Chapter 8 Infertility Services and Costs

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Chapter 8

Infertility Services and costs

This chapter examines the current state of infertility-related services from the perspectives of costs, affordability, and insurance coverage. For the purposes of this report, infertility-related services, referred to as infertility treatment, include medical and surgical diagnostics and treatments that attempt to directly overcome diseases and disorders that cause infertility as well as technological procedures and practices that attempt to circumvent infertility conditions.

As infertility-related services are adapted and refined, and as infertility treatment centers increase in number, questions arise about the costs of the services, the recipients of treatment, and the effectiveness of the services. This chapter considers:

- How much do various infertility treatments and technologies cost for typical courses of treatment? For atypical treatments?
- What are the total infertility -treatment-related expenditures in the United States? How is the infertility health care dollar spent? How is the cost burden distributed among individual, public, and private payers?

- How effective are different infertility treatments? Do certain types of infertility treatments have better success records than others and, if so, are these success rates correlated with identifiable factors?
- How widespread is access to infertility treatment for various types of infertile couples? Does access depend on income, geographic location, or other factors?

The number of new infertility cases per year is unknown, but has been estimated to be between 111,200 and 161,240 (6,7). The number of patients receiving treatment for infertility is estimated at between 200,000 and 300,000 per year, for the following disorders:

- ovulatory disorders, 120,000 patients;
- endometriosis, 30,000 patients;
- •tubal disorders, 20,000 to 40,000 patients; and
- seminal factors, 20,000 to 45,000 patients.

In addition to these estimates, the National Survey of Family Growth estimates that about 1 million couples use some form of infertility services annually (15,18).

INFERTILITY TREATMENT SCENARIOS

In most cases, infertile couples first seek medical assistance so that they can have a baby genetically related to each of them. Should these attempts fail, they may consider methods by which they can have a baby that is the genetic product of at least one member of the couple (i.e., artificial insemination by donor, embryo donation, ovum donation, or surrogate motherhood), or they may consider adoption. In comparing the costs and availability of assistance for infertile couples, it is important to keep in mind the widening range of alternatives that infertile couples face.

This discussion focuses on infertile married couples, primarily on the women. Although men and women are equally likely to be infertile, male infertility does not account for an equal proportion of the costs spent on infertility because there are relatively few diagnostic and treatment services for men.

In treating infertility, the more tailored the protocol is to the patient, the more likely the chance of success. Some specialists, for example, treat endometriosis with surgery, with drugs, or with both; the choice of therapy, the length of time, and the drug dosage prescribed depends on the woman's history and reactions as well as on the severity of the disease. Many patient-specific decisions may be made over the course of treatment; the results of each test and the success of each treatment indicate the next steps to be taken. Because of the varieties of sources and types of infertility, it is often difficult to determine whether standard treatment protocols exist, how much each treatment **costs**, and what the effectiveness is expected to be.

In addition, as in any advancing medical arena, infertility specialists disagree as to the proper course of action in many **cases**. Some physicians investigate mechanical problems such as blocked or scarred fallopian tubes as part of the routine workup; others wait until ovulatory problems are cleared up before determining the status of the tubes (4).

Finally, there are tradeoffs to be made in cost, convenience, and surgical invasiveness. For example, most infertility workups do not routinely include a sperm penetration (hamster~oocyte) test because of its \$300 price tag and the uncertainty of its importance. Nevertheless, hindsight can sometimes show that the test would have been appropriate and would have saved thousands of dollars and numerous invasive procedures.

More often, cost savings can be gained by grouping procedures together. For example, if a hysteroscopy, hysterosalpingogram, and laparoscopy are all performed at the same time, the cost to the patient will likely be lower than if the hysterosalpingogram is done earlier, in an outpatient setting. Furthermore, an early hysterosalpingogram may indicate no need to proceed with surgical diagnostics. Practices vary among specialists.

To examine the typical costs and procedures faced by an infertile couple, a series of hypothetical scenarios were developed to reflect the course of diagnosis and treatment of common infertility problems (4)12). The scenarios proceed from simple procedures to more complex techniques. A detailed description of the types and cost of possible procedures involved is presented in table 8-1. Table 8-2 summarizes the procedures and costs for each scenario.

Stage I Scenario—Initial Diagnosis and Treatment. Couple seeks treatment for infertility. Full patient histories and physicals are performed; routine tests are done to check hormone levels and sperm quantity and motility. Counseling may be offered to determine whether behavioral changes may be helpful and to inform the couple of options and prognoses. Assume, for purposes of the scenario, that the problem is oligomenorrhea (scanty or infrequent menstruation), a problem found in about 20 percent of infertile women and roughly applicable to women suffering ovulatory problems in general. The treatment prescribed in this stylized version of infertility services is the use of fertility drugs, first with clomiphene citrate, then (assuming that clomiphene citrate is ineffective) with menotropins (human menopausal gonadotropins).

Stage I diagnosis and treatment is estimated to require about 6 to 9 months to complete, yielding a pregnancy rate of about so percent. Thus, if 100 infertile women were to begin this course of treatment, so pregnancies would be expected at the end of Stage I. Total costs of Stage I for the couple are \$3,668.

Stage II Scenario-Comprehensive Infertility Evaluation for Persistent Infertility. This scenario includes the full range of diagnostic tests for nonovulatory causes of infertility, including investigation of infections, hysteroscopy, and cervical mucus tests. Some of the tests may have therapeutic value as well, and thus represent both diagnostic and treatment services. This is especially true for laparoscopy; where feasible and necessary, surgery for endometriosis or adhesions can be performed at the same time a diagnostic laparoscopy is done.

Stage II is likely to require about 1 year to complete, although for many couples less time is required for a diagnosis. This more comprehensive evaluation is likely to pinpoint fertility problems that are less obvious than oligomenorrhea, such as endometriosis, adhesions, sperm antibodies, lu teal phase defects, and others. Once diagnosed, these conditions would receive appropriate treatments. It is estimated that Stage II would have a 30-percent success rate, and would cost \$2,055. If the 70 couples who did not conceive after Stage I continued on to Stage II, at the end of 18 to 21 months (end of Stage II), out of the original 100 infertile women, there would be a total of 51 pregnancies (i.e., 30 plus 0.3 times 70). The total cost of only diagnostics from both Stages I and II is \$2,905 (7,11).

Stage III Scenario—*Tubal Surgery.* The assumption in the Stage III Scenario is that the Stage

Sanvica	Median survey cost	Survey range of costs	Other estimates
		Curvey range of costs	Other Countaico
Diagnostic services:	¢120		<u>ዮ</u> ር ር ስ ^b
	\$120	\$50-415 \$49,429	\$ 60
	\$40 \$100	\$18-138	
Sonography (per exam)	\$100	940-100 ¢25 95	
	\$50	⊕20-00 ¢19.75	\$ 40'
	540	\$10-75	\$ 40
Destenital Indulus.	\$40	¢25 100	\$ 25⁵
Mucus population	\$40	\$25-700	ψ 25
	\$150	\$50-1 500	\$100-300°
	\$100	400 1,000	\$150b
Endometrial biopsy	\$ 8 5	\$50-350	\$100-300°
	\$ 00	000 000	\$100-500 \$100b
Hysteroscopy	\$400	\$130-1 100	\$100b
	\$800	\$400-2 500	\$650-900 [∞]
Samon analysis	\$45	\$15-108	\$25-70 °\$15°
Sperm antibody test	Š75	\$35-300	\$300
	Š275	\$35-390	ŠŽŎŎ°
	Š 75'	\$38-135	\$000
	÷ · · ·	000 100	
Medical treatment:			
Clominhono citrato	\$ 30 per month	\$16-75	\$20/month bc
	\$ 28 per ampule	\$24-38	\$20/month \$40-42 ^{bc}
nmg	\$588 per month	Ψ24-50 \$200 1 500	\$420-504'
	\$300 per month \$20 per 5 000 unite	\$200-1,500	ψ 1 20 301
Danazol	\$160 per month	\$120-200	\$120 °\$135°
Bromocripting		\$30-450	ψ120, ψ100
	\$ 90 per RX	\$1 300-5 000	
Reversal of vasectomies	\$2 000h	\$1,000-2,500	
Tubal surgery forbid	\$2,000	\$750-3.800	\$3,000-6,000'
Repair of varicocele	N/A	N/A	\$2,000-2,500°
Laser lanaroscony	\$1.200	\$485-3.000	\$2,000 2,000
Endometriosis-ablation	\$1.200	\$400-5.000	
In vitro fertilization	\$4.688	\$775-6.200	\$4.000-6.000'
Frozen embryo transfer	\$500	\$220-1.800	
Gamete intrafallopian transfer (GIFT)	\$3,500	\$2,500-6,000	
Artificial insemination			
Husband's sperm			\$3 5-90 '
intracervical	\$53	\$30-105	
intrauterine, washed sperm	\$85	\$40-200	
Donor sperm			\$35-90,°\$25°
fresh	\$80	\$35-150	
frozen	\$100	\$40-350	
donor fee			\$50-100'

Table 8.1.- Estimated Costs of Infertility Services, 1986°

aMedian costs reported by IVF centers contacted in a November 1986 OTA survey, Figures reported are generally on a pertest or per procedure basis, for the first ^aMedian costs reported by IVF centers contacted in a November 1986 OTA survey, Figures reported are generally on a pertest or per procedure basis, for the first in aseries, where a series inapplicable. Forexample, one form of artificial insemination is reported a median cost of \$53. Typically, the \$53 would reflect the initial artificial insemination; subsequent attempts(up to, say, three times per month for 6 months) might be lower in cost. Similarly, only the cost per hormone test is given, although a battery of tests is usually done. Examples of actual costs to patients for a given protocol are provided in the scenarios developed in the next section bG. Cooper, "Th Magnitude and consequences of Intertility in theUnited States," prepared for Resolve, inc. February 1985, and G. Cooper, "An Analysis of the Costs of Infertility Treatments," *American Journal of Public Health* 76:1018-1019, *1988*, Cp. Harris, "WhatifCosts to Fight Infertility" *Money*, December 1984.
^{ch} Counseling Charges are often included in charges for full history and physical.
^{ch} Drug charges only: excludes physician charges.
^{ch} J.H. Bellina and J. Wilson, *You Car? Have a Baby* (New York, NY: Crown Publishers, Inc., 1985)
ⁿ Physician fees only: excludes hospital charges.

SOURCE: Office of Technology Assessment, 1986.

Infertility service		cost
Stage I Scenario-Oligomenorrhea Diagnostics		
Patient history and physical	\$120X2 \$50 per test, battery of 3 run 3X 1 month	\$ 240 \$ 450 \$ 40 \$ 45 \$ 45 \$ 75
Fortility Drug Trootmont	Total	\$ 850
Clomiphene citrate Drug costs	5 days per month \$40X3 \$40x2	\$ 30 \$ 120 \$ 100 \$ 80
	Total	\$ 330 \$1 330
HMG (L month)	X4 monuis	ψ1,000
Drug costs, 5-10 days Blood test run each day Ultrasound	\$28 per ampule X 3 per day X 7 days	\$ 588 \$ 350 \$ 250
HCG	\$40X7	\$20 \$280
	Total Drug treatment total Total, Stage I Scenario (6-9 months)	\$1,488 \$2,818 \$3,668
Stage ii Scenario-Complete infertility Evacuation		¢ 40
Screening for infections . Sonography Cervical mucus Endometrial biopsy . Hysterosalpingogram . Hysteroscopy Laparoscopy (outpatient) (including laser)		\$ 40 \$ 100 \$ 80 \$ 85 \$ 150 \$ 400 \$1,200
Stage III Scenario-Tubal Surgery	Total, Stage II Scenario (12 months)	\$2,055
Tubal surgery (for PID) Physician costs Hospital charges (anesthesia, operating room.		\$2,000
hospital stay) Laparoscopy		\$1,500 \$800 \$2,818
	Total, Stage III Scenario (18 months)	\$7,118
History and physical, counseling Drugs (chemical stimulation) Clomiphene citrate HMG		\$ 150 \$ 638
Ultrasound assessment of follicular growth Hormone blood tests Laparoscopy Physician fees Anesthesia		\$ 500 \$ 425 \$1,500
Operating Room Embryology and embryo transfer		\$1,100
Physician Hospital room		\$ 250 \$ 125
	x 20 cycles	\$4,688
	Total, Stage IV Scenario (6 months)	\$9,376

Table 8-2.—Scenarios of Infertility Diagnosis and Treatment

SOURCE: Office of Technology Assessment, 1988.

II evaluation indicates blocked or damaged tubes. Tubal surgery is then performed on the woman to repair or open blocked or damaged tubes. In the absence of pregnancy following surgery, another laparoscopy may be done and fertility drug treatment may be started again.

Stage III is estimated to last about 18 months and to result in a 30-percent pregnancy rate. If the 49 couples who had not conceived after Stage II had all proceeded to Stage III, about 15 would become pregnant, bringing the total of pregnancies to 66. Total cost of the Stage III scenario is estimated at \$7,118. Total cost for all three scenarios is \$12,841.

Stage IV Scenario–In Vitro Fertilization (IVF). When pregnancy does not result after tubal surgery, IVF may be considered. Only one-third to one-half of the women who make it to this stage are likely to be suited to IVF. If one-third of the remaining 34 couples undertake IVF, and assuming a pregnancy rate in expert hands of 25 percent for IVF, an additional three pregnancies would result among the 11 couples. Total cost of Stage IV, assuming an average of two IVF cycles per couple, is estimated at \$9,376 over 6 months. This estimate assumes retrieval of eggs is done by laparoscopy rather than with ultrasound, and that embryos are not frozen. Total cost for a couple undergoing all four stages is \$22,217.

All four scenarios thus yield a total of 69 pregnancies out of 100 original infertile women. With a 25-percent miscarriage rate, the number of women having successfully completed pregnancies resulting from these scenarios would be about 50.

Although these scenarios are a hypothetical version of the individualized treatment actually offered to patients, they represent most of the procedures commonly used in infertility treatment. Table 8-3 summarizes the scenarios, the associated investments of cost and time, and the resulting expected pregnancy rates.

Significant changes even in these stylized scenarios can be expected over the next several years as technological advances occur. Some of these developments are foreseeable, and some are already being applied in a few centers but have not vet taken hold industry-wide. Embryo freezing, for example, allows IVF to be tried a second, and possibly a third, time without requiring additional ovulation induction and oocyte-retrieval. As embryo freezing develops and becomes more successful, the costs of subsequent treatment cycles could drop by half. In addition, ultrasound rather than laparoscopy is gaining wider use for oocyte retrieval, potentially cutting costs by an additional 30 percent. The diffusion of new technology will take time, however. For example, IVF centers that have invested in developing skills and purchasing equipment used in laparoscopic surgery will not necessarily dispense with that procedure in favor of ultrasound retrieval of eggs.

The most significant change likely to occur may be the frequency with which tubal surgery is

Sconaria	Time	cost	Pregnancy rate	Number of
	Time	0001	iuto	prognanoloc
(after 12 months of unprotected intercourse)				
Stage I-Simple diagnosis and treatment				
of oligomenorrhea	6-9 months	\$3,668	300/0	30
70 couples continue				
Stage 11—Complete infertility evaluation	12 months	\$2,055	300/0	21
49 couples continue				
Stage III—Tubal surgery	18 months	\$ 7,118	30%	15
One-third of remaining 34 couples (11)				
are suited to continue				
Stage IV—in vitro fertilization	6 months	\$9,376	250/o	3
Total	at least 4.5 years	\$22,217	690/o	69

Table 8-3.—Summary of Infertility Diagnosis and Treatment Scenarios

SOURCE: Office of Technology Assessment, 1988.

bypassed in favor of IVF, gamete intrafallopian transfer (GIFT), or for a similar type of technology. To date, in most cases, IVF has been considered a last resort treatment, turned to after tubal surgery has been performed with unsuccessful results or for idiopathic infertility. There are, however, growing indications that IVF is now considered earlier on in the process—in effect collapsing Stages III and IV into a single stage. For

COSTS AND EFFECTIVENESS OF INFERTILITY SERVICES

Data included in this section were collected by OTA from IVF/infertility centers, published infertility cost information, and other sources.

costs

Diagnostic and treatment procedures tend to be slightly more expensive at nonprofit centers. This is most obvious for IVF, where charges may be \$1,000 greater than at for-profit centers. However, this may reflect the relatively more difficult cases that are treated by larger, longer-established, nonprofit IVF centers, or merely higher fees (some of which may support IVF research projects).

The median charges reported to OTA by infertility centers surveyed (see table 8-1) may or may not reflect typical charges for procedures commonly provided by individual gynecologists and urologists who are not infertility specialists or are not associated with an IVF program. (Other data sources, giving figures generally in the same range, are also noted on table 8-1.)

In interpreting the cost data in table 8-1, it is important to recognize that infertility treatment includes an ever-widening array of approaches. The experience of the medical community with regard to proper use and resulting success of this array are far from universal. Although about 20 to 30 of these procedures are commonly used by most infertility specialists, differences exist in methods of application, timing, and experience. These differences are reflected in both costs and pregnancy rates. Thus, on some of the procedures a wide range of costs are reported, and medians are used rather than means. example, should oocyte cryopreservation techniques improve, it may be routine to collect oocytes during diagnostic laparoscopies and store them for possible IVF or GIFT procedures at a later time. This approach further reduces both the cost of infertility treatment and the time involved, which is often of critical importance to couples nearing the end of their childbearing years.

Affordability

A couple proceeding through the four scenarios outlined earlier do not move automatically through each stage. Even at this highly stylized level of analysis, the process is dynamic. At each stage, some couples are successful in achieving pregnancy, while others are unsuccessful and continue on. Still other couples are unsuccessful and drop out, whether for reasons of cost and affordability, the strain on relationships and careers, advancing age, the attractiveness of other options such as adoption or surrogate motherhood, or another reason, As the couple proceeds through these stages of treatment, the chances of pregnancy recede, and the costs escalate.

To what extent are these costs affordable, both for infertile couples and for society? On an individual level, the substantial costs of the four scenarios are beyond the reach of low-income couples and represent a sizable investment for middleincome couples. Table 8-4 provides the basis for assessing the affordability of each scenario for married couples in the United States. For married couples with before-tax incomes under \$20,000, the out-f-pocket costs per stage range from 6 to 62 percent of annual income. For married couples with before-tax incomes ranging from \$20,000 to \$35,000, infertility expenditures represent between 2 and 23 percent of annual income. Finally, for the remaining married couples, those with incomes over \$35,000, costs represent between 1 and 12 percent of annual income. Alternative assumptions about the levels of income and insurance coverage of typical infertile couples would alter the results. These figures apply only

		Percent	t of annual househ	old income
Scenario		Low-income	Middle-income	High-income
Stage 1:		11	4	2
Diagnosis and fertility drug trea Total Cost: Cost to Couple:	tment \$3,668 \$1,100			
Stage II: Complete Evaluation Total Cost: Cost to Couple:	\$2,055 \$617	6	2	1
Stage III: Tubal Surgery Total Cost: Cost to Couple:	\$7,118 \$2,135	21	8	4
Stage IV: In Vitro Fertilization Total Cost: Cost to Couple:	\$9,376 \$6,188	62	23	12
Assumptions: Income profiles of infertile married coup • Low-income group • Middle-income group • High-income group —Insurance coverage: • Assumption all couples have health insur	oles: Median Median Median	income: \$10,000 income: \$27,500 income: \$50,000	Range: \$0 Range: \$2 Range: \$3	-19,999 0,000-34,999 5,000 plus

Table 8-4.—Affordability Analysis for Insured Couples

Assume an couples have nearth insurance coverage.
Assume two-thirds to three-quarters of non-IVF infertility expenditures are reimbursed (i.e., costs to couples = 70 per. cent of total costs).

Assume 66 percent of IVF costs are covered, at rate of 66 percent (i.e., 44 percent of IVF charges are covered by insurance).
SOURCE: Office of Technology Assessment, 1966.

to couples who have health insurance. They underestimate the burden of infertility costs on low- to middle-income couples, many of whom remain uninsured or underinsured.

Are the costs of pregnancies using the current range of infertility treatment services more than society is willing to pay? A recent analysis shows that such costs are roughly in line with average costs of adoption (\$3,000 to \$10,000) and of surrogacy (\$20)000 to \$45)000) (21).

Access to Services

In general, a higher proportion of white women (15 percent) than black women (10 percent) report using infertility services, particularly for women over age 24. Women who had ever been married, who had higher incomes, and who had higher educational levels reported greater use of infertility services than women never married or with low incomes or low levels of education (15,17). Women with primary infertility tend to seek services more than women with secondary infertility (13).

There is evidence that, at least in the 1976-82 period, infertility services were not reaching a considerable number of infertile couples. For example, as of 1982, about 200,000 married women with primary infertility had never sought infertility services although they wanted a baby (13). Another 550,000 married women with secondary infertility had never sought services. This lat - ter group of women, compared with those who have sought services, tended to be of lower socio-economic status, to have less education, and to never have worked (13,18).

With regard to financial barriers to treatment, among the private physicians surveyed by the Alan Guttmacher Institute (AGI) (l), 21 percent reported that they accept Medicaid patients; only 6 percent varied their fees for low-income patients. Among 19 specialized infertility centers, AGI reported that about half accept Medicaid reimbursement and 16 percent reduce their fees for low-income patients, The AGI study concluded that in general, people with adequate financial resources, either their own or insurance with infertility coverage, have no more difficulty obtaining infertility services than they do most other types of medical care. However, infertility services are less available to low-income couples, and low-income women face serious financial obstacles to obtaining specialized or complex infertility services.

Effectiveness

Interpreting effectiveness data in the field of infertility treatment is difficult and controversial. First, and most basically, it can be hard to determine what particular service may have been responsible for a pregnancy. Infertile couples seeking treatments are often told that their chances of success are about 50 percent. Various studies report that 21 to 62 percent of pregnancies of treated and untreated infertile couples appeared to be independent of treatment (5). An in-depth followup study of 1,145 infertile couples found that 41 percent of treated couples had pregnancies, while 35 percent of untreated couples became pregnant (5). One IVF clinic, for example, reported that five women became pregnant while on the waiting list for IVF, When a number of infertility approaches have been used over a relatively short period, it becomes virtually impossible to isolate the procedure that worked, if indeed any procedures were responsible for a subsequent pregnancy.

Effectiveness or success rate data for more traditional infertility treatments have not been as controversial as those for IVF and related approaches, in part, perhaps, because the traditional treatments have not been as closely scrutinized. Alternatively, greater emphasis on success rate and effectiveness data for IVF and related procedures may stem from the current lack of third-party reimbursement for them and the need to establish the procedures as acceptable, nonexperimental medical treatments. Rapid introduction and dissemination of these technologies may also be a contributing factor.

In evaluating the likely success of any particular procedure, there are difficulties in using most effectiveness measures (see chs. 9 and 15). One that is used is numbers of babies, but that figure may include multiple births, which do not reflect, in a sense, the desired outcome of a baby for each couple seeking one. Another measure commonly used is numbers of pregnancies, but definitions of pregnancy vary. A pregnancy may be defined as clinical, preclinical, chemical, viable, or live birth. Some IVF programs report pregnancy rates per patient, per treatment cycle, per laparoscopy, or per embryo transfer (19).

Neither babies born nor pregnancies achieved represent a full measure of effectiveness of infertility treatment. The object of infertility treatment is a safe pregnancy resulting in the live birth of a healthy baby. To the extent that certain infertility services result in increased health risks, either to the woman or to the baby, these risks diminish the "effectiveness" of the procedure. IVF pregnancies, for example, are about two to four times as likely as normal conception to result in an ectopic pregnancy (8,14,21). Other risks include the daily intake of hormones, anesthesia during egg retrieval, stress to the uterus, spontaneous abortion, and multiple pregnancies.

Finally, interpreting success rates on a centerby-center basis is difficult. Some IVF/infertility clinics are research centers; others offer only IVF, in a standard, almost production-line approach. IVF clinics associated with university medical schools and hospitals tend to receive the most difficult cases and claim that their success rates would be higher if they had a group of patients with infertility problems of varying severity. Overall, however, it is worth noting that technologies and experience take substantial time to diffuse industry-wide.

AGGREGATE U.S. EXPENDITURES

Non-IVF Expenditures

Estimates of the total cost of treating infertility in the United States allow measurement of the

amount of societal resources currently devoted to this problem. One report concluded that most couples spend little or nothing for infertility problems although a few spend an extraordinary amount. As a rough estimate the report assumes an average expenditure of \$200 per couple who seek help, yielding a total of \$200 million for 1982. Even if the correct figure were twice as high, the overall estimate for reproduction-related health expenditures would increase by only 1 percent (9).

Another estimate placed aggregate infertility expenditures between \$340 million and \$460 million in 1984, based on a survey of service prices and a construction of the cost of a typical set of infertility treatment procedures (6,7). The cost of each scenario was then multiplied by an estimate of the number of people who used the service, as derived from several sources.

Data derived from an analysis of a national population-based survey, the National Medical Care Utilization and Expenditure Survey (NMCUES), and from the International Classification of Diseases Code yield an estimate of U.S. expenditures of between \$345 million and \$676 million, with \$480 million as the intermediate estimate (21).'

Using the intermediate estimate, table 8-5 reports this sum by type of medical service and source of payment. Table 8-6 breaks down this figure into percentage terms of how these expenditures were distributed by type of service and source of payment. Hospital expenditures, for example, amounted to \$297 million, representing 62 percent of total infertility expenditures. The other major category of services was expenditures on doctors, accounting for \$151 million in 1980, or 31 percent of total infertility expenditures. Close to half that amount (\$70 million) was spent on doctors' charges of over \$300 per visit.

Table 8-6 also shows how a couple's dollar spent on infertility was divided among services. For every household dollar spent on infertility in 1980, more than half (55 percent) went for physician services. Over a third (36 percent) went to hospitals (mostl, for inpatient services), and less than 9 percent was spent on drugs (see figure 8-l).

The picture for expenditures by private insurance companies complements that for households, Private insurers spent 69 percent of their budget on hospital care and 26 percent on physician care. Two-thirds of the expenditures on physicians were for services that cost more than \$300.

The category of "all other sources" includes the amounts paid for infertility services by various government programs, philanthropy, and company clinics. whereas these payment sources play a considerable role in national health care expenditures, they account for less than 10 percent of infertility expenditures, with nearly three-quarters of that amount spent on services provided in hospital outpatient facilities. As indicated in a survey

Type of service	Total charges	Households	Private insurance	All other sources
Hospital.	\$296.9	\$36.7	\$232.8	\$27.4
• Emergency room	1.6	0.6	1.0	0.0
• Outpatient.	65.0	5.4	39.9	27.4
• Inpatient	230.3	30.7	191.9	0.0
Physician service cost	150.6	56.7	87.3	6.6
•\$0-100	43.0	27.3	12.4	3.3
•\$101-300	37.1	20.1	16.7	0.3
•\$301 +	70.5	9.3	58.2	3.0
Other professional	2.6	0.3	1.2	1.1
Drugs	25.5	8.8	15.6	1.1
Other	4.0	0.4	1.5	2.1
Total	\$479.6	\$102.9	\$338.4	\$38.3

Table 8-5.-infertility Expenditures in 1980, by Source of Payment (in millions)^a

a For persons aged 15 t. 44; estimates exclude health care expenditures by the institutional and noncivilian populations and all expenditures for nonprescription drugs,

SOURCE: Office of Technology Assessment, 1988.

IThis analysis employed a version of NMCUES made available by the National Institute on Aging and software developed at ICF Incorporated. The authors identified diseases related to infertility and the expenditures for those conditions. To estimate the percentage of expenditures on each disease that can be considered infertilityrelated, they consulted several additional infertility specialists (4, 12) who provided estimates of the percentage of treatments where concern for infertility was a primary factor in determining treatment, or where it was extremely to quite likely that a patient with the disease would be treated for infertility. They then applied these percentages to NMCUES data on expenditures for each disease.

Type of service	Total charges	Households	Private insurance	All other sources
Hospital.	62.0	35.7	68.8	71.5
Physician	31.4	55.1	25.8	17.2
Other professional.	0.5	0.3	0.4	2.9
Drug	5.3	8.5	4.6	2.9
Other health	0.8	0.4	0,4	5.5
_Total	100.0	100.0	100.0	100.0

Table 8-6.–infertility	/ Expenditures	in	1980, b	уΤ	ype	of	Service	(in	percentages	s)
				-						

aFor persons aged 15 to 44; estimates exclude health care expenditures by thenstitutional and noncivilian populations and all expenditures for nonprescription drugs.

SOURCE: Office of Technology Assessment, 19SS.

Figure 8-1.—Infertility Health Care Dollar: Household Expenditures



Hospital (35.7°/0)

How the infertility y health care dollar spent by households was divided among professionals, hospitals, drugs, and other **serv**ices in 1980. Developed from National Medical Care **Utiliza-tion** and Expenditure Survey.

SOURCE: Office of Technology Assessment, 19S8

of private physicians conducted by the Alan Guttmacher Institute (l), the primary sources of funds in infertility treatment are patient fees and private insurance.

IVF Expenditures

Data about the cost and number of IVF procedures in 1986 were collected from OTA's survey of centers, published estimates, personal communications, and other sources (21)23), OTA estimates that the average cost of IVF was between \$4,000 and \$6,000 (median \$4,688; see table 8-1), OTA estimates that approximately 14,000 completed IVF cycles were performed in 1987 in the United States. (One estimate places the number of IVF cycles at 21,000 (24).) At a median cost of \$4,688 per cycle, this represents a total expenditure on IVF of \$66 million in 1987.

Total Expenditures

OTA estimates the total 1987 expenditures on infertility as the sum of the non-IVF and IVF expenditures. To reach a figure for the former, the estimate of 1980 non-IVF expenditures is inflated by 10 percent each year to reflect changes in the cost of medical care and in the incidence of infertility diagnosis and treatment. This raises the 1980 estimate of \$480 million to about \$935 million in 1987. Together with IVF expenditures of \$66 million, total infertility expenditures in 1987 are therefore estimated at \$1.0 billion.

This approach assumes that the treatment of infertility has not changed '(structurally" (e.g., in the relative expenditures on hospital services v. doctors) since 1980. It also assumes that IVF does not replace previous treatments, but represents a new, supplemental cost.

THIRD-PARTY REIMBURSEMENT

Conventional infertility treatment services may be covered by insurance, as long as they can be associated with medical conditions or diseases **re**quiring diagnosis and/or treatment and not solely related to infertility and fertilization. However, this coverage is specific to each insurance plan, varying among underwriters, group policy **pur**chasers, and geographic location (10). Of total U.S. **non-IVF** infertility expenditures (estimated in the previous section as \$480 **million** in 1980), private insurance paid 70 percent and individuals paid 22 percent out-of-pocket, with the remainder paid by other sources.

While individuals paid 12 percent of hospital costs related to infertility, they paid 38 percent of physician charges. As would be expected, individuals paid a larger share (64 percent) of physician charges under \$101 than of charges over \$300 (13 percent).

In 1986, some 2.3 million organizations in the United States had health care plans, and 176,424 of these (8 percent) were reportedly self-funded (10,16). There are currently no comprehensive data available that detail the number of these third-party plans providing infertility coverage or the extent of this coverage. However, several general comments can be made about the provisions of these programs that can be applied to infertility coverage.

Examination of third-party reimbursement for infertility services must take into account that the technology applied to these services and to medical treatment in general is changing rapidly, as is the structure of third-party reimbursement, and that both of these trends can evoke a variety of responses. In the case of technology, for example, IVF, which was initially introduced to the United States in 1981, is still considered by many third-party payers to be "experimental" and therefore not insurable. At the same time, however, some carriers provide largely routine coverage for IVF, a rather remarkable development in such a short time (22).

With respect to the structure of third-party reimbursement, there has been a dramatic shift away from traditional group health insurance (Blue Cross/Blue Shield) and commercial insurance), which accounted for roughly 95 percent of the total as recently as 1980; some forecasts indicate that these traditional insurance plans may account for as little as 5 percent by 1990. Much of the shift is to health maintenance organizations (HMOS) and to preferred provider organizations, which did not even exist in 1980. As much as 25 percent of the total by 1990 maybe under '(managed care" plans, also a creature of the 1980s.

In general, most of these health care plans offer benefits that are a standard package of hospital, surgical, and medical services, with or without major medical or comprehensive provisions. Once these basic provisions are met, the insurer will normally be willing to tailor provisions to the tastes of the buyer. This tailoring may apply, for example, to combinations of deductibles and copayments, specific exclusions, and special additions to normal coverage. The most important variable here is typically the availability of premium dollars, since most group plans are experiencerated.

Given the fact that cost containment has been the dominant theme of both health insurers and employers during the 1980s, there is reason to believe that many group health plans may have chosen to restrict coverage for certain "fringe" services, of which infertility treatment is an example. Since many people still have a variety of moral and ethical concerns in reference to some infertility services, restrictions based on the source of eggs and semen (i.e., spouse versus donors) will undoubtedly continue to appear in some plans for years ahead.

Recent Developments in Insurance

Delaware

In Delaware, a statewide program was instituted by its Blue Cross/Blue Shield Association in response to a nearly successful attempt to have coverage mandated by the State. Since January 1, 1987, employees of the State of Delaware have been covered for IVF and employees of midsize firms (300 to 500 employees) have been offered coverage as a rider (21). Large employers have the option to purchase IVF coverage as their contracts are renewed throughout the year,

Delaware Blue Cross/Blue Shield does not require patients to undergo a minimum waiting period, although all other means, with the exception of tubal surgery, must be tried by the patient. The actuaries anticipate that some of the IVF costs will be offset by a reduction in the use of tubal surgery. Although no restrictions apply **to the** number of cycles a person may attempt or the cost per cycle, a lifetime maximum of \$25)000 will be paid; for artificial insemination, the lifetime limit is \$600, although either donor or spousal sperm will be covered. Surgical procedures, including tubal reconstruction, are covered if medically necessary, but not simply to reverse previous contraceptive sterilization. Delaware Blue Cross/Blue Shield routinely covers surgical sterilization without medical necessity, on request (10). Company actuaries estimate that 90 to 95 percent of costs per cycle will be reimbursed by the insurance plan. The cost of insurance is about \$0.60/person/month.

Maryland

In Maryland, the State has mandated coverage of infertility treatments. However, this mandate does not require coverage for artificial insemination, a treatment that normally precedes IVF, but Blue Cross/Blue Shield added this to its policy to assure that this less costly procedure would be attempted before IVF (10). Aside from the mandated IVF benefit, the standard Blue Cross/Blue Shield contracts in Maryland cover all other infertility services on the same basis as other medical procedures. If the group contract provides for diagnostic services (which 90 percent of their contracts do) or drug coverage (75 percent of basic contracts and 95 percent of major medical contracts do), they are covered in the same manner for infertility services as for any other. Similarly, the same rules apply for deductibles (usually \$100 t. \$200), coinsurance on major medical (normally 80 percent), and out-of-pocket limits on major medical expenses. About half the policies have such a limit, usually in the \$2,500 range (10).

Attempts by the insurance industry in Maryland to limit coverage to five IVF cycles were defeated, and in 1985 insurance plans were required to offer benefits for IVF at the same level as benefits for other pregnancy related procedures [Maryland Insurance Code Sees. 354DD, 470WW, 477EE, 1987]. This coverage extends to the insured and the insured's spouse. At the same time, some important restrictions on coverage were put in place:

- The couple seeking IVF treatment must be using their own gametes.
- The person seeking IVF treatment must have been seeking infertility treatment for at least 5 years, or the infertility must be associated with one or more of the following conditions:

endometriosis, exposure to diethylstilbestrol, or blockage or surgical removal of one or both fallopian tubes (it is not clear whether reversal of voluntary sterilization would be covered); however, IVF benefits for couples with male-factor only infertility are not covered.

- The person seeking IVF treatment must have exhausted all non-IVF treatments covered under the insurance plan.
- Only outpatient services are covered.
- The IVF procedures must be performed at a facility that conforms to the American College of Obstetricians and Gynecologists (ACOG) guidelines for IVF clinics or the American Fertility Society's (AFS) minimal standards for IVF programs.

Although the State mandated coverage by all insurance carriers, not everyone in Maryland is, in fact, covered. Since the State has no jurisdiction over Federal or municipal employees, the legislation does not apply to them. Consequently, neither Federal employees working or residing in Maryland nor employees of the City of Bahimore are covered, Furthermore, the mandate does not apply to groups that are self-insured. Many, if not most, organizations with 500 or more employees have Administrative Services Only contractual arrangements with an insurance carrier, whereby the insurer provides only administrative services and the benefits are self -insured. As a result, most employees of large organizations in Maryland may not be covered for IVF. In addition, Maryland's mandate to provide insurance coverage for IVF does not apply to its Medicaid program. The current cost charged by Blue Cross/Blue Shield in Maryland averages \$1.06/household/month, and the company anticipates that 75 to 80 percent of IVF expenses will be reimbursed by the plan.

Hawaii

Hawaii's legislation (Act 332, 1987), effective June 26, 1987, states that all individual and group health insurance plans that provide pregnancyrelated benefits must provide, in addition to any other benefits for treating infertility, a one-timeonly benefit for the outpatient expenses resulting from IVF for the insured or the insured's spouse. The one-time~only benefit is considered one IVF cycle. Restrictions on eligibility do not differ from those in Maryland except that abnormal male factor contributing to the infertility is also considered an indication for IVF treatment.

Texas

In Texas, legislation effective September 1, 1987 (Act HB 843, 1987), requires that all insurers or administrators of group health insurance policies, self-insured plans, and all health maintenance organizations must offer benefits for IVF in all plans that have maternity benefits. The policyholder does not have to accept these benefits. The benefits must be provided to the same extent as benefits provided for other pregnancy-related procedures under the policy. Only an insurer affiliated with a bona fide religious denomination that objects to IVF for moral reasons is exempt from the requirement to offer coverage for IVF. The restrictions on eligibility in Texas, like those in Hawaii, state that oligospermia is also an indication for treatment.

Arkansas

Arkansas legislation in 1987 (Act 779, 1987) directed the Insurance Commissioner to issue regulations setting benefit levels for IVF coverage. The regulations, effective December 31, 1987 [Regulation No. 1 (Nov. 18, 1987) pursuant to Act 779 (1987)], require that insurance policies offering maternity benefits offer IVF benefits as well, at the same level as those for maternity. Restrictions are basically the same as those in Hawaii except that the couple need only have a 2-year history of unexplained infertility, and a woman who has been voluntarily sterilized is explicitly ineligible. Cryopreservation is specifically included as an IVF procedure. The IVF must be performed in a Statelicensed or certified facility, with the Department of Health in charge of licensing and certifying. However, if no such facility is licensed or certified in Arkansas or no such licensing program is operational, then coverage shall be extended for any procedures performed at a facility that conforms to the ACOG guidelines for IVF clinics or to the AFS minimal standards for programs of IVF. Finally, a lifetime maximum benefit is set at \$15,000, which may also include other infertility treatments.

Massachusetts

Legislation in Massachusetts is more extensive than in the other States. In 1987, the Commonwealth of Massachusetts enacted legislation requiring that insurance plans covering pregnancyrelated benefits provide coverage for medically necessary expenses of diagnosis and treatment of infertility to the same extent that benefits are provided for other pregnancy-related procedures (Act H 3721, 1987). Infertility was defined as "the condition of a presumably healthy individual who is unable to conceive or produce a conception during a period of one year. " The resulting regulation on infertility benefits promulgated by the Division of Insurance outlined these benefits in more detail [211 C.M.R. 37.01 to 37.11, pursuant to Mass. Gen. Law chs. 175 and 176 (1987)]. Both the legislation and the regulations went into effect January 6, 1988.

Under the new regulations, insurers must provide benefits for all nonexperimental infertility procedures. These include, but are not limited to, artificial insemination, IVF, and other procedures recognized as generally accepted or nonexperimental by the AFS, ACOG, or another infertility expert recognized as such by the Commissioner of Insurance. Gamete intrafallopian transfer is considered experimental, and surrogacy, reversal of voluntary sterilization, and procuring donor eggs or sperm are specifically excluded. The insurers may establish reasonable eligibility requirements that must be available to the insured and the Commissioner upon request. The regulations suggest that standards or guidelines developed by AFS or ACOG may serve as eligibility requirements.

Private Insurers

The Prudential medical insurance programs recognize infertility as an illness, and routinely cover virtually all related services, including artificial insemination (restricted to only husband and wife, no donors or surrogates) and IVF, so long as the services conform to ACOG standards and are determined to be medically necessary. Drugs, such as clomiphene citrate and human menopausal gonadotropin, are covered, dependent on the plan (i.e., whether drugs are covered for other purposes). Deductibles, copayments, and out-ofpocket limits are the same for IVF as for all other covered services (10).

A number of insurance company representatives contacted specifically noted, however, that even under plans where no IVF or other infertility coverage exists or is intended, many if not most individual procedures can individually "slip by the screens." If claims for services are submitted by a physician as "medically necessary" and the word "infertility" does not specifically appear, coverage is more likely to result (10).

Future Developments

Future developments for third-party reimbursements are difficult to predict because of the changing structure of the health care delivery systems as well as the rapid development of innovative technologies. However, some general trends may be predicted:

- Greater movement by all types of insurers toward requiring preauthorization for an increasing number of services, second opinions for elective surgery, and a variety of other controls that do not deny coverage, but that tend to control utilization. Although many of these techniques originated in the context of "managed care" situations, they are now being adopted in virtually all settings.
- Lifetime limits and limited cycles of treatment in a given time period applied to some infertility treatments, and selective coinsurance applied to others.
- A growing proportion of infertility services being performed on an ambulatory basis, driven in that direction both by the pressure generated by these selective insurance provisions and, quite independently, by rapid changes in medical technology (10). As some of the more expensive infertility treatments grow in acceptance (because they are better known, clinically proven, and no longer experimental) and demand (because they will increasingly be covered), more infertile couples will be shielded by out-of-pocket limits.
- An increased number of States mandating infertility coverage (see table 8-7) (10,2 o).

The demand for health services, both in the United States and around the world, has always

Table 8-7.–Status	s of	Insurance	Coverage	for	Infertility
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	Legislation	Legislative	No legislation
State/jurisdiiction	exists	activity	on infertility
Alabama	· · · · · · · · · · ·		x
Alaska			Х
Arizona	• • • • • • • • • •		Х
Arkansas	х		
California		х	
Colorado			Х
Connecticut		Х	
Delaware		х	
District of Columbia			х
Florida			х
Georgia			X°
Hawaii	x		
Idaho			х
Illinois			х
Indiana			х
lowa			х
Kansas			х
Kentucky.			x
Louisiana			x
Maine			x
Marvland	X		
Massachusetts	х		
Michigan			x
Minnesota			x
Mississippi			x
Missouri			x
Montana			x
Nebraska			x
Nevada			x
New Hampshire			×
New Jersey			×
New Mexico			×
New York			×
North Carolina			×
North Dakota			×
			×
Oklahama			×
Oragon			X
Poppsylvania			×
Puorto Pigo			X
			X
			X
			X
			X
			X
I exas	X	• • • • • • • • •	
Utah			Х
vermont			X
			Х
Washington		X	
West Virginia			X
Wisconsin.		X	
Wyoming	<u> </u>		x
^a However, the Georgia insuran	ce department r	outinely require	sal insurance car-

"However, includorgia insurance department fourinety requires an insurance carriers to cover infertility treatment except for experimental procedures, and IVF is currently considered experimental (R. Terry, Chief Deputy Commissioner, Regulatory Law Division, Office of Commissioner of Insurance, Atlanta, GA, personal communication, September 1987),

SOURCE: Office of Technology Assessment, 1988.

been significantly influenced by the level of thirdparty reimbursement. Thus, assuming that most infertility services are eligible for at least some level of coverage, and that the overall level of reimbursement improves, demand can be expected to increase. When this will occur is difficult to predict. There is generally a timelag between the inproduction of new coverage and the increase in demand. This is explained by the learning curve of consumers and providers of care, who do not immediately perceive the change and therefore require some time before altering their behavior. Another factor that may contribute to an increase in demand is improvement in expected results (i.e., technology. This maybe a particularly important factor in relation to infertility services.

With the advent of IVF, gamete intrafallopian transfer, and other new reproductive technologies, the issue of insurance coverage has become more controversial and more influential in determining what types of treatment are sought and provided.

A major concern of insurers is to protect themselves from covering risks where the likelihood of the event occurring can be influenced by the insured party. This concern is generally referred to as moral hazard. Insurers who underwrite such risks could be subject to adverse selection. In their quest for a "fair bet," insurers will often pass up an insurable risk when they think they cannot at reasonable cost protect themselves from adverse selection. Insurance markets can fail altogether if insurers think they are buying a risk but are in fact buying a certainty.

Even if they can arrange a fair risk, insurers do not want the amount at which they are at risk to be extremely large. Furthermore, they prefer to insure events where the likelihood of the event occurring is known rather than uncertain. Finally, health insurers try to avoid covering procedures that have not met with general approval and that may be difficult to sell to policyholders. Examples include costly experimental procedures the efficacy of which has not yet been proved and procedures for which a societal consensus has not yet developed.

Coverage of IVF procedures poses several problems for insurers. First, IVF belongs to a class of risks where the purchasers of insurance may have better information than the insurer at the time of purchase regarding the likelihood that they will need the procedure. Using the same reasoning, insurers resisted coverage of pregnancy for a long time. They considered having a child to be a choice, not an unforeseen event, and believed that couples wishing to have a child should, therefore, simply save for that event, Unless all insurers provided pregnancy benefits (or IVF benefits), an insurer might fear that persons knowing in advance that they wanted children or needed IVF would sign up for that company's insurance.

In addition, the potentially high cost of IVF combined with a perception of low success makes it difficult to sell premium increases to policyholders. That IVF is perceived to be a procedure of uncertain benefit to a few at the expense of many has served to further deter insurers from entering this market.

When insurers do undertake to insure events where adverse selection is likely, where the possible losses are high or the risks not well known, or where it may be difficult to sell the need for the procedure to large employer/employee groups, they try to institute mechanisms to protect themselves. When this is not yet reasonably possible and, for reasons of social policy, it is desirable to protect certain individuals, then the risks are often borne by society as a whole through social insurance schemes (e.g., Medicare and Medicaid).

The majority of health insurance plans and health maintenance organizations exclude specific coverage for IVF (22). Typical is the language used by Blue Cross/Blue Shield in its coverage of Federal employees under the Federal Employee Health Benefits Program (FEHBP) (see figure 8-2). These programs state that they exclude from coverage artificial insemination by donor, IVF, and reversals of sterilization (10)21).

However, even though the majority of providers exclude IVF, this coverage may be increasing. A recent survey conducted by the Health Insurance Association of America of its 20 largest companies plus a random sample of 80 other members produced rather surprising results (22). While large companies were more likely than small companies to provide IVF benefits, there was little difference between coverage in group versus individual policies. On a weighted basis, an estimated 41 percent of those covered under group policies and 40 percent of those coverage for at least most of the services associated with IVF, though a variety of restrictions exist, particularly with respect Figure 8-2.-Typical Language Describing Health Care Benefits Related to IVF and Artificial Insemination



SOURCE: Office of Technology Assessment, 1968.

to the source of egg and sperm. These figures are based on a question that referred to '(typical" group and individual policies.

In a followup question, virtually all of the large and none of the small insurers who did not provide for IVF in their most typical policy did make the option available under other policies upon request for the benefit by the policyholder. The most common reason for not covering IVF under both group and individual contracts was that "it is not the treatment of an illness." The next most common reason given was that "it is still an experimental treatment. " Claims evaluation is done on a case-by-case basis, with no standard practice identified by most carriers (10). Despite the continued exclusion of IVF from coverage by a majority of insurers, OTA estimates that for the current patient population, insurance coverage is actually considerable for many aspects of the IVF workup and treatment procedures. If insurance claims for each of the individual diagnostic and treatment components of IVF are submitted separately, then the cost of the components may be reimbursed. One center reported that laparoscopies performed as part of an IVF procedure were covered by insurance at a reimbursement level that averaged 70 percent (21).

THE COST OF INSURANCE

As mentioned earlier, the extra cost of IVF coverage has been estimated by actuaries at Blue Cross/Blue Shield to range from \$1 .06/household/ month in Maryland to \$0.60/person/month in Delaware. It is important to recognize that these are short-term estimates. They have not been developed using estimates and projections of the incidence and prevalence of infertility or an estimate of the likely demand for IVF. They are based on the number of IVF services currently available and upon the assumption that every one of the currently available services will be used.

For example, actuaries for Maryland Blue Cross/ Blue Shield surveyed the IVF clinics in and near Maryland and found that the potential treatment capacity for these clinics in 1985 was 800 women per year, and that the average cost per patient would be \$12,800 based on three treatment cy cles per patient, with varying degrees of success. The total cost for all 800 women treated in or near Maryland would therefore be about \$10.2 million; it was assumed that Blue Cross/Blue Shield of Maryland would be responsible for about half the amount, or \$5.1 million. They then assumed that capacity would grow by 33 percent in 1986, so that the estimated total cost to them in 1986 would be 1.33 times \$5.1 million. or about \$7 million. Distributing this sum over the 550,000 households that would be insured for this coverage yielded the rate of \$1.06/household/month (21).

Where the demand for services is unknown, the supply of services is well known, and demand is thought to greatly exceed supply, near-term estimates based upon supply alone are reasonable and guite accurate. The estimation by Maryland Blue Cross/Blue Shield actuaries was done in June 1985. As of December 1, 1986, about 300 patients had applied for reimbursements of IVF expenses. Given the lag both in starting the program and in reporting by patients, it appears that the estimate of patient utilization was accurate. Unknown at this point is whether the estimates of the number of treatments per patient or the cost per treatment were close. Finally, Blue Cross/Blue Shield built into its rates a margin of error of at least 20 percent. They estimate that, after deductibles and coinsurance, they will only reimburse about 80 percent of charges.

Estimates of long-term or equilibrium costs of IVF coverage will have to be based on experience with the need and demand for services, and especially with the effect insurance will have on such demand. This will require a close look at the incidence of infertility, especially the kind for which IVF is a preferred procedure; at the cost structure of the industry that underlies the supply price; at the availability and demand for substitute procedures; and at the effect of insurance on the demand for IVF and non-IVF services.

Public programs

Coverage for infertility services by Medicaid varies among State programs. In the Federal Medicaid program many infertility services can be covered under the "family planning services" category. Many State programs will pay for drugs, counseling, and surgical procedures, including sterilization reversals if deemed medically necessary.

At present, no Federal Government programs cover IVF procedures, Furthermore, no Government health facility, such as those operated by the Department of Defense or the Veterans' Administration, has been identified that provides IVF services. However, just as the commercial insurance industry appears to be paying for some portion of the IVF expense even when its policies explicitly exclude such procedures, Government reimbursement programs may be paying for some of these benefits as well.

Although the Federal Medicaid program does not restrict State provision of IVF procedures (10,2 I), OTA has not identified any State program that has paid out IVF benefits. However, the District of Columbia, which appears to have the most liberal medical coverage in the country, may be an exception. It reported that it covers all types of infertility services. Though it had not received any requests for IVF, if they do come, it would "probably pay them" (10).

As with private insurers, it is likely that some IVF component services are inadvertently paid by most Medicaid plans. This "leakage" is far less likely to occur under HMOS and "managed care" plans. For the unwitting reimbursement of IVF charges by insurance carriers to occur, however, patients must have sufficient resources to pay the clinic and await reimbursement. This is a possibility for persons covered by private insurance and the Civilian Health and Medical Program of the Uniformed Services, but Medicaid beneficiaries are unlikely to have such resources. Therefore, it is unlikely that most Medicaid programs cover IVF benefits directly, although there may be partial coverage of various components of the IVF workup, such as ovulation induction or laparoscopy.

Federal Employee Health Benefits Program

The approximately 3 million current civilian employees of the Federal Government are covered by 435 different health plans nationwide. Although some smaller local health plans may provide IVF coverage, the U.S. Government Office of the Actuary could not readily identify any (21). As mentioned, the large nationwide plans serving Federal employees, such as Aetna and Blue Cross/Blue Shield, specifically exclude IVF, reversals of sterilization, and artificial insemination (21). Despite these specific exclusions, these plans may be providing some reimbursement for IVF components, as described earlier. HMOS, on the other hand, are more able to control patient utilization of infertility services and are therefore less likely to reimburse IVF-related charges.

The cost of extending insurance coverage for IVF to Federal civilian employees can be roughly estimated. There are about 690)000 female employees of the Federal Government between the ages of 15 and 44, and 1,2 million male employees aged 20 to 49. Some 52 percent of females between 15 and 44 are married (21), If this percentage holds for Federal employees as well, then about 360,000 female employees are married. If half the male Federal employees are married to women between 15 and 44, then there are 600,000 women between 15 and 44 married to male Federal employees, Altogether, that yields 960,000 couples with female partners between the ages of 15 and 44 potentially eligible for Federal insurance coverage (assuming for the sake of these rough estimates that Federal employees are not married to each other).

Assuming that 8.5 percent of married women between 15 and 44 were part of an infertile couple, and applying that rate to women covered by Federal plans, then 81,600 of these couples would be infertile. on average, approximately 31 percent of infertile couples seek infertility treatment (13). This would suggest that about 25,000 infertile couples who are eligible for Federal employees insurance coverage seek infertility treatment. OTA estimates that at the present level of pracIf the average cost of IVF treatments is between \$4,000 and \$6,000 per treatment cycle (see table

IVF/INFERTILITY CENTERS

This section provides a more detailed profile of IVF/infertility centers, focusing on their operations and the characteristics of the market in which they operate (21). Profile characteristics discussed include the organizational status of the clinics (nonprofit or for-profit), their size and age, funding sources, types of services offered, demand for services, barriers to entry, and future trends. In general, IVF/infertility facilities are well distributed geographically and evenly split between profit and nonprofit operations (see app. A). Most offer a variety of infertility services and are not limited to IVF.

General Operating Characteristics

OTA has identified 169 IVF/infertility centers in the United States as of early 1988. Most of these are listed with the American Fertility Society as offering IVF (2). However, it is estimated that only 80 to 90 of these centers are established facilities with particularly active programs (14). IVF/infertility centers are located in 41 States, the District of Columbia, and Puerto Rico; only five States have 10 or more centers (California with 22, Florida with 10, New York with 11, Ohio with 10, and Texas with 14).

Although the centers are fairly well distributed around the country, it should be noted that even on a State-by-State basis, infertile couples seeking services in nine States must travel elsewhere for treatment (see figure 8-3).

Most, though not an overwhelming majority, of IVF/infertility centers in the United States are nonprofit, The predominant organizational arrangement is a nonprofit infertility center that is part of a nonprofit university or hospital. The remaining centers include independent, for-profit out8-1), with on average two treatment cycles per patient, the current cost per patient is between \$8,000 and \$12,000. For the 2,783 women covered by FEHBP, the total expenditure for IVF would 'be \$22 million to \$33 'million.

fits and for-profit centers affiliated with a nonprofit institution (such as hospitals or universities).

Most IVF/infertility centers are relatively small, rarely exceeding 20 staff. Typically, the staff includes:

- one or two physicians specializing in reproductive endocrinology,
- one doctorate-level scientist (reproductive biologist),
- •two to four registered nurses,
- one to six technicians, and
- one psychologist or counselor (see box 8-A).

Type of Services Offered

These centers generally offered a variety of services in addition to IVF, including microsurgery. A growing number also offer alternative reproductive technologies such as gamete intrafallopian transfer and tubal ovum transfer. Yet a small but increasing number offer only IVF.

Some IVF/infertility centers have restrictive policies as to the types of patients they will serve. These policies include not serving individuals without partners, treating only married couples, age restrictions (no services to those under ages 17 to 20 or over ages 39 to 50), and restrictions on treatments of homosexuals. No pattern of restrictions related to the organizational status of the clinics appears present.

Most centers offer a variety of the well-established infertility diagnostic and treatment services. The only major exception is male microsurgery and artificial insemination. As expected, many IVF clinics appear to be much more oriented toward female microsurgery and treatment than treatment of male infertility.



Figure 8-3.—Distribution of IVF/infertility Centers in the United States

SOURCE: Office of Technology Assessment, 1988.

A second item of interest is that many facilities do not yet offer the latest techniques and advances in infertility treatment (such as embryo freezing, laser laparoscopy, or even frozen donor sperm for artificial insemination). The lag time for diffusion of new technology appears to be on the order of at least 2 years.

Funding Sources

Patient fees account for the largest source of funds for the IVF clinics, in general making up 80 to 100 percent of revenues. Aside from a small number of IVF/infertility clinic that treat many Medicaid patients, most programs receive less than 10 percent of total funding from Medicaid funds. other sources of funding for IVF centers include university subsidies and private research grants.

Demand for Services

The majority of IVF programs in the United States have a waiting list of patients. Although the older, more established programs can have waiting lists as long as 1 to 2 years, this is not the case with the smaller, recently started programs.

IVF/infertility centers receive a small amount of referrals from hospitals. A major source of patients for most IVF clinics is referrals from physicians. But referrals from other patients or selfreferrals by patients appear to be equally, if not more, important for IVF clinics,

As the demand for infertility services has grown, some couples with diagnosed or suspected infertility problems may place themselves on one or more IVF center waiting lists even before other

Box 8-A.-Integrating Psychological and Medical Treatment

Many couples surveyed at infertility clinics say they wished they had been offered psychological counseling during their treatment. Issues identified by infertile people as a potential focus for counseling include problems in the marital relationship, sexual dissatisfaction, crisis reactions, anxiety surrounding efforts to achieve a pregnancy, and alternative solutions to involuntary childlessness.

There are at least four ways that infertility clinics try to meet the psychological needs of their patients. Most common is to rely upon professional medical staff to be sensitive to the emotional stress of infertility diagnosis and treatment. Others use a consultant on a case-by-case basis. The consultant is alerted by medical staff when an individual or a couple exhibits emotional distress, particularly if their anxiety is interfering with the successful outcome of treatment.

Some clinics have a professional counselor on their staff. Usually this person's responsibilities involve meeting with each individual or couple on their first visit to orient them to the clinic services. At this time the professional also may make an effort to alert patients to the potential emotional strains of the diagnosis and treatment experience. Community resources are often mentioned at this time, particularly any nearby support groups of infertile people who meet on a regular basis.

Still other clinics have adopted a preventive mental health approach, in which each individual meets with the counseling professional on the first visit, both as a way of learning what to expect from the clinic, to explore his or her present emotional state, and to help develop acceptance of the stress infertility and its treatment can cause. The professional then offers ways to cope with the emotional distress for clinic patients, including regular visits with all patients, short-term counseling for particularly stressful times, referrals to community professionals for long-term counseling, and an invitation to join a support group of infertile patients conducted by the professional in the clinic. The professional may make daily visits to the surgical ward of the hospital, both to discuss patient apprehensions prior to surgery and to offer support and advocacy during a hospital stay.

Some infertile people may choose to decline these various offers of psychological counseling. Clinicbased counseling may be inconvenient if the patients live far from the site or visit it infrequently. Some may be reluctant to place in clinic records any information that may influence judgments about their acceptability as candidates for medical or surgical treatments, or for noncoital techniques for achieving pregnancy. Others may find the clinic staff insensitive, or feel that even well-meant offers of counseling are nonetheless unnecessary or intrusive. They may not care for this type of professional counseling, and prefer to seek help from family, friends, support groups, or outside professional counselors.

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non-IVF infertility treatments have been attempted. The extent of this practice is unknown. Despite the waiting lists, there also appears to be a growing amount of competition among IVF centers located in large metropolitan areas or among programs within the same general geographical area. Competition may increase as the number and efficacy of the infertility treatments improve.

Opening Up New Centers

To what extent is it difficult for infertility clinics to expand into the market for IVF services? Most IVF clinics begin as adjuncts to departments of obstetrics and gynecology that have been involved in infertility services for years and want to include this new technology. Although IVF requires a good deal of specialty equipment and labor, much of each is generally available in most hospitals. As a result, IVF clinics can often begin operation without equipment and labor specifically dedicated to IVF, as indicated by the wide range in the number of IVF cycles conducted around the country. Although the large, well-known clinics operate at the level of 800 to 1,000 treatment cycles per year, some programs perform fewer than 50.

The coexistence of clinics doing 50 and 800 cycles per year indicates the ease with which a viable clinic can be organized and run from an existing medical facility. The major items of equipment required for ovum preparation and embryo trans - fer include an incubator, high-purity water system, autoclave, and low temperature freezer to freeze embryos. The cost of purchasing this equipment has been estimated as in the neighborhood of \$40,000 to \$60,000 (21), although the actual cost may be as high as \$100,000 (14).

The remainder of equipment needed, such as microscopes, video camera and monitor for the laparoscope, and all the hospital and surgical equipment, is generally priced internally so that little of the cost is passed on to the IVF facility. In addition, the services of technicians and an embryologist can generally be found in the hospital, so these specialty labor costs can also be priced at the margin, Finally, an expanding obstetrics/ gynecology facility will not have to incur the expense of waiting and examining rooms. Thus if demand increases substantially due to wider insurance coverage of IVF, enhanced effectiveness of IVF, or a change in the public's perception of the cost and effectiveness of IVF, supply can be expected to increase to meet the new demand without necessarily encountering bottlenecks.

Future Trends

New developments in infertility diagnosis and treatment have the potential to revolutionize the way services are demanded and offered. A number of trends in particular could significantly affect the estimates developed in this section.

Charges for IVF and other infertility treatments can be expected to continue to increase in the next few years. In addition to the rise in fees associated with increases in all health care, some increases will result from the raising of fees as individual programs become more established and accomplished with the various techniques. Neither competition among facilities nor increased success rates for procedures such as GIFT and IVF are likely to reduce infertility costs drastically in the near future.

The majority of IVF/infertility centers will continue to introduce new procedures to their practices in the near future. In particular, many centers intend to expand into embryo freezing, the cryo preservation of oocytes, and the use of donor oocytes and embryos in IVF for women unable to produce eggs. Other techniques that are offered at some clinics but that have not yet been disseminated throughout the industry include laser laparoscopy, GIFT, intrauterine insemination, surrogate pregnancies, artificial insemination with frozen donor semen, artificial insemination with sex selection, and ultrasound-guided vaginal oocyte retrieval.

Other areas of likely expansion for IVF/infertility centers include andrologic diagnosis and treatment, immunologic studies, embryo transfer, estrogen replacement therapy, gamete manipulation, hormone evaluation and treatment correlation, and possible changes in the fertility drug stimulation regime for IVF and GIFT.

Most IVF/infertility centers agree that changes in third-party reimbursement policy would affect the number of patients seeking infertility services, Expanded insurance coverage of IVF and GIFT services could have a significant impact on the demand for these services. Couples who cannot currently afford IVF or GIFT, or who cannot afford more than one cycle, would be able to undergo the procedures. This expanded group would include both couples who are now "doing nothing" in the absence of IVF as well as women who are currently undergoing tubal surgery in lieu of IVF or GIFT. Making IVF or GIFT insurance-reimbursable could in some instances replace low-yield surgical procedures that are currently reimbursed.

SUMMARY AND CONCLUSIONS

Over the last decade infertility services have grown in scope and sophistication. The demand for infertility services has increased as well, to a point where between 300,000 and 1 million coupies in the United States seek infertility treatment services annually. Overall, doctors report that half the infertile couples who seek treatment are able to have a baby. An examination of U.S. expenditures on infertility treatment produced the following key findings:

• Access to infertility treatment. For the initial medical consultation on an infertility problem, couples are most likely to seek the advice of their gynecologist, general practitioner, or urologist. Most gynecologists and urologists can provide at least basic infertility diagnostic and treatment services. For problems serious enough for referral to an infertility specialist, access to specialized care is likely to be reduced. Sophisticated infertility care is generally located in urban areas. Procedures for more difficult infertility cases are more likely to be available at universities and medical centers,

Access to highly specialized infertility treatment, in addition to being geographically determined, is also a function of cost and insurance coverage for many procedures. In general, people with adequate financial resources, either their own or insurance with infertility coverage, have no more difficulty obtaining infertility services than they do most other types of medical care; however, infertility services are less available to lowincome couples, and low-income women face serious financial obstacles to obtaining specialized or complex infertility services.

• Choices of reproductive services. Infertility treatment represents only one of a number of options for achieving parenthood. Other options that are weighed by infertile couples side by side with medical treatment include adoption, embyro transfer or donation, and surrogacy. For couples with serious infertility problems, the choice of treatment maybe made several times and at several points over an extended period of time. In estimating the cost of infertility services, OTA hypothesizes four scenarios typical of female infertility diagnosis and treatment. Medical costs for each of the four stylized scenarios range from \$2.055 to \$9.376. Viewed together as a fourstage, worst-case treatment process, a couple starting out would have a 69-percent chance of achieving pregnancy (approximately 50

percent chance of a live birth), at a cost of more than \$22,000.

- Costs of infertility services to couples. Costs to individual couples receiving infertility treatment vary widely, depending on the severity of the infertility problem. Typically, a full diagnostic workup can cost \$2,500 to \$3,000, although many couples do not need to make such an extensive outlay. In addition to medical costs, couples often incur considerable expenses on travel, lost time from work, and hotel accommodations.
- **Total expenditures on infertility services.** Extrapolating from data from the National Medical Care Utilization and Expenditure Survey of 1980, infertility expenditures in 1987 were estimated to total \$1,0 billion. Of that amount, about \$66 million was spent on IVF, The remainder was spent on non-IVF infertility diagnosis and treatment.
- Coverage by third-party reimbursers. private health insurance is estimated to cover about 70 percent of infertility expenditures. Couples pay out-of-pocket about 20 percent of the cost of infertility diagnosis and treatment, while other sources such as Medicaid account for another 8 percent. For IVF-related treatment, although the majority of health insurance plans have specifically excluded coverage from their policies, there appears to be a significant amount of reimbursement for the various components of IVF treatment, such as laparoscopy.
- *Insurance perspective on IVF.* IVF is considered to be an expensive item for insurance companies, both because individual components are expensive, and because there is no defined upper limit on the number of times IVF can be undertaken. Insurance companies have therefore been reluctant to underwrite such a large potential liability without placing restrictions on the number of procedures covered. OTA estimates an average of two IVF cycles per patient, suggesting that unlimited IVF cycles per patient are not currently occurring. This figure may increase, however, if more insurance coverage becomes available.

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