

MINIMIZING THE NUMBER OF MULTIPLES BORN VIA IVF:
WHAT CAN POLICYMAKERS DO?

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THESIS

Submitted in partial satisfaction of
the requirements for the degree of

MASTER OF PUBLIC POLICY AND ADMINISTRATION

at

CALIFORNIA STATE UNIVERSITY, SACRAMENTO

FALL
2009

MINIMIZING THE NUMBER OF MULTIPLES BORN VIA IVF:
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A Thesis

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Abstract
of
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Statement of Problem

The number of infants born premature and low birth weight as a result of multiple birth via IVF is too high. Multiple gestation, including twins, poses serious health risks to both mothers and babies. They disproportionately contribute to infant and maternal morbidity and mortality rates. The true societal costs of these births are unknown but are likely to be significant when you add together the obstetric, neonatal and long-term rehabilitative and educational costs associated with caring for multiples. Neither professional guidelines, nor government regulations have sufficiently addressed this issue. In this thesis I provide a comprehensive review of the problem and assess options for minimizing the number of embryos transferred in each IVF cycle thereby lessening the high multiple birth rate.

Conclusions Reached

Using a Criteria-Alternative Matrix helped me to reach the conclusion that the best alternative at this time is to require a mandatory direct and sustained campaign of improved education directed to fertility patients on the levels and preponderance of the risks of multiples. It is important to note that the financial burden of paying for IVF coupled with the low success rates are likely the most important factors in embryo transfer choice. Working towards additional insurance coverage of IVF would result in less multiples being born and as a result greater healthcare cost savings.

_____, Committee Chair
Mary Kirlin, D.P.A.

Date

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Chapter 1

INTRODUCTION

The Problem

In 2006, a reported 54,656 infants were born as a result of in vitro fertilization (IVF) treatments in the United States. Nearly half of all IVF births were a multiple birth; as Table 1.1 shows below 43.4% were twins and 4.1% were triplets or higher order multiples (triplets+). For so called “multiples” being born premature or with low birth weight creates significant risks. Of these multiples, fully 65% of twins and 97.3% of triplets+ were born prematurely, while 48.1% of twins and 94.3% of triplets+ were born at low birth weight (CDC 2008). The California share of IVF infants was 7,288 births (13.3% of US IVF births) of which 44% were twins, and 4.7% were triplet+.

Table 1.1

IVF Births United States & California, 2006

	<i>United States</i>		<i>California</i>	
	<i>Number</i>	<i>Percent</i>	<i>Number</i>	<i>Percent</i>
Single	28,694	52.5%	3,739	51.3%
Twin	23,721	43.4%	3,207	44.0%
Triplet+	2,241	4.1%	343	4.7%
Total	54,656	100.0%	7,288	100.0%

Risks

Multiple gestation, including twins, poses serious health risks to both mothers and babies. They disproportionately contribute to infant and maternal morbidity and

mortality rates. Short-term and long-term health issues and conditions result in astronomical costs to both public and private healthcare systems (March of Dimes 2008).

Mothers Health

Risks to the mother include maternal anemia, high blood pressure, gestational diabetes and preeclampsia as well as greater risk of complications during delivery, which will almost always be by Caesarian section. It is estimated that each day babies remain in the womb will cut their Neo-natal Intensive Care Unit (NICU) stay by two days (March of Dimes 2008). Because of this, hospital stays extend over weeks or months in an effort to keep babies in the womb as long as possible.

In addition to the medical risks of multiples, there are psychological risks as well. Petok (2009) says that in some cases miscarriage is likely where one or more fetuses may die in utero. In other cases a decision may be made to voluntarily reduce the number of fetuses in order to preserve the life of the mother or improve the survival rates of the remaining fetus (es). In these cases parents must cope with the loss of either a planned or spontaneous reduction. Other psychological issues that can develop in parents of multiples include defensive and depressive reactions and a sense of social isolation, presumably because it is difficult for other parents to understand the additional stresses that raising several children of the same age can bring (March of Dimes 2008). Preterm and/or LBW births also cause substantial emotional and economic burdens for families.

Infants Health

Preterm birth occurs when a woman gives birth before 37 full weeks of pregnancy. Low birth weight (LBW) occurs when an infant is born weighing less than 5.5 pounds. Very-Low birth weight (VLBW) occurs when an infant is born weighing less than 3.3 pounds. Infants born pre-term are at greater risk for death in the first few days of life as well as adverse health outcomes including mental retardation, visual and hearing impairments, learning disabilities, and behavioral and emotional problems throughout life. LBW and VLBW infants are also at increased risk for death and short- and long-term disabilities such as cerebral palsy, and limitations in motor and cognitive skills (CDC 2008).

According to the March of Dimes (2008) the preterm birth rate is at an all time high of 12.7% in the US for all births. Fertility treatments are one of the main reasons for the 36 percent increase in prematurity in the last 25 years. While Assisted Reproductive Technologies (ART) is not responsible for the majority of preterm births, the attributable fraction has increased and is preventable. Most efforts at reducing premature birth have been focused on prevention and prenatal care for low-income women, but IVF multiples are generally the children of affluent women, and The March of Dimes has been campaigning to get this information out to the public as there is widespread recognition of the problem, yet the rate of twin gestation has not noticeably decreased.

Costs

A 2007 study conducted by the Centers for Disease Control and Prevention (CDC) and the US Department of Health and Human Services (DHHS) (Macaluso, Jeng & Cheng 2009) show the following delivery and NICU cost estimates based on a babies' delivery week and established weight ranges. For comparative purposes, the average IVF cycle cost in 2007 was \$15,549 with a range of \$11,279 to \$22,365 per cycle.

Table 1.2

Hospital Cost Estimates for Premature and Low Birth Weight Infants

<i>Delivery week, Birth Weight</i>	<i>NICU Charges (2007 \$'s per infant)</i>		
	<i>Average</i>	<i>Low</i>	<i>High</i>
>37 weeks, >5.5 lbs	\$28,580	\$16,071	\$32,111
>37 weeks, 3.3 to 5.5 lbs	\$55,785	\$52,090	\$68,074
>37 weeks, <3.3 lbs	\$478,621	\$294,521	\$602,267
<37 weeks, <5.5 lbs	\$90,115	\$65,656	\$243,552
<37 weeks, 3.3 to 5.5 lbs	\$139,059	\$67,254	\$316,891
<37 weeks, <3.3 lbs	\$684,623	\$523,930	\$793,981

The figures above represent the individual infant costs and do not include long-term hospitalizations and/or medical care for the mother prior to delivery or additional costs associated with medical care after original release from the hospital for each infant.

As illustrated above, the cost of multiples in terms of delivery and neonatal intensive care (NICU) to healthcare is tremendous. In March 2009 the US Chamber of Commerce and the March of Dimes held a meeting to discuss these costs. The acting

Surgeon General, Dr. Steven K. Galson, said “preterm birth is not just a significant public health issue, it also impacts businesses and employer health plans.” Examples presented include a woman whose hospitalization and doctor’s care for herself and her surviving twin (one twin was stillborn) exceeded \$1 million, her employers self-funded health plan resulted in a sharp increase in medical costs to her company. Several more families had babies in the NICU for three or four or five months were forced into discussions with their private insurance companies because each family had reached the lifetime limit of their medical coverage. Often times if no agreement can be reached, the continued medical costs are picked up by the State and/or Federal government. There is significant concern among public health officials that the number of babies in these categories may grow as fertility treatments become available to more people.

Chapter 2

BACKGROUND & ENVIRONMENT

The \$3 billion fertility industry in the US is a relatively new field of medicine which has been rapidly expanding over a relatively short time span (Asch 2009). This chapter begins with a brief overview of the IVF industry in the US, followed by the current regulatory practices at the national and states levels, with a special look at California specific regulation. Next is a review of the professional guidelines followed by a brief introduction of elective single embryo transfer (SET) and examples of successful practices, including a detailed case study, in reducing the rate of multiples.

IVF Industry in the US

Infertility is often defined as not being able to get or remain pregnant after trying for one year. Infertility affects about 7.3 million women and their partners in the US – about 12% of the reproductive-age population (CDC 2002). IVF has been used in the United States increasingly since 1981 to help some of these women become pregnant. As Table 1.3 shows below, the number of IVF cycles with resulting live births has rapidly increased over the past decade, more than doubling from 64,681 cycles in 1996 to 138,198 cycles in 2006. IVF cycles conducted in California have more than tripled from 5,540 to 18,886 over the same time period (CDC 2008).

Table 2.1

US: Number of IVF Cycles Performed, Live-Birth Deliveries, Success Rates, Number of Infants Born, 1996-2006; Percentage Multiple Births 2001-2006

<i>Year</i>	<i>IVF Cycles</i>	<i>Live Birth Deliveries</i>	<i>% Success Rates</i>	<i>Infants Born</i>	<i>% Multiple</i>
1996	64,681	14,507	22.4%	20,840	<i>n/a</i>
1997	72,397	17,186	23.7%	24,785	<i>n/a</i>
1998	81,438	20,126	24.7%	28,851	<i>n/a</i>
1999	87,636	21,746	24.8%	30,629	<i>n/a</i>
2000	99,629	25,228	25.3%	35,025	<i>n/a</i>
2001	107,587	29,344	27.3%	40,687	53.4%
2002	115,392	33,141	28.7%	45,751	52.8%
2003	122,872	35,785	29.1%	48,756	51.3%
2004	127,977	36,760	28.7%	49,458	49.6%
2005	134,260	38,910	29.0%	52,041	49.0%
2006	138,198	41,343	29.9%	54,656	47.5%

With an average cost of \$15,500 per cycle, and a rigorous course of treatment(s) involved, IVF is both expensive and time-consuming (Asch 2009). While success rates, defined here as a live birth (regardless of number of infants) are continually improving, they are still only approaching 30% (CDC 2008). Private insurance rarely covers infertility treatments let alone IVF, and many intended parents may be both desperate and/or impatient for success. This may drive some intended parents to risk transferring multiple embryos during IVF in their quest to achieve a pregnancy.

Regulatory Picture

National

The federal government enacted the Fertility Clinic Success Rate and Certification Act in 1992 to require reporting of success rates from IVF clinics. Oversight was assigned to the CDC which collects data but has no regulatory capacity. The CDC has in turn handed monitoring over to the Society for Assisted Reproductive Technologies (SART) which processes the information and posts it in both a national and state summary format as well as at the individual fertility clinic level. There are no penalties for failing to report, as such approximately 10-15% of clinics fail to report in a given year. Although most clinics participate, only about 10% have their data verified by the federal government annually. Annual data based on those clinics that have reported data is currently available for years 1995 through 2006 (CDC 2008).

Representative Anthony Weiner (D-NY₉) has recently introduced the Family Building Act of 2009, HR 697 which seeks to amend the Public Health Services Act and the Employee Retirement Income Security Act (ERISA) to require insurers who cover obstetrical services to extend coverage to non-experimental treatment of infertility, including IVF. It has been introduced and sent to committee as of October 2009. Passage of this amendment could expand the IVF market drastically as only an estimated 25% of the US market has been accessing these services thus far (Clemmitt 2009).

States

Medical practice has traditionally been regulated by State governments; as such fertility clinics and their practitioners are regulated to the extent that other medical practitioners are in regard to licensing and certification. ART differs from standard medical practice because most ART procedures do not treat the biological problems that result in infertility, but work around those issues to create children. States that have current policies in place regarding IVF usually address the areas of insurance coverage of infertility treatments, egg/sperm donation, and/or surrogacy (Meyer 2009). This thesis will not address the donation and surrogacy issues.

Fourteen States – Arkansas (AR), California (CA), Connecticut (CT), Hawaii (HI), Illinois (IL), Maryland (MD), Massachusetts (MA), Montana (MT), New Jersey (NJ), New York (NY), Ohio (OH), Rhode Island (RI), Texas (TX) and West Virginia (WV) have enacted legislation addressing insurance coverage of fertility services (National Conference of State Legislatures 2009). Appendix 1 provides a brief summary of these States mandates including the year each was implemented.

Seven (AR, CT, HI, IL, MD, NJ &TX) of the ten states (previous plus MA, OH & RI) that require insurance to cover IVF also have requirements in place for fertility clinics within those states to follow professional guidelines regarding the number of embryos to transfer in a given IVF cycle (National Conference of State Legislatures 2009).

Recent state legislation regarding embryo transfer numbers include a 2009 House bill presented in Missouri that would require fertility clinics to follow American Society for Reproductive Medicine (ASRM) guidelines and Georgia's which would limit women under 40 to two embryos and those 40 and over to three embryos transferred per cycle.

California

Regulations in effect since 1989 within California require group insurers to offer coverage of infertility treatment, excepting IVF. Employers may choose whether or not to include infertility coverage in their employee health benefit package. This single success, as well as other attempts to pass legislation, is detailed in Table 2.2 below.

Senate Bill 1630 introduced in 2000 by Senator Tom Hayden was seen as quite ambitious in its earliest version as it addressed wide-ranging ART related topics such as mandatory fertility drug risk warnings to patients by physicians, severe regulation over egg donors, requirements for mandatory infertility insurance coverage including IVF and limitations on the number of embryos transferred per cycle. Its progress was very closely watched nation-wide, of particular relevance to this discussion was the point of contention the Senator pointed out regarding whether infertility is a "sufficiently compelling health problem to justify requiring others to subsidize its treatment while the harms imposed by multiple-gestation pregnancies and by pregnancy reduction warrant mandatory limits on the number of embryos transferred into women." (Dresser 2000)

Ultimately the bill was amended myriad times and eventually died on file after then Governor Gray Davis refused to sign it.

Table 2.2

History of California Legislation on Assisted Reproductive Technologies

<i>Year</i>	<i>Bill/Code</i>	<i>Description</i>	<i>Outcome</i>
1989	CA Health & Safety Code Sec 1374.55 / CA Ins Code 10119.6	Requires group insurers to offer coverage of infertility treatment, except IVF. Employers may choose whether or not to include infertility coverage as part of their employee health benefit package.	In effect 1989
1994	SB1780	Required that ART health coverage be offered with an optional buy-in rider with a minimum of 4 covered IVF cycles.	Vetoed by Governor Wilson on 9/30/94 - he said that the unfortunate result of the bill would be to effectively price the optional benefit out of the hands of anyone who needed it.
2000	SB1630	Requires health care services plan and HMO group contracts to provide coverage for the treatment of infertility, including IVF, as part of the basic benefit package and requires licensure of physicians and labs that perform ART and egg cell donation services. Limits co-pays to 20% or less, no life-time cap on costs.	Amended many times, eventually died on file as Governor Davis refused to sign it.
2009	SB674	Places fertility clinics and cosmetic surgery providers under the jurisdiction of the Medical Board of California for the first time.	Vetoed by Governor Schwarzenegger on 11/3/09

Source: Maule & Schmid 2006

The most recent proposed legislation is SB674 presented in early 2009 from Senator Gloria Negrete McLeod which would place fertility clinics and cosmetic surgery providers under the jurisdiction of the Medical Board of California for the first time. If passed, fertility clinics and cosmetic surgery providers would have to face a whole new set of regulations in terms of accreditation standards, inspection and reporting systems. It was vetoed in early November 2009 by current Governor Arnold Schwarzenegger.

Professional Guidelines

ASRM Guidelines

The leading professional reproductive health group in the US is the American Society for Reproductive Medicine (ASRM). In response to the spike in triplet+ births exhibited in the early years (1995-1999) of the annual SART success rates reports, attributed to transfers of increasingly higher number of embryos per cycle in an effort to increase success rates, ASRM and SART issued voluntary guidelines to practitioners on the number of embryos to transfer (ASRM 2009). These guidelines were revised in 2004, 2006 and 2008 to reflect advances in the field that include better determination of quality embryos based on patient age and prognosis. Table 2.3 below shows the 2008 standard guidelines. For complete explanations of terms listed please see Appendix 2 – ASRM Recommendations for Embryo Transfer 2008.

Table 2.3

ASRM Summary Recommendations for Embryo Transfer 2008

<i>Cleavage-Stage Embryos^a</i>				
Prognosis	Age <35	Age 35-37	Age 38-40	Age >40
Favorable ^b	1 to 2	2	3	5
All others	2	3	4	5
<i>Blastocysts^a</i>				
Prognosis	Age <35	Age 35-37	Age 38-40	Age >40
Favorable ^b	1	2	2	3
All others	2	2	3	3

a - See text for more complete explanations. Justification for transferring more than the recommended number of embryos should be clearly documented in the patient's medical record.

b - Favorable = First cycle of IVF, good embryo quality, excess embryos available for cryopreservation, or previous successful IVF cycle.

Source: ASRM Practice Committee. *Guidelines on number of embryos transferred. Fertil Steril 2008.*

While the ASRM guidelines have tightened after every revision, they are still considered voluntary, and as a result, only 20% of clinics reporting rates to SART in 2006 met the guidelines based on their annual averages (CDC 2008).

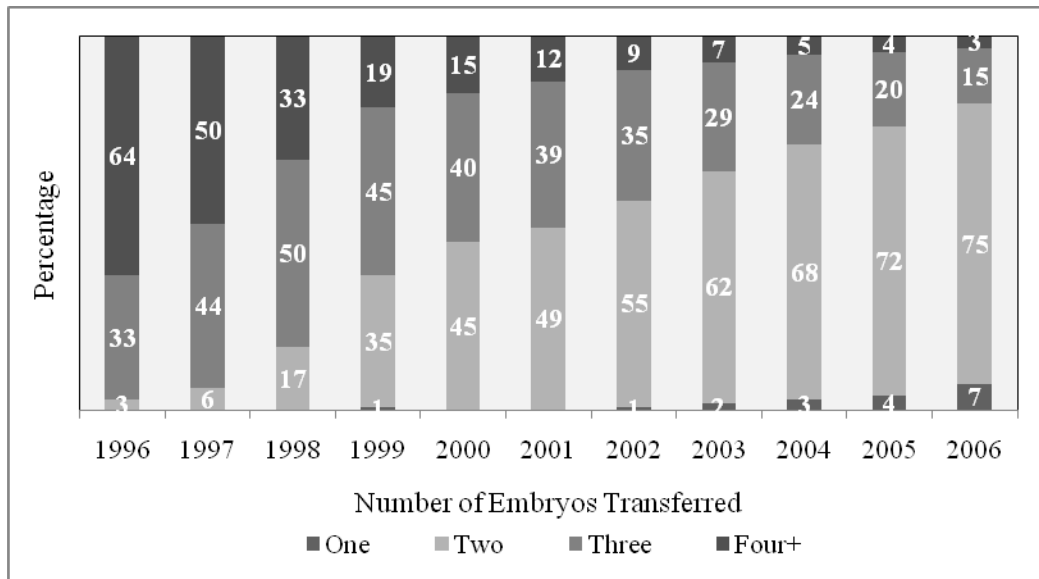
Elective Single Embryo Transfer (SET)

ASRM recommends elective single embryo transfer (SET) for patients who have a more favorable prognosis, defined by them as those patients independent of age, but

definitely those under age 35 exhibiting characteristics such as 1) first cycle of IVF, 2) good quality embryos as judged by morphologic criteria, and 3) excess of embryos of sufficient quality to warrant cryopreservation. Patients who have had previous success with IVF also should be regarded as being in a more favorable prognostic category and consideration should also be given to transferring only a single embryo (ASRM 2009). Chart 2.1 below shows the percentage of cycles by number of embryos transferred in patients that met the above criteria for SET from 1996 through 2006 (CDC 2008).

Chart 2.1

Percentage of IVF cycles by number of embryos transferred to patients meeting criteria for SET



While significant progress has been made in lowering the number of embryos transferred in the most favorable of circumstances, SET is still not being promoted to the extent that the ASRM guidelines call for.

Examples of Success

Doctors and researchers at the 2008 ASRM annual conference presented ways in which to persuade patients that a single healthy baby is a better outcome than ‘extra bonus babies from a risky twin or higher-order multiple pregnancy’ (ASRM 2008).

Limiting number of embryos transferred

An Australian study conducted in 2003 found that transferring one embryo instead of two during an IVF cycle did not reduce the chances of a woman having a baby, when frozen as well as fresh embryos were taken into account. In that study, Mason reports (2003) that under favorable conditions, twin pregnancies can be reduced drastically without compromising a patient’s chance of a successful pregnancy. All patients younger than 38 are now offered SET and approximately 70% of them accept with an acceptable on-going pregnancy rate of 40%. The Johnson City, TN fertility clinic has instituted a two-embryo transfer policy that has resulted in a plummeting rate of triplet+ births while maintaining their overall success rates. Their next step is to adopt a SET policy for all women during their first IVF cycle under the age of 36 or those using donor eggs. (Tarkin 2008).

Patient Education

Another Australian study conducted in 2005 found that while both brochures and counseling contributed to patients' knowledge of the risks of twin and triplet+ births, the ability of a DVD to connect with patients' emotions seemed to be a bigger influence. Of one hundred couples starting their first IVF cycle in this study, they were randomized to receive either an informational brochure or a DVD. These materials were identical in information with the exception that the DVD had two interviews with mothers of twins, one of whom had an uneventful pregnancy and the other who had premature labor. Patients completed questionnaires before and after viewing the brochure or DVD, and then again on the day of their embryo transfer. The group viewing the DVD was more likely to prefer SET, and was more concerned about the risks presented to babies by multiple pregnancy. On the day of embryo transfer, 87% of the DVD watchers chose SET versus 69% of the brochure readers (Veleva, Karinen, Tomas, Tapanainen & Martikainen 2009).

Case Study – Shady Grove Fertility Centers

Shady Grove Fertility Centers is one of the largest and most progressive fertility providers in the country performing more than 4,200 IVF cycles annually amidst their 15 clinics located in and around the greater Washington DC area. This clinic is considered progressive because they invest in the latest technology to improve clinical outcomes, they provide ongoing education to their physicians, staff and patients, they offer innovative financial programs to help more people afford treatment, their physicians

collaborate on patient care including clearly defined patient care teams, and they boast a dedicated in-house research team in which analysis of the large number of annual cycles conducted on site are evaluated. Shady Grove uses even more conservative embryo transfer guidelines than ASRM resulting in the lowest triplet+ birth rate (1.3%) in the nation while maintaining extremely high success rates (39% overall). Their philosophy is to recognize that patients have the final choice in the number of embryos to transfer, but accept the ‘important responsibility of their role in providing extensive counsel about the great risks of those choices’ (Shady Grove 2009).

Contributing factors to their success include a holistic, relationship-based approach to provide cutting edge fertility care in an environment that supports patients’ needs – emotionally and financially – to make future decisions based on what is in the best interest of the patients. To this end, Shady Grove makes sure each patient receives full and up-to-date education prior to their final choices including their internal study of more than 15,000 IVF cycles over 6 years (Stillman 2009) showing that good-prognosis patients can significantly reduce twin pregnancies without compromising pregnancy rates by using SET. This study further found that patients tend to use SET after they have been informed of the risks for multiple pregnancy. They also confirmed that the more a patient has to pay for their IVF cycle out of pocket, the less likely they are to choose SET. “Patients with insurance coverage, or who use ‘the Shared Risk 100% Refund Plan for IVF and Donor Egg’ (helps couples without insurance benefits pay for infertility treatments. This option gives qualified participants the option to lock in a flat fee -2009

estimate of \$27,500- for up to six treatment cycles and receive a 100% refund if a baby is not delivered) take fewer risks in an IVF cycle by transferring fewer embryos knowing they aren't on the financial hook if they are unsuccessful.” (Shady Grove 2009).

This data supports that insurance coverage of IVF will lead to more patients electing to transfer only one embryo which would result in lower costs to the insurance company by reducing the far greater NICU expenses that often come with twins and triplet+ multiples. Table 2.4 below shows how patient payment affects SET choice.

Table 2.4

Patient Payment Affect on SET Choice

	<i>Self Pay Per Cycle</i>	<i>Shared Risk</i>	<i>Insurance Coverage</i>
Number of Cycles	231	520	1082
% SET	16%	24%	25%

Patients who need IVF may overlook the inherent risks of multiple pregnancy, not because they really want to have a high-risk situation for themselves and their babies. Even with thorough information, this study shows that patients are more likely to choose SET when they feel freed from the financial constraints and resulting pressures to transfer more embryos in each IVF cycle.

Environment

All public policy decisions are made within a defined environment. The field of reproductive technologies is both complex and interrelated. Discussions over limiting the number of embryos transferred in an IVF cycle fall within a larger picture of regulating all ART. The medical system in the US is one of a traditionally free market, particularly in regard to elective treatments such as those offered at fertility clinics where guidance has largely been left to the domain of professional self-regulation and market preferences. While the federal government requires clinics to report IVF success rates, the lack of penalties for reporting coupled with the minimal verification reportedly conducted on that data leaves questions regarding how practices are really conducted.

Medical Community

There is competitiveness within the IVF marketplace where clinics recruit patients by advertising high pregnancy rates. Fertility doctors say there are many reasons clinics skirt the ASRM guidelines, pressure from patients who want to use more embryos to improve their chances of getting pregnant, financial concerns from those who are paying for their treatment out of pocket and the ever present competition among clinics to post good success rates. Many clinics with the highest pregnancy rates also have high rates of multiples while turning away from patients in lower success rate categories based on factors such as age (Clemmit 2009). The system is currently set up to reward better success rates, moving the emphasis from quality to quantity despite potentially dangerous and expensive health complications. Fertility doctors care for patients only up to the time

that they become pregnant. When patients are handed off to Obstetricians (OB's), the fertility doctors don't have to deal with the consequences of that pregnancy. The OB's and neo-natal professionals are becoming more vocal about their concerns with this seemingly irresponsible practice but are limited in what they are able to do.

There are some providers in the fertility industry that believe they are already overly regulated as they are required to report success rates that will then be publicly published. Additional fears are that new requirements will result in a cost burden to providers.

Political Factors

Advocates of increased regulation cite the gaps in the regulatory system and the limited impact of professional guidelines in preventing harm to patients and children. However, any efforts at regulation must be undertaken with care as they may be challenged as unconstitutional intrusions of government authority into the constitutionally protected area of reproductive rights related to personal liberty. There are also concerns over financial conflicts of interest that can influence policy and practice decisions by professional organizations and infertility clinics. But regulation requires reasonable consensus on the content of rules, and consensus could be difficult to come by as there are differing views about what rules are needed to protect children and patients. Even requirements to distribute basic information could prove difficult to implement if disputes arise over how to describe specific items. Proposals to impose substantive

restrictions on embryo transfer could encounter even more serious opposition. With the recent focus on rising healthcare costs regulatory efforts that attempt to mandate insurance coverage may be blocked, even with supporting evidence showing the benefits and cost-savings attributable to lower NICU multiple care.

Thesis Organization

This thesis will examine three alternatives that could be pursued at either the National or the California state level to help minimize the number of multiples born via IVF by limiting the number of embryos transferred. In Chapter 3 I will describe the methodology I will use to analyze this issue, including a summary of the three suggested alternatives. In Chapter 4 I will discuss the criteria for evaluating these alternatives. In Chapter 5, I will assess each alternative based on the criteria presented in Chapter 4. Chapter 6 will describe what recommendations and conclusion can be drawn from this analysis.

Chapter 3

METHODOLOGY AND ALTERNATIVES

The Eightfold Path and CAM Analysis

In order to assess the alternatives presented in this thesis, I will perform a Criteria-Alternative Matrix (CAM) analysis as describe by Munger (2000), to evaluate three specific solutions to this problem by determining their performance according to a specific set of criteria. Preparatory steps to conducting the CAM analysis are outlined in Bardach's (2005) Eightfold Path and will be used here to prepare for the CAM analysis.

Step one in Bardach's (2005) analysis process is to define the problem. In the introduction section of this thesis I have shown that the problem is that there is a high number of multiples born premature and at low birth weight conceived via IVF. The incidence of premature birth is an openly identified public health problem and the high costs of NICU care which are passed along to both insurance providers and/or government agencies have impacts on all insured parties as well as taxpayers. These items make this a public policy issue.

Step two in the Eightfold Path is to assemble some evidence (p10) in order to assess the extent of the problem, identify the environmental factors that are relevant to the problem and to gather policies that have been utilized thus far. To this end, I have presented an overview of the IVF industry, current and proposed National, State and California specific legislation, followed by professional guidelines. I then offered several

best practice examples found from specific research studies as well as a detailed case study based on the practices of the Shady Grove Fertility Center. Finally I included a brief overview of the medical and political environment surrounding possible embryo transfer regulation.

Bardach's third step is to construct alternatives for solving the problem. Emphasis is on the importance of thinking broadly about all possible solutions first and then simplifying those options to a more focused list. The fourth step in Bardach's Eightfold Path is to select criteria for evaluating the outcomes of the selected alternatives. Several types of criteria are frequently used including efficiency, equity, legality, political acceptability and robustness (Bardach, 2005 pp. 26-32). I will complete step three in the alternative portion of this Chapter, while step four will be described in Chapter 4.

The fifth step calls for projecting the possible outcomes of each alternative (Bardach 2005, p.36). I will use a CAM analysis to complete this step. This step will make up the bulk of the analysis performed and will be covered in greater detail in Chapter 5. The sixth step is to confront the tradeoffs. Bardach (2005) suggests that because it is unlikely that any alternative would dominate all criteria, weighting criteria differently depending on their significance almost always needs to be done. I will present this step in Chapter 5 as well.

Bardach's (2005) seventh step is to decide which alternative is best based on the analysis of the alternatives by the criteria listed. The final step in the Eightfold Path is to

tell your story. This means to present the information in all previous seven steps in a fashion that both appeals to your audience and constitutes a logical narrative flow. The goal of this thesis is to tell that story clearly and thoroughly.

The Alternatives

Most fertility practitioners have recognized that there is a fine balance between maintaining acceptable success rates (pregnancy) while minimizing multiple births. The technological advances that have been taking place within the fertility industry, while not yet globally used, have enabled more practitioners the ability to work closely on striking this balance. The Alternatives listed below can be considered for implementation at the State or the National level.

Alternative 1 – The Status Quo

Bardach (2005) promotes the idea that when constructing policy alternatives one should always include the option to “let present trends continue undisturbed” (p 16). So the first alternative that I will analyze will assess current practices. This means that there will be no national level mandate for education of patients, mandatory insurance requirement or requirement to follow ASRM guidelines on embryo transfer. This also means that within individual states and individual clinics within those states, the present policies in regard to education, insurance coverage and/or embryo transfer limits will remain unchanged.

Alternative 2 – Patient Education

Alternative 2 calls for a direct and sustained campaign of improved education directed to fertility patients on the levels and preponderance of the risks of multiples, particularly including twins. The information would be offered in a variety of formats (brochures, DVD's, in-person counseling, etc.) and at multiple points during the various stages before and during an IVF cycle. It would require regular training of all fertility staff and practitioners on the risks. This alternative would require consensus on included information for materials, funding and methods in which to produce and distribute materials and oversight to ensure the materials are being properly presented to patients.

Alternative 3 – Legislation Requiring Adherence to Professional Guidelines

While there are a variety of combinations in which legislation could be presented to limit embryo transfer numbers, Alternative 3 focuses specifically on a legislative requirement for fertility clinics to follow ASRM professional guidelines. Legislation is already in place for this requirement in seven states, and is pending in one additional state. This alternative would require instituting measures to ensure compliance and determination of penalties for clinics that are out of compliance.

Alternative 4 – Mandatory Insurance Coverage

Alternative 4 calls for legislative action requiring that IVF and other related infertility treatments are covered by health insurance. Within this alternative there is great flexibility in terms of which type of insurers must cover costs (all private carriers, HMO's, etc.) and which medical conditions warrant coverage (various state examples can be found in Appendix 1). Exceptions based on factors such as maternal age, number of IVF cycles, etc. could be negotiable as could the issues of limited co-pays and/or lifetime caps.

Chapter 4

CRITERIA FOR EVALUATING ALTERNATIVES

The Criteria

Bardach (2005) describes two types of criteria. Evaluative, which are derived from value judgments, and practical, which are derived from fact based judgments (pp. 26-35). For this analysis I have chosen cost efficiency, effectiveness and preservation of personal choice for evaluative criterion and feasibility for the practical criterion.

Criterion 1 – Cost-Efficiency

This criterion evaluates whether the benefits and cost savings of the alternative outweigh the costs of implementation and maintenance. Limiting the number of embryos transferred in IVF, whichever method is in place to do so, will result in the benefit of less multiple births thereby reducing the number of costly premature and LBW births. This will result in significant cost savings to the health insurance industry. However, a cost to the patient could be the possible need to undergo multiple IVF cycles in order to achieve a pregnancy, or if funds were not available for additional cycles, the chance that they would not be able to achieve a pregnancy at all. Fertility practitioners could consider the need for additional IVF cycles as a benefit as unless other measures were put into place to contain or limit costs, they would be making more money off of the additional cycles. However costs associated with implementation and/or maintenance of the alternative could impact perceived benefits, particularly on the part of providers who may be

required to expend additional time or efforts with individual clients. A high rating of the cost-efficiency criterion would have greater benefits than costs while a low rating would result in greater costs and/or lower benefits than engendered.

Criterion 2 – Effectiveness

This criterion evaluates the effectiveness of the alternative in regard to how successfully it would solve the problem. To a certain extent effectiveness may be evaluated along with the criteria cost efficiency however by breaking out effectiveness as a separate criterion, the importance of accomplishing the goal is separated out from the cost outlay. A high rating of the effectiveness criterion would create an outcome that would significantly lower the rates of embryos transferred to minimize multiples while a low rating would have minimum to no effect on the rates of embryo transfer.

Criterion 3 – Preservation of Personal Choice

This criterion evaluates whether the private and personal decisions in regard to reproductive health decisions are respected in regard to the alternative. IVF is an elective medical procedure in which there are limited guidelines found in statute. A conflict may exist if regulations are imposed that could be considered a challenge to the constitutionally protected area of reproductive rights relate to personal liberty. There is an inherent trust between provider and patient to benefit the patient. Outside influence to limit the number of embryos transferred in IVF for patients may be considered a challenge to personal choice. A high rating of the preservation of personal choice

criterion would create an outcome that respects doctor-patient choice while a low rating would infringe on doctor-patient choice.

Criteria 4 – Feasibility

This criterion evaluates if the alternative could be realistically implemented given the number of groups and individuals that the alternative would affect, the condition of the political climate and the additional requirements that would be demanded of fertility practitioners. The affected parties in question here are defined as IVF patients, IVF practitioners and the health insurance industry. Without political support for change it is unlikely the alternative could succeed. Implementation of the alternative could disproportionately concern the affected parties and result in perceived burdens which may make them more or less likely to be supportive of the alternative. A high rating of the feasibility criterion would have both political support and support from all affected parties while a low rating would not have political support or support from many or all affected parties.

Applying Weights

I have identified these criteria as the most relevant to analyzing the outcomes of the alternatives. All are extremely important, yet some may be more important than others in deciding on the best policy option to undertake. In response to this reality, I have applied weights to the criteria to begin the analysis. The prevalence of the problem

leads me to believe that effectiveness will be most important and should be weighted heavily in this analysis.

A second criterion that I believe should be weighted more heavily is feasibility. With the exception of Alternative 1 which calls for no change, each of the remaining alternatives would necessitate a policy change. Alternative 2 would require substantial support on the part of IVF practitioners as well as other groups. Alternatives 3 and 4 involve legislative mandates, so they will require support from the legislature. In addition because Alternative 4 deals directly with insurance requirements for coverage of specific procedures, passage will also require support from the health insurance industry.

Table 4.1 quantitatively shows how I have weighted the different criteria.

Table 4.1

Weighting of Criteria

<i>Criterion</i>	<i>Weighting</i>
Cost Efficiency	0.15
Effectiveness	0.40
Preservation of Personal Choice	0.15
Feasibility	0.30

Conclusion

The methodology described in this chapter, Bardach's Eightfold Path and CAM analysis, is used to analyze Alternatives 1 through 4 along the criteria of cost efficiency, effectiveness, preservation of personal choice and feasibility in Chapter 5.

Chapter 5

ANALYSIS OF ALTERNATIVES

Introduction

Chapters 3 and 4 have described the alternatives, the criteria and the weighting measures used to assess each alternative. Chapter 5 is the analysis of each alternative by assessing each alternative by each criterion: cost-efficiency, effectiveness, preservation of personal choice and feasibility. In appraising each criterion I will use the following rating system: very weak, weak, moderate, strong, and very strong.

Alternative 1 – The Status Quo

Description

Letting present trends continue would mean leaving the decision on the number of embryos to transfer in an IVF cycle up to the doctor and the patient. As was highlighted in the background chapter, there are several states that have varying laws in effect on this issue as well as individual clinic level policies that contribute to either the education of the patient on risks, limit the number of embryos transferred on their own, and/or assist patients in financing their treatment needs. But there is currently no universal approach.

Cost-Efficiency

This alternative ranks strong in terms of cost efficiency. It would result in no changes in the current environment that would necessitate the expenditure of funds. At

the same time there are no additional benefits to this alternative other than those that already exist.

Effectiveness

This alternative ranks very weak in effectiveness. Small changes are seen over time that are likely to continue, but the current structure does not make a significant improvement in the problem.

Preservation of Personal Choice

This alternative ranks very strong in preservation of personal choice. It does not infringe on the doctor-patient decision making process and does not address personal choice.

Feasibility

This alternative ranks very strong in feasibility as it requires no changes. The option is feasible because it already exists.

Alternative 2 – Patient Education

Description

This alternative calls for a direct and sustained campaign of improved education directed to fertility patients on the levels and preponderance of the risks of multiples from multiple embryo transfers. The materials envisioned would be in a variety of formats

(brochures, DVD's, in-person counseling, etc.) at multiple points during the IVF process, and would require regular training of all fertility staff and practitioners. Whether evaluated at the national or the state level, this alternative would require consensus on included information for materials, funding and methods in which to produce and distribute materials and oversight to ensure the materials are being properly presented to patients.

Cost Efficiency

This alternative ranks very strong in cost efficiency. There would be minimal public costs associated with production and distribution of materials that could be offset with grant funds through Public Health Departments and/or non-profits such as the March of Dimes. There would be low to moderate costs to providers as they would be required to train staff and spend additional time with individual patients to ensure all education components were completed. The benefits include more informed patients overall as well as better organized and informed practitioners who will hopefully be motivated by the information in working harder to minimize the number of embryos transferred.

Effectiveness

This alternative ranks very strong in effectiveness. Research presented earlier in this thesis confirm that when patients are adequately informed of the risks of multiples many will adjust their decisions to minimize the risks. The benefits, defined here as lower incidence of multiple embryos transferred, are predicted to be quite successful.

Preservation of Personal Choice

This alternative ranks very strong in preservation of personal choice. It does not infringe on the doctor-patient decision making process and addresses personal choice by informing the patient of risks.

Feasibility

This alternative ranks strong in feasibility. While there may be some disagreement over the content of materials, policymakers will likely welcome the low estimated costs to provide materials coupled with the potential for high results in terms of less multiple births while not imposing harsh mandates onto patients as a positive. IVF practitioners that do not already have an information system in place may have to adjust their patient schedules to accommodate the time required to share the information. There is little chance of resistance from interested parties on this alternative.

Alternative 3 – Legislation Requiring Adherence to Professional Guidelines

Description

This alternative would require all fertility clinics to follow ASRM professional guidelines regarding the number of embryos to transfer per IVF cycle. Legislation is already in place for this requirement in seven states, and is pending in one additional state. At the national level, clinics are already required to report success rates including their embryo transfer numbers, so this alternative would not require a new system for

reporting. However, additional measures would need to be in place to both ensure compliance as well as to enforce penalties for noncompliance. State level actions for this alternative would use the national reporting system as a framework for measuring compliance, but would likely have to create its own ability to audit clinics and penalize those clinics for noncompliance.

Cost Efficiency

This alternative ranks strong in cost efficiency. The budget for the national reporting system is already in place, so the only additional outlay of costs would be in increasing enforcement and penalizing of clinics that are not in compliance. These costs could be phased in as necessary dependent on the responses of providers. Currently 10% of reported clinics are audited with a single 2-person team (CDC 2009). Adding additional teams so that a higher proportion of clinics could be audited is one way of encouraging providers to comply. Costs to enforce penalization of clinics based on audit information could vary on cost depending on the form that it would take. If the form is exclusion from membership to ASRM/SART or a notice of noncompliance to be available to all potential clients then it would be relatively inexpensive. If medical license revocation became an issue then the resulting administrative and possible court costs could be highly expensive. The benefits include a relatively quick and strong impact on the number of embryos being transferred which will have the effect of lowering the rate of multiple birth rate and its subsequent premature and LBW infants

within the first year of its adoption. For legislation introduced at the state level there are little to no costs unless enforcement becomes important.

Effectiveness

This alternative ranks very strong in effectiveness. The mandatory limit on embryo transfer numbers would rapidly decrease the incident of multiples in patients that are younger than 35 and have a favorable diagnosis; flexibility within the ASRM guidelines for patients older than 40 in particular, and/or for patients with more unfavorable prognosis may limit the success in reducing multiples within that specific group of patients.

Preservation of Personal Choice

This alternative ranks very weak in preservation of personal choice. The mandatory limit on embryo transfer numbers takes the decision out of the hands of the doctors and patients so personal choice is no longer a factor to the extent that the patient is limited by the guidelines in place.

Feasibility

This alternative ranks weak in feasibility. At the national level it is unlikely to pass as there are strong reproductive technology groups representing both practitioners and patients that would keep the measure from passing at all, but at the very least without specific legislation on subsidizing fertility treatments. At the state level, precedence has

been set in seven states already – although they all have the additional requirement for IVF to be covered by health insurance. Opposition on most fronts makes this alternative unlikely to pass.

Alternative 4 – Mandatory Insurance Coverage

Description

Alternative 4 would require that IVF and other related infertility treatments be covered by health insurance. Within this alternative there is great flexibility in terms of which type of insurers must cover costs as well as exceptions based on factors such as maternal age, number of IVF cycles, etc. The details could be negotiable as could the issues of limited co-pays and/or lifetime caps. As healthcare costs at the national level are currently attracting a lot of attention, this option, which has some substantial potential costs savings, may be more palatable to policymakers. Cost averages presented in the introduction of this thesis highlight the astronomical NICU healthcare costs associated with premature and LBW infants. At the state level, ten already have some requirements in place to mandate IVF coverage with a wide variety of specific exceptions.

Cost Efficiency

This alternative ranks strong in cost efficiency. An important realization within this alternative is that if IVF was covered the demand for IVF services would likely dramatically increase. The ability for insurance companies to negotiate prices with

clinics would likely drive the cost of IVF cycles down while at the same time minimizing the number of embryos transferred in each IVF cycle so theoretically much of the economic pressures that patients face when making the decision on number to transfer would be mitigated. This in turn would lead to lower numbers of multiples and lower numbers of premature and LBW infants which would likely more than off-set the increased costs of additional cycles. Jones (2007) has estimated that only 25% of the IVF market is currently utilizing IVF services within the United States due to high costs. If this statistic is valid, and insurance coverage was readily available, that could mean a potential three-fold increase in demanded IVF cycles. However, Macaluso (2008) reports that for each \$100 million spent on SET IVF cycles, \$1 billion in healthcare costs would be saved by avoiding costly multiple births.

Effectiveness

This alternative ranks strong in effectiveness. The availability of insurance to cover the costs of IVF has been shown in the Shady Grove case study, to be the single largest factor in deciding on SET.

Preservation of Personal Choice

This alternative ranks strong in preservation of personal choice. It does not infringe on the doctor-patient decision making process and would likely help to make IVF services available to people that desire them but hadn't been able to access them thus

far. It may actually provide additional personal choice as financing IVF could be less of an issue.

Feasibility

This alternative ranks weak in feasibility. While substantial costs savings could be accomplished in the area of NICU costs with this alternative, any action – be it national or state level - perceived as increasing health benefits by covering elective procedures in this down economy with healthcare costs skyrocketing and the number of uninsured reaching ever higher levels are bound to face opposition from interested parties. This alternative would affect more groups than just those utilizing IVF services, so a much larger audience would have to be convinced of the benefits of this legislation before it could pass. While ultimately this alternative would likely offer the most benefit to IVF patients, I don't believe that the time is yet right to pass this legislation.

Summary of Analysis

The following matrix summarizes the results just described.

Table 5.1

Qualitative Criteria-Alternative Matrix

		ALTERNATIVES			
		<i>Alternative 1</i> Status Quo	<i>Alternative 2</i> Education	<i>Alternative 3</i> Requirement to follow guidelines	<i>Alternative 4</i> Mandate Insurance Coverage
CRITERIA	<i>Criterion 1</i> Cost Efficiency	Strong	Very Strong	Strong	Strong
	<i>Criterion 2</i> Effectiveness	Very Weak	Very Strong	Very Strong	Strong
	<i>Criterion 3</i> Preservation of Personal Choice	Strong	Very Strong	Very Weak	Strong
	<i>Criterion 4</i> Feasibility	Very Strong	Strong	Weak	Weak

The following matrix quantifies the results shown in the qualitative matrix which applies the predetermined weights previously described in Chapter 4.

Table 5.2

Quantitative Criteria-Alternative Matrix

		ALTERNATIVES			
		<i>Alternative 1</i> Status Quo	<i>Alternative 2</i> Education	<i>Alternative 3</i> Requirement to follow guidelines	<i>Alternative 4</i> Mandate Insurance Coverage
CRITERIA	<i>Criterion 1</i> Cost Efficiency (.15)	4 x .15 = 0.6	5 x .15 = 0.75	4 x .15 = 0.6	4 x .15 = 0.6
	<i>Criterion 2</i> Effectiveness (.40)	1 x .40 = .40	5 x .40 = 2.0	5 x .40 = 2.0	4 x .40 = 1.6
	<i>Criterion 3</i> Preservation of Personal Choice (.15)	4 x .15 = 0.6	5 x .15 = 0.75	1 x .15 = 0.15	4 x .15 = 0.6
	<i>Criterion 4</i> Feasibility (.30)	5 x .30 = 1.5	4 x .30 = 1.2	2 x .30 = 0.6	2 x .30 = 0.6
	TOTAL SCORE =	3.1	4.7	3.35	3.4

Ratings: 1=Very Weak, 2=Weak, 3=Moderate, 4=Strong, 5=Very Strong

Rating x Weight = Score

Confronting the Trade-Offs by Exploring Different Weights

As the analysis above shows the clearly dominant alternative is Alternative 2-Education. Within this particular weighting mechanism the status quo option received the lowest total score of all alternatives presented. I explained the chosen weights for each criterion earlier, but in order to account for different viewpoints on the importance of each of the criterion, I will create two other criteria-alternative matrices in which will weight the criterion differently.

Table 5.3

Criteria-Alternative Matrix with Cost Efficiency Weighted Heaviest

		ALTERNATIVES			
		<i>Alternative 1</i> Status Quo	<i>Alternative 2</i> Education	<i>Alternative 3</i> Requirement to follow guidelines	<i>Alternative 4</i> Mandate Insurance Coverage
CRITERIA	<i>Criterion 1</i> Cost Efficiency (.40)	4 x .40 = 1.6	5 x .40 = 2.0	4 x .40 = 1.6	4 x .40 = 1.6
	<i>Criterion 2</i> Effectiveness (.15)	1 x .15 = .15	5 x .15 = .75	5 x .15 = .75	4 x .15 = 0.6
	<i>Criterion 3</i> Preservation of Personal Choice (.15)	4 x .15 = 0.6	5 x .15 = 0.75	1 x .15 = 0.15	4 x .15 = 0.6
	<i>Criterion 4</i> Feasibility (.30)	5 x .30 = 1.5	4 x .30 = 1.2	2 x .30 = 0.6	2 x .30 = 0.6
TOTAL SCORE =		3.85	4.7	3.1	3.4

Ratings: 1=Very Weak, 2=Weak, 3=Moderate, 4=Strong, 5=Very Strong
Rating x Weight = Score

Table 5.4

Criteria-Alternative Matrix with Feasibility Weighted Heaviest

		ALTERNATIVES			
		<i>Alternative 1</i> Status Quo	<i>Alternative 2</i> Education	<i>Alternative 3</i> Requirement to follow guidelines	<i>Alternative 4</i> Mandate Insurance Coverage
CRITERIA	<i>Criterion 1</i> Cost Efficiency (.15)	4 x .15 = 0.6	5 x .15 = 0.75	4 x .150 = 0.6	4 x .15 = 0.6
	<i>Criterion 2</i> Effectiveness (.30)	1 x .40 = .40	5 x .40 = 2.0	5 x .40 = 2.0	4 x .40 = 1.6
	<i>Criterion 3</i> Preservation of Personal Choice (.15)	4 x .15 = 0.6	5 x .15 = 0.75	1 x .15 = 0.15	4 x .15 = 0.6
	<i>Criterion 4</i> Feasibility (.40)	5 x .40 = 2.0	4 x .40 = 1.6	2 x .40 = 0.8	2 x .40 = 0.8
TOTAL SCORE =		3.6	5.1	3.55	3.6

Ratings: 1=Very Weak, 2=Weak, 3=Moderate, 4=Strong, 5=Very Strong

Rating x Weight = Score

Table 5.5 summarizes the differences in the alternative rank when the different weights are applied.

Table 5.5

Summary of CAM Rankings

<i>Ranking</i>	<i>Original CAM Effectiveness Weighted Heaviest</i>	<i>Second CAM Cost Efficiency Weighted Heaviest</i>	<i>Third CAM Feasibility Weighted Heaviest</i>
Best Alternative	Alternative 2	Alternative 2	Alternative 2
Second Best Alternative	Alternative 4	Alternative 1	Alternative 1 & 4
Second Worst Alternative	Alternative 3	Alternative 4	Alternative 1 & 4
Worst Alternative	Alternative 1	Alternative 3	Alternative 3

In every outcome calculated here, Alternative 2 was clearly the best alternative based on the selected criteria as well as the variance in the weighting calculation. However the movement of the remaining three alternatives illustrates the importance of choosing weights and I recommend that future researchers further examine both additional criteria that they deem important along with different weighting options.

Chapter 6

RECOMMENDATIONS AND CONCLUSIONS

Summary

The purpose of this thesis was to explore how policymakers could help minimize the number of embryos transferred in IVF in order to minimize the number of multiple births that result in a high number of premature and low birth weight infants. I quantified the problem with available data, and explored some of the important issues related to the industry, its regulation and the interested parties involved. I used that information to develop a short list of alternative solutions for solving the problem. I selected criteria and then evaluated the alternatives based on those criteria in both qualitative and a quantitative fashion which resulted in a ranking of which alternatives would work best. I adjusted the weighting mechanism within the quantitative analysis to better assess the impact of the weighting mechanism on alternative ranking outcomes. This ultimately led to the determination that Alternative 2 – Education was clearly the superior choice.

Discussion and Recommendations

The fertility industry within the US has grown quickly and all signs point to continued growth in the specific demand for IVF services. If current trends continue, this will mean that while tens of thousands of infants will be born, thousands of those infants will either not survive or will suffer from both short-term and long-term complications of prematurity and LBW as a result of being born a multiple. The current system in place,

the lack of regulation let alone adherence to even professional guidelines is leading to too many uninformed, irresponsible decisions on the part of doctors and patients. These decisions too often result in negative outcomes for children, parents and the public good.

There is a fine line in regulating any sort of healthcare in this country, particularly in such an emotional area as infertility. Reproductive rights are considered an individual decision and should not be infringed upon by a government entity. At the same time, there are profound implications for public health as a result of these personal decisions. The true societal costs of these births are unknown but are likely to be significant when you add together the obstetric, neonatal and long-term rehabilitative and educational costs associated with caring for multiples.

The purpose of this thesis was to illustrate the scope of the problem and to explain why this issue is a public policy issue even though many parties believe it is an issue of individual choice. Ultimately, these are private choices that have public consequences. The major recommendation that emerges from this analysis is that educating the individual – be it patient, practitioner, policymaker or otherwise is of paramount importance. While additional actions such as restricting practitioners to ASRM guidelines and/or mandating insurance coverage of IVF would have an impact on the number of multiples born, in the US freedom of choice is highly valued, and educating people over dictating to them is generally the more acceptable road to take. A second recommendation would be to keep the insurance coverage option of IVF on the table. It

would likely have the greatest effect on the multiples rate as IVF costs are still a major factor in patient decision making.

My first recommendation is that a partnership between the public sphere (national would be preferable, but state is also optional) and the professional sphere (notably the ASRM and its affiliates) collaborate on improving patient education. The ASRM should be encouraged to take a leadership role in assessing the current information practices of their members, so that materials are based on real world applications. Centers with superior education programs would share their methods and results (patient choices pre-information and post-information) so that best practices could be developed. Public support could then help to ensure that materials were produced and distributed so that all fertility clinics had the materials readily available. Hopefully every fertility clinic would recognize the importance of educating their patients, and take advantage of the materials offered as they would be in the best interest of the patient. A mandated requirement would ensure that this would happen.

My second recommendation is for national and/or state level legislative committees on health to evaluate the work that the CDC and DHHS has conducted in regard to healthcare costs associated with multiple births. The next step would be for them to work more closely with the insurance industry via the national and/or state level Department of Insurance in order to highlight the benefits of IVF coverage and its related lower embryo transfer rates over the current high costs of multiple births. Legislative

action may not be necessary if the industries determine that greater cost savings can be achieved through coverage.

These combined efforts hold the best chances for policymakers to help minimize the number of multiples born via IVF.

Conclusion

Lowering the number of multiples born via IVF is an important issue within the United States and California. Thus far there has been minimal state and relatively no federal guidance on this issue, and professional guidelines have not been effectively followed. The purpose of this thesis was to demonstrate the need for legislative support in order to push affected parties into action in a consistent fashion. In this thesis I discussed possible strategies that could be undertaken given the current environment. As conditions change over time, additional strategies could be developed or undertaken as well. The goal of my analysis was to gather the myriad information on this topic that exists from the many different disciplines that it affects to determine some realistic strategies for addressing this problem. Individuals deserve to make independent decisions on their reproductive choices, but the possibility for negative public consequences complicates these choices. Ensuring that all IVF patients are educated on the risks that they are undertaking is the first step in solving this problem.

APPENDIX 1

States with Infertility Insurance Mandates

<i>State</i>	<i>Insurance Mandate</i>	<i>Year</i>
Arkansas	Insurers providing maternity benefits must cover IVF for couples with 2-year history of unexplained infertility; OR limited to infertility diagnoses of endometriosis, diethylstilbestrol exposure (DES), blocked fallopian tubes); HMOs exempted; lifetime maximum expenditure of \$15,000; IVF must be performed at a facility licensed or certified by the state and conform to the American College of Obstetricians & Gynecologists' (ACOG) and the ASRM guidelines.	1987
California	Insurers must inform employers about whether infertility services are covered; no requirements to provide coverage.	1989
Connecticut	Insurers must cover ovulation induction, insemination, and ART; limits procedures to women <40 years of age; lifetime cap of 4 cycles ovulation induction, 3 cycles intrauterine insemination; 2 cycles of IVF even if cycles privately funded. Requires infertility treatment or procedures to be performed at facilities that conform to the ASRM and the Society of Reproductive Endocrinology & Infertility Guidelines.	2005
Hawaii	Insurers providing maternity benefits must cover costs of one IVF cycle for couples with 5-year history of infertility who have failed less expensive infertility treatments. IVF procedures must be performed at medical facilities that conform to ACOG and ASRM guidelines.	1989, 2003
Illinois	Plans covering >25 people must reimburse infertility expenses including ART; coverage limited to 4 lifetime egg retrievals. The procedures must be performed at facilities that conform to ACOG and ASRM guidelines.	1991, 1997
Maryland	Insurers providing maternity benefits must cover costs of three IVF cycles to couples with 2-year history of infertility and associated with endometriosis, diethylstilbestrol exposure (DES), or blocked fallopian tubes; HMOs and plans covering <50 employees exempted. Lifetime maximum of \$100,000. IVF	2000

	procedures must be performed at clinics that conform to ASRM and ACOG guidelines.	
Massachusetts	Insurers providing maternity benefits must cover infertility including ART; no limit on number of cycles or a monetary lifetime cap.	1987
Montana	HMOs required to cover infertility services; non-HMO insurers exempted; infertility services not defined but interpreted to not include ART.	1987
New Jersey	Strict definitions of infertility, patient must be <46, group insurers and HMOs that provide pregnancy related coverage must provide infertility treatment including up to 4 egg retrievals per lifetime and IVF among other procedures. The procedures must be performed at facilities that conform to ACOG and ASRM guidelines.	2001
New York	Insurers must cover diagnosis and treatment of infertility but exempts ART.	1990, 2002
Ohio	Requires HMOs to cover basic health care services including infertility services when they are medically necessary. IVF may be covered, but is not required by law.	1991
Rhode Island	Insurers and HMOs that cover pregnancy benefits must provide coverage to women between the ages 25-40 with a lifetime cap of \$100,000. Insurer may impose up to a 20% co-payment.	1989
Texas	Requires group insurers to offer coverage of IVF. Employers may choose whether or not to include that coverage. If coverage offered, patients must have experienced 5+ years of infertility due to specific conditions and IVF procedures must be performed at medical facilities that conform to ACOG and ASRM guidelines.	1987
West Virginia	HMOs must cover infertility services; definition of infertility vague.	1995

Source: *State Laws Related to Insurance Coverage for Infertility Treatment*. National

Conference of State Legislators 2009

APPENDIX 2

Recommendations on Embryo Transfer 2008

Guidelines on number of embryos transferred

The Practice Committee of the Society for Assisted Reproductive Technology and the Practice Committee of the American Society for Reproductive Medicine

Birmingham, Alabama

Based on CDC/ASRM/SART data available in 2006, ASRM's guidelines for the number of embryos to be transferred in in vitro fertilization (IVF) cycles were refined in an effort to reduce the number of higher-order multiple pregnancies. (*Fertil Steril 2008;90:S163-4. 2008 by American Society for Reproductive Medicine.*)

High-order multiple pregnancy (three or more implanted embryos) is an undesirable consequence (outcome) of the assisted reproductive technologies (ART) (1). Multiple gestations lead to an increased risk of complications in both the fetuses and the mothers (2).

Although multifetal pregnancy reduction can be performed to reduce fetal number, the procedure may result in the loss of all fetuses, does not completely eliminate the risks associated with multiple pregnancy and may have adverse psychological consequences (3). Moreover, multifetal pregnancy reduction is not an acceptable option for many women.

In an effort to reduce the incidence of high-order multiple gestations, the ASRM and the SART have developed the following guidelines to assist ART programs and patients in determining the appropriate number of cleavage-stage (usually 2 or 3 days after fertilization) embryos or blastocysts (usually 5 or 6 days after fertilization) to transfer. 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. Accordingly, these guidelines may be modified, according to individual clinical conditions, including patient age, embryo quality, the opportunity for cryopreservation, and as clinical experience with newer techniques accumulates.

- I. Individual programs are encouraged to generate and use their own data regarding patient characteristics and the number of embryos to be transferred.

Accordingly, programs should monitor their results continually and adjust the number of embryos transferred in order to minimize undesirable outcomes. Programs that have a high-order multiple pregnancy rate that is greater than two standard deviations above the mean rate for all SART reporting clinics for two consecutive years will be audited by SART.

- II. Independent of age, the following characteristics have been associated with a more favorable prognosis: 1) first cycle of in vitro fertilization (IVF), 2) good quality embryos as judged by morphologic criteria, and 3) excess of embryos of sufficient quality to warrant cryopreservation. Patients who have had previous success with IVF also should be regarded as being in a more favorable prognostic category.

The number of embryos transferred should be agreed upon by the physician and the treated patient(s), informed consent documents completed, and the information recorded in the clinical record. In the absence of data generated by the individual program, and based on data generated by all clinics providing ART services, the following guidelines are recommended:

- A. For patients under the age of 35 who have a more favorable prognosis, consideration should be given to transferring only a single embryo. All others in this age group should have no more than 2 embryos (cleavage-stage or blastocyst) transferred in the absence of extraordinary circumstances.
- B. For patients between 35 and 37 years of age who have a more favorable prognosis, no more than 2 cleavage-stage embryos should be transferred. All others in this age group should have no more than 3 cleavage-stage embryos transferred. If extended culture is performed, no more than 2 blastocysts should be transferred to women in this age group.
- C. For patients between 38 and 40 years of age who have a more favorable prognosis, no more than 3 cleavage-stage embryos or more than 2 blastocysts should be transferred. All others in this age group should have no more than 4 cleavage-stage embryos or 3 blastocysts transferred.
- D. For patients greater than 40 years of age, no more than 5 cleavage-stage embryos or 3 blastocysts should be transferred.
- E. For patients with 2 or more previous failed IVF cycles or a less favorable prognosis, additional embryos may be transferred according to individual circumstances after appropriate consultation.

- F. In donor egg cycles, the age of the donor should be used to determine the appropriate number of embryos to transfer.
- III. Because not all oocytes may fertilize when GIFT is performed, one more oocyte than embryo may be transferred for each prognostic category (4).

ASRM Summary and Recommendations				
Recommended limits on the numbers of embryos to transfer.				
Cleavage-Stage Embryos ^a				
Prognosis	Age <35	Age 35-37	Age 38-40	Age >40
Favorable ^b	1 to 2	2	3	5
All others	2	3	4	5
Blastocysts ^a				
Prognosis	Age <35	Age 35-37	Age 38-40	Age >40
Favorable ^b	1	2	2	3
All others	2	2	3	3

a - See text for more complete explanations. Justification for transferring more than the recommended number of embryos should be clearly documented in the patient's medical record.

b - Favorable = First cycle of IVF, good embryo quality, excess embryos available for cryopreservation, or previous successful IVF cycle.

ASRM Practice Committee. Guidelines on number of embryos transferred. Fertil Steril 2008.

Acknowledgements: This report was developed under the direction of the Practice Committee of the Society for Assisted Reproductive Technology and the Practice Committee of the American Society for Reproductive Medicine as a service to their members and other practicing clinicians. While this document reflects appropriate management of a problem encountered in the practice of reproductive medicine, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment. Other plans of management may be appropriate, taking into account the needs of the individual patient, available resources, and institutional or clinical practice limitations. This report has been approved by the Executive Council

of the Society for Assisted Reproductive Technology and by the Board of Directors of the American Society for Reproductive Medicine.

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