

Infertility Services and Managed Care

Morgan S. Bron, BS, PharmD (cand); and J. Warren Salmon, PhD

Abstract

The birth of the McCaughey septuplets in Iowa in November 1997 brought issues of fertility assistance and their potential outcomes to worldwide attention. This Pergonal®-stimulated multiple pregnancy ended successfully, but not without health hurdles and economic consequences for the new siblings and their family. This article reviews the general situation surrounding infertility services and, within the current debate of epidemiological, economic, legal and social issues, posits that managed care may be able to make greater strides than the present fee-for-service system in providing more accessible and comprehensive care to the 5.3 million US citizens at risk for infertility. Our conclusions suggest that managed care plans for infertility can aid in assuring quality and decreasing unnecessary costs. Managed care organizations should take the lead in providing infertile couples with an organized, humanistic approach that is mindful of the attending social issues. On May 5, 1997, a US District court in Chicago ruled that infertility fits the definition of a disability, and thus is subject to the antidiscrimination enforcement under the Americans with Disabilities Act.

(*Am J Man Care* 1998;4:715-720)

All species have a biological instinct to propagate themselves and have offspring. Starting a family is seen as a natural progression in life for most humans. However, for approximately 5.3 million people in the United States, reproductive success is not as natural nor as simple as nature may have intended. For these individuals, infertility treatment is an option being chosen with increasing frequency. Nevertheless,

the journey toward a successful pregnancy and delivery can be stressful emotionally and financially. Even when a couple is subjected to all possible pathways to conceive through assisted reproduction, there remains no guarantee of a healthy child.

In most industrial countries, it is estimated that 15% of all couples experience infertility. A couple is said to have decreased fertility if they have not achieved pregnancy within one year of unprotected intercourse or are unable to carry a pregnancy to a live birth (RESOLVE of Illinois. Information packet; Chicago, IL 1996).¹ The cause of infertility for both men and women may be hormonal, genetic, immunological, or anatomical. Although the current prevalence of infertility in the population is relatively small, substantial social, scientific, economic, and ethical discussion and debates are taking place as a result of the social and psychological impact of infertility on couples, the new technology to assist reproductive success, and the likely increase in future at-risk cohorts. Witness the commentary surrounding the McCaughey septuplets, born in November 1997, in both the scientific and popular press. Consequently, managed care organizations face multiple issues both in designing infertility service benefits and in assuring optimal outcomes for enrollees.

Current Milieu for Infertility Services

According to a World Health Organization Task Force, the epidemiology of infertility for women in the United States, Asia, Europe, Latin America, and the Middle East lays cause to tubal factors (36%), ovulatory disorders (33%), endometriosis (6%), and no demonstrable cause (40%).² In industrial countries, the most common causes of infertility for women are tubal infertility, ovulatory disorders, oocyte factors, endometriosis, implantation failure, chromosomal abnormalities, recurrent miscarriages, and lifestyle factors (such as diet or use of alcohol, drugs, or tobacco). For men, the causes of infertility may include chromosomal disorders, lifestyle factors, sperm-oocyte fusion, and lowered sperm numbers and motility.¹

From the University of Illinois at Chicago College of Pharmacy, Chicago, IL.

Address correspondence to: J. Warren Salmon, PhD, Professor of Pharmacy Administration, University of Illinois at Chicago, 833 S. Wood St. MC 871, Chicago, IL 60612

Management of infertility may include techniques such as corrective surgery for reproductive tract abnormalities (eg, endometriosis and septate uterus); egg and sperm donation; and in vitro fertilization (hormonal treatments that stimulate ovulation and artificial insemination). The desired endpoint of any treatment for infertility is clear: to conceive, carry out a live pregnancy, and deliver a healthy child.

The cost of undergoing infertility care can be extremely high. For example, in the United States one cycle of in vitro fertilization that results in a successful delivery has an average cost of \$66,667. If couples choose to undergo up to six cycles, the cost may increase to \$114,286.³ For couples with a more complicated diagnosis—increased age (over 40) of the female partner and contributing male infertility such as a low sperm count—this estimation may increase dramatically to \$160,000 for the first cycle and \$800,000 for the sixth cycle. In addition, standard fertility treatments (such as hyperstimulation of the ovaries to increase the number of eggs for fertilization or transferring viable embryos) may lead to multiple gestations, which in turn are associated with an increased risk of prenatal morbidity and mortality, pre-term birth, and much higher healthcare costs.⁴ In fact, it is estimated that the hospital charges for triplet births were 11 times higher than for a singleton (one child) delivery.⁵ For children from multiple births, a higher incidence of postnatal medical problems, as well as later developmental disabilities, can lead to very high medical expenditures. Fetal reductions in the case of multiple pregnancies can be an agonizing decision for couples and practitioners alike, and have recently raised an ethical tempest.^{5,6}

Costs vary for specific infertility procedures, even within a single clinic, depending on what equipment is used and how long procedures take (eg, anesthesia and operating room charges in 15-minute blocks). Drug therapy costs vary widely, depending on agents, dosage, and time used. Regional variations within the United States in infertility costs expectedly follow similar patterns as charges and costs in other medical specialties. There have been few studies of relative cost-effectiveness of infertility treatments in the United States.^{7,8}

Inadequate infertility services from which no full-term pregnancies occur add much to the overall costs of healthcare for both insurers and our society. Relative to the age of the woman and other clinical factors, outcomes will differ. Between 1991 and 1993, the cost of infertility care for one insurance provider nearly doubled.⁹ If this trend continues, fee-for-service medicine will make infertility services affordable for only the wealthy.

At present, the issues of cost and effectiveness in infertility treatment have not been fully evaluated nor even sufficiently studied. In the recent past, infertility care was not often covered by private health insurance as a clear stated benefit, although many companies paid for some of it. However, a few states have mandated insurance coverage for selected infertility services. For example, in Illinois, the Family Building Act was passed in January 1992 to mandate that most Illinois citizens have access to the benefit of comprehensive infertility coverage. Those excluded from this coverage were recipients of public assistance, employees of companies with fewer than 25 employees or self-insured companies, federal beneficiaries, Illinois residents who bought insurance out of state, and individuals insured through religious organizations that chose not to opt for this coverage.¹⁰ Before state-mandated coverage of infertility, the insurance industry saw this service as an elective benefit, much like plastic surgery. Those who chose to undergo treatment for infertility spent a great deal of money out-of-pocket, personal time, and effort. In the fee-for-service system, the incentive for medical providers to reap economic rewards is inherent through repeating procedures or using less-effective therapies, without regard to measured outcomes.¹¹ Although this incentive remains a risk, it is likely that clinicians do try their best to secure pregnancies and rejoice when such positive outcomes occur. Because only 10 states mandate insurance coverage of infertility services, the majority of the US population is faced with determining what is the "best care" for the "best price" under fee-for-service medicine paid out-of-pocket.

Because of the great cost of infertility and related services and the limited outcome data for differing treatment protocols, numerous questions arise, among them: Who should have infertility care paid for? What type of services should be covered? To what extent should couples keep trying to get pregnant? The Society for Assisted Reproductive Technology, a self-regulatory group in Birmingham, Alabama, has compiled comparative success rates for infertility clinics, but otherwise few data exist that evaluate the outcomes of infertility care and the cost-effectiveness of various treatment plans. Studies remain limited on descriptions of programs, beyond the randomized clinical trials of treatment protocols. Recently, the US Centers for Disease Control and Prevention published for the first time a 1995 survey of voluntarily reporting assisted reproduction clinics, finding an overall success rate of about 20%.¹²

In sum, infertility care presently: (1) has little widespread standards of care; (2) has inadequate out-

comes data on cost-effectiveness; (3) is available to a small percentage of the population; (4) is growing biased toward a wealthier clientele; and (5) is usually covered under fee-for-service medicine, which rewards provider revenue and encourages mostly services that are covered by insurance plans, even when they might not be the "best" treatment options for patients/couples.

Issues Affecting Managed Care and Infertility Services

The design of infertility benefits and the provision of related services under managed care must take into account social, epidemiological, and demographic trends, as well as legal considerations.

Fertility plans should be developed so there is an opportunity for all who desire to conceive to explore infertility treatment as an option. Yet the fact remains that chances of miscarriages for a 40-year-old woman can be more than twice as much as those for a 20-year-old. Moreover, chromosomal abnormalities such as Down's syndrome can leap from 1 in 1,250 in a 25-year-old to 1 in 106 at age 40, according to the American Society for Reproductive Medicine. Thus, the statistics do not favor women as they age, and fertility plans may view the inclusion of older patients as a threat to their overall success rate and marketplace security. Nevertheless, age restrictions should be fairly set so as to allow the majority of infertile couples to participate in the program. Time and funds should also be allocated so they are reasonable. If there are exceptions to the rule, or if patients are insistent on infertility treatment although age and conditions may not be optimal as viewed by physician providers, then provisions might be made that allow participation on a shared-risk basis by the patient, as we describe below.

There are added social and ethical dilemmas that are part of the infertility issue. Many women have pursued their careers without thought to problems of later reproduction. Nature, however, does not stand still for women who put off having a family. Between the ages of 25 and 35, the female's ability to achieve a successful pregnancy decreases by 50%.¹³ Thus, women who choose to pursue careers instead of a family are making tradeoffs as time passes. Furthermore, when a woman decides to undergo infertility treatments in order to start a family, studies show that efficacy of infertility treatments decreases as women age.¹⁴⁻¹⁶

In addition, demands on time and energy burden women to juggle work with infertility treatment regimens and monitoring. In some protocols, daily blood samples are needed to monitor fertility drug

dosages as well as sonograms to track the rate of follicular development. Such demands may adversely impact women who have already full work and family schedules. In 1992, RESOLVE, an advocacy group for infertile couples, found in a survey of 487 members that 25% had voluntarily quit their jobs or reduced working hours, while an additional 16% found less demanding jobs.¹⁷

In some cases, patients undergoing treatment have claimed that their discharge from work was related to their infertility diagnosis. According to RESOLVE, some women have sued their employers on claims that their employers have illegally refused to reduce working hours to make time for infertility treatments or illegally refused to provide insurance, thus violating the Americans with Disabilities Act. Patients under treatment for infertility have claimed that their discharge from work has violated the Act with the argument that reproduction is a "major life activity," much like walking, seeing, breathing, learning, and working.¹⁷ However, employers in these cases do not view infertility as a disability that limits a "major life activity," and thus arguments were taken to federal courts where one judge in Chicago found that infertility was indeed a disability. By nature of its definition, infertility impairs one or more body systems.¹⁸ With the large number of women in the workforce, employers must watch the unfolding of this set of issues closely, and appropriately respond to new legal conditions. The conclusions of these cases will likely shape the type and extent of health plans that employers offer their workers in the near future.

The Family and Medical Leave Act (FMLA), effective August 5, 1993, for all public agency employers and private employers of 50 or more employees, allows certain employees 12 workweeks of unpaid, job-protected leave per year, and requires group health benefits to be maintained during leave. The FMLA contains a provision that allows employees to take reasonable leave for certain medical and family reasons. Medical reasons must be serious health conditions that are illnesses, injuries, impairments, or physical and mental conditions that involve any period of incapacity of treatment connected with: (1) inpatient care; (2) a need for 3 calendar days of absence; (3) pregnancy or prenatal care; (4) chronic illness; (5) permanent conditions such as stroke, cancer; and (6) absences to receive multiple treatments that would require more than 3 days if left untreated (eg, chemotherapy, physical therapy). As mentioned earlier, certain employees who were terminated after infertility treatment filed lawsuits against employers under the Americans with Disabilities Act with the claim that infertility was a disability. The

FMLA may help protect employees against such job loss in the future if medical certification by a health provider is consistent with the terms in the law.

These epidemiological trends confront the market mentality for cost containment in healthcare, leading to a host of potential conflicts between health plans and their enrollees. Since infertility services are inevitably high cost, managed care plans, like indemnity insurers, may seek to avoid outlays by whittling down services at the possible loss of efficacy. As with other specialty services under managed care arrangements, infertility treatment can be carved out as a benefit, with providers preferably having incentives for success and quality.

Managed Care as a Provider of Infertility Services

Providers, consultants, and practitioners have proposed that developing a managed care plan for infertility will help assure quality, provide accessible and comprehensive care, and help decrease unnecessary costs.^{8,9,11} The underlying rationale for these proposals is that care must be provided in an environment that allows accessibility, continuity, and efficient management. Step-by-step treatment protocols are defined in order to monitor care and costs. Once patients begin treatment within a given protocol, they are entitled to a defined amount of services as specified in their plan contract. Basic initial infertility services are provided by a primary gynecologist who acts as a gatekeeper for referral to infertility specialists who render the assisted reproductive technologies (ART). Patients are diagnosed by caregivers who are held accountable for their services and must meet quality standards as defined by the managed care organization. Moreover, financial risk may be assumed by the insurer, provider, or patient so as to incorporate incentives for success.

One example of a managed care infertility plan is in a policy developed by US Healthcare.⁸ Unfortunately, its new parent, Aetna Insurance, recently scaled back its coverage for infertile couples. In the previous policy by US Healthcare, infertility services began after a case manager assured a confirmed diagnosis of infertility for a couple. The couple was then referred to a gynecologist who performed a basic infertility evaluation that included a history and physical examination, semen analysis, and endocrinologic evaluations to determine whether there was an ovulatory dysfunction. The plan also allowed the gynecologist to perform a hysterosalpingogram (HSG). If the HSG showed anatomical defects, the patient was referred to a certified infertility specialist within the network. If there was an ovulatory dysfunction, the patient was treated for 4 months with hormonal therapy. If pregnancy occurred, the

patient was referred to the obstetrician of her choice. All services were authorized by the case manager during the basic fertility work-up and were paid for on a predetermined fee-for-service basis.

However, if pregnancy did not occur after the basic treatment, the patient was referred to an infertility specialist within the network for a consultation. If provider and patient agreed, the case manager authorized advanced infertility care for 2 years. Within the advanced infertility program, the patient was entitled to a predetermined set of services. Moreover, the case manager authorized all treatment by the specialist for 2 years. For US Healthcare, this contract of care included: surgery, including hysteroscopy; monitoring of ovulation induction; ultrasound use; inseminations; one cycle of ART, such as in vitro fertilization, gamete intrafallopian transfer, or zygote intrafallopian transfer; and one transfer of cryopreserved embryos. The embryologist, anesthesiologist, and transfer and recovery room charges were also covered. Care under the advanced fertility protocol was paid for by a global fee that covers all of these services, paid in installments every 3 months for 2 years. Care by the board-certified infertility specialist was held to performance guidelines and was compared with other specialists participating in the network. This allowed outcomes data comparison among providers and helped measure and maintain quality within the network.

In this protocol, managed care seemingly offers organizational insight into a previously undefined treatment area. In the previous US Healthcare policy, containing overutilization and controlling costs in a comprehensive delivery system eliminated waste, increased efficiency, and provided measures of quality and outcomes. However, lessons learned from managed care dilemmas in oncology and obstetrics must not be forgotten. Consumers remain doubtful about some managed care plans' greater concern for the bottom line rather than for the quality of care. Given the recent public outcry against health plans that promote only 1-day hospital stays for postpartum care, offer outpatient mastectomies, compromise rehabilitation services, and impose "gag rules" (*Time*, April 14, 1997;32),¹⁹ caution is advisable for managed care plans that choose to skimp on infertility benefits and services to the point that a threat (or perceived threat) to patients' health arises.

One way to lessen the risk of financial interests controlling care is for safeguards to be put in place to assure clinically focused care for the patients' well-being. Perhaps in the future, the National Committee for Quality Assurance (NCQA), the Joint Commission on Accreditation of Healthcare Organizations, or other

accrediting guidelines for infertility services can be defined and applied to existing health maintenance organizations (HMOs). In order to give the "best care" in the true interest of patients, managed care programs should use quality standards preferably set at their inception as well as throughout their program development. Accreditation by the NCQA's HEDIS 3.0+ may someday assure to a great degree that managed care organizations operate at a high standard, although quality assurance still remains in its incipient stage in the 1990s. An eventual evaluation by an accrediting organization for infertility services should ideally be based on criteria developed in collaboration with physician and nurse practitioner/certified nurse specialist providers, with perhaps input from patient advocacy groups to promote acceptability.

Although managed care entities may be attempting to find a means to serve the infertile in a comprehensive and efficient manner through standardized protocols, such programs warrant constant scrutiny. Until outcomes studies on standard protocols can demonstrate their impact on quality and efficacy, no health plan should be taken at face value as the most cost-effective means of treatment.

Putting Patients First in Managed Care Infertility Services

As we have noted, infertility is a subject that uncovers a myriad of issues that span medical, financial, social, ethical, and legal arenas. The infertile couple must deal not only with the medical and psychological issues of the diagnosis, but also with the financial burden of high-cost services. Moreover, the accessibility and availability to care for patients are paramount. For working women, infertility service demands on time for monitoring and treatment may conflict with work productivity and career continuity.

Managed care infertility protocols have been proposed in an attempt to provide the most comprehensive and efficient medical care for the best price. They offer the patient quality care in a cost-effective environment. Some health plans are aware that constant evaluation, monitoring, and outcomes studies are needed to best assess the effects of protocols on practice. However, these policies must address the humanistic, ethical, and social issues that are integral to infertility.

Managed care plans should approach future development of infertility protocols with the individual enrollee first and foremost in mind. Policies targeted toward providing care for all those who need infertility services instead of only those who will most likely

succeed will eliminate performance-based population selectivity. The danger of patient preselection becomes more salient when plans want to increase success rates in order to compete for employer contracts. However, the medical needs of couples with clinical problems that preclude their ability to conceive warrant attention across the child-bearing years. Experimentation with health benefits and innovative treatment processes are underway as the knowledge base and technology develop to aid the infertile.²⁰

One way to expand availability is to spread the costs out to all parties in the process. In a managed care infertility plan described by Bates and Bates,¹¹ all stake holders in the infertility treatment process would share economic risk: physicians, insurers, and patients. Patient cost-sharing may seem reasonable, especially when compared to a fee-for-service program. If the total economic burden is assumed by third-party payers, then there is little incentive to use resources wisely and efficiently. For example, in the plan offered by Reproductive Health Associates in St. Paul, Minnesota, programs are economically stratified according to patient age, donor services, and specialized assisted reproduction technology services. Regardless of program type, however, patients were expected to cover certain costs such as patient pre-screening, medications for infertility and frozen embryo transfer, and medical care following the diagnosis of pregnancy.

Two infertility centers, Pacific Fertility Center, based in California, and the previously mentioned Reproductive Health Associates, are offering their patients partial refunds if they fail to become pregnant or miscarry early in the pregnancy.¹³ Typically, these clinics offer the plan only to patients who are considered most likely to succeed. Moreover, the money-back plan usually costs more than the standard plan for infertility services and does not offer refunds for drugs and laboratory tests. Supporters say that this strategy increases risk-sharing and may reduce financial and emotional stress. On the other hand, critics are wary that the pressure to achieve successful pregnancies may encourage risky medical practices, selection of patients with the best chances of pregnancy, and a breach in medical ethics. In addition, some critics suggest that these programs may overcharge, as well as overwhelm, the average consumer, who may be unable to assess the true costs of infertility services.

Insurers and HMOs should have clear means to evaluate infertility managed care proposals. These should take into account the geographic patient population served, existing laboratory and support facilities, the primary facility's location, physician and other

provider credibility and certification, support services for the patient and spouse, and explicit clinical measures of success. The success of a program can be evaluated by the number of live births achieved in comparison to cost, time, and treatment protocol. Of course, acceptance of a proposal by an HMO and/or insurance company should be based on meeting the needs of the population that it will serve.

In addition, policies by managed care organizations must consider the increasing numbers and changed roles of women in the work force, and tailor programs to minimize disruption to work productivity. Interventions should be put into place that can address issues of work and career continuity. Because infertility increases as population cohorts age, policies that are humanistic, yet sensible, are needed so that all patients have equal opportunities to infertility care. Thus, in addition to basic managed care tenants of accessible, cost-conscious comprehensive care, managed care organizations should strive to provide the infertile with an organized, humanistic approach mindful of the attending social issues of infertility. The realities of assessment and accountability found in the current health marketplace challenge the reproductive health community of programs and practitioners to seek suitable collaborations with managed care entities. Employers and employees alike will predictably respond positively to such approaches that seek to enhance consumer welfare.

Acknowledgments

The authors wish to thank the editors, two anonymous reviewers, and Janet Engstrom, PhD, RN and Elena M. Dimopolous, JD, for comments on an earlier draft.

... REFERENCES ...

1. Healy DL, Trounson AO, Andersen AN. Female infertility: Causes and treatment. *Lancet* 1994;343:1539-1544.
2. Cates W, Farley TMM, Rowe PJ. Worldwide patterns of infertility: Is Africa different? *Lancet* 1985;1:596.
3. Neumann PJ, Gharib SD, Weinstein MC. The cost of a successful delivery with in vitro fertilization. *N Engl J Med* 1994;331:239-243.
4. Collins JA. Reproductive technology: The price of progress. *N Engl J Med* 1994;331:270-271.
5. Carton B. Multiple pregnancies are often pared back in fetal reduction. *The Wall Street Journal*. November 21, 1997:A1, A6.
6. Callahan TL, Hall JE, Ettner SL, Christiansen CL, Greene MF, Crowley WF JR. The economic impact of multiple-gestation pregnancies and the contribution of assisted-reproduction techniques to their incidence. *N Engl J Med* 1994;331:244-249.
7. Van Voorhis BJ. Cost-effectiveness of infertility treatments: A cohort study. *Fertil Steril* 1997;67:830-835.
8. Cohen AW. Managed health care's approach to infertility. *Contemp OB/GYN* 1996;93-107.
9. Pratt D. News and views: Reproductive health care policies around the world: A managed care providers' approach toward mandated infertility coverage. The Illinois family building act. *J Assist Repro Genetics* 1994;11:433-437.
10. Option Two: Infertility Education advocacy support. What the bill says. Chicago, IL: RESOLVE of Illinois, Inc. 1991;13(4):2.
11. Bates G, Bates SR. The economics of infertility: Developing an infertility managed care plan. *Am J Obstet Gynecol* 1996;174:1200-1207.
12. Centers for Disease Control. 1995 Assisted reproductive technology success rates. Atlanta, GA: US CDC Division of Reproductive Health;1996.
13. Wozencraft A. It's a baby or it's your money back: Fertility clinics test consumer rebates. *The New York Times*. August 25, 1996:A3.
14. Van Noord-Zaadstra BM, Looman CWN, Alsbach H, Habbema JDF, te Velde ER, Karbaat J. Delayed child-bearing: Effect of age on fecundity and outcome of pregnancy. *Br Med J* 1991;302:1361-1365.
15. Jones HW, Toner JP. The infertile couple. *N Engl J Med* 1993;329:1710-1715.
16. Maroulis GB. The effect of aging on fertility and pregnancy. *Sem Repro Endocrinol* 1992;9:165-173.
17. Jacobs MA. Women seek infertility benefits under federal disabilities law. *The Wall Street Journal*. June 12, 1996:B5.
18. Spielman F. Infertility ruled disability. *Chicago Sun Times*. January 30, 1998:1,2.
19. Johannes L. Some HMOs now put doctors on a budget for prescription drugs. *The Wall Street Journal*. May 22, 1997:A1.
20. Selz M. Birth business races to aid the infertile. *The Wall Street Journal*. November 26, 1997:B1, B9.