Multiple pregnancy: Legal and ethical issues

Bernard M. Dickens*, Rebecca J. Cook

Faculty of Law, Faculty of Medicine and Joint Centre for Bioethics, University of Toronto, Toronto, Canada

KEYWORDS
Ethics of fetal reduction; Fetal reduction; Legal liability in multiple pregnancy; Multiple pregnancy; Single embryo transfer; Twin pregnancy; Wrongful birth

Abstract

Multiple pregnancy is increasingly considered a complication of in vitro fertilization (IVF) and ovarian stimulation for natural fertilization. Harms to fetuses, newborn and older children, mothers, families, and healthcare systems are encouraging single embryo transfer. When patients knowingly accept multiple pregnancy risks from IVF or ovarian stimulation, they are unlikely to succeed in litigation against healthcare providers for wrongful pregnancy or wrongful birth. More challenging are impaired children's claims for "wrongful life." These are unlikely to succeed against parents, but courts are ambivalent to claims against healthcare providers. Historically, courts rejected these claims, under the principle that live birth is not a legal injury. European and other courts, however, have been more sympathetic to these claims. Multiple pregnancy treated by fetal reduction is not usually found to offend abortion laws. This poses ethical concerns, however, of "lifeboat ethics," involving how fetal reduction choices are made.

1. Introduction

The 30 years since the birth in England of the world's first "test tube" or in vitro fertilization (IVF) baby, Louise Brown, in 1978, have seen a progressive refinement in the medical techniques and popular perceptions of medically assisted reproduction (MAR). The term IVF is now applied generically to cover various forms of MAR, of which intracytoplasmic sperm injection (ICSI) is the most widely undertaken in many MAR facilities. In popular perception, IVF is no longer considered sensational or scandalous even despite condemnation by conservative religious hierarchies. The number of IVF children born worldwide is estimated to exceed 3 million [1], so the technique is not regarded as exceptional, although it remains inaccessible to many infertile patients particularly, but not only, in economically developing countries on grounds of cost and local unavailability of MAR facilities [2].

An important development in both medical procedure and popular perception is that multiple pregnancy is increasingly seen as a complication or dysfunction rather than a success or unavoidable incident of MAR. The relatively high incidence of multiple pregnancy in MAR, and its negative effects on the survival and health of resulting children, the physical, emotional, social, and economic well-being of mothers and families, and the functioning of healthcare facilities and health service systems, increasingly favor the movement toward single embryo transfer in IVF treatment.

Many higher multiple pregnancies do not result from IVF, where the number of embryos transferred to a woman's uterus can be controlled, but from natural insemination following ovarian (hyper)stimulation. The number of ova released from women's ovaries and fertilized naturally is a matter of chance in this treatment of subfertility. Ovarian stimulation may also be employed in IVF with a comparable risk of inducing the hazards of ovarian hyperstimulation.
syndrome (OHSS). Progress is reported to reduce the more severe incidence of OHSS [3], and single embryo transfer (SET) is urged in IVF to reduce the harmful risks of multiple pregnancy, although the chance of spontaneous, single-embryo (monozygotic) twinning remains [4].

2. Incidence of multiple pregnancy

The modern concern arises from the effects of multiple pregnancies due to ovarian stimulation and IVF; that is, from dizygotic (2 or more embryo) pregnancies. It was observed in 2001 that the incidence of multiple pregnancy had increased considerably in the economically developed world over the previous two decades. Women undergoing IVF treatment “face a 20-fold increased risk of twins and 400-fold increased risk of higher-order pregnancies...related to the current practice of transferring multiple embryos into the uterus” [5]. It has similarly been observed that “[t]he incidence of multiple pregnancy has risen four-fold over the same period...up to 80% of higher order multiple births are attributable to ovarian hyperstimulation and ARTs [assisted reproductive technologies]” [6]. Multiple pregnancy rates after ovarian stimulation are considerably higher than multiple birth rates, since fetal reduction procedures may be available particularly for higher order pregnancies, and risk of spontaneous miscarriage is increased (below) [7].

Reasons for ovarian stimulation and multiple embryo transfer are varied, but commonly related to the eagerness of infertile and subfertile couples to increase their prospects of childbearing. This itself is related to their likelihood to be of relatively advanced maternal age, such as their mid or late 30s. From the early development of IVF, it was accepted that the best chance of a live birth was from transfer of 3 or 4 embryos [8]. Another reason, however, not only where ART clinics operate in a competitive commercial environment, is for clinics to achieve high rates of births. A clinic may promote its services by producing data showing, for instance, that treatment of 10 couples over a given time produced 7 live births, creating an appearance of a 70% “success” rate. It may be otherwise, however, if the 7 were composed of 1 singleton birth, one set of twin and another of quadruplet births, leaving 7 couples childless.

3. Health effects of multiple pregnancy

It has been observed that “[t]he exact risk of miscarriage in multiple pregnancy is difficult to determine because of the incompletely documented phenomenon of the ‘vanishing’ twin” [9]. Many multiple pregnancies diagnosed by early ultrasound deliver singleton births, due to resorption of nonviable embryos and other causes. However, “miscarriage, either threatened or inevitable, was reported as a common complication of multiple pregnancy. The risk is an exponential function of the number of fetuses” [9].

Fetal death late in pregnancy is described as stillbirth, but individual countries define the gestational age at which miscarriage becomes stillbirth differently. The World Health Organization (WHO) defines the perinatal period as 22 weeks or more of gestational age or, if age is unknown, it includes infants with a birth weight of 500 g or more, and ends 7 days after birth. For international comparisons, stillbirths are defined as infants born showing no signs of life in the perinatal period [10], earlier fetal loss being miscarriage.

Early miscarriage following embryo implantation often goes unrecognized, because women do not identify their pregnancy, although they may experience menstrual abnormality, but perinatal mortality is usually obvious. A study in the UK has observed that “[o]ver the past two decades, rates of twin pregnancies have more than doubled and higher order multiples have increased by six-fold to 12-fold. The stillbirth rate for multiples is four-fold higher than it is for singletons (19.6 per 1000 vs. 4.7 per 1000 respectively) with all types of death more common for multiples than for singletons... Multiple gestations are a substantial contributor to overall perinatal mortality rates” [11].

Preterm labor and delivery are an associated complication of multiple pregnancy, often leading to low birth-weight in infants. Preterm deliveries, whether spontaneous or induced, such as by cesarean delivery, occur at less than 37 weeks of gestational age. A study in the US found that 60%–70% are at 34–36 weeks (near term), about 20% at 32–33 weeks (moderate prematurity), about 15% at 28–31 weeks (severe prematurity), and about 5% at less than 28 weeks (extreme prematurity) [12]. Survival rates for infants born at 24 and 25 weeks of gestation have improved in recent years, but even modern intensive care for those born at 23 weeks has not improved their poor survival prospects.

The US study observes that a high number of preterm multiple gestations associated with ARTs contributed significantly to the increase in preterm births from 9.5% in 1981 to 12.7% in 2005. In the US and other high-income countries, this is the leading cause of perinatal morbidity and mortality. The study notes that “[p]reterm births account for 75% of perinatal mortality and more than half the long-term morbidity. Although most preterm babies survive, they are at increased risk of neurodevelopmental impairments and respiratory and gastrointestinal complications” [12].

Long-term health problems associated with uterine restrictions on growth and development can include infants’ cerebral palsy, language and learning disabilities, and poor postbirth growth. Recent studies indicate that early life events, including prenatal, play a powerful role in influencing later susceptibility to certain cancers, cardiovascular disease, metabolic disease, osteoporosis, and other chronic diseases [13]. This risk is not necessarily due to ART. A Swedish study found that “twins born after IVF, ovarian stimulation without IVF; or spontaneously have a five- to seven-fold increased risk of cerebral palsy syndrome” [14]. Similarly, a long-term follow-up study of nearly 1 million infants born at or just after 23 weeks of gestation, without congenital anomalies, found that risks of medical and social disabilities increased with decreasing gestational age [15].

Risks of multiple pregnancy to mothers include increased risks of anemia, toxemia, high blood pressure, kidney trouble, complicated delivery, and postbirth hemorrhage, as well as the physical and emotional consequences of miscarriage and stillbirth [16]. The physical risks are considerable, including of heart attack during pregnancy and, for instance, blood clots and deep vein thrombosis, but emotional or psychological risks may be as severe, and more long lasting.
They include not only feelings of inadequacy to cope, but also distress at the loss of an embryo or fetus, and at perinatal mortality. Experienced counselors have recorded that “[p]arents who lose a twin or one or two of triplets and still have a surviving multiple, face special problems. They have a constant reminder of the dead child in the surviving child...their bereavement is often underestimated by other people who may indeed tell them that they are fortunate to still have a surviving baby. These factors further inhibit the grieving process which has already been delayed by their inevitable preoccupation with the surviving child” [17]. Difficulties are aggravated when the surviving child is severely disabled.

In addition to the physical and emotional costs of multiple pregnancy are the financial costs. Many of these fall on the parents who, in addition to ordinary costs of feeding, clothing and caring for their newborns as they become infants, school children and adolescents, have additional costs of caring for them if they are physically, neurologically or otherwise disabled. Many costs are also imposed on public authorities that provide health, welfare, and social support services. These costs to a governmentally funded health system may begin before birth, in the mother's prenatal medical services and hospitalization, and extend through management of childbirth complications to neonatal intensive care services, and quite possibly to decades-long support of severely compromised individuals.

A common reason why infertile couples want transfer of high numbers of IVF embryos in a single cycle of treatment is to maximize chances of pregnancy when they cannot afford repeated treatment cycles. Governmental health services may decline to fund any or repeated treatment cycles on grounds of cost. This proves a false economy, however, when multiple pregnancies result that impose heavy costs on them for hospitalization and for prenatal, delivery, neonatal, and subsequent care, to which may be added health and social service costs of care for severely disabled recipients, for many years.

4. Legal liability

In the US, it can be relatively risk-free for someone to sue another, because the person's own lawyer can be retained under a contingency fee ("no win, no fee") arrangement, and, if the claim fails, the person is usually not required to pay the defendant's legal costs, unlike in most other legal systems. That is, it costs nothing to sue, even unsuccessfully. US physicians and health facilities often are sued, and some limit the services they provide for fear of litigation. This makes it more striking that, in the litigious climate of the US, relatively few malpractice claims are recorded against the growing supply of MAR and ART practitioners and clinics, except for some OHSS claims.

Patients' claims have succeeded in many countries for so-called "wrongful pregnancy" (if no birth results) and "wrongful birth," usually for such causes as negligently conducted sterilization procedures and, for instance, negligent genetic advice or diagnosis. Claims are based on unplanned pregnancies or births, or births of unexpectedly impaired children [18]. Underlying these proceedings is the contention that, if properly treated or advised, claimants would have avoided pregnancies or parenthood.

Patients of MAR are different, however, in that they strongly desire to have pregnancies and children. They voluntarily and knowingly take the risk that transfer of more than a single embryo, or use of ovarian stimulation, may result in multiple pregnancy. Under the legal doctrines of informed consent and "assumption of risk" (volenti non fit injuria), they have no cause of legal action if MAR results in multiple pregnancy, and the foreseeable consequences to their own health and to the viability and well-being of their unborn and born children. They cannot claim that their pregnancies or births of children were legally wrongful.

The resourcefulness of plaintiffs' lawyers should, however, not be underestimated. An obvious basis of claim is that patients were not adequately informed of risks, particularly of ovarian stimulation. For instance, the Ontario Court of Appeal upheld a decision that an obstetrician who indicated that risk of twin pregnancy on a low dose of the fertility drug Clomid was almost zero was negligent, and liable when twins were born prematurely with severe disabilities [19]. Claims may also arise, for instance, that embryos created in vitro should have been better screened for transfer, so that parents would have delivered other, healthier babies. The visual, morphological evaluation or scoring of embryos for priority of transfer is perhaps as much an art form as a science, but as techniques such as preimplantation genetic diagnosis (PGD) and aneuploidy screening develop [20], failure to offer them or to apply them properly may become credible bases of legal claims, although such techniques would not anticipate the nature of congenital injuries from uterine crowding and fetal growth impairment.

More challenging, to both legal doctrines and social comfort, are claims on behalf of disabled children, often described as "wrongful life" claims, although "diminished life" is a preferable term. A child's claim that it should not have been conceived or, if conceived, should have been aborted, perhaps arguing that another child should have been born in its place, raises insoluble conflicts characteristic of the abortion issue. Claims against parents are almost inevitably doomed to fail. Many US states have doctrines of parental immunity, founded on preservation of the harmony of the household, but almost everywhere else parents' rights to plan, and to risk, pregnancy and childbirth preclude children's claims of injury, including illegitimacy [21]. The thrust of wrongful life actions is against physicians and clinics whose alleged negligence resulted in births of usually severely disabled children.

Historically, courts have almost invariably rejected wrongful life claims. Some have invoked the moral offensiveness of the claim that the (divine) gift of life is a legal injury. Others have found that a system of legal compensation, which can measure in money the difference between normality and disability, cannot address wrongful life. They reflect the 1967 language of the New Jersey Supreme Court [22] that:

The infant plaintiff would have us measure the difference between his life with defects against the utter void of non-existence, but it is impossible to make such a determination. This Court cannot weigh the value of life with impairments against the non-existence of life itself.

This approach remains followed, for instance, in Canada [19], England [23], and Australia [24], although each court has reached its decision only after profound deliberation.
This appears appropriate, since other courts have allowed wrongful life claims. In the US, courts in California, Washington State, and significantly the Supreme Court of New Jersey [25], reversing its 1967 decision and finding compensation calculable, have been sympathetic to claims by or on behalf of severely impaired children. Similarly, leading courts in France, Germany, Israel, and the Netherlands have accepted such a claim [26], although public reaction in France resulted in restrictive legislation. Several US states, such as Utah, Idaho, Minnesota, Pennsylvania, and Georgia limit or bar wrongful life claims. Support may grow, however, for reasoning of the dissenting judge in Australia’s highest court, who noted [27]:

Denying the existence of wrongful life actions erects an immunity around health care providers whose negligence results in a child who would not otherwise have existed being born into a life of suffering. Here, that suffering is profound, substantial and apparently lifelong... The law should not approve a course which would afford such an immunity and which would offer no legal deterrent to professional carelessness or even professional irresponsibility.

The negligence in multiple pregnancy would not be transfer of any given number of IVF embryos or administration of any particular fertility drug dosage, but failure to ensure that patients were properly given, and adequately understood, information of the chance they are accepting of multiple pregnancy. Ten or so years ago, advice was to transfer no more than 2 embryos [28], and this is still widely followed for patients aged under 35 years. The modern emphasis, however, is moving to single embryo transfer. It has been observed, for instance, that “[s]ingle-embryo transfer (SET) is becoming the norm in Scandinavian countries and has led to a substantial reduction in the rate of multiple pregnancies there...this procedure – eventually combined with transfer of single frozen-thawed embryos in subsequent cycles – results in similar pregnancy rates to those from transfer of two embryos at once, but with substantial reduction of multiple pregnancy rates” [29].

When IVF patients lack means of treatment in subsequent cycles or, for instance, are of advanced maternal age, and approve transfer of more than single or two embryos in one cycle, or when they receive ovarian stimulation by fertility drugs [6], they may experience unwanted multiple pregnancy, and approve fetal reduction.

Developments in ultrasound and fetoscopy have made fetal reduction (FR) possible. Distinctions are sometimes drawn between elective fetal reduction, for reasons of social choice, and multifetal pregnancy reduction (MFPR), when carrying multiple fetuses poses serious health risks for the mother and the fetuses. The distinction fades, however, when one fetus is shown to be severely deformed. There are various techniques of FR [5], all raising ethical issues, but the key legal issue, apart from routine concerns such as patients’ informed choice and confidentiality, is their status under abortion laws.

However abortion may be understood in medical and social settings, its legal understanding usually falls under the terms of prohibitive legislation. Developed before the emergence of FR, laws tend to refer to “termination of pregnancy,” or more historically to “procuring the miscarriage of a [woman].” In intent, FR does neither. It is intended, particularly in MFPR, to increase prospects of pregnancy continuation. Abortion legislation in the UK has been amended to include FR, but all except one or two restrictive laws accommodate therapeutic abortion. MFPR would be therapeutically indicated for the health of the mother, including her mental health in preventing births of several prematurely born children [30]. The therapeutic ground would clearly apply where ultrasound or another means shows distressing fetal deformity, but the adverse maternal health effects of even a normal twin pregnancy may satisfy therapeutic criteria.

A basic principle of criminal justice under the rule of law is that any uncertainty in the meaning or scope of a penal law, and any uncertainty in an accused person’s intention, must be resolved in favor of that person. That is, ambivalence or uncertainty in whether conduct falls under penal law must result in nonprosecution or acquittal, and any ambivalence or uncertainty in a suspect’s intention must be determined according to the presumption of innocence. It seems that FR cannot easily be considered to violate laws against abortion under legally principled systems of justice respectful of women’s and born children’s health.

5. Fetal reduction and the law

The professional challenge is to inform and advise infertile patients on how to maximize the chance to have a healthy child and minimize the risk of multiple pregnancy. Ten or so years ago, advice was to transfer no more than 2 embryos [28], and this is still widely followed for patients aged under 35 years. The modern emphasis, however, is moving to single embryo transfer. It has been observed, for instance, that “[s]ingle-embryo transfer (SET) is becoming the norm in Scandinavian countries and has led to a substantial reduction in the rate of multiple pregnancies there...this procedure – eventually combined with transfer of single frozen-thawed embryos in subsequent cycles – results in similar pregnancy rates to those from transfer of two embryos at once, but with substantial reduction of multiple pregnancy rates” [29].

When IVF patients lack means of treatment in subsequent cycles or, for instance, are of advanced maternal age, and approve transfer of more than single or two embryos in one cycle, or when they receive ovarian stimulation by fertility drugs [6], they may experience unwanted multiple pregnancy, and approve fetal reduction.

Developments in ultrasound and fetoscopy have made fetal reduction (FR) possible. Distinctions are sometimes drawn between elective fetal reduction, for reasons of social choice, and multifetal pregnancy reduction (MFPR), when carrying multiple fetuses poses serious health risks for the mother and the fetuses. The distinction fades, however, when one fetus is shown to be severely deformed. There are various techniques of FR [5], all raising ethical issues, but the key legal issue, apart from routine concerns such as patients’ informed choice and confidentiality, is their status under abortion laws.

However abortion may be understood in medical and social settings, its legal understanding usually falls under the terms of prohibitive legislation. Developed before the emergence of FR, laws tend to refer to “termination of pregnancy,” or more historically to “procuring the miscarriage of a [woman].” In intent, FR does neither. It is intended, particularly in MFPR, to increase prospects of pregnancy continuation. Abortion legislation in the UK has been amended to include FR, but all except one or two restrictive laws accommodate therapeutic abortion. MFPR would be therapeutically indicated for the health of the mother, including her mental health in preventing births of several prematurely born children [30]. The therapeutic ground would clearly apply where ultrasound or another means shows distressing fetal deformity, but the adverse maternal health effects of even a normal twin pregnancy may satisfy therapeutic criteria.

A basic principle of criminal justice under the rule of law is that any uncertainty in the meaning or scope of a penal law, and any uncertainty in an accused person’s intention, must be resolved in favor of that person. That is, ambivalence or uncertainty in whether conduct falls under penal law must result in nonprosecution or acquittal, and any ambivalence or uncertainty in a suspect’s intention must be determined according to the presumption of innocence. It seems that FR cannot easily be considered to violate laws against abortion under legally principled systems of justice respectful of women’s and born children’s health.

6. Ethical issues

Ethical principles of beneficence, the duty to do and to maximize good, and non-maleficence, that is to do no, or to minimize, harm, should be carefully observed and balanced in IVF and ovarian stimulation, because of the risk of multiple pregnancy. The ethical as well as the legal duty is to ensure patients’ unpressured consent to the risks of multiple pregnancy, and to the calculable risks of FR, which include inadvertent loss of an entire pregnancy [31]. When multiple pregnancy occurs, FR should be offered, and available. Practitioners who have conscientious objections are ethically bound to refer patients to non-objecting practitioners [32].

It may be supposed that physicians who object to the embryo wastage recognized as inherent in many forms of MAR will not enter this specialty. Some specialists may object, however, to FR from twin to singleton pregnancies on grounds that the risks to maternal health and to each twin are not exceptional, and were freely accepted by the patients before they undertook MAR. There is the argument of inadvertent use of the technology, and also of the risk that, on random selection of either of apparently healthy twin fetuses for FR, the survivor may suffer spontaneous death in utero, or be born with an undiagnosed severe impairment. Improved but possibly costly techniques of prenatal fetal diagnosis and screening of chromosomal, biochemical, and multifactorial disorders may reduce this risk. However, when ultrasound or another form of prenatal diagnosis shows one fetus to be seriously impaired, terminating its viability is
unobjectionable to patients, practitioners and others able to tolerate induced abortion, provided that FR of that one will not unavoidably jeopardize the life or health of the survivor.

Perhaps the most critical ethical challenge in FR is to answer the question "[u]nder what circumstances can it be considered just to kill some so that others may survive?" [33]. If a fetus is nonviable or if its pathological condition endangers the survival or well-being of its healthy twin, its sacrifice to promote the safe delivery and health of the surviving twin, as with conjoined born twins [34], can appear ethically justifiable. When twin or higher numbers of embryos appear of equal health status, however, the sacrifice of one or more to save the other(s), by reducing their risks from cramped growth in utero, poses a classical ethical dilemma, sometimes characterized as concerning "lifeboat ethics." That is, when the lifeboat has inadequate room for all, on what basis are some passengers of the sinking ship to be denied access, or later to be thrown overboard?

If selection is not to be arbitrary, it may be by lots, providing an equal chance to each individual. Where circumstances do not allow a fair or equal process of selection, choice may be by convenience. In FR, this means selection of the most accessible fetus(es), minimizing risk of the procedure to the other(s), and to the mother. If convenience of access in utero for the termination procedure is the ethical criterion, it has to be applied in the judgment of the responsible surgeon. Different surgeons may approach the same patient differently, reaching agreement on the number of fetuses intended to survive and on the FR technique to be employed differently. The surgeon in charge of the individual case cannot be ethically contradicted, however, by another not bearing that responsibility for the exercise of clinical judgment.

References