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Assisted reproductive technologies: Impact on neonatology and a call for reform

Shetal I. Shah[a,*] and S. Van McCrary[b]
[a]*Department of Pediatrics, Stony Brook University School of Medicine, Stony Brook, NY, USA*
[b]*Center for Medical Humanities, Compassionate Care, and Bioethics, Stony Brook University School of Medicine, Stony Brook, NY, USA*

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Neonatologists regularly struggle with fetal, and indirectly maternal, morbidities resulting from assisted reproductive technologies (ART), a term that includes *in vitro* fertilization (IVF) and all other forms of fertility assistance. Yet, continuity of care between reproductive endocrinologists, obstetricians, and neonatologists in the United States (US) remains fragmented at best. Simultaneously, government regulation of ART is minimal and professional guidelines are generally unenforced. When multiple pregnancies result from application of ART, the fetuses typically produced are often extremely premature and beset with profound medical problems [1]. Many neonatologists respond with alarm to these results, citing decisions about which they often feel they have had insufficient opportunity to influence and which they suspect may have been conducted without fully informed consent. We present two cases of extreme prematurity under complex medical circumstances that illuminate some of the potential negative repercussions of such decisions and offer some initial analysis and a few suggestions about a way forward.

*Corresponding author: S. Van McCrary, PhD, JD, MPH, Clinical Ethics Consultation Service, Center for Medical Humanities, Compassionate Care, and Bioethics, Stony Brook University School of Medicine, HSC, Level 3, Stony Brook, NY 11794-8335, USA. Tel.: +1 631 444 9676; Fax: +1 631 444 9744; E-mail: smccrary@notes.cc.sunysb.edu.

Case 1: A 36 year old African American woman with a history of cocaine abuse and Roux-En-Y Gastric Bypass surgery delivered 3 uncomplicated pregnancies in 1999, 2003 and 2005. The last pregnancy was delivered by Cesarean section with accompanying bilateral tubal ligation at the mother's request. All children had 3 different fathers and were removed from parental custody by local child and protective service authorities because of the maternal cocaine use and were placed with foster parents. After six months on welfare, she was placed as part of a "Back to Work" program as a housekeeper at a local hospital which provided health benefits, including coverage of assisted reproductive technology (ART). She subsequently met another man with whom she wanted to have children. As natural fertilization was not possible secondary to the tubal ligation, she consulted a reproductive, endocrinology and infertility specialist. The physician implanted 3 IVF eggs from a donor using the partner's sperm. Triplets were conceived and during the pregnancy she was fired from her position because of a failed urine drug screen which was positive for cocaine. She delivered triplets at 25 weeks gestation (contributed in part by the drug use and the gastric bypass surgery, which limited her caloric intake during the high nutritional stress of triple pregnancy) while receiving Medicaid services, which each spending an average of 90 days in a university-

based level III neonatal intensive care unit (NICU) facility for which the hospital received approximately $410,000 per child in Medicaid payments. The children were released to the mother with weekly, unannounced social service visits and require upwards of $25,000/year per child in expenditures for management and medical sequellae of their prematurity.

Case 2: A 34 year old Caucasian woman with polycystic ovarian syndrome (PCOS) and morbid obesity presented to an REI specialist after trying to conceive for 16 months. Her health insurance, obtained as part of her husband's occupation as a sheriff in a rural upstate county, provides a $25,000 cap on infertility reimbursements which must be used over a 1 year span. She presented to an infertility specialist in her rural county who refused to treat her, counseling her that the risks of child birth, Cesarean section and multiple pregnancy to her health were significant. She then travelled to another fertility specialist in New York, expressing concern over having lost one month in her one year of allowable insurance coverage. The REI specialist transferred 3 embryos to the mother, maximizing her $25,000 insurance limit. She conceived triplets and refused multi-fetal pregnancy reduction on religious grounds. She underwent Cesarean section at 33 weeks gestation for fetal indications, delivering triplets with an average NICU stay of 21 days. However, during the surgery the mother developed significant bleeding, deep venous thrombosis and pneumonia – all conditions with increased risk is the pregnant, obese woman. She spent 2 weeks in surgical intensive care.

1. Introduction

In 30 years since the first IVF birth, ART in the US has become a very profitable industry, accounting for $2 Billion in expenditures in 1994 and upwards of $76 Billion in 2005 [2]. ART is also the leading cause of multiple gestation, particularly higher-order gestation (triplets or greater) which increases prematurity risk [3]. The cost of neonatal intensive care at birth and subsequent healthcare for these patients is $48 Billion, a cost shared by private insurers and the public via Medicaid and the State Child Health Insurance Plan [3]. In the United Kingdom (UK), total direct costs of twins resulting from IVF are approximately 3 times the costs of single pregnancies while IVF triplets cost almost 10 times as much as singletons; neonatal intensive care costs account disproportionately for these differences [4]. The tremendous financial costs alone have been used to justify regulation and judicious use of resources for ART, however critics charge such regulation impinges on procreative rights.

But all freedoms are "bounded." Procreative rights are not unlimited if they would jeopardize the health of the egg donor, fetus, egg recipient, sperm donor, or adversely affect public health. As Cynthia Cohen points out, "Private moral choices have public consequences... The physiological fact of infertility does not entitle us to do whatever is necessary in order to reproduce. It does not morally warrant impairing the health of gamete donors. It does not morally warrant knowingly bringing children into the world that will have serious deficits. It does not warrant assisting couples who wish to... seek to create 'designer children'" [5]. Similarly, she argues that "the importance of having healthy children and families... offers the primary justification for regulating" ART [5]. Writing in 1997, Cohen was referring specifically to egg donation and IVF, the dominant modes of ART at the time; nonetheless, her comments are perhaps even more relevant to all forms of ART today.

In a world of limited resources, funds used to support ART and the health issues of the subsequent children must typically subtract resources from other health-promoting agendas, thus framing ART as a public health issue. In issues balancing individual freedoms and public health, the courts have clearly sided with the public on many issues. In 1905, *Jacobsen vs. Massachusetts*, the US Supreme Court noted that limitations on certain aspects of liberty are the bargain made for civilization. The court noted "persons and property are subjected to all kinds of restraints and burdens, in order to secure the general comfort, health, and prosperity of the State; of the perfect right of the legislature to do which no question ever was, or upon acknowledged general principles ever can be made, so far as natural persons are concerned" [6]. Given the stakes of national welfare, the court went further and asserted that a state may compel vaccination and other reasonable public health measures upon citizens using the inherent authority to exercise its police powers [6].

Nineteen states require a minimum number of vaccines prior to entering public school without allowance for conscientious exemption on anything but religious grounds [7]. Based on these precedents, the government would be wise to solicit input from the public, physicians, and ethicists to create a regulatory framework under which ART may operate fairly.

Table 1
Summary of selected countries' policies and results of assisted reproductive technologies (ART)

Country	Summary of IVF regulation	Result of regulation
Australia [28,29]	Government regulation varies widely by state/territory; Fertility Soc. Australia requires ART centers to minimize multiple births; no more than 2 embryos for implantation in women < 40yrs; recommends single embryo transfer (SET) for women < 35 yrs	In 2006, SET accounted for 57% of IVF cycles (a > 50% increase in SET after guidelines tightened); 86% of deliveries following IVF are singletons
Canada [28]	No government regulation; only one province partially covers costs of ART; Can. Soc. OB/GYN voluntary guidelines maximum double embryo transfer (DET) in women < 35; new government regulations are under review	30% of ART births are multiple; 90% of IVF cycles include multiple embryos
United States [17,28]	No government regulation; Am. Soc. Assisted Repro. Tech. voluntary guidelines encourage SET in women < 35 yrs, encourage no more than DET in women 35–37 yrs, encourage no more than 4 embryos in women 38–40 yrs, > 40 yrs permits more embryos transplanted; guidelines are not enforced; substantial variation in insurance coverage for ART; federal statute requires Centers for Disease Control to develop a model program for the certification of embryo laboratories, to be carried out voluntarily by interested States (Fertility Clinic Success Rate and Certification Act of 1992)	Increasing incidence of twins and late preterm births; decreasing trend of triplets
Belgium [28]	Government permits up to 6 IVF cycles funded by national health insurance; SET required for 1st cycle in women < 36 yrs; number of embryos transferred after 1st cycle depends on patient's age and quality of embryos	Triplet births virtually eliminated; twin rate has dropped to 7%; overall pregnancy rates have not decreased significantly
Finland [28]	No government regulation; professional guidelines are closely followed; SET used in almost 60% of cases; triplet embryo transfer limited to <1%	No triplet deliveries in 2006-2008; 13 triplet embryo transfers in 2006; overall pregnancy rates remain unchanged
Germany [28]	Government maximum of 3 immature eggs may be cultured beyond early stage; embryo selection practices not permitted; no cleavage stage embryos may be frozen, so all embryos must be transferred	Effective embryo selection is prevented; triplet and twin rates are very high
Hungary [28]	Government maximum of 3 embryos may be transferred, except in special circumstances (e.g., older women or history of failed IVF; when max. is 4)	In 2002–4, 10% SET, 25% DET, 50% were 3-embryo transfers, 15% were 4-embryo transfers; resulting twin rate 30%
Sweden [28]	Government regulation requires SET, except in exceptional circumstances	70% of IVF cycles are SET; twin rate 5%; overall pregnancy rates remain unchanged
United Kingdom [28]	Government regulation through Human Fertilization & Embryology Authority (HFEA); no more than DET allowed for women <40 yrs; 3 embryos permitted in women > 40 yrs; all licensed treatment centers required to have a strategy to minimize multiple births	Triplet rates have decreased; twin rate is rising

Many western nations place limits on ART services and regulate the number of embryos transferred, except for the US; All these other countries have national health care systems.
SET, Single embryo transfer; DET, double embryo transfer; ART, assisted reproductive technologies; IVF, *in vitro* fertilization.

2. Status of regulation

In countries with national healthcare systems, such as Sweden, England, and Australia, this argument has been used to introduce regulation of the ART industry. A selected summary of regulations in different countries and their outcomes is presented in Table 1. Of note, these data are disparate, non-centralized, and evolving, making global interpretations challenging. What is clear is that in many countries with explicit restrictions on the number of embryos that can be transferred and implanted during one cycle, a resultant decrease in higher-order gestation and an increase in single gestation infants is observed. Finland, Sweden and Belgium, who control the number of embryos transferred, have eliminated triplet gestations. Australia has decreased the number of multiple embryo transfers by 50%. The international experience is clear that state regulation

of ART can have a tangible effect on the number of pregnancies delivered and reduce the costs of caring for those newborns. Contrary to what critics in the United States claim, regulation of the ART industry could be a useful mechanism for decreasing maternal and neonatal healthcare burdens. Further, researchers in the UK have noted that redirecting funds saved by implementation of a mandatory single-embryo transfer (SET) policy, with resulting lower neonatal intensive care costs, into increased funding for IVF treatment could possibly double the number of treatment cycles funded, without any increase in overall expenditures [4]. There appears to be no obvious reason why such a policy could not be used by both public and private health insurers in the US to achieve a similar result. Yet, the primary political objection in the US to such regulation is that "procreative liberty takes priority over all other values" [5].

Regulation of ART has been rejected here, considered too rigid for US physicians. Even the ASRM's voluntary guidelines on the number of embryos transferred clearly states, "strict limitations on the number of embryos transferred, as required by law in some countries, do not allow treatment plans to be individualized after careful consideration of each patient's own unique circumstances" (a statement which clearly undermines the power of the entire document) [8]. In the US, efforts to place limits on embryo transfers has been hampered by failure to enforce compliance with voluntary guidelines and failure to mandate inclusion of all REI physicians. The latest ASRM "Guidelines on the Number of Embryos Transferred," last reviewed in June, 2008, states that programs with a high rate of multiple order pregnancy greater than 2 standard deviations above the mean for all reporting RET clinics will be audited by the Society for Reproductive Technology. However enrollment in this surveillance system is voluntary and no punitive measures or authority is actionable.

The Fertility Clinic Success Rate and Certification Act, passed in 1992, established a voluntary certification program for laboratories and suggested quality control measures [9]. No minimum standards for infertility specialists were developed and no punitive action for non-participants were issued. The law mandated that participating clinics report their pregnancy success rates, but not multiple gestation rates or premature birth rates. The law worsened the situation, giving clinics an incentive to provide aggressive ART regiments to increase success rates (defined as the number of women who conceived any pregnancy) and thus be more competitive and attractive to insurance companies and insured patients, who were prone to seek out such information. The law does not require mandated reporting of rates of prematurity, high-order multiples and the subsequent co-morbidities of the infants [10].

The lack of oversight has led physicians in the REI industry to tout market forces as the principle mechanism for regulation. They claim that reckless specialists, as in all other medical fields, will be whittled down by decreased patient volume and punitive lawsuits. However, the porous guidelines of the industry, and the substantial leeway they provide physicians, mean that the standard of care is difficult to define. The high variability of practice standards makes deviation of such standards difficult to establish, hindering the tort system from imposing authority [5].

3. Financial incentives

State-sponsored insurance programs such as Medicaid typically do not provide financial coverage for ART services. ART patients therefore tend to be self-pay clients who can usually afford the approximately $25,000 required for IVF and/or hormonal therapy or otherwise privately-insured patients [11]. In both Cases 1 and 2, ART was used only while the patient was insured. In the second case, the physician may have accelerated and altered his treatment regimen in order to ensure payment for services before they expired. While programs differ, the typical policy includes a financial cap on the amount of services reimbursed. Ethicists have questioned the construct in which REI services are provided, arguing that like plastic surgeons (where standard of care is elusive and the system is self-pay) the system is designed to create an incentive for providers to perform services in exchange for reimbursement, eroding objectivity. REI physicians are well compensated earning upwards of $500,000/year – two standard deviations above the average, similarly trained physician [12].

In ART, this problem is exacerbated by the payment structure, in which the financial incentives, and pressure from patients, may motivate physicians to provide overly aggressive services (i.e., an increased number of embryos per cycle) in order to maximize the chance of pregnancy (improving success rates) while simultaneously remaining under the patient's insurance cap. While many REI's practice responsibly, the system, as designed, creates potential incentives for abuse [5]. Given the social responsibility and power invested in physicians by society, even the potential impropriety

created by this system can be construed as conflicted. It may erode the public trust in a physician making an unbiased, scientific judgment based on a patient's best welfare. Consider the analogy of an internist reimbursed not by the complexity of his patients or the number he sees, but by the prescriptions written. Such a system may encourage improper use of antibiotics for example, and excess use of medications which are not indicated. Further, many reimbursement systems may not adequately compensate health care providers for counseling services that might influence patients to limit the number of embryos transferred. Such a system could motivate physicians to offer ART services without a critical appraisal of the full sequelae of multiple births to mothers and babies.

Such factors may have motivated the physician in Case 2 to provide services to a high-risk patient. Obese, pregnant patients, have a higher Cesarean section rate, a higher maternal mortality and higher co-morbidity – all factors increased with multiple gestation in the obese [13,14]. However, single embryo transfer, in this case, would have taken too much time, and if failed to result in pregnancy, the patient would have expired the time limit on her insurance coverage for this expensive care she could never afford to self-pay. Further, so long as the mother understands the risk and was willing to accept them, providing care to high-risk patients is reasonable. This demonstrates how the atmosphere of incentives in this industry can result in poor judgment from physicians and patients and call into question their validity.

The REI in this case expressed concern that failure to provide services to this patient could be seen as discriminatory – a common argument among REI specialists regarding situations exemplified in both cases. However discrimination is hard to define, and unfortunately the US medical system can already be viewed as discriminatory. Wealthy patients receive better care. Health outcomes parallel racial lines and poor children often receive a disproportionately low share of resources [15]. The REI patient base inherently discriminates against the indigent. In this case it would probably not be discriminatory or unethical to refuse the patient ART. Despite the patient's full awareness of the risks, her obesity is a relative contraindication to pregnancy and increases her risk of harm, violating a fundamental tenet of medicine not to harm patients. Similarities can be seen in medicine's handling of patients requesting bariatric surgical procedures. These procedures, which can dramatically reduce obesity, are medically indicated for a selected patient group, yet many patients request the services outside of the traditional medical indications for the procedure. To ensure these that patients fully understand the risks and are not blinded by ultimate results, many bariatric surgical groups require pre-surgical psychological counseling to determine motivation and ensure reasonable expectations [16]. For high risk mothers and other cases where use of ART is questioned, utilizing this mechanism would provide not just a quality control, but independent determination of the patient's comprehension of the procedure. As noted above, it is perhaps *more* concerning to provide the service to the patient. Given the myriad of issues involved, a local hospital ethics committee, with input from REI, maternal-fetal medicine, and neonatal specialists perhaps should have been consulted prior to proceeding.

4. Past proposals for oversight in the United States

Shortly after the birth in the UK of the first test-tube baby in 1978, President Jimmy Carter convened an Ethics Advisory Board to study issues raised by IVF, especially issues concerning the safety of babies created in this manner [17]. The Board issued its report in 1979, which recommended that a permanent board be established to monitor ART. As the numbers of IVF babies grew, with few reported health complications, the safety issue waned in apparent importance while political discord grew to the extent that a new ethics advisory board was never appointed and no other agency has since replaced it [17]. In 1997, following allegations of misuse of human eggs in the US, Cynthia Cohen analyzed reasons for the reluctance of US policy makers to regulate IVF. Cohen noted four categories of resistance: first, use of ART was politically controversial; second, regulation of any sort was in disfavor; third, some persons did not consider infertility a disease; and fourth, some believed regulation would interfere with an unfettered right to reproduce [5]. She recognized that creating a new regulatory body was not politically feasible at the time and, instead, proposed that the newly established National Bioethics Advisory Commission (NBAC) could provide a context for debate of these issues [5]. The NBAC also became mired in political controversies and produced few meaningful results.

The issue resurfaced in 1997 when Furger and Fukuyama called for a new federal regulatory agency, with a "robust procedure of public consultation" [18]. Likewise, this proposal was swiftly met with a wave

of opposition from various quarters. Among the arguments against the proposal were: first, that a decentralized set of governing policies was both preferable and more achievable than a national agency [19]; second, that a nonsystematic, incremental approach based on a mixed public-private regulatory system, backed by a strong common law tradition, was preferable [20]; and third, that "rational democratic deliberation", working within the current political system, was capable of producing a trustworthy and politically legitimate regulatory structure [21]. Others supported the proposal, noting that the current, fragmented "non-system" has failed to promote the interests of women, children and the general public [22]. Recognizing the political strength of the various opposed factions, Arthur Caplan proposed a few practical alternatives: first, the US Food and Drug Administration should exercise greater control over all new forms of ART; second, insurance companies and third-party payers "should pay only for those programs accredited by the American Society for Reproductive Medicine (ASRM), who are in full compliance..." with the Society's guidelines and existing laws; and third, the National Conference of Commissioners on Uniform State Laws should review the current fragmented state laws and develop model legislation to systematize, to the extent possible, legal approaches among states [17].

5. Suggestions

We conclude the Reproductive Endocrinology and Infertility (REI) system in the United States creates, perhaps unintentionally, numerous incentives that impede the reasonable application of unbiased ethical and medical analysis. When a REI physician is faced with a woman desperate to get pregnant, requesting high-order multiple embryo transfer, and apparently willing to undertake substantial medical risks, the incentives for physician and patient are completely congruent in the absence of a strong sense of ethical restraint, with no practical countervailing incentives. There are a number of potential methods of addressing this problem, which we will now discuss. First, a national commission would be an appropriate venue to discuss and mitigate these issues, as has been done in several other countries. The public clearly has a right to provide input on these issues considering that the social policy implications of caring for potential premature newborns are substantial, and that REI physicians bear some responsibility for the foreseeable actions of multiple gestation infants. The recent controversy and backlash about the California octuplets born in January, 2009, (including an inquest into the practice of the physician involved, death threats against the public relations firm handling the so-called "Octomom", and bills quickly filed in several state legislatures combining an anti-abortion agenda with restrictions on the number of implanted embryos) also suggests a strong degree of public interest in society's role in such decisions [23–26].

In order to rightly account for the myriad of difficulties regarding incentives, regulation, neonatal outcome and private choice, a dedicated presidential commission could be convened to formally provide recommendations on the appropriate use of IVF and ART technologies. These private matters have significant public impact, and thus the public should have input on how resources are utilized for the good of the community. Using standard plans for all patients is derided as "assembly-line medicine," and is the basis of the ASRM caveat in embryo implantation guidelines. Yet this reasoning fails to consider that much of medicine – asthma care, hypertension treatment, routine and critically-ill newborn care is already standardized by protocols, and have resulted in better medical outcomes for large populations of patients [27]. Hence mandatory community input in deciding the limits of ART are required for several reasons.

1. To solicit insight and opinion from all segments of society – preventing injustice;
2. To validate the need for community resources to care for infants with health issues related to prematurity and higher-order gestation – conditions of increased incidence with ART;
3. To prevent physicians from acting solely out of financial incentives built into insurance coverage.

As Caplan has recognized, however, political opposition to a national-level administrative board of this type in the US has historically proven to be fierce and there appears to be no current reason to expect this has changed sufficiently to make national regulation a reasonable possibility [17]. However, strict regulation could have unintended consequences, such as "procreative tourism" or creating black market ART services.

A second strategy would be a regional, state, or local regulatory approach. Regional medical practices in the United States vary significantly, and recommendations from regional regulatory boards could form the basis of practice, allowing for individualized treatment plans. The local hospital and ethics committees, with their roots in the community, inclusion of physicians, awareness of regional medical practices, mandates of impar-

tiality, and input from community members could be a useful way to determine use of ART services in cases of potential controversies. By remaining distanced from the decision over who receives the services, the individual physicians' concern could be eliminated. Arguments strongly resisting a national regulatory body making decisions without sensitivity to local medical practices could be invalidated with a regional approach.

However, in the absence of regulation at either national, regional, state or local levels, both Cases we present could provide critics with legitimate justifications for claims of discrimination on the basis of social worth criteria, e.g. chronic substance abuse and morbid obesity, in the event a physician refused to provide ART. Instead, a *uniformly enforced* professional policy or state regulatory framework, based on medical criteria and considering the best interests of both mother and children as informed by public comment, could potentially avoid challenges on the basis of social worth. Hence, regulation may have dual benefits in terms of first, promoting well being of families and second, by avoiding some neonatal intensive care, promoting increased funding for IVF treatments, even though limiting the numbers of embryos transferred per cycle. Paradoxically, under this analysis such stricter regulation could promote patient and family welfare while producing healthier babies and maintaining fertility rates.

Third, a multi-step incremental approach, similar to that suggested by Caplan, would be a reasonable alternative to comprehensive regulation [17]. An incremental approach that combined FDA oversight, limiting third-party payment to facilities and providers in full compliance with ASRM rules, urging ASRM to tighten existing guidelines, and the establishment of model statutes, would be a good start toward a system that better balances procreative liberty with fostering healthy babies and families. Any approach should include funding for counseling at multiple times prior to initiating ART.

The means of such supervision may be comprehensive or incremental, but they must be more effective than current practice.

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