign a written statement of consent to a physical examination and interview by a medical practitioner[22]. including an evaluation of the donors psychological suitability for the purposes of artificial insemination[23]. Consent must also be given for the taking of samples of gametes for the purposes of testing and analysing as deemed necessary by the medical practitioner[24]. If the donor comes from a population group in which there is a high risk of being a carrier of a specific genetic defect, then the donor must be tested for the characteristics concerned[25]. If the donor is found to be a carrier of that specific defect then the gametes of that donor will not be used for artificial insemination[26].

The donor must also consent to personal details being made available to certain persons[27]. The recipient[28] needs to be informed of the donor's age height mass eye-colour, complexion, population group, nationality, sex, religion, occupation, highest educational qualification and fields of interest. The doctor performing the insemination needs to know the same information as the recipient, including family history with special reference to possible genetic carrier conditions and mental disorders[29], wishes in respect

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[21] Ibid
[22] Regulation 4.(d)(i)
[23] Regulation 6.(1)(c)
[24] Regulation 4.(d)(ii)
[25] Regulation 9(e)(iv)
[26] Regulation 9(e)(bb)
[27] Regulation 4.(iii)-(v)
[28] Regulation 6(ii)
[29] Regulation 6(1)(a)(iii)

of the population group and religion of the recipient[30] and wishes in respect of the number of artificial inseminations for which his gametes may be used[31]. The Director-General[32] of National Health and Population Development must be informed of the donor's identity number, the identity number of the donor's file, the number of donations and their dates, the identity number of the recipients file and the number of live births reported with the file identity number of the recipient concerned[33].

The donor must also have in his/her possession written permission from his/her spouse if married[34]. This is in contradiction of the Constitution, which states that everyone has the right to make decisions concerning reproduction,[35] and to security in and control over their body[36].

In addition to the above, the Human Tissue Act stipulates that the donor must not be mentally ill within the scope of the Mental Health Act[37], or a person who has been declared a habitual criminal in terms of the Criminal Procedure Act[38] 51 of 1977[39].

The Human Tissue Act also prohibits the use of gonads for certain purposes[40]. It prohibits the removal and transplantation of a gonad from a dead person to the body of a living person if the result of such transplantation may be procreation. Gonad is defined in the

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30 Regulation 6(1)(a)(iv)
31 Regulation 6.(1)(a)(v)
32 Regulation 4.(d)(v)
33 Regulation 6.(2)(d)
34 Regulation 5.(d)
35 Section 12(2)(a)
36 Section 12(2)(b)
37 Act 18 of 1973 A mental illness is defined as any disorder or disability of the mind, and includes any development of the mind and any psychopathic disorder.
38 Act 51 of 1977 s286. A habitual criminal is defined as a person who if convicted by a superior court or a regional court of one or more offences, may, if it is satisfied that the said person habitually commits offences and that the community should be protected against him, declare him a habitual criminal.
39 Section 286
40 Section 16

Act as the human organ, which produces gametes[41]. The definition of gonad includes the organ and the gametes therein, and therefore the use of gametes from a dead person is prohibited for use in IVF. The proposed new Regulations[42] regarding artificial insemination specifically state that gametes, which have been removed from the body of a deceased person, may not be used for the artificial fertilization of a person[43].

Postmortem sperm procurement is possible and was first reported in 1980 by Rothman[44]. In June 1994, a newly wed wife stated that she wished to preserve the sperm of her deceased husband so that she could bear his child in the future[45]. Between 1980-1995 in the United States, a total of 82 requests for postmortem procurement were revealed[46]. More than half of these requests (43) occurred between 1994 and 1995, indicating a growing trend. In terms of the British Human Fertilization and Embryology Act 1990[47], gametes are referred to as live gametes, and therefore removing and using gametes from dead persons are not allowed. The United States does not have such legislation[48]. Postmortem sperm must be retrieved within 24 hours of death to have any chance of being viable[49].

Sperm may be obtained by electro-ejaculation whereby an electrical probe is inserted into the rectum and an electric current is used with increasing voltage. An assistant milks the urethra to direct semen into a container. Stimulation is terminated when no more fluid

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[41] Act 65 of 1983
[42] Notice 433 of 1991
[43] Proposed Regulation 8 (5)(c)
[44] C.M.Rothman 'A Method for Obtaining Viable Sperm in the Postmortem State' (1980) 34 *Fertility and Sterility* 512
[45] W. Lowther 'I Want a Baby by My Dead Husband; Ethics Row after Sperm is Taken from Crash Victim' 19 June 1984. *Associated Newspapers Ltd.* 13
[46] S.M.Kerr, A.Kaplan, G.Polin, S.Smugar, K.O'Neill and S.Urowitz 'Postmortem Sperm Procurement' (1997) 157 *Journal of Urology* 2154-2158
[47] Section 1(4)
[48] Kerr *et al* op cit
[49] Ibid

exits the urethra. Other methods are vas deferens irrigation (the vas deferens is dissected out of the scrotum and then irrigated with tubal fluid); epididymal extraction (a biopsy of the testis is taken); and epididymal aspiration (a section of the testis is aspirated with a needle or a biopsy gun)[50]. It is therefore apparent that sperm may be obtained without the transplantation of the gonads.

In terms of the Constitution[51], everyone has the right to bodily and physical integrity[52], which includes the right to security in and control over their body and to make decisions regarding reproduction. It is therefore submitted that if an individual gives his consent, perhaps an advanced directive, to the removal of his sperm after his death for use by his partner then it should be permitted.

The Human Tissue Act allows for the storage of gametes for a specific purpose[53]. The intention here is not to relinquish the gametes but to use them for a defined purpose as submitted by Pretorius[54]. This means that if a couple are undergoing IVF treatment using the husband's frozen sperm, and the husband dies, then the wife would still be able to utilize the sperm as the sperm would have been stored for the specific purpose of fertilizing the wives' egg. This would then allow for posthumous conception. Giesen[55] submits that posthumous insemination should not be permitted because the right to dispose of the sperm ends with the death of the sperm donor. The Warnock Committee stated that the birth of a posthumous conceived child might give rise to profound psychological problems for the child and the mother[56]. The UK's White Paper of

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[50] Ibid
[51] Act 108 of 1996
[52] Section 13(2)
[53] Section 36
[54] D.Pretorius 'Rights to Gametes, Zygotes and Embryos in Storage' (1993) 12 *Medicine and Law* 607-616
[55] Giesen op cit 1359
[56] Warnock Report para4.4

November 1987 stated that the donor's wishes must be paramount and only if the donor has consented, may the gametes be used[57]. The White Paper also stated that posthumous conception should not be actively encouraged[58]. The British HFEA states that persons giving consent to the storage of any gametes or embryo must state what is to be done with the gametes or embryo if the person who gave the consent dies or is unable because of incapacity to vary the terms of the consent or to revoke it[59]. This may be interpreted as permitting posthumous transfer. However, the child so conceived is to be regarded as illegitimate in terms of the HFEA[60] because the sperm of a man or any embryo the creation of which was brought about with his sperm, after his death, is not to be treated as the father of the child. Therefore, although the HFEA does not prohibit posthumous use of stored sperm or embryos, it ensures that any child born will not have a claim on the estate of the dead man[61].

In the French case brought against the CECOS[62], Mrs. Parpalaix asked that she use her husband's sperm that was stored in a fertility clinic after her husband had died. The court decided that there was a specific contract for the CECOS to preserve the sperm and to restore it to the donor or to hand it over to the person for whom it was intended. In South Africa, embryos conceived before the death of the father and only transferred after his death are the legitimate children of that man because they were conceived whilst the

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[57] HMSO 'Human Fertilization and Embryology: A Framework for Legislation' (White Paper of November 1987) para 51
[58] Section 59
[59] Schedule 3: 2.(2)(b)
[60] Section 28(6)(b)
[61] Kennedy I. and Grubb A. *Medical Law: Text and Materials* 2nd ed. (1994) 819
[62] *Parpalaix v CECOS* (Centre d'Etude et de Conservation du Sperme) and Federation Francaise des Centres d'Etude et de Conservation du Sperme 1 August 1984

couple was still married[63]. Therefore, children conceived after the death of a parent is deemed to be illegitimate.

It is submitted that since posthumous conception is permitted, then it is irrelevant whether the person is alive or dead when the sperm is removed, as long there is a valid consent.

2.2.1.CONCLUSION

There are many reasons why a person who desires a child may resort to the use of donated gametes. The woman may be single or in a lesbian relationship or she may have medical problems relating to infertility or may even be post-menopausal. The man may be homosexual or he may also have a medical problem relating to infertility. Everyone has the right to make decisions concerning reproduction[64]. According to the 1950 European Convention of Human Rights, men and women of marriageable age have the right to marry and to found a family[65]. Therefore everyone has the right to procreate even if it means using donated gametes. The British HFEA does not prohibit posthumous conception, but the Warnock Committee has grave misgivings about posthumous conception because it may give rise to profound psychological problems for the child and the mother[66]. The HFEA refers to gametes as live gametes and the South African Human Tissue Act prohibits the transplantation of gonads from dead persons. It is submitted that postmortem sperm procurement be allowed with the written consent of the donor.

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[63] Schafer *Family Law Service* E8:3
[64] Bill of Rights s12(2)
[65] Article 12
[66] para 4.4

2.3.SELECTION OF THE GAMETES

The assessment of the fertilizing capacity of eggs and spermatozoa before IVF is very important. Furthermore it is necessary to ensure that the appropriate method of treatment for infertility is chosen[67].

2.3.1.SELECTION OF THE SPERM

The quality of semen is generally assessed by the parameters of sperm concentration, motility, forward progression and morphology[68], as determined by the World Health Organization (WHO) criteria[69] or strict Kruger *et al* criteria[70]. The WHO laboratory manual describes standard conditions for the collection of semen samples, their delivery, and the standardization of laboratory assessment procedures. The Kruger criteria evaluate spermatozoa according to the number of abnormal spermatozoa (abnormal heads, abnormal tails, midpiece abnormalities and immature forms)[71].

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[67] K.Ohashi, F.Saji, M.Kato, T.Tsutsui, T.Tomiyama and O.Tanizawa 'Acrobeads Test: A New Diagnostic Test for Assessment of the Fertilizing Capacity of Human Spermatozoa' (1995) 63 *Fertility and Sterility* 625-630

[68] Ibid

[69] World Health Organization. *WHO Laboratory Manual for the Examination of Human Semen and Semen-Cervical Mucus Interaction*. 2nd ed. 1987:67

[70] T.F.Kruger, A.A.Acosta, K.F.Simmons, R.J.Swanson, J.F.Matta and S.Oehninger 'Predictive Value of Abnormal Sperm Morphology in In Vitro Fertilization '(1988) 49 *Fertility and Sterility* 112-7

[71] Ibid

Figure 2[72] below illustrates the structure of spermatozoa.

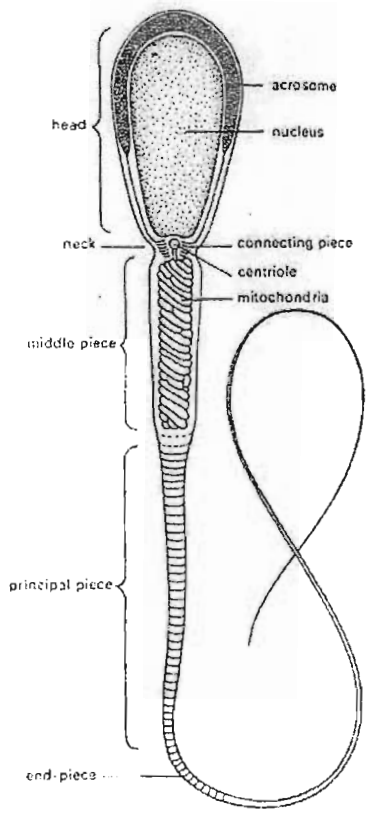

Figure 2. Structure of spermatozoa

[72] A.L.Smit and D.E. van Dijk *Introduction to Modern Biology* (1982) 534

Figure 3[73] below illustrates the different types of spermatozoa morphology.

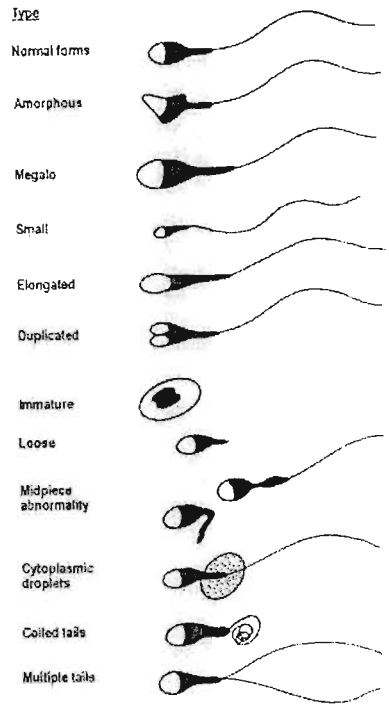

Figure 3. The different types of spermatozoa morphology

Sperm morphology is assessed by the number of sperms with abnormal heads, abnormalities in the tail section, midpiece abnormalities and the number of immature sperms[74].

The WHO standards indicate that a normal semen sample should contain at least 20 million sperm with at least 50% having good to excellent forward progressive movement within 60 minutes after ejaculation[75]. The seminal plasma (semen) contains factors that inhibit fertilization[76].

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[73] B.Dale and K.Elder *In Vitro Fertilization* (1997) 88
[74] Dale and Elder op cit 87
[75] Dale and Elder op cit 85
[76] S.Gelllert-Mortimer, G.N.Clarke, H.W.Gordon Baker, R.V.Hyne and W.H.Johnson 'Evaluation of Nycodenz and Percoll Density Gradients for the Selection of Motile Human Spermatozoa' (1988) 49 *Fertility and Sterility* 335-340

Before gaining the ability to fertilize eggs, the ejaculated sperm must undergo a process called capacitation. Capacitation is a change involving the shedding of a part of the sperm cell head that occurs as the sperm passes through the female genital tract[77]. This is necessary for the sperm to penetration through the zona pellucida[78] of the egg. The zona pellucida is the noncellular layer surrounding the egg[79]. Washing the sperm in a basic salt solution is adequate for capacitation to occur *in vitro*[80]. Sperm washing is also necessary to remove the seminal plasma and to select the motile spermatozoa prior to the *in vitro* egg fertilization[81]. Seminal plasma is made up of spermatozoa (live and dead), and secretions from the testis, the epididymis and the prostate[82]. These procedures normally occur at the cervix *in vivo*[83], where the cervical mucus blocks the transport of non-motile and poorly motile spermatozoa[84].

In an attempt to imitate *in vivo* conditions, many IVF laboratories separate the motile from the immotile spermatozoa. Motility and progressive motility are essential qualities for the spermatozoa to penetrate the egg during IVF[85]. There are a variety of sperm preparation methods and function tests available for assisted reproductive technology

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77 C.Wood and A.Westmore *Test-Tube Conception* (1984) 11

78 K.Takahashi, A.M.M.Wetzels, H.J.M.Goverde, B.A.Bastiaans, H.J.G.Janssen and R.Rolland 'The Kinetics of the Acrosome Reaction of Human Spermatozoa and its Correlation with In Vitro Fertilization' (1992) 57 No. 4 *Fertility and Sterility* 889-894

79 See Fig. 1

80 S.Fishel and E.M.Symonds *In Vitro Fertilization Past, Present, Future* (1986) 108

81 Ibid

82 Dale and Elder op cit 90

83 D.Mortimer 'The Male Factor in Infertility. Part II:Sperm Function Testing.'(1985) 3 No.8 *In Current Problems in Obstetrics, Gynecology and Fertility* 75

84 J.Rhemrev, R.S.Jeyendran, J.P.W.Vermeiden and L.J.D.Zaneveld 'Human Sperm Selection by Glass Wool Filtration and Two-layer, Discontinuous Percoll Gradient Centrifugation' (1989) 51 *Fertility and Sterility* 685-690

85 P.M.Zavos 'Semen Preparation by Sperm Prep and Swim-up' (1992) 57 No.6 *Fertility and Sterility* 1326-1330

laboratory use[86]. There are also new technologies that allow the separation of male and female spermatozoa, thereby permitting the use of ICSI[87](injecting a single sperm into an egg) to avoid the birth of children with sex-linked diseases[88]. Smith[89] submits that sperm samples should be individually prescreened before use in assisted reproductive technology (ART) procedures, because no single sperm separation technique is always superior.

2.3.2.SELECTION OF THE EGG

Egg donation programs have allowed young women without functioning ovaries or the inability to use their eggs because of genetic or other reasons to become pregnant through IVF of donated eggs. During IVF, one must correctly estimate the egg's developmental stage in order to determine its suitability for fertilization[90]. Eggs may be obtained by laparoscopy[91]. Laparoscopic egg retrieval is a surgical technique requiring general anaesthesia and distension of the woman's abdomen with a carbon dioxide gas mixture. To remove eggs, the doctor makes three incisions below the woman's navel through which instruments are inserted. The laparoscope is a light guide allowing observation of the ovaries; a pair of forceps is used to grasp and rotate the ovary; and a suction device is used to pull out ripe eggs. Another method of egg retrieval is via ultrasound-guided

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[86] S.Smith, S.Hosid and L.Scott 'Use of Postseparation Sperm Parameters to Determine the Method of Choice for Sperm Preparation for Assisted Reproductive Technology' (1995) 63 *Fertility and Sterility* 591-597

[87] Intra cytoplasmic sperm injection See page 4

[88] J.T.Queenan and G.Whitman-Elia 'An Appreciation of Modern ART's' (2000) 43 No.4 *Clinical Obstetrics and Gynecology* 942-957

[89] Smith *et al* op cit 596

[90] F.Gulamali-Majid 'Kinetic Immunonephelometric Determination of Protein Concentrations in Follicular Fluid' (1987) 33 No.7 *Clinical Chemistry* 1185-1189

[91] P.Spallone *Beyond Conception* (1989) 60

aspiration[92]. Ultrasound scanning[93] is the use of high frequency sound waves to show visual outlines of internal body parts. It is also used to guide doctors when removing eggs from the ovaries. Once removed the eggs are assessed using a microscope for their maturity and fertilizing capacity[94]. The eggs are incubated in a culture medium for 3-4 hours before fertilization[95]. Immature eggs are incubated for a longer period to lead to better rates of fertilization[96].

2.3.3 CONCLUSION

The use of donated gametes has enabled many women to have children. When selecting gametes for assisted reproductive techniques, the gametes that exhibit the best potential for fertilization must be selected. Gametes that are free of heredity diseases must also be selected. It is therefore submitted that adequate assessments be made on gametes so that the woman has the best possible chance of conception and of delivering a normal, healthy infant. Older women have a decreased reproductive potential[97]. It is therefore submitted that the egg donor be under the age of 35 years[98]. The ability to conceive may be impaired in egg donors. It is therefore submitted that the egg donor has at least one child[99] before accepted into an egg donation program.

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[92] H.W.Jones, G.Seegar Jones, G.D.Hodgen and Z.Rosenwaks *In Vitro Fertilization- Norfolk* (1986) 52
[93] P.Spallone op cit 38
[94] B.Dale and K.Elder *In Vitro Fertilization* (1997) 107
[95] Ibid
[96] Queenan *et al* op cit
[97] N.Nikolettos, W.Kupker, S. Al-Hasani, L.C.Demirel, B.Schopper, R.Sturm and K.Diedrich 'ICSI Outcome in Patients of 40 years Age and Over: A Retrospective analysis' (2000) 91 *European Journal of Obstetrics and Gynecology* 177-182
[98] See section 2.7.6.
[99] See section 2.7.5.

2.4.SELECTION OF THE RECIPIENT

Before artificial insemination/fertilization is performed, the recipient must consent in writing to a physical examination and interview by a medical practitioner[100] and the removal or withdrawal of gametes for the purposes of testing and analysing as deemed necessary by the medical practitioner[101]. The recipient may be single or married. She must also be biologically, physically, socially and mentally suited for artificial insemination[102].

The recipient must also give an informed consent to her artificial insemination[103]. If the recipient is married and she requests donor spermatozoa, the consent of her husband must also be obtained. The child born as a result of such fertilization is therefore deemed to be the legitimate child of that woman and her husband[104]. For the consent to be informed the recipient must receive all information regarding the implications of artificial insemination including the problems that exist with the technique, the chances of success, the financial aspects, the risks attached to the genetic properties of a gamete, the status of the child and legal advice which may be obtained with regard to artificial insemination[105]. Consent must also be given for certain personal details to be made available to the Director-General[106], (National Health and Population Development) viz. her identity number, the

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[100] Regulation 9(d)(i)
[101] Regulation 9(d)(ii)
[102] Regulation 9 (e)(ii)
[103] Regulation 9(d)(iii)
[104] Children's Status Act 82 of 1987 s5.(1)(a)
[105] Regulation 9(e)(bb)
[106] Regulation 9(d)(iv)

identity number of the appropriate recipient's file, the date of successful artificial insemination, and the result of the pregnancy, if known[107].

If the recipient comes from a population group that has a high risk of being a carrier of a specific defect[108], then both the donor and the recipient must be tested and the gamete of a donor with the same characteristics as the recipient may not be used for artificial insemination[109]. If the recipient is a carrier of a genetic defect then the recipient shall be given genetic counselling[110]. For instance Caucasians are at a greater risk of cystic fibrosis, Southeast Asians (Vietmanese, Laotian, Cambodian, Filipino, Chinese) are at risk of thalassemia, Mediterranean people/Chinese are at risk of thalassemia, Ashkenazi Jews are at risk of Tay-Sachs disease, the Afrikaner population in South Africa is at a risk of familial hyperlipidaemia and porphyria and the South African Indian population is also at a risk of thallaseamia.

The success of egg donation to older women makes pregnancy possible in virtually any woman with a normal uterus, regardless of age or the absence of ovaries or ovarian function.[111]. The uterus seems to retain its receptivity to embryo implantation beyond the age of natural menopause as long as the female hormones of progesterone and estrogen are administered[112]. A postmenopausal woman who loses her only child may choose to have another, or a postmenopausal woman who never had children may now desire a child. Society protects the individual's right to privacy and reproductive choice.

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[107] Regulation 10(2)(c)

[108] For example Tay-Sachs disease S.A.Strauss *Doctor, Patient and the Law* 3rd ed. (1991) 182

[109] Regulation 9(e)(iv)

[110] Regulation 9(e)(aa)

[111] The Ethics Committee of the American Society for Reproductive Medicine 'Ethical Considerations of ART's' (1997) 67 No. 5 *Fertility and Sterility* 2S-3S

[112] S.J.Fasouliotis and J.G.Schenker 'Ethics and Assisted Reproduction' (2000) 90 *European Journal of Obstetrics and Gynecology* 171-180

Society, however, does not view men and women equally when it comes to age, so that an older woman is considered unable to have a child[113]. It is true that older men may father children, but denying women a successful alternative for reproduction at ages equivalent to men is sexist, especially as women live longer than men[114].

However advanced maternal age is associated with an increase in maternal and foetal morbidity and mortality[115]. In a postmenopausal pregnancy, Fasouliotis and Schenker[116] submit, the woman does not genetically reproduce, but she alone faces the risks of hypertension (high blood pressure), diabetes, multiple gestations, preterm labour and all the other complications of pregnancy and child-birth. Since it is the woman who bears the child, and delivers it and nurses it, it should therefore be her choice to make.

People against egg donation to older women argue that the older individual is less capable of coping with the physical and psychological stress of parenting[117]. Having parents of advanced age may cause the children to endure a greater generational gap or the lack of grandparents[118]. But, there is greater financial and professional security in older couples. They also have a greater motivation for parenthood. Pregnancy in an older woman must be carefully monitored to reduce the risk of death. The Ethics Committee of the American Fertility Society[119] feels that fertility is the norm during the reproductive years and doctors are justified in their efforts to correct deficient ovarian function. Therefore infertility should remain the natural characteristic of menopause. It is also felt

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[113] Ibid
[114] Ethics Committee of the American Fertility Society op cit 2S
[115] Fasouliotis and Schenker op cit 174
[116] Ibid
[117] Ibid
[118] Ibid
[119] Ethics Committee of the American Fertility Society op cit 3S

that because of the physical and psychological risks involved, postmenopausal pregnancy should be discouraged.

Reproduction however is a fundamental right in a free society. Denying egg donation to a population of women who must rely on it to procreate deprives them of this freedom[120]. Doctors who attempt egg donation in older women may be accused of tampering with nature, acting irresponsibly or playing God[121]. Life expectancy at 50 is long enough to enable a healthy woman to raise a child to adulthood[122]. It has been suggested that by taking into consideration both the mother's and the child's welfare, that an age limit of 55 years be set[123].

2.4.1 CONCLUSION

Everyone has the right to make decisions concerning reproduction[124] and to security in and control over their body[125]. A woman, who wants to conceive using assisted reproductive technologies, ought to be able to receive relevant information pertaining to all the alternatives that are available to her, the disadvantages as well as the advantages, and including all the risks. Older women are at greater risk of complications during pregnancy, but if it is a risk that they are already aware of, then it is their choice to continue with fertility treatment. There is a decrease in fertility in women older than 35

[120] Fasouliotis and Schenker op cit 175
[121] Ibid
[122] Fasouliotis and Schenker op cit 174
[123] Fasouliotis and Schenker op cit 175
[124] Bill of Rights s12(2)(a)
[125] Bill of Rights s12(2)(b)

years[126]. It is submitted that if the recipient is older than 40 years she be informed of the alternative of egg donation.

2.5.SELECTION OF THE DOCTOR

The medical practitioner who wishes to perform artificial fertilization must make an application to the Director-General of National Health and Population Development[127]. The medical practitioner must be registered with the Director-General and the premises (laboratory) that he wishes to practice the artificial fertilization in must be granted approval by the Director-General. On the application form, the medical practitioner must submit full details and the street address of the premises, a brief summary of the procedure to be followed during the artificial insemination of a person and a brief description of the doctors' qualifications and abilities to carry out the said procedure.

The Director-General may request an inspection by an inspector of anatomy of the premises when considering the application. The Director General may appoint a person/persons in the Department of Health as inspectors of anatomy. An inspector of anatomy has the power to enter, at any reasonable time for the performance of their duties and without prior notice, premises on which artificial insemination is affected or is reasonably suspected to be affected[128].

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[126] See Section 2.7.6.
[127] Regulation 11(3)(a)
[128] S.A.Strauss *Doctor, Patient and the Law* 3rd ed. (1991) 186

2.5.1 CONCLUSION

The doctor intending to perform assisted reproductive technologies must be registered with the Director General of National Health and Population Development and must work in a laboratory that is approved by the Director General[129]. The consent to the storage and use of the donor's gametes must be gained in writing to ensure that the gametes are used in accordance with the clear wishes of the donor. The consent of the recipient and her husband if married must also be obtained in writing. The recipient is entitled to receive information concerning material risks associated with therapy. Once the information is provided, the patient and not the doctor who makes the choice. The need for information disclosure is based on the autonomy of the individual[130]. The doctor may be sued for negligence if inherent risks associated with medical procedures are not brought to the attention of the patient. If the doctor treated the patient without the patient's consent, this would constitute an *inuria* towards the patient[131].

2.6.MEDICAL ASPECTS

Assisted reproductive technology is considered a reasonable solution for most male and female infertility problems. However, it is not risk free and several complications do exist[132].

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[129] Regulations regarding Artificial Insemination No.1182 s12((3)
[130] S.McLean 'Consent and the Law' (1997) Consultation Document and Questionnaire 8
[131] S.A.Strauss op cit 185
[132] G.I.Serour 'Complications of Medically Assisted Conception in 3500 cycles' (1998) 70 No.4 *Fertility and Sterility* 638-642

2.6.1.THE EGG DONOR

When donating eggs, the intention of superovulation is to collect more than one egg[133]. The woman's ovaries are stimulated with drugs so that they produce many eggs per cycle instead of the usual one egg[134]. The chances of a pregnancy increase when more than one embryo is transferred. When ovarian stimulation is too vigorous, ovarian hyperstimulation syndrome may result. It is one of the most serious complications of ART[135], and can be potentially life-threatening. It is very difficult to predict and once diagnosed there is no definitive treatment. Complications also include injury to blood vessels (vaginal bleeding), trauma to pelvic organs, pelvic infection and urinary tract infections[136], in addition to the complications that occur when egg retrieval occurs under anaesthesia (hypotension, headaches).

2.6.2.AGE OF RECIPIENT

The practice of egg donation has enabled menopausal and post-menopausal women to have children[137]. Advanced maternal age is associated with an increase in maternal and foetal morbidity and mortality[138]. These women must be informed of all possible risks before undertaking IVF.

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[133] Queenan *et al* op cit
[134] P.Spallone *Beyond Conception* (1989) 58
[135] Ibid
[136] D.Dicker, J.Ashkenazi, D.Feldberg, T.Levy, A.Dekel and Z. Ben-Rafael 'Severe Abdominal Complications after Transvaginal Ultrasonographically Guided Retrieval of Oocytes for In Vitro Fertilization and Embryo Transfer' (1993) 59 No.6 *Fertility and Sterility* 1313-1315
[137] S.J.Fasouliotis and J.G.Schenker 'Ethics and Assisted Reproduction' (2000) 90 *European Journal of Obstetrics and Gynecology and Reproductive Biology* 171-180
[138] Ibid

2.6.3.THE EGG

The potentially harmful effect of the anaesthetic on the eggs must also be considered[139]. No information is presently available as to what effect these anaesthetics may have on the eggs during and after retrieval[140]. It is assumed that all anaesthetic drugs administered (intravenous, inhaled or local) are capable of being transferred to the ovaries. The selection of the anaesthesia and how it is administered must be carefully considered because the eggs must be given the best chance for fertilization and the patient must be provided with the safest and the most comfortable anaesthesia.[141].

2.6.4.THE SPERM

Before a sample is removed for semen analysis it is recommended that a standard abstinence period from sex of 3-7 days be used[142]. Shorter intervals may result in reduced sperm counts because of insufficient time in replenishing the population of spermatozoa in the vas deferens (the excretory duct of the testis) and the epididymis (cord-like structure that provides for the storage, transit and maturation of sperm)(See Figure 4[143]). Longer abstinence periods are associated with a reduction in semen quality, which is thought to reflect the accumulation of aged spermatozoa in the vas deferens and the epididymis[144].

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[139] H.W.Jones Jr. *et al In Vitro Fertilization Norfolk* 54
[140] Ibid
[141] Ibid
[142] op cit 137
[143] Fig. 4 Diagram illustrating male genitalia C.Wood and A.Westmore *Test-Tube Conception* (1984) 8
[144] Ibid

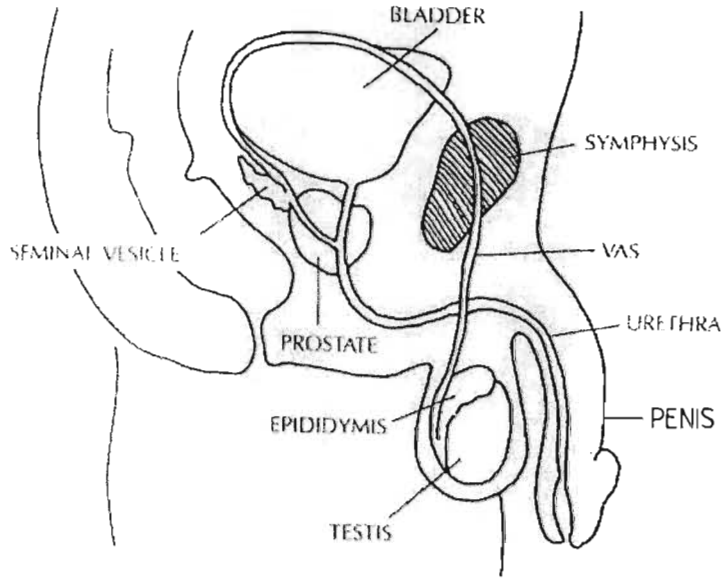

Figure 4.Diagram illustrating male reproductive organs

A number of sperm preparation methods are available to obtain the best quality sperm. Damage to the outer membrane of the sperm may occur with these techniques during washing and centrifugation (the process of separating the lighter portions of a mixture or suspension, from the heavier portions by centrifugal force[145]), resulting in a reduction in fertilizing capacity[146].

The use of sub-fertile or immature sperm in ICSI[147] and SZI[148] gives cause for concern. Several stages of natural selection of the individual sperm for fertilization are bypassed when fertilization is accomplished by micromanipulation. Examples of micromanipulation techniques include ICSI and SZI whereby a single sperm is injected into the egg. These techniques are performed while using a microscope. There is a slight

[145] Dorland's *Illustrated Medical Dictionary*
[146] Smith S. *et al* op cit
[147] See Chaper 1
[148] See Chapter 1

increase in the risk of sex chromosomal alterations[149] to the gene. Persons with azoospermia[150] and patients undergoing IVF with ICSI must be properly counselled as to the possible genetic consequences for the offspring.

Removal of Sperm

Sperm samples may be obtained by the following methods:

- Testicular sperm extraction (TESE): This is usually performed by an open biopsy under local anaesthetic. A small incision is made in the testis and a small portion of the testicular tissue is removed for sperm extraction. When no sperm is found, the surgeon repeats the procedure in another area of the testis until sperms are found for ICSI[151].
- Testicular fine needle aspiration (TEFNA) and Testicular sperm aspiration (TESA) whereby a needle is introduced into the testis and by suction tubular material is removed and flushed back into a culture medium. A 23-gauge needle or a biopsy gun needle is usually used for this technique. If necessary different areas can be aspirated. This method yields a much lower amount of sperm than testicular sperm extraction.
- When removing testicular sperm samples, it has been suggested that the TESE procedure and even the TEFNA or TESA can devascularise[152] regions of the testis and may adversely affect sperm production up to 6 months post-operatively[153].

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[149] Queenan op cit
[150] Azoospermia is the absence of spermatozoa in the semen Dorland's *Illustrated Medical Dictionary*
[151] M.M.H.Nijs and J.C.J.Van Der Elst 'Biological Aspects of Testicular Sperm Extraction' (2000) 92 *European Journal of Obstetrics and Gynecology*1-6
[152] Devascularise means the blood supply is reduced *Dorland's Illustrated Medical Dictionary*
[153] M.M.H.Nijs and J.C.J. Van Der Elst op cit

2.7.ETHICAL ASPECTS

2.7.1.DONOR ANONYMITY

There are many people who view IVF with donated gametes as harmful to society[154]. Mitchell submits the two main reasons is that, firstly, a donation is frequently shrouded in secrecy and therefore leads family members to be deceitful and, secondly, it gives rise to births of children who are denied adequate knowledge of their genetic origins[155]. The first objection is relevant to social welfare since families are the means whereby social values are instilled.

Truthfulness and trust are essential values for day-to-day life. Secrecy over donated gametes leads to mistrust in families where donated gametes were used and also mistrust in families where children have been born to their genetic parents[156]. Mitchell continues to submit that as AID becomes more widely practiced, children conceived normally may ask themselves if their parents are their 'real mothers and fathers'- they will question their genetic origin. Knowing that AID families almost never tell the child or other members of the family the 'truth', the child can never be sure of any answer they are given.

Mitchell's the second objection lies in the fact that the child is deprived of its genetic origin. Knowledge of parentage normally entails knowledge of genetic origin. This helps a child acquire an identity, a sense of belonging. The child also has no medical/genetic history of the donor that may be relevant to an accurate diagnosis of disease and

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[154] G.D.Mitchell. 'In Vitro Fertilization: The Major Issues-a Comment' (1983) 9 *Journal of Medical Ethics* 196-199

[155] G.D.Mitchell op cit 197

[156] Ibid

suitability of treatment. Fifty percent of the children's genetic background and family histories are unknown to the nurturing parents and to the children themselves as they grow up[157]. In one instance, the lack of knowledge of the sperm donor resulted in the medical misdiagnosis for two years in one child[158]. Most semen donors prefer anonymity not only to avoid paternity suits but also to avoid unwanted later contact with their 'offspring'[159].

The Ontario Law Reform Commission's Report[160] indicated that it might be necessary for a doctor to trace donors after children have been born using their gametes, to discover relevant genetic information necessary to treat children born from those gametes. Ethics Committees in France and the US discourage the use of non-anonymous donors[161]. It is believed that anonymous donation limits the possible tension in the future between the participating parties, i.e. the donor and the recipient couple and the resulting children. Swedish law[162] has given the child the right to know the identity of the semen donor on reaching the age of 18. The donor has complete legal protection, and the child has no rights against the donor other than knowledge of his identity. The child's concern with his identity was the main motive for this policy[163]. When a married woman undergoes IVF using donor semen, it is submitted that her husband's consent is also required so that no difficulty arises when establishing paternity.

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[157] A. McWhinnie 'A Study of Parenting of IVF and DI Children' (1995) 14 *Medicine and Law* 501-508
[158] Ibid
[159] Glover Report *Fertility and the Family* 1989
[160] The Ontario Law Reform Commission *Report Human Artificial Reproduction and Related Matters* (1984)
[161] R.Frydman *et al* op cit
[162] Law on Insemination No.1140, 20 Dec 1984
[163] Glover Report *Fertility and the Family* (1989)

2.7.2.GAMETE DONORS

Gamete donors have a moral obligation to disclose familial genetic problems and to cooperate in appropriate screening tests[164].

2.7.3.POSTHUMOUS CONCEPTION

The ability to freeze-store semen poses special ethical dilemmas. This would include a woman's request to conceive a child after the death of her husband. The desire for posthumous conception is a loving expression in memory of the lost spouse according to Corrigan et al[165], but the child has no such memory. Is the creation of a child after the death of the father in the best interest of the child? Should society encourage permit or even encourage the creation of children after the death of the father[166]?

2.7.4.SELECTION OF DONOR

The Regulations allow the recipient to select donor gametes with specific characteristics e.g. eye colour etc. It is of concern that these new reproductive technologies even allow adults to choose the kind of children they want to have[167]. Some sperm banks, including one that has obtained the sperm of several Nobel laureates, also advertise selectivity[168]. In both Britain and Italy, black women have been implanted with the eggs of white women in order to give birth to white children. Their reason for this was that their children would have a better future if they were white[169]. This is an example of modern reproductive technology being used for sociological purposes.

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[164] Ethics Committee of the American Fertility Society op cit 25S

[165] E. Corrigan, S.E.Mumford and M.G.R.Hull 'Posthumous Storage and Use of Sperm and Embryos: Survey of Opinion of Treatment Centers (1996) 313 *BMJ* 24

[166] S.M.Kerr, A.Caplan, G.Polin, S.Smugar, K.O'Neill and S.Urowitz 'Postmortem Sperm Procurement' (1997) 157 *The Journal of Urology* 2154-2158

[167] D.Wasserman and R.Wachbroit 'The Technology, Law and Ethics of In Vitro Fertilization, Gamete Donation and Surrogate Motherhood (1992) 12 No.3 *Clinics in Reproductive Medicine* 429-448

[168] The Repository for Germinal Choice. *Regulating Reproduction.* (1990)

[169] L.Donegan and C. Lihill *The Weekly Mail and Guardian*, 27 January 1994, 7

2.7.5.EGG DONOR

The Human Tissue Act[170] states that gametes may be withdrawn from living persons if the consent is obtained from the person when the person is a major and from a minor only if the parents or the guardians of the minor consents[171].

The regulations governing artificial insemination in South Africa do not specify a maximum age limit for gamete donation nor do they specify that an egg donor have at least one child. The exact impact of egg retrieval on the further ability to conceive of the donee mother is unknown as this procedure is normally performed on infertile women[172]. Although it is unlikely that infertility will result from laparoscopic[173] or ultrasound-guided aspiration of eggs, it cannot be ruled out that multiple ovarian punctures have played a role where infertility occurred in the future[174].

The American Fertility Society has formulated ethical guidelines stating, "utmost care must be exercised in using donors who do not have the necessity of having an accompanying procedure"[175]. The French Fertility Ethic Committee excludes women who do not have children from volunteer egg donation. They advise that all donations of human gametes should be from donors who have already had children[176]. This requirement is justified by a fear of child-searching conduct or of psychological disturbances if an individual volunteering to make a gamete donation ultimately becomes

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[170] Act 65 of 1983
[171] Section 18(b)
[172] Frydman *et al* op cit 671
[173] See section 2.3.2.
[174] Ibid
[175] The Ethics Committee of The American Fertility Society: 'Donor Egg in In Vitro Fertilization' (1986)46 *Fertility and Sterility* Suppl 1:425
[176] G.David: "*Don et utilisation du sperme*"Acte Sud Hubert Nyssen (ed.) *In Actes du Collque Genetique Procreation et Droit* (1985) 203

childless[177]. It is submitted that the South African Regulations should be amended to exclude egg donors who have not had at least one child, so that if the donor's ability to conceive were compromised, she would already have a child. In an IVF program, if eggs are labelled as spare, great care must be exercised not to compromise the opportunity of pregnancy for the donor[178]. The woman undergoing IVF, and also donating eggs to another recipient must be given the best possible chance at conception before donating eggs. It would be very unfortunate if the recipient conceived with the donated eggs and the donor did not.

2.7.6.AGE OF EGG DONOR

Significant decreases in fertility have been noted in women older than age 35 years[179]. There is a clear cut-off for poor reproductive potential at an age of over 40 years[180]. In IVF as well, there is a decrease in pregnancy rates, which is reportedly caused by a reduction in egg quality[181] of older women, and a reduction in the numbers of eggs recovered. These women respond normally to medication, and fertilization may be normal, but they still have lower rates of pregnancy and embryo cleavage[182]. The major problem associated with age relates to the egg, which shows both reduced ability to fertilize and reduced implantation potential in the older women[183]. It is therefore submitted that the cut-off age of the egg donor should be less than 35 years and that

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177 Ibid
178 Jones op cit 299
179 Queenan op cit
180 N.Nikolettos, S.Al-Hasani, C.Demirel, W.Kupker, M.Bals-Pratsch, J.Sandman, P.Fornara, B.Schopper, R.Sturm, and K.Diedrich 'ISCI Outcome on Patients of 40 years of age and Over: A Retrospective Analysis' (2000) 91 European *Journal of Obstetrics and Gynecology and Reproductive Biology* 177-182
181 D.Navot 'Poor Oocyte Quality Rather than Implantation Failure as a Cause of Age-related Decline in Female Fertility' (1991) 337 *Lancet* 1375-7
182 Queenan op cit
183 Nikolettos op cit

women receiving IVF therapy need be informed of the low success rate and of the alternate use of donor eggs.

2.7.7.USE OF FOETAL EGGS

Using foetal eggs could help meet a need in egg donation. However, it also raises a number of ethical concerns. The use of foetal eggs may pose an ethical problem when gaining the informed consent of the donor and the recipient. In this case the donor is a woman who has just terminated her pregnancy. She is now placed in a position of having to decide to continue her and her partner's genetic line through the potential birth of grandchildren at the same time she had decided not to continue this line through the birth of a child[184]. The Ethics Committee suggest that this request would be very problematic if it is made immediately following the abortion when the woman is emotionally vulnerable because making a decision to terminate a pregnancy is not easy. This option should be suggested before the abortion procedure. The woman's decision to terminate her pregnancy should be made prior to the decision to donate[185].

In utilizing foetal eggs there is also the need to obtain consent of the male partner. No such consent is necessary for the termination of pregnancy but this would change if egg donation considered. The eggs would be used to continue the male partners genetic line as well so it is important that he also give consent[186]. Gaining informed consent from the recipient and her husband may also be problematic. The parents would face unknown emotional feelings in conceiving a child whose genetic mother was never born[187].

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[184] Ethics Committee of the American Fertility Society for Reproductive Medicine 'Ethical Considerations of ART's' (1997) 67 No.5 *Fertility and Sterility* 6-7S

[185] Ibid

[186] Ibid

[187] Ibid

The well being of the child is also of major concern. The psychological consequences of discovering that one was conceived from a deliberately aborted foetus are potentially unsettling.

The Ethics committee submit that the recipient couple would have to decide if the child should be told the truth of his conception and if so, how. The knowledge that one's genetic mother was aborted could have a serious impact on the child[188]. The consequences of learning that one could never trace one's genetic mother are unknown. A child might feel emotionally unsettled in knowing that she could never find her genetic mother because the latter was never born[189]. The most the child would be able to learn about would be the genetic grandparents (the woman who terminated the pregnancy and her partner). Foetal eggs have health advantages in that they have not been exposed to a lifetime of environmental toxins, but the safety of using eggs that have not matured over time needs to be demonstrated[190]. The foetus's predisposition to ill health cannot be detected if it was never born. A child with no genetic mother will not have access to a maternal medical history if an illness were to develop[191]. Persons who regard abortion as illicit are also likely to object to the use of foetal tissue. Using the foetus' ovary to give life when the foetus itself is not given the opportunity for life may be considered ironical[192].

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[188] Ibid
[189] Ibid
[190] Ibid
[191] Ibid
[192] Ibid

2.7.8.SELECTION OF DOCTOR

A patient who enters an IVF program is interested in her chances of conception under her physician's care[193]. Before the patient submits herself to costly and invasive fertility treatment she has the right to know the success rate of her physician[194]. It is then possible for her to make an informed and autonomous decision, not only about what will be done with her body, but also about the physician doing it. But success rates may be misleading, because they often have to do more with patient selection than the physician's performance[195]. Patient selection may occur in many ways as submitted by Lu[196]. Patients may select the physician. Patients with a low probability of success may be referred to a physician with a reputation of accepting and treating difficult cases. Or, physicians may select patients. Patients with a low probability of success may be placed at the end of the waiting list, moved to donor egg services, classified as research subjects or encouraged to exit the program altogether. Patients with a high probability of success may be assigned to the head of the waiting list. Some physicians therefore select patients with favourable characteristics and deny those with unfavourable characteristics[197].

2.8.LEGAL ASPECTS

Artificial insemination is a lawful procedure provided a medical practitioner in accordance with the regulations promulgated in terms of the Human Tissue Act performs

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[193] Vishvanath C.Karande, R.Morris, C.Chapman, J.Rinehart and N.Gleicher 'Impact of the "Physician Factor" on Pregnancy Rates in a Large Assisted Reproductive Technology Program: Do Too Many Cooks Spoil the Broth?' (1999) 71 No.6 *Fertility and Sterility* 1001-1009

[194] Michael C.Lu 'Impact of "Non-physician Factors" on the "Physician Factor" of In Vitro Fertilization Success: Is it the Broth, the Cooks, or the Statistics?' (1999) 71 No.6 *Fertility and Sterility* 998-1000

[195] Ibid

[196] Ibid

[197] Ibid

it[198]. In the United Kingdom artificial fertilization is regulated by the Human Fertilization and Embryology Act[199] (HFEA). The technique of IVF-ET requires a degree of skill beyond that of the average specialist[200]. Success with ICSI and other microsurgical techniques require appropriate microtools that provides precise injection control, and specific technical expertise[201].

The removal of gametes and performing artificial insemination without the person's consent is an assault against that person. In terms of the Constitution, everyone has the right to bodily and psychological integrity and to security in and control over their body[202]. The Constitution also grants everyone the right to have his or her dignity respected and protected[203]. The doctor must therefore only remove gametes with the donor's consent. The doctor must also explain all risks and any other important information to the donor/recipient so that an informed decision may be made.

When selecting gametes, the gametes must be properly tested to ensure that no disease, infection or hereditary illness is transmitted in this way. If the doctor is negligent in the selection of gametes and a deformed child is born, the child could sue for wrongful life[204]. An action for wrongful life is a claim for damages brought by or on behalf of the abnormal or disabled child itself. It is a claim by the child that it has a right not to be born with defects, viz. a right not to be born at all[205]. Wrongful birth occurs when the parents of a severely defective child sue the doctors for negligently failing to inform them of the

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198 Section 37
199 Act 1990
200 Lupton *Medico-legal Aspects* op cit J119
201 Aitee *et al* op cit 654
202 Section 12(2)
203 Section 10
204 *Park v Chessin* 400 N.Y.S.2d 110.111(App Div. 1977)
205 S.A.Strauss *Doctor, Patient and the Law* 3rd ed. (1991) 197

possibility of their bearing a severely defective child[206]. The parents of a defective child born as a result of negligence can claim for its upkeep, and the child born handicapped as a result of negligence on the part of the doctor can claim for the difference between a damaged and a healthy existence[207].

No medical treatment can guarantee a successful outcome. If the doctor guarantees a successful outcome and it fails, then the doctor would be negligent and may be sued for breach of contract[208]. For instance, gametes intended to be used by someone else might be mixed up and used for the wrong patient[209]. A white woman in New York sued a sperm bank, which had been storing her white husband's semen, after giving birth to a black child. The doctor performing the artificial insemination and/or the storage facility may be sued if the gametes/embryos are destroyed through faulty handling. It is up to the plaintiff to prove that the doctor or the laboratory was negligent. The woman might be injured in some way, such as developing hyperstimulation syndrome after taking super-ovulatory drugs. Therefore the doctor owes a duty of care to the patient to ensure that he informs her of all possible risks and monitors her carefully, to reduce any risk that would already be present. The woman might also contract an infection from faulty insemination procedures if the doctor is negligent and does not use sterile equipment.

If the doctor obtaining the gametes, asks the donor for a complete medical history and the latter does not provide it, if a defective child is born resulting from such a donation, the donor may be sued with negligence or failure for providing a full medical history.

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[206] M.E.Cohen '*Park v Chessin*: The Continuing Judicial Development of the Theory of "Wrongful Life"'4:2 *American Journal of Law and Medicine* 211-232

[207] M.Davies *Textbook on Medical Law* (1996) 180

[208] Strauss op cit 185

[209] See *Bulletin of Medical Ethics* (5 March 1990) 56:5

The doctor, who performs an artificial insemination, must report the details of the birth of the child within 30 days to the doctor who effected the donation. The child's date of birth, the ID numbers of the donor and the recipient files concerned and any defects of the child must be reported the doctor[210]. If the doctor effecting the donation has reason to believe that a prospective donor has artificially produced at least 5 children with the aid of gametes, then the donor must be advised that no further donations may be made[211]. There is a limit on the number of children born from donor semen so that the chances of genetic siblings meeting and getting married are reduced. The Warnock Committee recommended that no more than 10 children be born from one donor[212].

If it should come to the notice of the doctor who performed an artificial insemination that a child was born with a genetic defect or mental disorder, the doctor must try to determine if the defect can[213] be traced back to the donor or the recipient. If the defect is traced to the donor, then the donor must inform the doctor who effected the donation.

If the recipient and her spouse have both consented to the use of donor gametes, no legal obligation exists between the child born and the gamete donor, in terms of the Children's Status Act[214]. The child born is deemed to be the legitimate child of the woman and her husband. In the UK, in terms of the HFEA[215], a register is kept of identifiable individuals whose gametes have been treated, whose gametes have been stored or used and who were, or may have been born as a result of treatment services. Thereafter a person who has attained the age of 18 years may make a request to the authority, inquiring about the

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[210] Regulation 12(1)
[211] Regulation 4(e)
[212] para 4.26
[213] Regulation 13
[214] Act 82 of 1987 Section 5
[215] Section 31(2)

chances of been born as a consequence to assisted reproductive treatment[216]. No regulations have been made to specify the level of information that may be disclosed to the applicant[217]. The Warnock Committee recommended that the information be restricted to basic genetic and ethnic information[218]. The European Convention for the Protection of Human Rights and Fundamental Freedoms[219], states that 'everyone should be able to establish details of their identity as individual human beings'. The HFEA does however provide for the disclosure of information in specific circumstances:

- Under s. 34 a court can require the Authority to disclose information where there is a parentage dispute.
- Under s. 35 a court may also require the authority to divulge information where there is a claim by the child under s. 1 of the Congenital Disabilities (Civil Liability) Act[220].
- Under s. 33(6B)-(6D) the consent of the patient who underwent the infertility treatment may allow for disclosure, but only as long as the implications of the disclosure have been explained.

If the egg donor is over 35 years of age, it is submitted that the age of the donor must be revealed to the recipient as part of the informed consent concerning genetic risks and the appropriate testing (e.g. the danger of Down's Syndrome). It is also to be noted that egg donation is not allowed in some countries (Austria, Germany, Norway)[221]. This is blatant sexual discrimination. The 1950 European Convention for the Protection of Human

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[216] Section 31(3)
[217] M.Davies *Textbook on Medical Law* (1996) 219
[218] Ibid para 1
[219] 1950, article 8
[220] Congenital Disabilities Act 1976
[221] H.W.Jones and J.Cohen 'International Federation of Fertility Societies Surveillance 98' (1999) 71 No.5 *Fertility and Sterility* Supp.2 :18S

Rights, states that men and women of marriageable age have the right to marry and found a family[222]. It also states that the rights set in the Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status[223]. This means that if the donation of sperm is allowed, then egg donation should be allowed. If a person is able to utilize donated sperm to conceive, then so too should donated eggs be allowed.

2.9.CONCLUSION

Everyone has the right to bodily and psychological integrity[224], which includes the right to make decisions concerning reproduction. In *Stanley v Illinois*[225] the court observed that "the rights to conceive and raise one's children have been deemed 'essential'". Everyone also has the right to privacy[226]. It was stated in *Eisenstadt v Baird* that "if the right of privacy means anything, it is the right of the individual, married or single, to be free of unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child[227]". It is submitted that all persons participating in assisted reproductive technologies should be given the fullest possible detail of the procedures to be followed, the risks entailed and the chances of both success and failure, if they are to exercise their autonomy and make an informed decision.

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[222] Article 12
[223] Article 14
[224] The South African Constitution s12 (2)
[225] *Stanley v Illinois* 405 US 645, 661 (1972)
[226] The Constitution s14
[227] *Eisenstadt v Baird* 405 US 438, 453 (1972)

CHAPTER 3

CONCEPTION AND PRE-IMPLANTATION DIAGNOSIS

3.1.CONCEPTION

Fertilization is not a single event but a process[1]. Fertilization begins with the penetration of the egg by the sperm[2]. Eggs are routinely placed together in a petri dish with a concentration of 100 000 normal motile sperm per ml[3]. Approximately 17-20 hours after insemination, the eggs are examined microscopically to assess fertilization. Fertilized eggs that appear normal are then transferred into a culture medium and placed in an incubator until the time of transfer[4].

Assisted hatching or artificial opening of the zona pellucida[5] (holes are made into the zona pellucida using a micropipette or an acid solution as with zona drilling[6]) improves the pregnancy rate[7]. If a large number of eggs have been fertilized, a select number can be kept in the incubator for transfer and the remainder can be cryopreserved[8]. The embryos are placed in serum and a cryoprotectant (a chemical that protects the embryo from being damaged at low temperatures), and are frozen in liquid nitrogen at a

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1 G. Douglas *Law Fertility and Reproduction* (1991) 28
2 Ibid
3 B.Dale & K.Elder *In Vitro Fertilization* (1997) 110
4 op cit 13
5 The zona pellucida is the outer membrane of the egg.
6 See Chapter 1
7 K.H.Chao, S.U.Chen, H.F.Chen, M.Y.Wu, Y.S.Yang and H.N.Ho 'Assisted Hatching Increases the Implantation and Pregnancy Rate of In Vitro Fertilization-Embryo Transfer, but not That of IVF-tubal ET in Patients with Repeated IVF Failures' (1997) 67 No.5 *Fertility and Sterility* 904-908
8 Dale and Elder op cit 115

temperature of –196F[9]. Cryopreserved embryos have many advantages such as reducing the risk of multiple pregnancies by transferring a few embryos and storing the others, increasing the delivery rate per retrieval cycle by increasing the embryo's chances to develop to term because a few have been transferred, reducing the severity of ovarian hyperstimulation by delaying embryo transfer, avoiding the destruction of surplus embryos, and reducing the cost of treatment.[10].

3.1.1.MEDICAL ASPECTS

Usually, as soon as a sperm enters the egg, a barrier to further sperm cell entry is created by chemicals released by the egg[11]. If more than one sperm enters, then fertilization may be abnormal or unsuccessful or embryo development may be abnormal. In IVF because of the larger number of sperms that are present, it is more likely that several sperm cells could enter simultaneously. *In vivo*, only about 100 sperm reach the vicinity of the egg[12]. Eggs allowed to ripen in the laboratory for a few hours develop the ability to prevent more than one sperm cell from entering the egg[13].

The culture media used in *in vitro* fertilization is very important. The media must be able to support the fertilization process, and must provide adequate energy sources to maintain sperm motility and metabolism of the eggs[14]. The success of IVF also depends on an

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[9] P.Spallone *Beyond Conception* (1989) 199

[10] A.Senn, C.Vozzi, A.Chanson, P. De Grandi, and M.Germond 'Prospective Randomized Study of Two Cryopreservation Policies avoiding Embryo Selection: the Pronucleate Stage Leads to a Higher Cumulative Delivery Rate than the Early Cleavage Stage' (2000) 74 No. 5 *Fertility and Sterility* 946-952

[11] C.Wood & A.Westmore *Test-Tube Conception* (1984) 70

[12] Wood and Westmore op cit 8

[13] Wood & Westmore op cit 62

[14] E.S.E.Hafez and K.Semm *In Vitro Fertilization and Embryo Transfer* (1982) 368

incubation temperature of 37C and a pH of 7.5-7.6[15]. If any of the above conditions are not met, then fertilization will not be successful or abnormal fertilization will occur. The combination of assisted hatching and embryo transfer[16] increases the risk of identical twins.

3.1.2.ETHICAL ASPECTS

Once several eggs have been fertilized, the recipient must be informed of the alternatives that are available regarding the fertilized eggs. She has to decide whether to have some implanted and the others frozen for another later attempt if this attempt fails. She may also decide to donate the fertilized eggs to another couple or to a research facility.

The prospect of achieving a single pregnancy is greater when four to six embryos are placed in the uterus[17]. There is also a greater risk of multiple pregnancies. Multiple pregnancies are associated with medical and psychological problems[18]. There is an increased risk of preterm labor, prematurity, congenital abnormalities, anaemia and perinatal and postnatal death[19]. The procedure of selective reduction is used to circumvent the problems related to multiple pregnancies, but there is also a risk of early spontaneous miscarriage.

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[15] Hafez and Semm op cit 369

[16] M.C.Graham, K.M.Hoeger and W.R.Phipps 'Initial IVF-ET Experience with Assisted Hatching Performed 3 Days after Retrieval Followed by Day 5 Embryo Transfer' (2000) 74 No. 4 *Fertility and Sterility* 668-671

[17] B.M.Dickens and R.J.Cook 'Some Ethical and Legal Issues in Assisted Reproductive Technology' (1999) 66 *International Journal of Gynecology and Obstetrics* 55-61

[18] M.Nijs, L.Geerts, E. van Roosendaal, G. Segal-Bertin, P.Vanderzwalmen and R.Schoysman 'Prevention of Multiple Pregnancies in an In Vitro Fertilization Program' (1993) 59 *Fertility and Sterility* 1245-1250

[19] Ibid

The *MRC Guidelines* in South Africa[20] recommend that no more than 4 embryos be transferred in any one cycle. Several countries also have legislation that prevents the transfer of more than 3 embryos (France, Germany, United Kingdom)[21]. The Warnock Committee recommend that no more than three embryos should be transferred in any one cycle, unless there are exceptional clinical reasons when up to four may be replaced per cycle[22].

The advantages of cryopreserving the embryos are that the woman would be able to undergo another embryo transfer without the discomfort of hyperstimulation and ultrasound guided laparoscopy to retrieve eggs.

The woman must be informed of all the alternatives open to her including all benefits and risks. Before the woman gives her consent to treatment she must have knowledge of the nature and the extent of the risk and she must appreciate and understand the nature of the risk[23]. This is necessary for her to make an autonomous decision.

3.1.3.LEGAL ASPECTS

It has been noted that physical factors affect the development of pre-implantation embryos[24]. Damage was detected by exposure to both light and temperature[25]. If the recipient can prove that the embryo was damaged because of negligence in the laboratory

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[20] South African Medical Research Council *Guidelines on Ethics for Medical Research* (1993) Section 15.9

[21] H.W.Jones 'New Reproductive Technologies' (1999) 13 No.4 *Ballieres Clinical Obstetrics and Gynecology* 473-490

[22] Section 12

[23] D.J.McQuoid-Mason *Forensic Medicine, Medical Law and Ethics* (2001) 16

[24] B.Fischer, A.Schumacher, C.Hegele-Hartung and H.M.Beier 'Potential Risk of Light and Room Temperature Exposure to Pre-implantation Embryos' (1988) 50 No. 6 *Fertility and Sterility* 938-944

[25] Ibid

or in the procedure itself, then the recipient may sue for damages. In the *Del Zio* case[26], Mr. and Mrs. Del Zio filed for an action of wrongful termination of an *in vitro* procedure. The embryo was taken out of the incubator and allowed to die without informing or getting the consent of the gamete donors. Mrs. Del Zio was awarded $50 000 for emotional distress. It was recognized that there was a loss of an interest similar to personal property. If the embryos are destroyed without the gamete donor's consent, it is submitted that it would be an infringement of their right to dignity[27]. The right to dignity encompasses personality rights and the couple could claim for *solatium* for their injured feelings if the act was done intentionally[28].

The HFEA[29] states that where a child born as a result of certain infertility treatment is born disabled, and this disability results from negligence in the selection, keeping or use outside the body of the embryo or gametes, such disability is to be regarded as damage resulting from such act or omission.

3.1.4.CONCLUSION

The ability to create an embryo *in vitro* has been a great help to many women. Many factors must be taken into consideration when creating the embryo viz. the selection of the gametes, selection of the culture media, temperature and pH are a few. The doctor performing the fertilization must imitate *in vivo* conditions as closely as possible.

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[26] *Del Zio v. Manhattan's Columbia Presbyterian Med. Center.* No. 74-3588 (S.D.N.Y. Apr. 12, 1978)
[27] Constitution of South Africa Act 108 of 1996 Section 10
[28] J.Neethling, J.M.Potgieter and P.J.Visser *Neethling's Law of Personality* (1996) 225
[29] Section 1A

The creation of the *in vitro* embryo has brought with it many ethical and legal problems e.g. cryopreservation and selective reduction to name a few. It is therefore submitted that not more than 3 eggs be fertilized and transferred.

3.2.PRE-IMPLANTATION DIAGNOSIS

Pre-implantation genetic diagnosis was developed in an effort to offer choices to women at risk of having children with genetic defects, to provide reassurance to them and to allow the transfer only of apparently unaffected embryos[30]. People with a family history of inherited disease can undergo DNA tests to determine their genetic status[31] .The basis of pre-implantation testing is that single cells are obtained by biopsy from 4-8 cell embryos, and genetic testing (DNA) is done to check for a particular disease. The advantage that pre-implantation diagnosis has over prenatal testing is the fact that the termination of a pregnancy is avoided. High-risk couples also have the opportunity to overcome the worrisome burden of a possible abortion[32].

The disadvantages of pre-implantation diagnosis are the high costs, lack of large research trials to confirm their tests and the potential for methodological errors[33].

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[30] H.W.Jones and J. Cohen 'International Federation of Fertility Societies Surveillance 98' (1999) 71 No.5 *Fertility and Sterility* Supp 2 at 24S

[31] C.Wood 'Future Trends in Human Reproduction' (2000) 40 No.2 *Australian and New Zealand Journal of Obstetrics and Gynecology* 127-132

[32] Jones and Cohen 'International Federation of Fertility Societies' op cit 24S

[33] V.H.Eisenberg and J.G.Schenker 'The Moral Aspects of Prenatal Diagnosis' (1997) 72 *European Journal of Obstetrics and Gynecology* 35-45

3.2.1.MEDICAL ASPECTS

Genetic testing is usually performed by the technique of the polymerase chain reaction (PCR)[34]. The polymerase chain reaction is a genetic test whereby the relevant gene sequence is amplified and the sequences are then observed[35]. There is the possibility that the embryo could be contaminated with other DNA (the genetic material of a cell), thus invalidating the test, and resulting in misdiagnosis.

The greater the number of biopsied cells available for analysis, the more reliable any diagnosis is going to be[36].

However, Tarin and Handyside submit that there is a limitation on the cell number and /or cellular mass that can be biopsied without seriously reducing the viability of the embryo[37]. They submit that if a single cell is removed at the 2-cell stage, it may compromise the ability of the embryo to form normal blastocysts for *in vivo* development[38]. Pre-implantation diagnosis at the blastocyst stage (5-6 days post-insemination) is not advisable because of the low pregnancy rate[39]. The biopsy of a quarter of the cellular mass of the embryo on the 3rd day after insemination is thought to be the optimum stage for biopsy[40]. There has been a report of an adverse reaction after

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[34] J.A Raeburn 'Commentary: Pre-implantation Diagnosis Raised a Philosophical Dilemma' (1995) 311 *BMJ* 311

[35] Ibid

[36] J.J.Tarin and A.H.Handyside 'Embryo Biopsy Strategies for Pre-implantation Diagnosis' (1993) 59 No. 5 *Fertility and Sterility* 943-952

[37] Ibid

[38] Ibid

[39] Ibid

[40] Ibid

pre-implantation diagnosis[41]. This has been the development of an imperfectly formed twin foetus lacking a heart and other body parts [42].

There may not be a direct link to the actual process of embryo biopsy, but it is suggested that there may be an association between the embryo biopsy and the subsequent foetal anomalies despite the fact that these cells are thought to be pluripotent (possessing the power to develop into any one of several possible organs) at this stage[43].

3.2.2.ETHICAL ASPECTS

There are many reasons why one might hesitate to bring children into this world. Some of the reasons might include the prospect of poverty, continuing war, or for some people, it is the risk of passing on a harmful genetic disease to their offspring. The advantage that pre-implantation diagnosis has is that it avoids the implantation of defective embryos and this process of selection eliminates the need for a future termination of pregnancy[44].

Pre-implantation diagnosis, therefore avoids all the controversies related to the issue of abortion in society and in individual cases, reduces or prevents suffering for the affected family, foetus and society. It also protects society's resources[45]. The existence of genetically compromised children can be avoided by preventing implantation in the first place.

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[41] R.L.Schild, H.Plath, H.J.Fodisch, P.Bartmann, and M.Hansmann 'Triplet Pregnancy with Acardius Acranius after Pre-implantation Diagnosis' (1998) 70 No. 6 *Fertility and Sterility* 1167-1168

[42] Ibid

[43] Ibid

[44] S.J.Fasouliotis and J.G.Schenker 'Ethics and Assisted Reproduction' (2000) 90 *European Journal of Obstetrics and Gynecology* 171-180

[45] Ibid

There is always some possibility that reproduction will result in a child with a serious disease or handicap, and genetic counsellors can help individuals determine whether they are at unusual risk[46]. If they are at a risk, then Purdy[47] submits that it is morally wrong to reproduce when it is known that there is a high risk of transmitting a serious disease or defect.

It is also possible that the view of society towards those children that are born with defects will change. Kass[48] submits that a child born defective may be looked upon by the community as one unfit to be alive or as a second-class citizen. In a disease such as cystic fibrosis, the carrier couples have a one in four risk of having an affected offspring[49]. However, does this mean that carrier embryos should also be allowed to perish? That they too are abnormal? It has been submitted[50] that the decision should be left to the couples concerned that may or may not choose to accept some low degree of risk of having a cystic fibrosis pregnancy.

Embryo selection based on sex is generally permissible if gender-linked heredity diseases are to be avoided in an embryo[51]. Gender selection can be used in order to avoid the almost 300 X-linked[52] recessive diseases that are known today[53]. The objection to sex selection arises from the examples of countries like China, India and the Middle East in which boys are highly prized for economic, heredity or religious/cultural reasons[54].

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[46] L.M.Purdy 'Genetics and Reproductive Risk: Can Having Children be Immoral?' *Biomedical Ethics* (1996) Mappes and de Grazza 492-498

[47] Ibid

[48] L.R.Kass 'Implications of Prenatal Diagnosis for the Human Right to Life' (1996) *Biomedical Ethics* Mappes and de Grazza 488-492

[49] J.A.Raeburn 'Commentary: Pre-implantation Diagnosis Raises a Philosophical Dilemma' (1995) 311 *BMJ* 540

[50] Ibid

[51] Giesen page 649 para 1379

[52] Sex linked genetic diseases

[53] Fasouliotis and Schenker op cit 176

[54] Ibid

The financial hardship of raising girls in some of these countries has led to the abandonment of female children and the widespread use of abortion and infanticide in favour of boys and this ultimately alters the established sex ratio[55].

3.2.3.LEGAL ASPECTS

If a doctor fails either to advise prospective parents of the risk of genetic illness or to carry out and interpret correctly laboratory results which would disclose an abnormality in the embryo, the parents of an afflicted child may choose to bring an action against him in respect of his negligence. This is because the doctor owes them a duty of care in which he has failed. The action would be one for wrongful birth. An action of wrongful life by or on behalf of a defective child may also be brought against the doctor. The doctor must fully inform the prospective parents that the results of the laboratory tests cannot be guaranteed.

3.2.4.CONCLUSION

The incidence of significant birth defects or genetic disorders in pregnancy is approximately 3%[56]. Prenatal diagnosis makes it possible for a couple to screen for genetic disorders before the embryo can be implanted. The safety and efficiency of these techniques have not yet been established[57]. It is submitted that prospective parents receive adequate information regarding pre-implantation diagnosis, including the risks

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[55] Ibid

[56] V.H.Eisenberg and J.G.Schenker 'The Moral Aspects of Prenatal Diagnosis' (1997) 72 *Fertility and Sterility* 35-45

[57] Eisenberg and Schenker op cit 35

and the chances of success and failure. It is up to the prospective parents to decide if they are prepared to care for a child that may be the carrier of a disease.

CHAPTER 4

POST-CONCEPTION AND IMPLANTATION

4.1.POST-CONCEPTION

If a large number of eggs have been successfully fertilized, then a select number can be kept in a culture for transfer and the remainder considered for cryopreservation. The benefits of cryopreservation include:

a) Preventing the wastage of excess embryos;

b) Reducing the risk of multiple pregnancy by allowing some embryos to be transferred;

c) As an alternative when maternal conditions at the scheduled time of transfer are not ideal;

d) Greater flexibility in synchronizing donor programs; and

e) For use during genetic screening.

4.2.IMPLANTATION/EMBRYO TRANSFER

In clinical practice of *in vitro* fertilization, the majority of pregnancy failures occur after embryo transfer. While most patients achieve egg recovery, fertilization and cleavage of embryos, only a small proportion of transferred embryos actually implant and result in viable pregnancies[1]. Two main factors contribute to successful implantation. They are embryo quality and endometrial receptivity[2].

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[1] R.J.Paulson, M.V.Sauer and R.A.Lobo 'Embryo Implantation after Human In Vitro Fertilization: Importance of Endometrial Receptivity' (1990) 53 No. 5 *Fertility and Sterility* 870-874

[2] Ibid

Endometrial receptivity means the receptivity of the uterus in accepting an embryo for implantation. Controlled ovarian hyperstimulation results in an overall increase in pregnancy rates when multiple embryos are replaced, but this also leads to a less receptive endometrial environment. For successful embryo transfer, synchronization between the stage of embryo development and the site of transfer is important[3]. Embryos are usually transferred 48 hours after egg retrieval. It has now been suggested that transferring embryos on day 5 greatly enhances implantation[4]. Embryos that show a thick, even zona pellucida on day 2 have a poor prognosis for implantation[5]. It is suggested that assisted hatching (by drilling holes into the zona pellucida) increases the implantation rate[6].

4.2.1.MEDICAL ASPECTS

The presence of blood and its location on the transfer catheter influences the chance of pregnancy with the use of IVF-ET[7]. Blood found on the outside of the transfer catheter was associated with a 6 fold decrease in the rates of embryo implantation and clinical pregnancy per transfer, with the greatest amount of blood in this area accompanied by the lowest chance of pregnancy[8]. Bleeding and cervical trauma at the time of embryo transfer diminish the embryo implantation rate. The chance of conception with the use of IVF-ET

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3 E.S.E. Hafez and K. Semm *In Vitro Fertilization and Embryo Transfer* (1982) 375
4 B.Dale and K.Elder *In Vitro Fertilization* (1997) 120
5 Dale and Elder op cit 176
6 Ibid
7 V.T.Goudas, D.G.Hammitt, M.A.Damario, D.R.Session, A.P.Singh and D.A.Dumesic 'Blood on the Embryo Transfer Catheter is Associated with Decreased Rates of Embryo Implantation and Clinical Pregnancy with the Use of In Vitro Fertilization-Embryo Transfer' (1998) 70 No. 5 *Fertility and Sterility* 878-882
8 Ibid

is unaffected by the presence of blood inside the transfer catheter[9]. Emphasis on atraumatic transfer techniques that prevent bleeding at the time of embryo transfer should contribute to an improved pregnancy outcome with the use of IVF-ET[10]. The type of catheter used may also affect the implantation and pregnancy rate[11]. This may be caused by the difference in degree of trauma caused to the uterus during embryo transfer[12].

Allergic reactions to culture media necessary for *in vitro* fertilization have been known to occur[13]. In one case after the patient had had an anaphylactic (allergic) reaction, her medical history revealed allergies to cow's milk, cats and dogs[14]. Bovine serum albumin (a serum derived from cattle) is used in transport media. Bovine serum albumin has been identified as an allergen in cow's milk allergy. Four instances of anaphylactic reaction to bovine serum albumin during bone marrow transplants or insemination have been reported[15]. Sensitization can result from previous insemination or IVF, consumption of certain foods, inhalation of bovine serum albumin or animal skin cells[16]. The risk of anaphylactic reactions can be greatly reduced if a detailed medical history is obtained. The use of the patient's own albumin should be considered in patients that are at a higher risk[17].

IVF-ET procedures involve needle puncture of the vagina and catheter placement of embryos through the cervix, therefore contamination is possible from vaginal-cervical

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[9] Ibid
[10] Ibid
[11] J.Meriano, A.Weissman, E.M.Greenblatt, S.Ward and R.F.Casper 'The Choice of Embryo Transfer Catheter Affects Embryo Implantation after IVF' (2000) 74 No. 4 *Fertility and Sterility* 678-682
[12] Ibid
[13] J.Wehner-Caroli, T.Schreiner, W.Schippert, G.Lischka, G. Fierlbeck and G.Rassner 'Anaphylactic Reaction to Bovine Serum Albumin after Embryo Transfer' (1998) 70 No. 4 *Fertility and Sterility* 771-773
[14] Ibid
[15] Ibid
[16] Ibid
[17] Ibid

microorganisms[18]. Vaginal antiseptics are usually not used during egg retrieval or embryo transfer to avoid injury to the eggs or the embryos. Most *in vitro* fertilization programs use systemic antibiotics to prevent clinical infections[19]. The presence of bacteria in the cervix at the time of embryo transfer is associated with a decrease in IVF-ET success rates[20]. Improvements in pregnancy rates occur after the administration of specific antibiotic therapy[21].

The implantation of a normal cryopreserved embryo, sometimes results in the formation of a partial hydatidiform mole[22] (this is an abnormal pregnancy, that develops into a mass of cysts resembling a bunch of grapes)[23]. This implies that the success of producing an embryo does not guarantee the health or viability of the embryo. Visual assessment of the embryo is subject to human error and is imperfect because chromosomal abnormalities still occur in embryos with a normal appearance[24].

4.2.2.ETHICAL ASPECTS

The chances of pregnancy are greater when more than one embryo is transferred. When women are deciding on multiple implantations, the risks they will encounter must be clearly explained. Their free consent[25] must be considered since they may be subject to

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[18] D.E.Moore, M.R.Soules, N.A.Klein, V.Y.Fujimoto, K.J.Egnew and D.A.Eschenbach 'Bacteria in the Transfer Catheter Tip Influence the Live-birth Rate After In Vitro Fertilization' (2000) 74 No.6 *Fertility and Sterility* 1118-1124

[19] Ibid

[20] R.Fanchin, A.Harmas, Farida Benaoudia, U.Lundkvist, F.Olivennes and R.Frydman 'Microbial Flora of the Cervix Assessed at the Time of Embryo Transfer Adversely Affects In Vitro Fertilization Outcome' (1998) 70 No. 5 *Fertility and Sterility* 866-870

[21] Ibid

[22] Dorland's *Illustrated Medical Dictionary*

[23] M.R.Fluker 'Partial Hydatidiform Mole Following Transfer of a Cryopreserved-thawed Blastocyst' (2000) 74 *Fertility and Sterility* 828-829

[24] Ibid

[25] B.M.Dickens and R.J.Cook 'Some Ethical and Legal Issues in Assisted Reproductive Technology' (1999) 66 *International Journal of Gynecology and Obstetrics* 55-61

powerful external pressured to conceive. Pressure from family members may weigh in the woman's balancing of the interests in maximizing chances of conception against risks of total foetal loss, birth of non-viable neonates and their own pregnancy-related morbidity[26]. Economic factors may also exert pressure. When a woman reaches the limit of her financial means, and can only afford one more cycle of treatment, she may want to maximize her last bid for pregnancy by implantation of all her preserved embryos[27]. But if the numbers of embryos implanted are limited, the chances for pregnancy are reduced. The South African M.R.C. *Guidelines* suggest that 3 or 4 embryos may be transferred[28].

4.2.3.LEGAL ASPECTS

When performing the embryo transfer, the doctor must ensure that she does it with the minimal trauma to the recipient. The doctor must also be aware of the risk of infection to the recipient and she would be negligent if she did not practice under aseptic conditions. The doctor must also follow protocols that would reduce or eliminate the risk of infection by also prescribing antibiotic therapy. The doctor would be negligent in the duty of care that she owes the patient if she does not do so.

The doctor must also ensure that she obtains a full medical history from the recipient including any allergic reactions. She would be negligent if she neglected to ask relevant questions and an allergic reaction resulted. A reasonable doctor should know that there is a possibility of an allergic reaction occurring to the culture and transport media in the laboratory.

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[26] Dickens and Cook op cit 58
[27] Dickens and Cook op cit 59
[28] Section 15.9

The doctor may be sued for wrongful birth and wrongful life if she guarantees that the embryo that she is transferring is normal when it is not. It would be in the doctor's best interest to inform the recipient that a small chance of error does exist and that once pregnancy is established she will perform further tests with the recipient's consent to determine if the foetus is normal.

4.2.4.CONCLUSION

The practice of multiple implantations increases the possibility of a multiple pregnancy. It also increases the risks of health hazards to the woman. It is submitted that the regulations governing artificial fertilization include a maximum number of embryos to be transferred to prevent and to reduce multiple pregnancies in IVF programs. The performance of IVF-ET requires a skill beyond that of a basic gynaecologist and obstetrician. It is submitted that the performance of embryo transfer should be in knowledgeable and experienced hands to eliminate any risks to the recipient. The doctor must inform her patient about her track record so that the patient is able to make an informed decision.

4.3.PREGNANCY

Early gestation requires identification of a gestational sac (the membrane surrounding the embryo) in the uterus by ultrasonography[29]. Abnormal implantation or ectopic[30]

[29] Y.Kawakame 'Assessment of the Implantation Site by Transvaginal Ultrasonography' (1993) 59 No.5 *Fertility and Sterility* 1003-1006

[30] An ectopic pregnancy is when the embryo implants in the fallopian tube and not the uterus.

pregnancy has frequently occurred[31]. Couples are advised not to have intercourse until tests indicate whether pregnancy has occurred[32]. Low levels of pregnancy hormones are associated with an increased risk of natural abortion.[33].

4.3.1.PRENATAL TESTING

The incidence of birth and genetic defects in pregnancy is approximately 3%[34]. The demands of modern society are for a healthy 'perfect' baby. The new techniques of prenatal testing are aimed at an early diagnosis of the abnormal foetus at a point at which parents who wish to do so may terminate a pregnancy[35].

The objectives of prenatal diagnosis as submitted by Eisenberg and Schenker[36] is to offer the widest possible range of choices to women at risk of having children with a genetic abnormality, to provide reassurance and reduce the anxiety associated with reproduction, especially among high-risk women, to enable high-risk women to continue a pregnancy by confirming the absence of a certain genetic disease, and to facilitate optimal treatment of affected infants through early diagnosis.

They submit that the first step in prenatal diagnosis is preconceptual counselling. This may identify the risk factors of maternal or paternal medical disorders, exposure to teratogens (an agent or factor that causes the physical defects in the developing embryo) or adverse lifestyles and family history. Certain racial and ethnic groups are at an

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[31] Bocciolone L. 'Early Detection of Ectopic Pregnancy. Use of a Sensitive Urine Pregnancy Test and Transvaginal Ultrasonography' (1991) 36 *Journal of Reproductive Medicine* 496-499

[32] C.Wood and A.Westmore *Test-Tube Conception* (1984) 78

[33] Ibid

[34] V.H.Eisenberg and J.G.Schenker 'The Moral Aspects of Prenatal Diagnosis' (1997) 72 *European Journal of Obstetrics and Gynecology* 35

[35] Ibid

[36] Ibid

increased risk for specific disorders, such as Tay-Sachs in Ashkenazi Jews[37]. Family history is the most important tool for assessing genetic risk. It is important to assess the following for older mothers according to Eisenberg and Schenker:

- A previous child affected by a chromosomal abnormality,
- A history of recurrent abortions,
- Stillbirths,
- Children with abnormalities,
- A genetic disorder or birth defect in the family[38].

Ultrasound is often used for the detection of foetal abnormalities. The foetus may be visualized as early as 5 weeks gestation, but a thorough evaluation is usually performed at around 15 weeks or later at between 20-22 weeks[39].

Foetal cells can be obtained from the maternal blood supply. These cells can be tested for the sex of the foetus and for genetic diseases. The mother's blood may also be tested to determine prenatal abnormalities. There is an association between a low maternal serum alpha-feto protein and an increased risk of trisomy 21[40](Down's Syndrome).

Chorionic villus sampling (CVS- a small amount of chorion tissue surrounding the foetus is removed through the pregnant woman's cervix or the abdomen) is usually performed between 9 and 12 weeks gestation. CVS is performed transabdominally (through the abdomen) or transcervically (through the cervix) using ultrasound guidance. Amniocentesis can be performed as early as between 9-14 weeks gestation or usually between 15-18 weeks gestation.

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[37] Ibid
[38] Ibid
[39] Ibid
[40] Ibid

Amniocentesis[41] is the testing of foetal cells in the amniotic fluid. The pregnant woman is given a local anaesthetic and a needle is inserted through the abdominal wall and into the womb. A sample of the amniotic fluid that surrounds the foetus is withdrawn and analysed to detect chrososomal or genetic abnormalities.

Foetal blood sampling or chordocentesis is usually performed by umbilical blood sampling under the guidance of ultrasound.[42].

Foetal biopsy may be the only diagnostic option if DNA analysis is not informative. Foetal biopsy is usually performed between 17 and 20 weeks gestation.

4.3.2.MEDICAL ASPECTS

When using ultrasound as a diagnostic tool to detect foetal abnormalities, the accuracy of the report is dependant on the skill and experience of the operator as submitted by Spallone[43]. Thus the inexperienced operator might not observe a foetal abnormality, and inform the mother that all is well. Tests on foetal cells obtained from the maternal blood sample may be cells from a previous pregnancy or a spontaneous abortion that remained in the maternal circulation and may therefore result in an incorrect diagnosis. The complications associated with CVS include an increased incidence of limb reduction defects, vaginal bleeding or spotting, infections and rupture of the membranes[44]. The risks associated with amniocentesis includes, septic shock, amniotic fluid leakage, vaginal bleeding, cramping and lower abdominal discomfort[45].

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[41] P.Spallone *Beyond Conception* (1989) 196
[42] Ibid
[43] Ibid
[44] Ibid
[45] Ibid

Foetal blood sampling also has risks that include membrane rupture, bleeding from the puncture site and thrombosis. Cordocentesis is not recommended for growth retarded foetuses, as they tend to develop foetal distress resulting in cesarean section. The complications of foetal biopsy include spontaneous abortion, amniotic fluid leakage, haemorrhage, infection, prematurity and foetal injury. The loss of foetal life is 5% with foetal biopsy[46].

4.3.3.ETHICAL ASPECTS

Improved health care allows the detection of foetal abnormalities, thus giving the woman a choice of whether to continue or to terminate the pregnancy of a deformed foetus. Prenatal testing therefore enhances a woman's ability to make an informed reproductive decision[47]. Some of the prenatal techniques are invasive and the doctor performing the prenatal examination must inform the woman all the risks. The ethic of beneficence must outweigh the harm that is being done in the performance of the test. When considering the other ethic of non-maleficence, the benefit of the test must be far greater. But, it is to be noted that it is up to the woman to weigh the pros and the cons, thus making an autonomous decision.

The selective abortions of female foetus's has long been practiced in certain countries e.g. India[48]. Girls are seen as an economic burden by parents because they need a dowry for marriage. Male children are supposed to carry on the family trade and support their parents in their old age. India has banned female foeticide with the passing of the Prenatal

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[46] Ibid
[47] Eisenberg and Schenker op cit 39
[48] Z.Imam 'India Bans Female Feticide' (1994) 309 *BMJ* 428

Diagnostic Techniques Bill[49]. Doctors who offer to identify the sex of a foetus will be struck off the medical register and will face 3 years in prison and a fine of 10 000 rupees[50]. Pregnant women who undergo the tests to determine the sex of the foetus will be subject to the same fine and prison term[51].

4.3.4.LEGAL ASPECTS

Invasive testing involves taking cells from the foetus while transversing the pregnant woman's body. The doctor involved in the testing has an obligation to be certain that the diagnostic procedure is accurate and reliable. The procedure must also be beneficial in achieving the stated goals. The woman is subjected to some risks during the procedure, but she may benefit from the results by being able to make informed choices concerning the pregnancy. The unskilled or inexperienced ultrasonographer, the laboratory technician or the doctor who incorrectly diagnoses an abnormal foetus may be sued for negligence and wrongful life.

An action by or on behalf of a defective child for the negligent infliction of a prenatal injury may be brought against the doctor.

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[49] Ibid
[50] Ibid
[51] Ibid

4.3.5.CONCLUSION

Prenatal testing gives pregnant women the freedom of having to decide whether or not to abort a defective foetus. However, prenatal testing is not without risks. It is submitted that women should be screened to identify those at high risk by an interview with a genetic counsellor prior to conception. Further tests should only be performed if necessary and with the informed consent of the woman. All risks must be explained to her in a way that is understandable.

4.4.SELECTIVE REDUCTION

Selective reduction[52] is the termination of one or more foetuses in a multifoetal pregnancy. The foetuses are killed *in utero* thus allowing for the pregnancy to continue and the surviving foetuses are intended to develop to viability and to be born[53]. The technique of selective reduction originated[54] to stop the development of abnormal embryos in a multiple pregnancy where the remainder was normal. Selective reduction or selective foeticide as it is sometimes called, can prevent the birth of an abnormal twin foetus without also aborting its normal foetal sibling and can allow some foetuses of a high multiple pregnancy to survive when the alternative is for all to die from prematurity[55]. Selective reduction is commonly achieved by an injection of potassium chloride into targeted foetuses. Reduction is performed between 8-12 weeks gestation,

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[52] R.L.Berkowitz and L.Lynch 'Selective Reduction: An Unfortunate Misnomer' (1990) 75 *Obstetrics and Gynecology* 873

[53] R.P.S.Jansen 'Unfinished Feticide' (1990) 16 *Journal of Medical Ethics* 61-65

[54] Kennedy and Grubb *Medical Ethics* (1989) 793

[55] Jansen op cit 62

and is guided by ultrasound[56]. The needle is passed into the beating foetal heart either transvaginally or transabdominally. After the injection there is in most cases instantaneous cessation of cardiac activity. The needle is removed after no signs of cardiac activity for 2 minutes[57]. Repeat ultrasound examinations after 1 day and thereafter weekly after the procedure shows a gradual decrease in the size of the injected foetal sacs, and a complete spontaneous resorption.

During ART's, the chances of achieving a single pregnancy increases when 4-6 embryo's are implanted[58]. In 1996 in the US, the live birth rate with 3 embryos transferred was 35.8% as compared with a rate of 36.9% for 6 embryos transferred[59]. Mason and McCall-Smith state that pregnancy rates vary from 10% when 1 embryo is transferred to 25% when 3 are transferred[60]. Therefore since multiple implantations are necessary to achieve a single pregnancy, it also increases the chances of a multiple pregnancy.

Mothers who had triplet pregnancies reported that after 4 years after the birth, they still reported fatigue, emotional distress and having a difficult relationship with the children[61]. Because most infertile patients desperately want a child they are unaware of the realistic 'cost' of a triplet pregnancy. Patients should be given adequate information and counselling of all the risks associated with a multiple pregnancy[62].

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[56] Y.Gonen, J.Blankier and R.F.Casperl 'Transvaginal Ultrasound In Selective Embryo Reduction for Multiple Pregnancy' (1990) 75 *Obstetrics and Gynecology* 720

[57] Ibid

[58] B.M.Dickens and R.J.Cook 'Some Ethical and Legal Issues in Assisted Reproductive Technology' (1999) 66 *International Journal of Gynecology and Obstetrics* 55-61

[59] Ibid

[60] Mason and McCall-Smith *Law and Medical Ethics* (1991) 65

[61] M.Garel, C.Salobir and B. Blondel 'Psychological Consequences of Having Triplets: A 4-year Follow-up Study' (1997) 67 No. 6 *Fertility and Sterility* 1162-1165

[62] Ibid

4.4.1.MEDICAL ASPECTS

Health hazards to the woman are increased in multiple pregnancies. Mothers of triplets have a 20% rate of pre-eclampsia (an illness during pregnancy characterised by high blood pressure, protein in the urine and retention of fluid) and a 35% risk of serious post partum haemorrhage[63]. There are the risks of spontaneous foetal loss. There is also the risk of extremely premature babies who face health risks associated with low birth weight. Major risks are neonatal death and survival with severe brain damage. The risks associated with selective reduction include infection, septic abortion, bleeding or damage to gestational sacs[64].

4.4.2.ETHICAL ASPECTS

Multiple pregnancies force health care providers with the dilemma of how and whether ailing neonates should be given aggressive treatment. Multiple deliveries expose the family or the health service providers with the cost of caring for several low birth weight newborns. These infants occupy the facilities of a neonatal intensive care almost exclusively, leading to costly medical bills. The parents may also face the spectre of their children dying one by one over a period of weeks[65].

Since selective reduction in a multiple pregnancy is usually performed before 12 weeks gestation, foetal sex cannot be determined with ultrasound scanning[66]. Because of the large number of foetuses present, DNA studies of chorionic villus sampling material and

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[63] Gonen *et al* op cit
[64] Ibid
[65] Mason and McCall-Smith op cit 65
[66] Berkowitz and Lynch op cit 873

amniotic fluid sampling is almost never done. As a result, nothing is known about the foetus at the time of the procedure. The foetuses that are terminated are selected purely for their physical accessibility[67]. Are the deaths of some foetuses to be regarded as 'best for all concerned" using the utilitarian approach or in the best interests of the mother (her health); or in the best interests of the surviving foetuses (greater chance of surviving to term); or in the best interests of the health care providers (limited resources)?

Patients who undergo selective reduction have a difficult time deciding to do so. After years of infertility/childlessness, the thought of intentionally terminating the life of a foetus that is seemingly healthy is repugnant. The decision to opt for selective reduction procedures may be psychologically damaging to patients and their spouses.

4.4.3.LEGAL ASPECTS

It is apparent that a need for selective reduction exists although risks are attached to the procedure. Is the procedure legal? Termination of pregnancy in terms of the Choice on Termination of pregnancy in terms of the Act[68] is defined to mean "the separation and expulsion, by medical or surgical means, of the contents of the uterus of a pregnant woman". It is to be noted that in selective reduction the foetus is not expelled from the uterus but is absorbed. In selective reduction the number of foetal lives are reduced and the pregnancy is not terminated. The woman is still pregnant albeit with fewer foetuses. The Act refers to for the separation and expulsion of the contents of the uterus but does not refer to the foetus being killed *in utero*. The fact that selective reduction does not terminate a pregnancy by the expelling of the contents of the uterus is irrelevant because

[67] Ibid
[68] Act 92 of 1996

the Act allows for abortion up to the 12th week on demand[69], even if the foetus were to be expelled rather than absorbed.

When one speaks of a multiple pregnancy, one refers to the fact that there is more than one foetus *in utero*. Therefore a termination of pregnancy could mean the termination of one or more pregnancies and the continuation of the other pregnancies to term. In terms of the Constitution[70], everyone has the right to bodily and psychological integrity[71], which includes the right to make decisions concerning reproduction[72], and to security in and control over their body[73]. Therefore if a pregnant woman is allowed to terminate her entire pregnancy up to the 12th week on demand, there is no good reason why she should not be able to terminate some of her pregnancies and allow the others to continue to full term. The Constitution also provides for the right of everyone to have access to health care services including reproductive health care[74]. Therefore if a woman in a multiple pregnancy chooses to selectively reduce her pregnancy, the State should be able to provide the care and expertise needed to perform the reduction procedure. It is submitted that without evacuation of the uterus, and without termination of pregnancy as a whole, selective reduction falls outside the scope of the Act. It is submitted that the doctor owes the patient a duty of care (in this case a woman who desperately desires a child) by preserving her pregnancy unless it would cause her unacceptable harm.

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[69] Section 2(1)(a)
[70] Act 108 of 1996
[71] Section 12(2)
[72] Section 12(2)(a)
[73] Section 12(2)(b)
[74] Section 27(1)(a)

4.4.4.CONCLUSION

Selective reduction is acceptable in a multiple pregnancy when it represents a clear threat to the life or the health of the mother and the reduction of the foetuses may lessen the risk. When a mother of a multiple pregnancy delivers, there is an increased strain to the family. Parents face the social and economical problems of raising two, three or more children resulting from a multiple pregnancy. Therefore it is submitted that no more than 3 embryos be implanted to avoid selective reduction.

4.5.EUGENIC SELECTIVE REDUCTION

Selective reduction for eugenic reasons is normally carried out in the second trimester. This is after genetic testing has been performed on the foetuses. Selective reduction has been suggested in multiple pregnancies (usually twins) when a foetus has a severe physical defect or mental handicap[75]. If selective reduction/foeticide were not performed, the alternatives would be for either the entire pregnancy to continue in the interests of the apparently normal twin and in the knowledge that the abnormal twin will also be delivered, or to terminate the entire pregnancy, sacrificing the normal foetus along with the abnormal foetus[76]. Selective reduction/selective foeticide allows the termination the abnormal foetus and allows the normal twin to continue developing normally. But this would also mean accepting the risks of the procedure, which includes spontaneous

[75] J.H.S.Ball and F.Guidozzi 'Selective Feticide- Ethical and Legal Considerations' (1994) 84 *SAMJ* 57-58

[76] Ibid

abortion, premature labour and birth.[77]. In this case the foetus does not become absorbed. This formed, unexpelled, dead foetus is called a '*foetus papyraceous*'[78]. It describes a foetus that is shrunken and parchment-like[79].

4.5.1.MEDICAL ASPECTS

There is the risk of inadvertent damage to the surviving foetus by the compromised uterine environment during foetal reduction[80]. This may occur immediately during the foeticidal operation or later from the hostile environment that led to the death of the survivors' foetal sibling. The surviving twin may have its growth retarded before delivery. There is also a risk that the degenerating foetal and placental tissues will precipitate labour. If selective foeticide was not an alternative, then the mother could either choose for the entire pregnancy to be terminated or she could choose to carry both foetuses to term.

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[77] J.Svigo 'Selective Feticide in Twin Pregnancy: A Case Report' (1990) 152 *The Medical Journal of Australia* 492-293

[78] R.P.Jansen op cit 62

[79] Dorland's *Illustrated Medical Dictionary*

[80] Jansen op cit

4.5.2.ETHICAL ASPECTS

It is morally wrong to sacrifice a normal foetus when terminating an entire pregnancy to avoid the birth of an abnormal twin. It is also unacceptable to allow a severely deformed baby with an abnormality that is not compatible with life to be born. The parents may then face the alternatives of allowing the child to die or allow the child to undergo major medical intervention to keep it alive. The pregnant woman must be informed of the alternatives available to her so that an informed choice may be made, whatever the decision.

4.5.3.LEGAL ASPECTS

The procedure of eugenic selective reduction is covered by the Choice on Termination of Pregnancy Act[81]. Section 2(b)(ii) states that after the 12th week and before the 20th week a woman may have her pregnancy terminated if there exists a substantial risk that the foetus would suffer from a severe physical or mental abnormality. The Act also allows for the termination of pregnancy after the 20th week if there is the possibility that the continued pregnancy would result in a severe malformation of the foetus. This abnormal foetus would then be terminated by an injection of potassium chloride and the resulting *foetus papyraceous* would be separated and expelled when the other sibling is born.

The doctor would be negligent if he terminated the life of the normal foetus and allowed the defective foetus to live. An action of wrongful birth may be instituted by the parents or and action of wrongful life may be brought against the doctor by or on behalf of the defective child.

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[81] Act 92 of 1996

4.5.4.CONCLUSION

Everyone has the right to make decisions regarding reproduction. It is the mother's right to make a decision regarding the fate of the unborn children with the help of her doctor and guided by the law. Up to the 12th week of pregnancy, the decision to terminate a pregnancy is up to the woman. From the 13th week to the 20th week, the woman may request a termination of pregnancy but the medical practitioner makes the decision after consultation with the woman. The decision to terminate a pregnancy after the 20th week must be made by a medical practitioner in consultation with another medical practitioner or midwife.

CHAPTER 5

THE SURPLUS EMBRYO

The success rates of IVF depend on the number of embryos transferred to the uterus for implantation. Pregnancy rates vary from 10% when one embryo is transferred to 25% when three are implanted[1]. Therefore consideration must be given to ensuring that whilst a woman has the best chance of achieving a pregnancy, the risks of a large multiple pregnancy occurring is minimized[2]. Health hazards to women are increased by multiple pregnancies, as are risks of spontaneous foetal loss, and births of extremely premature babies that face severe health risks associated with low birth weight[3]. The care of higher order multiple births can be devastating to the financial and social welfare of the child[4].

In several countries it is illegal to transfer more than 3 embryos (France, Germany, UK)[5]. In South Africa, the *Medical Research Council Guidelines*[6] suggest that no more than 4 embryos be transferred. Since the failure rate of IVF is high, and 3-4 embryos are usually transferred, this implies that the woman needs to be superovulated so that a number of eggs are fertilized *in vitro*. It is thus inevitable that surplus eggs will be harvested and surplus embryos will be produced during IVF. What will be the fate of these embryos? The embryos are usually cryopreserved for future use by the couple that created them.

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1 Mason and McCall-Smith *Law and Medical Ethics* (1991) 55
2 Kennedy and Grubb *Medical Ethics* (1989) 638
3 B.M.Dickens and R.J.Cook 'Some Ethical and Legal Issues in Assisted Reproductive Technology' (1999) 66 *International Journal of Gynecology and Obstetrics* 55-61
4 H.W.Jones 'New Reproductive Technologies' (1999) 13 No.4 Ballieres *Clinical Obstetrics and Gynecology* 473-490
5 Ibid
6 South African Medical Research Council *Guidelines on Ethics for Medical Research* (1993) Section 15.9

5.1.RESEARCH

IVF would have been impossible without experimentation on the human embryo. Jones and Cohen[7] submit that there is a need for research involving the human embryo to improve the success rate of IVF, to learn more about factors affecting implantation, how to avoid foetal chromosomal abnormalities, and to discover more about maternal, paternal and environmental factors that may affect early embryonic development.

5.1.1. MEDICAL ASPECTS

The benefits of research on embryos as submitted by Kennedy and Grubb[8] include improving the treatment of infertility, gaining further knowledge about factors leading to congenital disease, developing more elective forms of contraception, and detecting chromosomal abnormalities before implantation.

Research on embryos is justified provided that the goal of the experiment is to improve the human condition[9]. This does not mean that embryos may be created solely for research. On the contrary the Proposed Draft Protocol for the European Convention on Biomedicine[10], states that 'no embryo should be created *in vitro* for the sole ends of research'[11].

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[7] H.W.Jones. and J.Cohen 'International Federation of Fertility Societies Surveillance 98'(1999) 71(5).Fertility and Sterility Supp 2:26S

[8] Kennedy and Grubb op cit (1989) 677

[9] Jones op cit

[10] C.Byk 'A Proposed Draft Protocol for the European Convention on Biomedicine relating to Research on the Human Embryo and Fetus' (1997) 23 *Journal of Medical Ethics* 32-7

[11] Article six

The Waller Committee[12] stated that research could be done on spare embryos but not on embryos that were specifically created for research. However, Dr.Barbara Burton[13] stated that it is perhaps preferable for embryos to be created specifically for research purposes rather than using spare embryos generated in IVF programs as infertile couples would prefer to see all spare embryos frozen for use in a later treatment cycle.

5.1.2. ETHICAL ASPECTS

Kennedy and Grubb[14] submit there are many arguments against using human embryos for research viz. that it is morally wrong because they are human. The human embryo is seen as having the same status as a child or adult, by virtue of its potential for human life. The right to life is seen as a fundamental right, and to take the life of an innocent is an outrage. It is also seen to be unethical to carry out research (harmful or not) without first obtaining an informed consent, and therefore it is unacceptable to carry out research on a human embryo, which cannot give consent. Some people feel an instinctive opposition to research because they see it as tampering with the creation of human life.

5.1.3.LEGAL ASPECTS

The *Guidelines*[15] of the South African Medical Research Council permit research on embryos up to 14th days after the gametes were mixed, excluding any time for which the embryo was stored.

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[12] Kennedy and Grubb (1989) op cit 673
[13] Speaking for the Infertility Federation of Australasia Kennedy and Grubb op cit 673 at 3.28
[14] Kennedy and Grubb op cit (1989) 661
[15] *MRC Guidelines* Section 15.2

The Human Tissue Amendment Act[16] does not permit genetic manipulation outside the human body of gametes or zygotes. Many countries forbid research on embryos (Germany, Norway, Austria, Israel)[17]. The UK permits research on embryos as allowed by the Human Embryo and Fertilization Act[18] only if the Human Fertilization and Embryology Authority grant a licence. The Asche Committee[19] voiced its concern about the possibility of spare embryos, because it felt that doctors would superovulate the woman a more than necessary to end up with excess embryos, which could be used for research. Dr. Robert Jansen[20] further pointed out 'that it is a fallacy to distinguish between surplus embryos and specially created embryos in terms of embryo research.... any intelligent administrator of an IVF program can, by minor changes in his ordinary way of doing things, change the number of embryos that are fertilized'. It is also necessary that both gamete donors consent to the research being performed and an ethical committee must authorize the research[21]. The Warnock Committee recommended that no live human embryo derived from *in vitro* fertilization, whether frozen or unfrozen, may be kept alive, if not transferred to a woman beyond 14 days after fertilization, nor may it be used as a research subject beyond 14 days after fertilization. Fourteen days is seen as the cut-off point because it is just before the point of the 'primitive streak', which later becomes the spinal cord.

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[16] Act 51 of 1989, Section 39A

[17] B.J.Van Voorhis, D.M.Grinstead, A.E.T.Sparks, J.L.Gerard and R.F.Weir 'Establishment of a Successful Donor Embryo Program: Medical, Ethical, and Policy issues' (1999) 71 No.4 *Fertility and Sterility* 604-608

[18] Act 1990

[19] Kennedy and Grubb op cit 674

[20] Kennedy and Grubb op cit 674

[21] J.G.Schenker and V.H.Eisenberg 'Ethical Issues Relating to Reproduction Control and Women's Health' (1997) 58 *International Journal of Gynecology and Obstetrics* 167-176

Before then, Dame Warnock stated[22] 'the embryo hasn't yet decided how many people it is going to be'. The Warnock Committee Report also stated that the embryo ought to have a special status and no one should undertake research on human embryos for the purposes of which could be achieved by the use of animals or in some other way[23].

5.1.4.CONCLUSION

Embryo research includes the study of its development, the improvement of techniques for assisted reproductive technology and the diagnosis of sex or genetic abnormalities[24]. The whole question of research on the embryo rests on the issue of the embryo being a person or not. It is submitted that the embryo is entitled to special respect but not the full legal rights as a person.

The creation of embryos specifically for research is unethical. The embryo should not be used as a means to an end. Spare embryos from IVF programs that have been donated by the gamete donors should be considered in research projects that have Ethical Approval. Therefore it is submitted that research be allowed on the embryo up to the 14th day post-conception.

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[22] Kennedy and Grubb (1989) op cit 665

[23] Ibid

[24] C.Byk 'Medical and Biological Progress and the European Convention on Human Rights' (1992) 11 *Medicine and the Law* 187-219

5.2.DONATING THE EMBRYO TO ANOTHER COUPLE

Many patients who sign documents about cryopreservation prior to the event often indicate that if they do not use all their frozen embryos, they would be prepared to donate them to other infertile couples.

5.2.1.MEDICAL ASPECTS

If embryos are to be donated to another couple, it should be noted that these embryos might have been created for use within a particular family. As a result the usual genetic screening carried out with donor sperm and donor eggs may not have been done and the ethnic background and age of the donor may not have been considered. Recipients need to be made aware that there can be no guarantee of a child born without birth defects or illness in such cases[25]. There is a 70 % success rate with cryopreserved embryos and the recipient couple needs to know what their chances are of conceiving[26]. Embryo donors must also be informed of the remote chance that their children could unknowingly meet and even marry a genetic sibling[27].

5.2.2.ETHICAL ASPECTS

It often happens that if IVF-ET couples are successful with freshly transferred material, they change their mind when they realize that their child might have a genetic sibling somewhere without their knowledge[28]. Jones[29] submits that before using embryos for

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[25] Van Voorhis *et al* op cit 607
[26] H.W.Jones 'Cryopreservation and Its Problems' (1990) 53 No.5 *Fertility and Sterility* 780-784
[27] Ibid
[28] M.L.Lupton 'Artificial Insemination in South Africa in Light of the Human Tissue Act 65 of 1983'(1985) 49 *Tydskrift HRHT* 210
[29] Jones op cit 482

donation, the gamete donors of the cryopreserved material need to reaffirm their wishes with respect to the ultimate disposition of the unwanted cryopreserved material.

5.2.3.LEGAL ASPECTS

In the United States, Texas[30] and Florida[31] are the only two states that have statutes that recognize embryo donation. The Human Fertilization and Embryology Act of 1990[32], limits the storage of cryopreserved embryos at 5 years and these embryos may be donated to other couples. The proposed new regulations for artificial fertilization allow the donation of the embryo to another couple with the consent of the recipient and her spouse[33].

5.2.4.CONCLUSION

Couples usually seek donated embryos that both have gamete deficiencies[34]. The most likely source of embryos would be frozen embryos from couples that have achieved their reproductive goal[35]. These embryos were created for a specific couple; therefore genetic testing may not have been done. The recipient must be made aware of this. It is submitted that donation of embryos should be allowed with the consent of both of the genetic donors.

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[30] Tex. Family Code Ann sec. 12.03B. (West Supp.,1995)
[31] Fla. Stat. Ann. Sec. 742.11(2) (West, 1986 and Supp., 1995)
[32] Section 14(4)
[33] Regulation 8(7)(ii)(bb)
[34] H.W.Jones 'New Reproductive Technologies' (1999) 13 No.4 *Balliere's Clinical Obstetrics and Gynecology* 473-490
[35] Jones op cit 482

5.3.ALLOWING THE EMBRYO TO DIE

Allowing the embryo to die entails removing the embryo from cryopreservation or the incubator and allowing it to perish. The Warnock Committee[36] likened removal of the embryo from storage and setting it aside to the removal of life-support systems from a mortally ill person. Life is allowed to end. The following are issues that arise:

- **5.3.1. IS THIS AN ABORTION/TERMINATION OF PREGNANCY?**

An abortion[37] is defined as 'an operation or other procedure to terminate pregnancy before the foetus is viable'. Viability is biologically speaking the ability of the foetus to survive independently outside the uterus. Pregnancy[38] is defined as 'the state or condition of being pregnant'. Pregnant[39] is defined as 'carrying a foetus or foetuses within the womb'. Allowing the embryo to die is therefore not an abortion. In terms of the Choice on Termination of Pregnancy Act[40], a termination of pregnancy is taken to mean the separation and expulsion, by medical or surgical means, of the contents of the uterus of a pregnant woman. Therefore allowing the embryo to die is also not a termination of a pregnancy since the embryo is not being expelled from the uterus.

- **5.3.2. IS IT MURDER?**

For it to be murder, the embryo must be regarded as a person. In terms of the Constitution[41] section 11, everyone has a right to life but the foetus is only regarded as a

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[36] Kennedy and Grubb op cit 689
[37] Collins *English Dictionary*
[38] Ibid
[39] Ibid
[40] Act 92 of 1996
[41] Act 108 of 1996

person with legal rights when it is born. It has been suggested that the embryo is entitled to profound respect, but this respect does not necessarily encompass the full legal and moral rights attributable to persons[42]. Mason and McCall-Smith[43] submit that allowing an embryo to die is not murder because the embryo cannot be considered to have a separate existence in a legal sense. But death through non-use is not acceptable for those respecting the human status of the fertilized egg. Another approach may be to stop using hormones to induce super-ovulation to recover a large number of eggs for fertilization. Instead, one egg at a time could be retrieved at a time during the woman's natural cycle to be used in the *in vitro* fertilization procedure[44].

- **5.3.3. IS THE EMBRYO PROPERTY?**

Property is defined as something of value, the right to possess, use and dispose of anything[45]. A 'thing' is defined as any object or right that may be the subject of property[46]. A thing is also anything of which the courts take cognisance[47]. Property can have either economic or sentimental value. Property can also be corporeal (it can be felt or touched, and occupies space). In *Davis v Davis*[48], the trial court considered embryos as persons. However, the Supreme Court of Tennessee rejected the characterization of embryos as persons but concluded that they 'occupy an interim category that entitles them to special respect because of their potential for human life[49]. The court also ruled

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[42] Mason and McCall-Smith op cit61
[43] Mason and McCall-Smith op cit 60
[44] G.P.Smith 'Australia's Frozen "Orphan" Embryos: A Medical, Legal and Ethical Dilemma' (1985-86) 24 *Journal of Family Law* 27-41
[45] Collins *English Dictionary*
[46] Collins *English Dictionary*
[47] Silverberg and Schoeman's *The Law of Property* 3rd ed. (1987) 10
[48] *Davis v Davis*, 842 S.W 2d 588. (Tenn. 1992)
[49] Jones op cit 478

that embryos are neither persons nor property but governed separately[50]. In *York v Jones*[51], the embryos were regarded as chattels (possessions in an inanimate sense). It has also been submitted that if the decision-making authority is vested with the couple in respect of decisions concerning storage, donation and allowing to die, then this implies the couples' property interest in their embryos[52]. In the *Del Zio*[53] case, an action was brought for wrongful termination of an IVF procedure where the embryo was taken out of the incubator and allowed to perish without informing or getting the consent of the gamete donors. Mrs. Del Zio was awarded damages for emotional distress. It was recognized that there was the loss of an interest similar to personal property. It is therefore possible that the embryo can be property in certain respects because it does have sentimental value. Although the embryo is not a person and does not have any legal rights, it is treated with the utmost respect because it is a human entity.

- **5.3.4.CONCLUSION**

It is submitted that the embryo should be treated as a *sui generis* as it is neither property nor a person. If the embryos are destroyed intentionally, it is submitted that it would be an infringement of the parents right to dignity[54]. The right to dignity encompasses one's personality rights. The couple could claim for *solatium* for their injured feelings[55].

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[50] *Davis v Davis*, 842 S. 2d 588 (Tenn. 1992)
[51] 717 F Supp 421 (ED VA 1989)
[52] L.P.Knowles 'Property, Progeny and Patents' (1999) 29 No.2 *Hasting Center Report* 38-40
[53] *Del Zio v. Manhattan's Columbia Presbyterian Med Center.* No. 74-3588 (S.D.N.Y. Apr. 12, 1978)
[54] Section 10 of the Constitution
[55] J.Neethling, J.M.Potgieter and P.J.Visser *Neethling's Law of Personality* (1996) 225

5.4.CRYOPRESERVATION

The advantage[56] of cryopreservation is that it improves a woman's chances of pregnancy because the thawed embryo can be inserted during a non-stimulated cycle. This is believed to enhance the embryos chance for implantation. Some patients are unsuitable for embryo transfer after IVF because of uterine bleeding, serious illness including hemorrhage or distress after laparoscopy[57]. Cryopreservation would allow time to correct these problems so that embryo transfer could be performed during later ovulatory cycles. There is a 70% rate of survival in cryopreserved embryos and gametes[58]. Cryopreservation gives the patient undergoing *in vitro* fertilization the opportunity to achieve pregnancies from more than one embryo transfer without being subjected to hyperstimulation and egg retrieval each time. If cryopreservation were not possible, then the woman may feel compelled to transfer all fertilized eggs to her uterus at the risk of multiple pregnancies.

Many laws concerning artificial reproductive technologies require that preservation of embryos be for a limited time. In the UK preservation is allowed for 5 years, renewable on request, but not to extend beyond the eggs donor's 55th birthday[59]. The Australian research *Guidelines*[60] suggest that embryos should not be stored for more than 10 years. However the time limit should not be beyond the time of conventional reproductive need or competence of the female donor. These guideline are intended to reduce the possibility

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[56] M.L.Lupton 'Artificial Reproduction and the Family of the Future' (1998) 17 *Medicine and Law* 93-111
[57] Lupton THRHR op cit 215
[58] H.W.Jones 'Cryopreservation and Its Problems' (1990) 53 No. 5 *Fertility and Sterility* 780-784
[59] Dickens and Cook op cit 58
[60] Lupton *Medicine and Law* op cit 214

of intergenerational embryo transfer. Lupton[61] submits that the couple should agree when commencing IVF therapy that when the female enters the menopausal period of her life her frozen embryos should be destroyed, donated to another recipient or utilized for research purposes. He also submits that long-term storage and later release of embryos could result in "jumped" or mixed generations causing family traumas, difficulties in regard to succession to property and the administration of estates and to problems concerning legitimacy and maintenance orders.

Many countries have established time limits for maintaining cryopreserved embryos in storage and attempt to restrict the accumulation of these embryos[62]. Legal storage limits of 1 year exists in Austria, Norway and Sweden, 5 years in Spain, Canada and France, and 10 years in Australia[63]. There is no limit to the duration of the storage of embryos in Egypt, Jordan, Italy and Poland[64].

There are many problems, which may arise from the cryopreservation of embryos, including the following as submitted by Jones[65]:

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[61] Ibid

[62] Van Voorhis et al 'Establishment of a Successful Donor Embryo Program: Medical, Ethical, and Policy Issues' (1999) 71 No.4 *Fertility and Sterility* 604-608

[63] Ibid

[64] H.W.Jones and J Cohen 'International Federation of Fertility Societies Surveillance 98' (1999) 71 No. 5 *Fertility and Sterility* Supp. 2: 15S

[65] H.W.Jones 'Cryopreservation and Its Problems' (1990) 53 No. 5 *Fertility and Sterility* 780-784

- The death or disability of the prospective parents.
- The death or disability of one of the prospective parents.
- The legal separation of the prospective parents.
- The divorce of the prospective parents.
- The cryopreserved material may remains in storage beyond the reproductive limit of the prospective mother or beyond some other agreed time limit.
- The loss of contact with the prospective parents, including their failure to pay current cryopreservation fees and charges.
- The loss of interest by the prospective parents in attempting a pregnancy.
- The wish of one prospective parent to remove the cryopreserved embryo from the original program.
- The wish of both prospective parents to remove the cryopreserved embryo from the original program.
- The voluntary or involuntary discontinuation of a cryopreservation program by an *in vitro* fertilization program.

Because of the possibility of an unexpected catastrophe to one or both of the prospective parents after cryopreservation of embryos, it is recommended that a pre-freeze agreement be drawn up to provide for the disposition of the embryos[66]. The couple must be able to decide the ultimate disposal of the embryo. If at cryopreservation, the couple decide to store the embryos for their own goal of bearing a child, it follows that if both prospective parents cannot participate in the use of the embryos as originally planned, then the original intent cannot be fulfilled. If the original intent cannot be fulfilled then there are

[66] Ibid

four options[67] available to the prospective parents. They could make the embryos available to other couples; the embryos may be made available for a pathological examination as with any discarded tissue; the embryos could be discarded without further development or examination; or the embryos may be made available for research in an approved research project.

In *Kass v Kass*[68], the judge ruled in favour of a divorcing husband who wanted the embryos donated to an IVF clinic for research. The wife wanted to use the embryos for reproduction. The couple's agreement at the time the embryos were created was that the embryos should be donated for research[69].

The court found that the couple's decision concerning disposition was legally binding at the time of divorce, when they were unable to agree on a different disposition. If a couple's prior directive for disposition of frozen embryos carries such weight, then IVF programs should be able to rely on such directives in disposing of embryos[70]. But, what is to be done if the couple's do not leave a prior directive or agreement between the divorcing couples?

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[67] Ibid

[68] *Kass v. Kass*, 673 N.Y.S.2d 350. (N.Y. 1998)

[69] J.A.Robertson 'Disposition of Frozen Embryos by Divorcing Couples Without Prior Agreement' (1999) 71 No.6 *Fertility and Sterility* 996-997

[70] Ibid

In *Davis v Davis*[71], the divorcing couple disagreed on the disposition of the embryos. Mrs. Davis wanted the embryos to be implanted in her after the divorce. Mr. Davis objected and claimed joint custody to protect his reproductive rights. The court ruled that the partner who preferred the avoidance of reproduction (through discard or nontransfer of embryos) should be favoured over the partner wishing to use the embryos for reproduction. The court ruled that Mr. Davis should not be forced into fatherhood against his will. It was within Mr. Davis' right to procreate to also have the right not to have children. It could also be interpreted as the right not to have one's genetic material passed on nor to have one's gametes implanted, gestated to term and raised by another individual[72]. The American Bar Association (ABA), proposes that 'in cases of marriage dissolution where the couple has previously stored frozen embryos with the intent to procreate, that the party wishing to proceed in good faith and in a reasonable time, with gestation to term, and to assume parental rights and responsibilities should have possession and control of all the frozen embryos'[73].

In the *Rios*[74] case, a Californian couple died in an aeroplane crash and did not leave any directives as to the disposition of the embryos that they had cryopreserved in Australia. Mrs. Rios had one embryo implanted and the other 2 were frozen for later use. Mrs. Rios miscarried and was emotionally unable to undertake any further implantations. The issues that arose were: Do they have a right to live, and when and if born, do they assert inheritance rights in the Rios estate? If they are implanted in a surrogate mother, and if

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[71] *Davis v Davis*, 842 S.W. 2d 588 (Tenn.1992)

[72] H.Forster. C.Donley and J.Slomka 'Comment of ABA's Proposed Frozen Embryo Disposition Policy' (1999) 71 No. 6 *Fertility and Sterility* 994-995

[73] Ibid

[74] Goerge P.Smith 'Australia's Frozen 'Orphan' Embryos: A Medical, Legal and Ethical Dilemma' (1985) 24 *Journal of Family Law* 27-41

they are born alive, they are the legal offspring of the surrogate mother and her husband[75].

In *York v Jones*[76], there was a dispute between a married couple undergoing IVF procedures at the Jones Institute for Reproductive Medicine in Virginia. When the York's decided to move to California, they asked the Institute to transfer the remaining 'frozen embryo' that they had produced to a fertility clinic in San Diego for later implantation. The Institute refused and the York's sued. The court held that the cryopreservation agreement between the York's and the Institute created a bailment relationship, obligating the Institute to return the subject of the bailment to the York's once the bailment had terminated.

If one partner dies, then the right to use or dispose of the stored embryo should pass to the survivor as recommended by the Warnock Committee[77]. The Warnock Committee also recommended that if both parties die then the right to the embryos should pass to the storage facility[78]. The Human Fertilization and Embryology Act 1990, s (2), states that the gamete donors must give consent to the storage and specify conditions as to what must be done to the embryo if the person who gave the consent is unable to do so or has died.

The proposed new regulations[79] governing artificial fertilization s8 (7) allows for the storage of embryos for the duration of the recipient's existing marriage or for the donation to another couple only with the consent of the recipient and her spouse.

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[75] Children's Status Act 82 of 1987 s.5
[76] *York v Jones*, 717 F Supp 421 (ED Va 1989)
[77] para 10.12
[78] Ibid
[79] *Government Gazette* no.13228 Notice 433 of 1991

5.4.1. CONCLUSION

Cryopreservation is a very successful procedure[80]. The implantation rate of cryopreserved embryos is almost the same as with fresh embryos[81]. Although cryopreservation gives a couple greater reproductive choices in deciding what to do with the spare embryos, it also brings up the issue of the fate of the embryo. It is submitted that the couple for which the embryos were created should determine the fate of the embryos. It is also submitted that if the couple do not decide what to do with the surplus embryos that they be allowed to die after informing the couple of this intention.

[80] Jones op cit 483
[81] Ibid

CHAPTER 6

CONCLUSION

In the light of the above discussions on the medico-legal and ethical issues surrounding the creation of a human embryo, the following conclusions can be drawn:

1) Before a specific technique is decided upon, that the donor and the recipient has all the information available to them so that a fully informed decision can be made. Each person needs to be able to weigh the risks attached to each technique and balance it against the benefits.[1]

2) Children born from donated gametes should be allowed to find out who their genetic parent is at the age of 18 years if they so desire, especially for medical reasons. It is also submitted that postmortem sperm procurement should be allowed only if there is specific consent by the donor[2].

3) Adequate assessments should be made on gametes so that the woman has the best possible chance at conception. It is also submitted that the egg donor should be under the age of 35 years and that she must have had at least one child[3].

4) If the recipient is older than 40 years she should be informed of the alternative of egg donation[4].

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1 Cf Chapter 1 at 1.2
2 Cf Chapter 2 at 2.2.1
3 Cf Chapter 2 at 2.3.3
4 Cf Chapter 2 at 2.4.1

5) Before embarking on *in vitro* fertilization, recipients should 'shop' around and speak to other women who have undergone fertility treatment to find the most qualified and experienced practitioner to assist them in their quest for a child[5].

6) All persons participating in assisted reproductive technologies should be given the fullest possible details of the procedures to be followed, the risks entailed and the chances of both success and failure, if they are to exercise their autonomy and make an informed decision[6].

7) Not more than 3 eggs need be fertilized with a view of transferring 3 at the most[7].

8) The prospective parents receive adequate information regarding pre-implantation diagnosis, including the risks and the chances for success and failure. It is up to the prospective parents to decide if they are prepared to care for a child that may be the carrier of a disease[8].

9) The performance of embryo transfer should be in knowledgeable and experienced hands to eliminate any risks to the recipient. The doctor must inform the patient of his credentials so that the patient is able to make an informed decision[9].

10) Women who are in the high-risk category should be identified by an interview with a genetic counsellor prior to conception. Further tests should only be

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[5] Cf Chapter 2 at 2.5.1
[6] Cf Chapter 2 at 2.9
[7] Cf Chapter 3 at 3.1.4.
[8] Cf Chapter 3 at 3.2.4.
[9] Cf Chapter 4 at 4.2.4

performed if necessary and with the informed consent of the woman. All risks must be explained to her in a way that is understandable[10].

11) No more than 3 embryos should be implanted to avoid selective reduction[11].

12) Since termination of pregnancy past the 20th week gestation is allowed for severely deformed foetuses then the decision should be with the mother in consultation with a medical practitioner[12].

13) Research should be allowed on the embryos up to the 14th day post-conception[13].

14) Donation of embryos should be allowed with the consent of both of the genetic donors[14].

15) The embryo should be classified, as *sui generis* as it is neither property nor a person. If the embryos are destroyed intentionally, it is submitted that it would be an infringement of the right to dignity of their parents. The right to dignity encompasses ones personality rights and the couple could claim *solatium* for their injured feelings[15].

16) The couple for which the embryos were created should determine the fate of the embryos. If the couple do not decide what to do with the surplus embryos then the embryos should be allowed to die after the institution holding them informs the couple of this intention[16].

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[10] Cf Chapter 4 at 4.3.5
[11] Cf Chapter 4 at 4.4.4
[12] Cf Chapter 4 at 4.5.4
[13] Cf Chapter 5 at 5.1.4
[14] Cf Chapter 5 at 5.2.4
[15] Cf Chapter 5 at 5.3.4
[16] Cf Chapter 5 at 5.4.1

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