

Putting Too Many (Fertilized) Eggs in One Basket: Methods of Reducing Multifetal Pregnancies in the United States*

I. Introduction

In January 2009, California resident Nadia Suleman gave birth to the longest surviving octuplets in American history.¹ A public furor erupted when it was discovered that the mother was unemployed, single, and had conceived all fourteen of her children with the help of in vitro fertilization (IVF).² Questions about how one woman was impregnated with eight embryos prompted the California Medical Board to investigate Michael Kamrava, Suleman's fertility doctor.³ Ms. Suleman claims that Dr. Kamrava transferred six frozen embryos into her, two of which twinned.⁴ The implantation of six embryos exceeded by threefold the number suggested by the American Society for Reproductive Medicine (ASRM) guidelines, which recommended that at most two embryos be transferred to a woman under the age of thirty-five "in the absence of extraordinary circumstances."⁵ The ASRM also suggests that women in this age group who have had prior success with IVF should consider transferring only one embryo.⁶

The ASRM guidelines were updated in 2009 but would provide exactly the same guidance in this case.⁷ The ASRM promulgates the voluntary

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1. Randal C. Archibold, *Octuplets, 6 Siblings, and Many More Questions*, N.Y. TIMES, Feb. 4, 2009, at A14.

2. See, e.g., Ellen Goodman, Op-Ed., *The Ethical Failures of Fertility Treatment*, BOSTON GLOBE, Feb. 6, 2009, at A15 (criticizing the policies that permitted an unemployed, single mother of six to conceive eight more babies through IVF).

3. Stephanie Saul, *Birth of Octuplets Puts Focus on Fertility Clinics*, N.Y. TIMES, Feb. 12, 2009, at A1. Kamrava has since been expelled from the American Society of Reproductive Medicine but will still be permitted to practice. *Doctor in Octuplets Case Expelled from Group*, BOSTON GLOBE, Oct. 20, 2009, at A2.

4. Saul, *supra* note 3. Monozygotic twins develop when a single fertilized egg splits after conception, developing into two fetuses. ALESSANDRA PIONTELLI, TWINS: FROM FETUS TO CHILD 5 (2002).

5. Practice Comm., Soc'y for Assisted Reprod. Tech. & Practice Comm., Am. Soc'y for Reprod. Med., *Guidelines on Number of Embryos Transferred*, 90 FERTILITY & STERILITY (Supp. 3) S163, S163 (2008).

6. *Id.*

7. Practice Comm'n, Soc'y for Assisted Reprod. Tech. & Practice Comm'n, Am. Soc'y for Reprod. Med., *Guidelines on Number of Embryos Transferred*, 92 FERTILITY & STERILITY (Supp. 5) 1518, 1518 (2009), available at http://www.asrm.org/Media/Practice/Guidelines_on_number_of_embryos.pdf [hereinafter *Guidelines on Embryos Transferred*].

guidelines to inform patients and clinicians in the absence of state or federal statutes regulating the IVF process.⁸ The Society recommends a number of embryos based on the female patient's age and pregnancy prognosis.⁹ Factors affecting the favorability of the prognosis include the quality of the embryos created, the success or failure of past IVF, and the availability of excess embryos for cryopreservation.¹⁰ If embryos present favorable morphological characteristics, a patient has previously undergone a successful IVF round, or if excess embryos are available for freezing, then fewer need to be transferred.

For women under thirty-five years old, the guidelines suggest a transfer of one or two embryos; for women thirty-five to thirty-seven years old, two to three embryos; for women thirty-eight to forty years old, three to four embryos; and for women over forty years old, up to five embryos.¹¹ The guidelines also distinguish between cleavage-stage embryos (for which numbers are reported above) and blastocysts, of which fewer should be transferred for each age group.¹² The ASRM includes an exception for physicians to transfer more than the recommended number of embryos on an individualized basis.¹³ However, to comply with the guidelines, the treating physician must note in the patient's medical records the justification for transferring more than the recommended number of embryos.¹⁴

While clinics are not legally bound to follow the guidelines, they can face consequences for noncompliance.¹⁵ But some commentators think the

8. *Id.*

9. *Id.*

10. *Id.*

11. *Id.*

12. *Id.* Some evidence suggests that the transfer of five-day-old blastocysts is associated with a higher implantation rate than the transfer of three-day-old embryos, perhaps because the additional two days of culture allows clinicians to better screen against embryos that are not developmentally viable. Alan Trounson, *Embryo Stage and Transfer Number*, in *ASSISTED REPRODUCTIVE TECHNOLOGY: ACCOMPLISHMENTS AND NEW HORIZONS* 311, 315–16 (Christopher J. De Jonge & Christopher L.R. Barratt eds., 2002). Therefore, use of blastocysts in IVF “reduces the risk of multiple pregnancy without compromising the success of IVF procedures.” *Id.* at 316.

13. *Guidelines on Embryos Transferred*, *supra* note 7, at 1518.

14. The 2009 guidelines clarify that “extraordinary circumstances” means that one additional embryo may be transferred for every two previous failed IVF attempts. *Id.* at 1519. They also provided that the patient must be counseled about the risks of multifetal pregnancy. *Id.*

15. A clinic may be subject to an audit if it reports a rate of multiple pregnancies exceeding the national average by two standard deviations for two consecutive years. *Id.* at 1518. Additionally, a clinic that fails to comply with either the Society for Assisted Reproductive Technology's (SART's) or ASRM's advertising, practice, or ethical guidelines may have its membership revoked by these societies. David Adamson, *Regulation of Assisted Reproductive Technologies in the United States*, in *REPRODUCTIVE TECHNOLOGIES: A READER* 1, 14 (Thomas A. Shannon ed., 2004). Over 95% of all fertility clinics in the U.S. are members of SART. *Id.* at 15. Loss of membership is economically detrimental for two reasons. First, sophisticated IVF patients seek out clinics with SART membership by selecting from the list of clinics on the organization's public website. Joe Leigh Simpson et al., *Professional Self-Regulation for Preimplantation Genetic Diagnosis: Experience of the American Society for Reproductive Medicine and Other Professional Societies*, 85 *FERTILITY & STERILITY* 1653, 1656 (2006). Second, insurance coverage often only applies to

guidelines are not enough to prevent multiple births and have recently renewed the call for governmental regulation restricting the number of embryos that can be transferred in a single IVF cycle.¹⁶ This Note presents an alternate, nonlegislative solution to reduce multifetal pregnancies in the United States. At least three forces surrounding the IVF process incentivize patients and doctors to implant more embryos than necessary during each round of treatment.¹⁷ By redirecting these forces, Americans can reduce the number of embryos transferred without committing to a legislated limit.¹⁸

Part II of this Note discusses the societal and medical problems associated with multifetal pregnancies. Part III describes the incentives that push patients and clinicians to transfer multiple embryos in one fertility cycle. These incentives include the physical and emotional burden associated with IVF, the level of insurance coverage provided for assisted reproductive procedures like IVF, and the method of publishing clinic success rates. Part IV evaluates the effectiveness of the legislation that has been passed in other countries, and Part V presents the case for alternate methods of solving the multifetal pregnancy problem: providing patients with better information about the risks of multifetal pregnancies, improving insurance coverage for IVF patients, and implementing the BESST (Birth Emphasizing a Successful Singleton at Term) standard for publication of clinic success rates.

II. The Problems Associated with Multifetal Pregnancies

Because IVF gives the doctor the ability to transfer multiple embryos at once, the global rates of multiple births skyrocketed after the introduction of

procedures done by member clinics. *Id.*; *see, e.g.*, CONN. GEN. STAT. ANN. § 38a-536 (West 2007); HAW. REV. STAT. § 431:10A-116.5 (2004) (both mandating insurance coverage only for IVF procedures performed at clinics in compliance with ASRM, or another industry group's, guidelines).

16. *See, e.g.*, Urska Velikonja, *The Costs of Multiple Gestation Pregnancies in Assisted Reproduction*, 32 HARV. J.L. & GENDER 463, 504 (2009) (arguing that the United States should shift from a laissez-faire approach for decreasing multifetal pregnancies toward a more heavily regulated European approach); Note, *Assessing the Viability of a Substantive Due Process Right to In Vitro Fertilization*, 118 HARV. L. REV. 2792, 2808–13 (2005) (providing possible justifications for why regulation of IVF should survive constitutional scrutiny); *see also* Stephanie Nano, *Octuplet Mom's Fertility Doctor Doesn't Stand Alone*, HOUS. CHRON., Feb. 21, 2009, at A8 (reporting that since “most programs are not adhering to the guidelines,” some advocates are calling for public regulation).

17. *See infra* Part III.

18. Note that any Assisted Reproductive Technology (ART) procedure that uses ovarian stimulation, including intrauterine insemination and donor insemination, can result in multiple births. David H. Barlow, *The Debate on Single Embryo Transfer in IVF: How Will Today's Arguments Be Viewed from the Perspective of 2020?*, 20 HUM. REPROD. 1, 2 (2005). Altering the incentives discussed here will not affect these procedures because they do not involve the transfer of embryos. Instead, preventing these multiple pregnancies will come from minimizing the stimulation used in both male infertility cases and unexplained infertility cases. *Id.*

IVF.¹⁹ Exacerbating the problem are infertile couples that prefer to have twins or triplets over a singleton birth.²⁰ Society, however, should prefer singleton births due to the significant public burdens associated with multiple births, especially higher order multiples (triplets and above).²¹ One study calculated that the United States annually spends \$10.2 billion on neonatal care, most likely for low-birth-weight and preterm infants.²²

Those societal costs also include significant medical risks to mothers and children. A 1997 study found that twins were five times as likely—and triplets and other higher orders thirteen times as likely—as a singleton baby to die during the first year of life.²³ Data from 2005 collected by the Centers for Disease Control and Prevention (CDC) indicates that while only 9% of Assisted Reproductive Technology (ART) singleton babies were low birth weight, 57% of ART twins and a stunning 95% of ART higher order multiples were low birth weight.²⁴ Additionally, 66% of ART twins and 97% of ART higher orders born in 2005 were preterm.²⁵ Doctors have long known that low-birth-weight and preterm babies can suffer from a litany of physical impairments including blindness, deafness, mental retardation, and cerebral palsy.²⁶ Gestating multiples can be harmful to the mother as well, often causing high blood pressure or gestational diabetes.²⁷

Yet the incidence of multiples is great. Of all ART babies born in 2005, 49% were born in multiple-birth deliveries.²⁸ That accounts for

19. See Melinda B. Henne & M. Kate Bundorf, *Insurance Mandates and Trends in Infertility Treatments*, 89 FERTILITY & STERILITY 66, 66 (2008) (reporting a 397% increase in the number of higher order multiples born between 1980 and 2002).

20. See Ginny L. Ryan et al., *The Desire of Infertile Patients for Multiple Births*, 81 FERTILITY & STERILITY 500, 501–02 (2004) (examining the prevalence of the desire for multiple births among patients). The study found that 20% of infertility patients questioned listed multiple births (twins, triplets, or quadruplets) as the most desirable outcome of their fertility treatments. *Id.* All of the patients questioned were more concerned about conceiving quickly than avoiding multiple births. *Id.* at 502.

21. See Victoria Clay Wright et al., *Assisted Reproductive Technology Surveillance—United States, 2005*, 57 MORBIDITY & MORTALITY WKLY. REP. (Surveillance Summaries 5) 1, 23 tbl.10 (2008) (showing higher percentages of adverse outcomes among ART twins and higher order multiples).

22. Elaine B. St. John et al., *Cost of Neonatal Care According to Gestational Age at Birth and Survival Status*, 182 AM. J. OBSTETRICS & GYNECOLOGY 170, 172–73 (2000).

23. Laura A. Schieve et al., *Live-Birth Rates and Multiple-Birth Risk Using In Vitro Fertilization*, 282 JAMA 1832, 1832 (1999).

24. See Wright et al., *supra* note 21, at 23 tbl.10 (defining low birth weight as under 2,500 grams, or 5.5 pounds).

25. See *id.* (defining preterm as less than thirty-seven weeks gestational age at birth).

26. Robert L. Goldenberg & Jennifer F. Culhane, *Low Birth Weight in the United States*, 85 AM. J. CLINICAL NUTRITION (Feb. Supp.) 584S, 585S (2007).

27. AM. SOC'Y FOR REPROD. MED., PATIENT FACT SHEET: COMPLICATIONS AND PROBLEMS ASSOCIATED WITH MULTIPLE BIRTHS 1 (2008), http://www.asrm.org/Patients/FactSheets/complications_multiplebirths.pdf.

28. Wright et al., *supra* note 21, at 1.

approximately 25,500 babies.²⁹ Only 1% of babies born in the United States were conceived with the help of ART, but nearly 17% of all multiples born nationwide were ART babies.³⁰ While the number of triplets and higher order multiples born as a result of IVF has dropped to under 2%, in 2007 almost a third of all IVF babies born to women under thirty-five using non-donor oocytes were twins.³¹ The birth of higher order multiples like the octuplets is rather rare in the United States,³² but the rate of twins still poses challenges for doctors and associations like the ASRM and the Society for Assisted Reproductive Technology (SART) that defend the practice of self-regulation.³³ While many Americans do not view twins as medical risks, the ideal outcome of an ART procedure should be the delivery of a healthy baby.³⁴ This goal is best achieved when the baby is a singleton.

The costs and medical risks associated with multiple births have instigated a global push to legislatively regulate the number of embryos that can be transferred in a single cycle of IVF. These policy choices require balancing a couple's potential desire to have multiple offspring during one pregnancy against the potential societal costs associated with multiples.³⁵ But legislative solutions are not the only ones available. By identifying the incentives for transferring multiple embryos, policy makers can design nonlegislative solutions to the multiple-birth problem.

III. Incentives to Transfer Multiple Embryos

The extraordinary association between multiple births and IVF has a simple explanation. Because the embryos are manipulated outside of the body before IVF, physicians are able to implant multiple embryos at one

29. *See id.* (noting that 52,041 infants were born using ART in 2005).

30. *Id.*

31. Soc'y for Assisted Reprod. Tech., Clinic Summary Report, https://www.sartcorsonline.com/rptCSR_PublicMultYear.aspx?ClinicPKID=0.

32. *See id.* (noting that in 2005, only 1.8% of live births by women under thirty-five who had undergone IVF using nondonor oocytes resulted in triplets or higher order multiples).

33. *See* Wright et al., *supra* note 21, at 8 (reporting that, in 2005, 44% of ART babies were born as twins); Soc'y for Assisted Reprod. Tech., *supra* note 31 (reporting that, in 2007, 32.9% of births by women under thirty-five who had undergone IVF using nondonor oocytes produced twins). Despite these numbers and the risks associated with multiple births, the ASRM and SART continue to defend self-regulation. *See* Simpson et al., *supra* note 15, at 1659 ("In 2004, The President's Council on Bioethics issued its report, 'Reproduction and Responsibility.' This report is in fundamental agreement with the policy of self-regulation pursued by ASRM/SART . . . and other professional organizations." (citation omitted)).

34. *See* Armin Gollogly, *Octuplets Case Study: Should We Regulate Reproduction?*, PENN. BIOETHICS J., Apr. 2009, at 4, 5 (arguing that the desire to have children must be weighed against the countervailing interest in avoiding the health complications possible in multiple births).

35. *See* John A. Robertson, *Assisting Reproduction, Choosing Genes, and the Scope of Reproductive Freedom*, 76 GEO. WASH. L. REV. 1490, 1501 (2008) ("Wise social policy and practice here would take steps to minimize the birth of twins, but doing so raises many issues about the meaning and limits of procreative autonomy, e.g., the right to have twins despite the costs that it imposes on others.").

time.³⁶ And, in fact, they often do. Data show that of women under the age of thirty-five who underwent IVF in 2005, almost 35% received an IVF transfer of three or more embryos.³⁷ More than 60% of women over the age of forty-two received a transfer of three embryos or more.³⁸ In 2007, the clinic that helped conceive the octuplets transferred an average of 4.1 embryos into women under thirty-five.³⁹ Strangely, women between the ages of forty-one and forty-two received only an average of 2.5 embryos from the same clinic.⁴⁰ According to the ASRM guidelines, a forty-two-year-old woman is likely to need more embryos transferred than a younger woman.⁴¹ While there may be a medically significant reason for the clinic's practices—fewer viable embryos generated by an older woman means fewer are available to be transferred—this data is curious. Additionally, not even one of the clinic's forty-two cycles was performed using the transfer of a single embryo,⁴² a practice that the ASRM believes clinicians should consider for younger patients—especially those like Ms. Suleman who have had prior IVF success.⁴³ Regardless of an individual clinic's transfer practices, a question remains. If IVF “poses a major risk for multiples births” and multiple births “are associated with adverse maternal and infant outcomes,”⁴⁴ why do physicians still transfer multiple embryos, especially to young women?

A. *Emotional and Physical Toll on the Patient*

While there may not be a clear answer to this question, many of the factors facing both couples and fertility specialists incentivize the transfer of multiple embryos during a single round of IVF. Consider first the emotional state of a couple going through IVF. Infertility is defined by the CDC as twelve months of unprotected intercourse without conception; thus, these men and women have likely faced at least a year of disappointments before

36. See Trounson, *supra* note 12, at 311 (explaining that multiple embryos are implanted on the fifth or sixth day after external insemination).

37. Wright et al., *supra* note 21, at 17. Note that it is not possible from this data to determine how many of these transfers were based on the legitimate medical reasons for multiple transfers described in the ASRM guidelines and how many of these transfers were simply the result of a doctor ignoring the guidelines. One article has estimated that fewer than 20% of all American clinics follow the guidelines. Nano, *supra* note 16.

38. Wright et al., *supra* note 21, at 17.

39. Ctrs. for Disease Control & Prevention, Dep't of Health & Human Servs., Assisted Reproductive Technology (ART) Report: Fertility Clinic Reports, <http://apps.nccd.cdc.gov/ART/FCT.aspx?SelectedYear=2007> (select the state of “California,” select the clinic “West Coast IVF Clinic, Inc.” then select the year “2007”).

40. *Id.*

41. See *supra* note 11 and accompanying text.

42. Ctrs. for Disease Control & Prevention, *supra* note 39.

43. See *supra* notes 5–6 and accompanying text.

44. Wright et al., *supra* note 21, at 1.

they step foot in a fertility clinic.⁴⁵ The national infertility support group RESOLVE recognizes that emotional stress—grief after a miscarriage, shame, inadequacy, etc.—may be the hardest part of the infertility experience.⁴⁶ Several countries have recognized the emotional burdens of IVF as well. For example, the United Kingdom requires that before a patient can consent to an ART procedure, she must be informed of the availability of patient counseling.⁴⁷ The mental-health aspects of infertility are significant and worthy of being addressed by U.S. policy makers as well.

While enduring emotional stress, a woman must bear rounds of hormone injections, vaginal ultrasounds, blood tests, and egg retrieval via aspiration before the transfer of embryos into her womb can even take place.⁴⁸ The physically and emotionally taxing process only increases a patient's desire to be successful *now* and avoid having to make future attempts at a pregnancy. An easy way to ensure a pregnancy, at least in the patient's eyes, is to elect to transfer multiple embryos.

B. Lack of Insurance Coverage

The IVF process is often financially burdensome as well, with the average round of IVF costing \$12,400.⁴⁹ Because not every cycle results in a pregnancy, estimates put the cost of each IVF live birth at between \$38,000 and \$85,000.⁵⁰ Most insurance companies do not cover the process, leaving couples to pick up the entire tab.⁵¹ Only eight states—Arkansas, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, New Jersey, and Rhode Island—have some form of explicit, mandatory coverage for IVF.⁵² Two other states—California and Texas—require that supplemental coverage for ART be *offered* in addition to traditional benefit plans but do not require

45. *Id.* at 9.

46. RESOLVE: The Nat'l Infertility Ass'n, The Emotions of Infertility, http://www.resolve.org/site/PageServer?pagename=cop_mis_manem.

47. See Human Fertilisation and Embryology Act, 2008, c. 22, § 14(3) (U.K.) (requiring licensed clinics to provide their patients "a suitable opportunity to receive proper counseling").

48. AM. SOC'Y FOR REPROD. MED., ASSISTED REPRODUCTIVE TECHNOLOGIES: A GUIDE FOR PATIENTS 5–7 (2008), available at <http://www.asrm.org/Patients/patientbooklets/ART.pdf>.

49. Am. Soc'y for Reprod. Med., Frequently Asked Questions About Infertility, <http://www.asrm.org/Patients/faqs.html>.

50. Henne & Bundorf, *supra* note 19, at 66.

51. According to one study, only 25% of employer health-insurance plans covered treatment for infertility, and among those only a few types of treatments were covered. Jessica L. Hawkins, Note, *Separating Fact from Fiction: Mandated Insurance Coverage of Infertility Treatments*, 23 WASH. U. J.L. & POL'Y 203, 204 (2007).

52. ARK. CODE ANN. §§ 23-85-137, 23-86-118 (2004); CONN. GEN. STAT. ANN. § 38a-536 (West 2007); HAW. REV. STAT. § 431:10A-116.5 (2004); 215 ILL. COMP. STAT. 5/356m (2004); MD. CODE ANN., INS. § 15-810 (LexisNexis 2006); N.J. STAT. ANN. § 17:48-6x (West 2008); see MASS. GEN. LAWS ch. 175, § 47H (1998); R.I. GEN. LAWS § 27-18-30 (2002) (both providing for "medically necessary" infertility treatments if the coverage also includes pregnancy-related benefits); see also Hawkins, *supra* note 51, at 214–18 (describing in detail each state's statute and the limitations that each places on coverage).

ordinary health plans to cover these services.⁵³ Of those states with mandatory coverage, several allow insurance companies to place limitations on the coverage of IVF procedures, including limits on the age of the patient,⁵⁴ the number of IVF cycles that can be performed,⁵⁵ the source of the semen used to fertilize the patient's oocytes,⁵⁶ and an overall price cap on lifetime infertility treatments.⁵⁷ Additionally, any self-insured plan covered under ERISA is not subject to state insurance laws and therefore would not have to provide coverage for ARTs at all—even in states with mandatory coverage—unless required to do so by federal law.⁵⁸

But no federal statutes require health-insurance companies to cover the cost of infertility treatments. Following the Supreme Court's 1998 decision in *Bragdon v. Abbott*,⁵⁹ which held that reproduction qualified as a major life activity under the ADA,⁶⁰ many thought that mandatory coverage would follow.⁶¹ However, things have not changed much for patients seeking IVF in the new millennium. A post-*Bragdon* district court decision held that while an infertile woman did constitute a disabled person under the ADA,⁶² her insurance plan excluding IVF was valid under the Act because it treated both fertile and infertile couples equally.⁶³ Additionally, courts have been

53. See CAL. INS. CODE § 10119.6 (West 2005) (requiring that insurance providers offer infertility coverage and communicate its availability to patients); TEX. INS. CODE ANN. §§ 1366.003, .006 (Vernon 2009) (requiring that where coverage is provided, it only need apply to patients with a five-year continuous history of infertility).

54. See CONN. GEN. STAT. ANN. § 38a-536 (allowing insurance providers to limit coverage for IVF after the patient's fortieth birthday); N.J. STAT. ANN. § 17:48-6x (allowing insurance providers to limit coverage to patients forty-five years or younger); R.I. GEN. LAWS § 27-18-30 (requiring coverage for the treatment of infertility only in women between the ages of twenty-five and forty-two).

55. See CONN. GEN. STAT. ANN. § 38a-536 (allowing insurance providers to limit coverage to two cycles of IVF); HAW. REV. STAT. § 431:10A-116.5 (requiring coverage only for a single cycle of IVF); MD. CODE ANN., INS. § 15-810 (limiting coverage to three IVF attempts per live birth); N.J. STAT. ANN. § 17:48-6x (allowing insurance providers to limit coverage to four cycles of egg retrieval).

56. See 054-00-001 ARK. CODE R. § 5(b) (Weil 2009); HAW. REV. STAT. § 431:10A-116.5; MD. CODE ANN., INS. § 15-810 (all requiring coverage only when the patient's oocytes are fertilized with her husband's sperm); see also R.I. GEN. LAWS § 27-18-30 (2002) (defining infertility as a condition occurring in a married individual).

57. See MD. CODE ANN., INS. § 15-810 (allowing insurance providers to limit IVF coverage to a lifetime benefit of \$100,000).

58. Hawkins, *supra* note 51, at 219–20.

59. 524 U.S. 624 (1998).

60. *Id.* at 638.

61. See, e.g., Thomas D. Flanigan, *Assisted Reproductive Technologies and Insurance Laws Under the Americans with Disabilities Act of 1990*, 38 BRANDEIS L.J. 777, 804 (2000) (suggesting that a refusal to provide infertility treatment would render an employer liable for disability discrimination).

62. Americans with Disabilities Act of 1990, 42 U.S.C. §§ 12101–12300 (2006).

63. *Saks v. Franklin Covey Co.*, 117 F. Supp. 2d 318, 326–27 (S.D.N.Y. 2000), *aff'd in part, remanded in part*, 316 F.3d 337 (2d. Cir. 2003).

split as to whether the Pregnancy Discrimination Act's⁶⁴ language requiring insurance coverage for pregnancy-related medical conditions includes IVF and other fertility treatments.⁶⁵ One court argued that unlike pregnancy, which occurs *after* conception, infertility *prevents* conception and therefore is conceptually distinct from pregnancy and its "related medical conditions."⁶⁶ Generally, commentators agree that neither the PDA nor the ADA will be helpful in compelling insurance companies to include IVF benefits in their plans, which leaves patients empty-handed both at the state and federal level.

The bottom line is that even insured couples may not be able to afford multiple rounds of IVF. This reality also incentivizes them to try and get pregnant *this* time, leading to more aggressive transfer practices.⁶⁷

C. Publication of Clinic Success Rates

Additional forces act to incentivize doctors to transfer multiple embryos in one round of IVF. The only federal regulation of IVF requires clinics to report pregnancy success rates to the CDC, which then publishes them.⁶⁸ Rates are expressed as the number of successful live births that the clinic was responsible for each year divided by the number of cycles performed.⁶⁹ So, if a patient gives birth to triplets, the clinic gets three live birth "successes" added to their annual total. The CDC also reports clinic-specific multiple-birth rates,⁷⁰ but patients are not greatly concerned with this rate. As one article put it, "Patients who pay out of pocket shop around for infertility specialists with good track records."⁷¹ And to a patient who is seeking to get pregnant, a good track record means a high rate of pregnancies achieved at

64. 42 U.S.C. § 2000e(k). The statute provides that employers cannot discriminate on the basis of "pregnancy, childbirth, or related medical conditions." *Id.* The provision was interpreted to apply to health-insurance benefits in *Newport News Shipbuilding & Dry Dock Co. v. EEOC*, 462 U.S. 669, 682 (1983).

65. *Compare* Pacourek v. Inland Steel Co., 858 F. Supp. 1393, 1401–02 (N.D. Ill. 1994) (finding that the generous language used in the statute did include infertility treatments), *with* Saks v. Franklin Covey Co., 316 F.3d 337, 346 (2d. Cir. 2003) (holding that the PDA, which only applies to the medical needs of women, did not include infertility, which can afflict both men and women).

66. *Krauel v. Iowa Methodist Med. Ctr.*, 95 F.3d 674, 679–80 (8th Cir. 1996).

67. Lower family income has been associated with a desire to conceive multiples. Ryan et al., *supra* note 20, at 502. One explanation for this association is that a couple with meager financial means may recognize a monetary limit on how many IVF cycles they can undergo and therefore want to "maximize their results in the fewest possible treatment cycles." *Id.* at 503.

68. Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. §§ 263a-1, 263a-5 (2006). The method of calculating success rates is determined by the Secretary of Health in collaboration with professional organizations such as SART and ASRM. *Id.* § 263a-1. In determining an appropriate rate calculation, the Secretary is directed to consider the live-birth rate divided by either the number of stimulation procedures attempted or the number of egg-retrieval procedures attempted. *Id.*

69. Soc'y for Assisted Reprod. Tech., *supra* note 31.

70. Wright et al., *supra* note 21, at 2.

71. Carson Strong, *Too Many Twins, Triplets, Quadruplets, and So On: A Call for New Priorities*, 31 J.L. MED. & ETHICS 272, 275 (2003).

the clinic. Implanting multiple embryos certainly increases the chances of pregnancy and therefore increases valuable success rates. Overall, this method of reporting may give some clinics an incentive to transfer multiple embryos, thereby inflating their success rates.

Once a multifetal pregnancy occurs, doctors may suggest that the woman undergo multifetal pregnancy reduction. In this procedure, one or more of the fetuses is injected with a chemical that ends the fetal heart beat.⁷² This procedure is not an acceptable solution to the increase in multiples associated with IVF and other fertility treatments. First, the procedure is associated with a slight risk of miscarriage.⁷³ While a 4%–5% risk⁷⁴ is small, parents who have endured a long struggle on the road to pregnancy may view any risk as too great. Second, the procedure may not prevent the physical problems associated with multiples—even if reduction is performed, the children that are carried may still be preterm.⁷⁵ Third, the procedure may be too emotionally taxing for a couple that has already endured much heartache.⁷⁶ Last, many couples are likely to have moral objections to a procedure that essentially amounts to abortion.⁷⁷ Therefore, after a multifetal pregnancy has begun, there is little choice for most couples but to carry all of the babies to term.

IV. Legislative Solutions

With so many forces incentivizing the transfer of multiple embryos and little that can be done afterwards, some countries have legislatively limited the number of embryos that can be transferred during a round of IVF. Great Britain's Human Fertilisation and Embryology Authority (HFEA) has capped the number of embryos at two.⁷⁸ Sweden made the transfer of a single embryo the norm for almost all IVF procedures.⁷⁹ Belgium has legislated

72. AM. SOC'Y FOR REPROD. MED., *supra* note 27, at 1.

73. *Id.*; see also Strong, *supra* note 71, at 275 (“The main complication associated with multifetal reduction is loss of the entire pregnancy.”). But see AM. SOC'Y FOR REPROD. MED., *supra* note 27, at 1 (explaining that miscarriage is a risk factor associated with multiple gestation generally and implying that it is thus one factor that may encourage some mothers to undergo the multiple fetal reduction).

74. AM. SOC'Y FOR REPROD. MED., *supra* note 27, at 1.

75. See *id.* (asserting that because there are “too many babies in the womb,” multiple gestation is associated with a risk of premature delivery—and the various physical problems of the babies associated therewith—but also clarifying that even after undergoing multifetal pregnancy reduction, there is still a risk of premature delivery).

76. See *id.* (acknowledging the difficulty of the decision and cautioning that both professional counseling and emotional support may be necessary before, during, and after the procedure); see also Strong, *supra* note 71, at 275 (“[F]etal reduction is a highly stressful and emotionally painful experience for the women who undergo it.”).

77. See Strong, *supra* note 71, at 275 (“[B]ased on patient surveys, approximately one-third of infertile couples would not choose fetal reduction, for religious and/or ethical reasons.”).

78. *Id.* at 276.

79. Barlow, *supra* note 18, at 2. There are exceptions allowed for poor embryo quality. *Id.* Double-embryo transfers are permitted for women over the age of thirty-nine and women who have

more flexible guidelines, stratified by age and cycle number.⁸⁰ They provide that for a woman under the age of thirty-six, the first cycle involves the transfer of a single fresh embryo, and the second involves the transfer of a single frozen embryo.⁸¹ Up to four subsequent cycles are state-funded and can involve the transfer of two embryos.⁸²

Legislated maximums have been successful at reducing the rate of multiples in European countries,⁸³ but experts in the United States are hesitant to adopt similar approaches.⁸⁴ Self-regulation is the norm in U.S. medicine, as evidenced by physician-created certification boards and individualized guidelines created by almost every medical specialty.⁸⁵ Not even the government itself was initially convinced of its competency to regulate reproduction, and when Congress passed the Fertility Clinic Success Rate and Certification Act of 1992,⁸⁶ the governmental agency in charge of collecting and reporting success rates contracted with the private sector to do the job.⁸⁷

Members of the ASRM and SART also oppose European-style regulation of IVF.⁸⁸ One justification for the resistance is the feeling that funding should parallel oversight—if, unlike European governments, the U.S. government does not fund IVF, it should not regulate the procedure.⁸⁹

undergone three or more failed cycles. Pia Saldeen & Per Sundström, *Would Legislation Imposing Single Embryo Transfer Be a Feasible Way to Reduce the Rate of Multiple Pregnancies After IVF Treatment?*, 20 HUM. REPROD. 4, 5 (2005).

80. Barlow, *supra* note 18, at 2.

81. *Id.*

82. *Id.*

83. In Sweden, the rate of single-embryo transfers has risen to over 70%, the overall birth rate has stayed the same, and the rate of twins has fallen. Barlow, *supra* note 18, at 2. Before the switch to single-embryo transfer, about 23% of viable pregnancies were multiples. Saldeen & Sundström, *supra* note 79, at 6. This figure dropped to about 6% after the transition to single-embryo transfer became mandatory for both publicly and privately funded IVF. *Id.* Preliminary reports indicate that Belgium's system has also been successful in reducing the multiple-pregnancy rate without lowering the overall pregnancy rate. Willem Ombelet et al., *Multiple Gestation and Infertility Treatment: Registration, Reflection, and Reaction—The Belgian Project*, 11 HUM. REPROD. UPDATE 3, 8 (2005).

84. See Strong, *supra* note 71, at 276 (relating that there has been strong opposition to governmental regulation among American fertility specialists).

85. Simpson et al., *supra* note 15, at 1653.

86. Pub. L. No. 102-493, 106 Stat. 3146 (codified at 42 U.S.C. §§ 263a-1 to -7 (2006)).

87. See Simpson et al., *supra* note 15, at 1653 (indicating that at the time of the statute's passage, "governmental agencies lacked the requisite organization to translate legislative goals into reality; thus, CDC contracted with ASRM and SART, and together, the groups devised the current system" of publication).

88. See Strong, *supra* note 71, at 276 ("The leading officers of the Society for Assisted Reproductive Technology (SART) stated, 'The worst thing that could occur would be for the federal government to step in and tell us how to practice our specialty.'"); cf. Simpson et al., *supra* note 15, at 1655 ("The ASRM can be considered prototypic for a professional organization espousing self-regulation in reproductive medicine.").

89. Simpson et al., *supra* note 15, at 1658. All of the European models discussed above have some form of state-funded IVF. See, e.g., Mark Henderson, *Infertile Couples to Be Priority for*

Another concern is that overregulation will cause patients to seek treatment overseas, a phenomenon that the stem-cell community is all too familiar with.⁹⁰ Reproductive tourism is already popular among couples who cannot afford pricey U.S. clinics and thus travel to countries like Argentina, South Africa, Ukraine, and Spain to obtain treatment.⁹¹ The cost of funding an oversight agency like the United Kingdom's HFEA is another concern, especially amid a general push to reduce health-care costs.

The reproductive-medicine community also worries that an inflexible statute will prevent clinicians from tailoring the procedure for clients with extreme cases.⁹² Consider the story of a forty-six-year-old U.K. woman who had unsuccessfully undergone eight rounds of IVF, all the while complying with HFEA regulations.⁹³ Her doctor thought that transferring five embryos would increase her chances for success, so she petitioned the court to review the HFEA guidelines.⁹⁴ The court refused to make an exception, likely precluding the woman from ever achieving a viable pregnancy.⁹⁵ On the other hand, a flexible system like Sweden's might be unenforceable in America. If the incentives for transferring multiple embryos are not also changed, doctors may find ways to fit patients into the excepted categories.⁹⁶ In this regard, a legislative solution would be no more effective than the current voluntary guidelines.

Finally, some scholars contend that regulation of this sort would violate patients' constitutional rights.⁹⁷ At the very least, the debate creates uncertainty about the scope of reproductive rights: Does the right to procreate include the right to have multiples, regardless of the costs that society must bear in terms of health care and welfare? In the end, these legislative

NHS, TIMES (London), Aug. 22, 2008, at 3 (“[L]imited NHS provision means that about 75 per cent of [IVF cycles] are conducted privately.”); Jordana Huber, *Panel Pushes for Ontario Gov't to Fund In Vitro*, EDMONTON J., Aug. 27, 2009, at A8 (“Belgium, Sweden, Denmark and Australia fund IVF treatments.”).

90. See Simpson et al., *supra* note 15, at 1658–59 (“The paradoxical effect of rigid regulations will be that the U.S. public will be less well served because activities will transpire overseas without oversight of the type that U.S. citizens expect. Cutting-edge research and clinical application pursued outside the United States is already a familiar occurrence in reproductive medicine . . .”).

91. Suz Redfearn, *Pursuing a Baby to the Ends of the Earth*, WASH. POST, Jan. 14, 2007, at 16.

92. *Guidelines on Embryos Transferred*, *supra* note 7, at 1518.

93. Alicia Ouellette et al., *Lessons from Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States*, 31 AM. J.L. & MED. 419, 443–44 (2005).

94. *Id.*

95. *Id.* at 444.

96. See Saldeen & Sundström, *supra* note 79, at 5, 7 tbl.4 (noting that, due to the many exceptions in Sweden's single-embryo-transfer regime, 27% of Swedish patients received a double-embryo transfer).

97. See, e.g., Robertson, *supra* note 35, at 1496 (warning that constitutional limits would apply to laws violating reproductive or other rights and that “[r]estrictions on testing and selecting embryos . . . might well violate liberty interests and rights in having children”).

guidelines are likely to be politically infeasible⁹⁸ and unnecessary⁹⁹ in the United States. For these reasons, U.S. policy makers should focus on altering the existing system of voluntary guidelines and incentives, and not on potential legislation.

V. Changing Existing Incentives as an Alternative to Legislation

The three incentives identified in Part III can all be manipulated to make the transfer of multiple embryos an unattractive option for both patients and physicians. Changing these incentives will provide the flexibility that the ASRM desires while costing much less than the European-agency-type solution. The remainder of this Note describes how each incentive to transfer multiple embryos can be mitigated.

To combat the desperation that patients face, physicians must better counsel patients about the risks of multiple births before the IVF process is begun. State legislation increasing mandatory insurance coverage for IVF procedures can correct a lack of insurance coverage. Finally, using the BESST standard of publication will decrease the practice of inflating success rates.

A. Increased Patient Counseling

Patients must be informed of the risk of multiples and the ASRM guidelines before a single gamete is harvested. While this may be the common practice among reputable clinics, both anecdotal and statistical evidence suggests that not all patients receive this kind of care.¹⁰⁰ One patient claims that her physician neither explained the ASRM guidelines nor discussed the clinic's transfer protocol with her.¹⁰¹ As the patient was laying on the transfer table, her doctor informed her that he would transfer only two of the three cultured embryos.¹⁰² The patient was understandably angry. In

98. See John A. Robertson, *The Virtues of Muddling Through*, HASTINGS CENTER REP., July–Aug. 2007, at 26, 27 (“[T]here [will not] be unanimity that mandatory coverage of ARTs for infertile couples is a high priority, given their costs and competing health care concerns.”).

99. The ASRM's guidelines seem to be having their desired effect. Robert W. Rebar & Alan H. DeCherney, *Assisted Reproductive Technology in the United States*, 350 NEW ENG. J. MED. 1603, 1604 (2004). Since 1997, the rate of higher order pregnancies has been decreasing. *Id.* The rate of twins born as a result of IVF is still high, and the ASRM anticipates that reducing the number of twins will be the next challenge it faces in self-regulating the industry. *Id.*

100. See Ryan et al., *supra* note 20, at 502 (indicating that a majority of infertility patients are unaware of the increased risk in twins of cerebral palsy and infant mortality, though there is more awareness of these complications in triplets).

101. See A Thursday Redux—She Wanted to Know If It Was Legal?, The Fertility Advocate Blog, <http://www.thefertilityadvocate.com/wpblog/?cat=297> (Mar. 31, 2009) (recounting one IVF patient's story). The content of the Fertility Advocate Blog is provided by Pamela Madsen, the Director of Public Education for East Coast Fertility and “one of the nation's most outspoken and recognized fertility educators and patient advocates.” About Pamela Madsen, The Fertility Advocate Blog, <http://www.thefertilityadvocate.com/wpblog/wp-content/about.html>.

102. A Thursday Redux—She Wanted to Know If It Was Legal?, *supra* note 101.

her mind, the incentives for transferring three greatly outweighed the reasons for using only two—she was concerned with the cost of a second IVF cycle and was skeptical about the chance of success.¹⁰³ The correct time and place to counsel a patient about the number of embryos that will be transferred is long before she reaches the transfer table.¹⁰⁴

In fact, evidence demonstrates that patient counseling is successful in diffusing patient pressure to transfer multiple embryos. In Sweden, patients initially resisted using the single-embryo transfer technique.¹⁰⁵ Researchers speculate that the increase in the use of single-embryo transfer was due not to “the decree as such, but rather to more thorough and careful counselling regarding the increased risks with multiple pregnancies.”¹⁰⁶ The Swedish experience lends support to the idea that patient concerns do play a part in determining how many embryos to transfer. As patient counseling increases, the use of single-embryo transfers also increases.¹⁰⁷ Counseling is especially necessary for patients with financial apprehensions about future cycles, for if the patient cannot afford a second round of IVF, she is unlikely to be financially capable of raising multiples.¹⁰⁸

Tort liability alone is unlikely to reduce the incidence of multiples, but failing to counsel patients about the risk of multiples should nevertheless expose physicians to malpractice liability. As discussed below, tort liability for wrongful birth is not going to change physician incentives because wrongful birth cases pose difficult logical and philosophical questions about how harm should be demonstrated.¹⁰⁹ But at the very least, the standard of care for IVF needs to include counseling about the potential risk of multiples and how to balance this risk with the patient’s desire to conceive.

B. Insurance Reform

The second incentive to transfer multiple embryos that this Note identifies is the sparse insurance coverage for IVF procedures. A recent

103. *Id.*

104. *Id.*

105. Saldeen & Sundström, *supra* note 79, at 7.

106. *Id.*

107. See A.M. van Peperstraten, *Why Don't We Perform Elective Single Embryo Transfer? A Qualitative Study Among IVF Patients and Professionals*, 23 HUM. REPROD. 2036, 2040 (2008) (“Previous research demonstrated that, if patients understood the complications associated with twins, this might result in a change of attitude in favour of eSET [elective single-embryo transfer].”). But see M. Blennborn et al., *The Couple's Decision-Making in IVF: One or Two Embryos at Transfer?*, 20 HUM. REPROD. 1292, 1297 (2005) (“Perceived awareness of risks of multiple pregnancies was equal in patients who chose one or two embryos.”).

108. See Denny Sakkas & David K. Gardner, *Evaluation of Embryo Quality: Sequential Analysis of Embryo Development with the Aim of Single Embryo Transfer*, in TEXTBOOK OF ASSISTED REPRODUCTIVE TECHNIQUES: LABORATORY AND CLINICAL PERSPECTIVES 235, 235 (David K. Gardner et al. eds., 2d ed. 2004) (“[T]he financial costs of supporting infants born from multiple pregnancies after IVF are in many cases higher than the cost of supporting IVF.”).

109. See *infra* subpart V(C).

study compared each state population's use of ART procedures and birth rates with the level of insurance coverage mandated by that state.¹¹⁰ Not surprisingly, states with the most comprehensive insurance coverage mandates have seen an increase in the use of ART procedures.¹¹¹ But more importantly, the study also linked comprehensive insurance coverage to lower multiple-birth rates.¹¹² Two other studies have linked comprehensive coverage to a decrease in the number of embryos transferred per cycle.¹¹³ If insured patients are not burdened with large out-of-pocket expenses, they have less incentive to conceive in fewer cycles and therefore less incentive to transfer multiple embryos at a time.¹¹⁴ This may be one cause of the association between lower multiple-birth rates and insurance coverage,¹¹⁵ indicating both that the incentives identified in Part III are correct and that one way to decrease multiple births is to increase coverage of IVF.

However, not all scholars are convinced.¹¹⁶ The comprehensive dataset that is needed in order to evaluate the true effect of insurance mandates on embryo-transfer practices has not yet been developed.¹¹⁷ Before statisticians are willing to draw concrete conclusions, research must include data regarding the patient's financial status,¹¹⁸ insurance coverage levels,¹¹⁹

110. Henne & Bundorf, *supra* note 19, at 67. The study controlled for population differences among the states, including the number of women of reproductive age, the number of women in the work force, and the average salary of the states' citizens. *Id.* at 70. The goal was to ensure that the results reflected only the effect of the insurance mandates and not other factors. *Id.* at 66–67.

111. *Id.* at 71 fig.1.

112. *See id.* at 70 (concluding that births per cycle and multiples per ART birth were lower in states with comprehensive insurance mandates).

113. *See* Tarun Jain et al., *Insurance Coverage and Outcomes of In Vitro Fertilization*, 347 *NEW ENG. J. MED.* 661, 666 (2002) (“In conclusion, state-mandated health insurance coverage of [IVF] services is associated with greater utilization of such services but with reductions in the number of embryos transferred per cycle . . .”); Meredith A. Reynolds et al., *Does Insurance Coverage Decrease the Risk for Multiple Births Associated with Assisted Reproductive Technology*, 80 *FERTILITY & STERILITY* 16, 22 (2003) (“Our results support the argument that mandated insurance coverage can affect practice patterns by resulting in the transfer of fewer embryos.”).

114. Henne & Bundorf, *supra* note 19, at 66–67.

115. *Id.* at 66. The study also suggests, however, that the patient demographic may explain the lower multiple-birth rates in states with comprehensive coverage. *Id.* at 69. For example, women that have extreme infertility conditions might be more willing to try IVF if the procedure is covered, even though the chances of getting pregnant remain low. *Id.* at 71. If these women do not get pregnant, the number of multiple births per IVF cycle will still decrease. *Id.*

116. Meredith Reynolds, for instance, suggests that changing insurance coverage levels alone is not sufficient to combat the multiple birth problem—“[a]n attitude shift among ART patients and providers to view treatment success in terms of singleton pregnancies will also be required.” Meredith A. Reynolds et al., *Insurance Is Not a Magic Bullet for the Multiple Birth Problem Associated with Assisted Reproductive Technology*, 80 *FERTILITY & STERILITY* 32, 32 (2003); *see also, e.g.*, William D. Schlaff, *Impact of Insurance Coverage on In Vitro Fertilization Practice Patterns: A Complex Relationship*, 80 *FERTILITY & STERILITY* 30, 31 (2003) (opining that “the proportion of high-order transfers is at best only modestly affected by the insurance status of patients”).

117. *See* Henne & Bundorf, *supra* note 19, at 73 (observing deficiencies in the current methodology).

118. *See id.* (noting the uncertainty of economic disparities among beneficiaries).

understanding of multiple-birth risks,¹²⁰ and the provider's recommendations about the number of embryos to transfer.¹²¹

But further evidence can be drawn from European practices. Doctors in the United Kingdom are legally permitted to transfer up to two embryos,¹²² but over 13% of transfers involve only one.¹²³ Insurance in the United Kingdom generally covers IVF procedures, making patients more willing to try a round using one embryo instead of the allowed two.¹²⁴ Simple cost-benefit analysis also reinforces this point. If the costs of multiple IVF cycles, mitigated by insurance coverage, are lower than the risks associated with multiple births, then a prudent patient will choose to err on the side of transferring fewer embryos.

Insurance programs do not have to be limited to the broad mandatory-coverage approach used in the existing state statutes. Legislators with a bit of drafting creativity could more effectively target the multiple-birth problem in other ways. For example, statutes could require comprehensive coverage for the first IVF cycle only if a single embryo is transferred. Coverage for subsequent cycles would only be required if the first cycle was a single-embryo transfer. Or a statute could require coverage only if the ASRM guidelines were followed for each transfer.

Salient challenges to these proposals remain. Most prominent, perhaps, is the objection that the cost of covering IVF would be too much for the American health-care system to bear.¹²⁵ But an equally salient response is that while IVF treatments are certainly expensive, they represent only an estimated 0.3% of the total health-care expenses in the United States.¹²⁶ Additionally, the care of preterm, low-weight multiples is extraordinarily expensive and might actually prove to be more costly than increased IVF coverage. One scholar estimates that the cost of delivering multiples is almost ten times the cost of delivering a singleton baby.¹²⁷ And the delivery

119. See Henderson, *supra* note 89, at 3 (reporting that limited coverage affects who can receive treatment).

120. See *supra* note 107 and accompanying text.

121. See *supra* notes 13–15 and accompanying text.

122. HUM. FERTILISATION & EMBRYOLOGY AUTH., CODE OF PRACTICE §§ 7.2–7.3 (2009).

123. HUM. FERTILISATION & EMBRYOLOGY AUTH., A LONG TERM ANALYSIS OF THE HFEA REGISTER DATA 1991–2006, at 63, 64 fig.15b (2007).

124. See Kimberly D. Krawiec, *Why We Should Ignore the "Octomom,"* 104 NW. U. L. REV. 120, 126 (2009) (acknowledging that increased insurance coverage decreases the economic incentive for multiple-embryo transfers).

125. See, e.g., Amy B. Monahan, *Value-Based Mandated Health Benefits*, 80 U. COLO. L. REV. 127, 128 (2009) ("Mandated benefit laws figure prominently in health reform debates because they present a fundamental tension in our health care system: the desire to keep costs low versus the desire to spread the risk of loss as widely as possible. Critics of these laws are concerned with both the premium cost increases that can result and the limits on choice they place on consumers in the health insurance marketplace.").

126. Hawkins, *supra* note 51, at 207.

127. David Frankfurter, *To Insure or Not to Insure: That Is the Question*, 80 FERTILITY & STERILITY 24, 24 (2003).

is the one part of the IVF process that is likely to be covered by all insurance policies.¹²⁸ If the cost of lifetime care for multiples is more than the cost of IVF procedures, then increased coverage for infertility will actually decrease the country's overall health-care burden.

C. *The BESST Standard*

A patient's autonomy is the focus of the American health-care system, and therefore the patient makes the ultimate decisions regarding her care.¹²⁹ Thus, changing the two incentives affecting the patient—emotional stress and insurance coverage—is crucial in reducing the number of multiple births. If patients do not push for multiple transfers, the rate of multiple births is likely to decrease significantly. However, changing the incentives for physicians is also a concern, as physicians still play a very large role in deciding how many embryos to transfer. The best way to do this is by targeting their financial interests. If patients seek out clinics with high success rates, and transferring multiple embryos no longer leads to increased success rates, then physicians will no longer have an incentive to transfer multiple embryos.

Currently, the success rates for clinics in the United States are reported as a function of live births per IVF cycle.¹³⁰ While the SART data also includes the percentage of live births involving multiples, the patient is most likely to look for the number that is of ultimate concern to her—the number of live births attained divided by the total number of cycles initiated.¹³¹ The data is also categorized by the age of the patient,¹³² making it hard to determine an ultimate success rate that can be used to compare clinics. One suggestion is to calculate the “birth per embryo transferred” rate.¹³³ This would expose clinics that have low success rates, but it would not effectively eliminate the incentive for transferring multiple embryos. A clinic that transfers three embryos for every patient, often resulting in the birth of triplets, will have a very good “birth per embryo transferred” rate—almost a 1:1 ratio. But the multiple-birth rate is far from clear using this calculation.

If instead the SART and the CDC used a method that only considers singleton, full-term, live babies delivered per ART cycle begun, it could reduce the incentive for clinicians to transfer more embryos than necessary.

128. See Velikonja, *supra* note 16, at 479 (“Many infertility patients have health insurance, which covers most or all prenatal, delivery, and postnatal medical expenses.”).

129. See Leslie J. Blackhall et al., *Ethnicity and Attitudes About Patient Autonomy*, in *HEALTH CARE ETHICS AND HUMAN VALUES: AN INTRODUCTORY TEXT WITH READINGS AND CASE STUDIES* 187, 187 (K.W.M. Fulford et al. eds., 2002) (recognizing that while the ideal of patient autonomy is “imperfectly realized in actual practice,” “[f]or the past 25 years, legal and ethical analysis of medical decision making in the United States has revolved around the idea of patient autonomy,” and giving examples of ways in which the standard of practice reflects this).

130. See *supra* notes 68–70 and accompanying text.

131. See *supra* note 71 and accompanying text.

132. Soc’y for Assisted Reprod. Tech., *supra* note 31.

133. Saldeen & Sundström, *supra* note 79, at 7.

The BESST standard was first proposed in 2004 by a group of researchers.¹³⁴ The standard recognizes that in the advanced era of reproductive medicine, a pregnancy alone is no longer a successful outcome.¹³⁵ Patients and physicians alike should begin to consider the neonatal outcomes of the pregnancy, with only singleton, full-term babies considered true successes.¹³⁶ The focus on singletons (and the exclusion of twins from the calculation) is a direct response to the problem of multiple births.¹³⁷

The BESST denominator is measured by the number of ART cycles initiated.¹³⁸ The inclusion of all cycles initiated, whether or not the cycle was discontinued before transfer, is important. Inclusion of all initiated cycles best represents the physical and financial burdens endured by a couple, which makes the BESST standard a truer representation of patients' concerns.¹³⁹ The BESST numerator is measured by the number of singleton, full-term, live births resulting from the ART cycles initiated.

A simple mathematical demonstration will clarify how use of the BESST standard will eliminate a clinic's incentive to transfer multiple embryos. An ART cycle resulting in multiple births will achieve a zero BESST success rate. So if a clinic transfers three embryos into three women and each gives birth to triplets, the clinic will have a 0% BESST rate. While these numbers are clearly exaggerated, no patient, savvy or otherwise, is going to choose a clinic with a 0% success rate. Compare this to the same clinic's 100% success rate using the "births per embryo transferred" standard.

Because each cycle begun is included in the denominator, clinicians will also be concerned with transfers that do not result in any pregnancy. Using a traditional method, this concern incentivizes the transfer of multiple embryos to increase the chances that a pregnancy of any kind results. However, using the BESST system introduces a competing concern: creating too many multifetal pregnancies. By allowing these two competing interests to balance one another out, the BESST standard forces the physician to use his medical judgment about what would be "best" for the individual patient.

Certainly, not all clinicians are making decisions based wholly on their success rates, and a facility like Dr. Kamrava's is the not the norm. But use of the BESST standard will adversely affect clinics like Kamrava's with high

134. Jason K. Min et al., *What Is the Most Relevant Standard of Success in Assisted Reproduction? The Singleton, Term Gestation, Live Birth Rate per Cycle Initiated: The BESST Endpoint for Assisted Reproduction*, 19 HUM. REPROD. 3, 3 (2004).

135. *Id.*

136. *Id.*

137. *Id.*

138. *Id.* This includes not only IVF but also GIFT (gamete intra-Fallopian transfer), ZIFT (zygote intra-Fallopian transfer), and MIFT (microinjection intra-Fallopian transfer) techniques. *Id.* Because multiples can result from any procedure involving ovarian stimulation, this is an appropriate measure.

139. *Id.*

rates of multiples while leaving clinics without high multiple rates unaffected. Of course, BESST is not a perfect solution. Data show that the BESST rate can rise simultaneously with the rate of multiple births if overall birth rates rise.¹⁴⁰ However, it is the most effective standard proposed to date for eliminating the incentives identified in Part III.

Using the BESST standard as an international, uniform method for calculating program success rates would also help comparative studies. Currently, each study, agency, and nation reports statistics differently, and a patient can never be sure that she is comparing apples to apples. A uniform method would help North American clinics, which typically favor the implantation of more embryos, compare birth rates with their European counterparts, which are more dedicated to reducing the problem of multiple births.

D. Other Potential Solutions

Of course, other potential solutions to the multiple-birth problem exist, but they are unsatisfactory or impossible at this stage in the technology's development. First, increasing scientific knowledge about which morphological characteristics indicate viable embryos will help physicians select fewer embryos while still maintaining a high pregnancy rate.¹⁴¹ Second, transferring five-day blastocysts instead of three-day embryos may allow physicians to reduce the number of potential fetuses transferred.¹⁴² These technological advances will enable physicians to transfer fewer embryos while maintaining pregnancy rates, but technology alone will not fully solve the complex problem of multifetal pregnancies. Extensive patient counseling will still be necessary to overcome the perception that the transfer of more embryos necessarily leads to—and is necessary to achieve—better results.¹⁴³

Third, the ASRM guidelines could also be used as the standard for tort liability, thus increasing physicians' incentive to comply. But the effectiveness of this last solution is unclear. If the ASRM guidelines represent the standard of care in IVF procedures, a physician who transfers too many embryos may be liable for medical malpractice if the mother sustains injuries

140. Michael J. Davies et al., *What Is the Most Relevant Standard of Success in Assisted Reproduction? Assessing the BESST Index for Reproductive Treatment*, 19 HUM. REPROD. 1049, 1050 (2004).

141. See F. Guerif et al., *Limited Value of Morphological Assessment at Days 1 and 2 to Predict Blastocyst Development Potential: A Prospective Study Based on 4042 Embryos*, 22 HUM. REPROD. 1973, 1973 (2007) (stating that selecting embryos with a high rate of success in assisted reproduction is difficult under current morphological evaluation methods and concluding that new evaluation criteria should be developed to improve success rates for elective single-embryo transfer).

142. See *supra* note 12.

143. See *supra* notes 105–06 and accompanying text.

during childbirth. However, the use of the ASRM guidelines in a wrongful birth suit brought against the physician would be much more complex.¹⁴⁴

The high rate of twins, however, is not going to be lowered significantly until more IVF cycles involve the transfer of a single embryo. While a single embryo is capable of twinning, this possibility is a slight one, and one that technology at this stage probably cannot prevent. Because single-embryo transfer has become the norm in both Sweden and Belgium, U.S. policy makers should keep a close eye on these nations' programs. Both claim to have had significant success with single-embryo transfer methods, and if data confirms early reports, their technology could be implemented by rest of the world.

VI. Conclusion

Multiple births are a serious problem—one of the many frontiers remaining in reproductive medicine. Because a legislative solution is not likely the best or most probable one for the United States, changing the incentives to implant multiple embryos should be considered. Increased counseling and increased insurance coverage can reduce the incentive for the patient, while using the proposed BESST standard for publication of success rates can remove the financial incentives for a clinic. The octuplet case is a rarity, but it helps to remind us that a singleton baby should be the ideal goal of each IVF cycle. Even twins, who remain a significant portion of all IVF births, can no longer be considered acceptable. While single-embryo transfer is likely the ultimate goal, changing these incentives is certainly a step in the right direction.

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144. Wrongful birth suits present a philosophical paradox—a child born with a physical or mental impairment as a result of the number of embryos transferred during IVF would have to argue that the doctor should not have implanted so many embryos. If fewer embryos had been transferred, the child plaintiff might never have been born at all. Commentators have called this the “non-identity problem” because if the protection sought had been implemented, the person seeking protection would never have been born. John A. Robertson, *Procreative Liberty and Harm to Offspring in Assisted Reproduction*, 30 AM. J.L. & MED. 7, 8 (2004). Robertson also discusses the application of the non-identity problem to multiple gestation. *Id.* at 15.