

Chapter 2
Introduction

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Introduction

About 3.8 million babies were born in the United States in 1987. This report is about the portion of those babies conceived with medical assistance—babies who were desired but who could not be routinely conceived or carried to term without help. Most of all, this report is about the adult men and women who undergo months and years of invasive medical diagnosis and intervention in order to have a baby.

Infertility has always been a concern for those affected, but beginning with baby Louise Brown, the first person conceived outside of a human body, and continuing through the surrogate mother case of Baby M, the public's collective imagination has been captured by new options in the age-old process of procreation. At the same time, new and provocative scientific, legal, economic, and ethical questions about conception have arisen. Therefore, at the request of the Senate Committee on Veterans' Affairs and of the Subcommittee on Human Resources and Intergovernmental Relations of the House Committee on

Government Operations, OTA undertook this broad study of the factors leading to infertility and of its prevention and treatment.

This report covers the scientific, legal, economic, and ethical issues surrounding medically assisted conception, surgically assisted conception (including in vitro fertilization and gamete intrafallopian transfer), artificial insemination, basic research supporting reproductive technologies, and surrogate motherhood. The recent attention to these techniques should not obscure the fact that many have been in existence for sometime (see table 2-1).

This report is limited to technologies that help establish a pregnancy. Certain allied issues, such as management of pregnancy, prenatal diagnosis including embryo biopsy, termination of pregnancy, fetal research, child health, adoption, and alternate family arrangements involving child sharing are beyond the scope of this report. OTA has recently reported elsewhere on technologies for child health (9).

DEFINING INFERTILITY

The standard medical definition of infertility is the inability of a couple to conceive after 12 months of intercourse without contraception. There are several variations on this definition, such as:

- the inability of a woman to conceive after 12 months of intercourse without contraception (1);
- the inability to conceive a pregnancy after a year or more of regular sexual relations without contraception or the incapacity to carry a pregnancy to a live birth (6);
- the inability of a woman to achieve a first pregnancy after engaging in sexual activity without using contraceptive methods for a period of 2 years or longer (4);
- the inability of a couple to conceive after 2 years of intercourse without contraception (2); and

- the inability of male and female gametes (sperm and ova) to fertilize and appropriately implant (3).

An ongoing study of the epidemiology of infertility conducted by the Centers for Disease Control reveals that the standard medical definition of infertility is a poor predictor of future conception: Only 16 to 21 percent of couples meeting this definition actually remain infertile throughout their lives (2). With an increase since 1980 in visits to physicians for infertility treatment (see ch. 3), the choice of a definition has important clinical implications. Under a more stringent definition, the predictive value is more accurate and interventions can be initiated with some precision. If a broader definition is used, predictive value decreases but interventions may be sought earlier by a greater proportion of individuals who may eventually need them. This OTA report adopts the standard medical definition of infertility be-

Table 2-1.—Some Landmarks in Reproductive Technology

	In animals	In humans
1782	Use of artificial insemination in dogs	
1799		Pregnancy reported from artificial insemination
1890s	Birth from embryo transplantation in rabbits	Artificial insemination by donor
1949	Use of cryoprotectant to successfully freeze and thaw animal sperm	
1951	First calf born after embryo transplantation	
1952	Live calf born after insemination with frozen sperm	
1953		First reported pregnancy after insemination with frozen sperm
1959	Live rabbit offspring produced from in vitro fertilization (IVF)	
1972	Live offspring from frozen mouse embryos	
1976		First commercial surrogate motherhood arrangement reported in United States
1978	Transplantation of ovaries from one female to another in cattle	Baby born after IVF in United Kingdom
1980		Baby born after IVF in Australia
1981	Calf born after IVF	Baby born after IVF in United States
1982	Sexing of embryos in rabbits Cattle embryos split to produce genetically identical twins	
1983		Embryo transfer after uterine lavage
1984		Baby born in Australia from embryo that was frozen and thawed
1985		Baby born after gamete intrafallopian transfer (GIFT) First gestational surrogacy arrangement reported in the United States
1986		Baby born in the United States from embryo that was frozen and thawed

SOURCE Office of Technology Assessment, 1988.

cause it is most consistent with the accumulating database regarding the behaviors of individuals seeking infertility treatment (see ch. 3).

Factors that contribute to infertility maybe attributable to a man, a woman, or a couple as an entity, or they may be unknown. Likewise, treatment may be directed toward a man, a woman, or both together. In some instances, infertility may resolve without treatment. Couples who have been unable to conceive for months or years may suddenly do so with no medical assistance. In contrast, other couples may have conceived children

in the past but find themselves unable to conceive again. In the broadest sense, infertile couples include not only those who are childless but also those with fewer children than they desire. (See box 2-A for a discussion of the impact of infertility on a couple.) The important reasons for treating infertility as a shared condition do not obviate concern for infertility as occasionally an individual problem. A young man, for example, who discovers he has a low sperm count may want that investigated and, if possible, treated, even if he is not at that time thinking of forming a family.

IS INFERTILITY A DISEASE?

Infertility has been characterized as a disease, disorder, disability, handicap, illness, syndrome, condition, or condition caused by disease. These terms are used to describe, explain, and evaluate

clinical problems. The simple assertion that infertility is a disease has both advantages and disadvantages. For one thing, achieving a pregnancy may not *cure* the underlying cause of infertility.

Box 2-A.—Impact of Infertility on a Couple

Infertility is a painful private experience. The fertile world is unprepared to provide a comfortable opening for the individual or couple who is experiencing the pain of wanting a child and not being able to achieve a pregnancy and birth. Sadness, depression, and avoidance of baby showers, maternity shops, children's toys, and pregnant friends can often be misunderstood.

The couple finds that the infertility experience invades many areas of their lives. Work, at times the only escape from other distresses, can become a place of deception and some risk. The business trip conflicts with scheduled intercourse. Frequent late arrivals due to doctor's visits and irritability from stress or drug side effects are disguised as some other illness or problem.

Partners often cannot even count on each other for the needed support and understanding. The acceptance of infertility and the road to its resolution are individual experiences. No two persons, married or not, proceed through this process at the same pace. Learning to accept their infertility may put a terrible strain on partners' love for each other. Sometimes partners disagree on the medical efforts they are willing to pursue in order to conceive a child. One person may wish to continue treatments, while the other may be ready to stop. or, one may be willing to explore adoption while the other still wishes to pursue options for having a genetically related baby. Even when both agree to pursue adoption, there may be disagreements such as whether to seek a baby of another ethnic group or perhaps with a disability. All these strains may cause a reassessment of their commitment to have a baby or continue their marriage.

Some fertile partners are reluctant to discuss their own sadness for fear of making their mate feel guilty or responsible. others make their anger clear. Some infertile people provocatively suggest that the fertile partner could have a baby in a different relationship, calling into question whether they ought to remain together. In some cases the efforts of the fertile individual to reassure the infertile partner may prevent the fertile partner from acknowledging actual emotions of feeling trapped, angry, or immensely sad at the couple's predicament.

source Office of Technology Assessment 1988

Some commentators therefore talk of technologies that result in pregnancy versus those that correct any underlying impairment in normal female or male reproductive function. On the other hand, calling infertility a disease and thereby placing it within the medical model is often considered advantageous in terms of acquiring insurance coverage or third-party payments of various types.

The concept of disease has been a bone of contention throughout the history of medicine. Some physicians argue that all disease categories are arbitrary and that the only meaningful entities are patients and laws of physiology and pathol-

ogy. Others contend that disease terms identify real objects or realities. To avoid this dispute, it is useful to talk about infertility as a clinical problem for which the medical community can sometimes offer a remedy. Using this approach, it is not necessary to ask whether infertility is a disease, and which partner has the disease. As a practical matter, this is important because many cases of infertility can be attributed to subfertility in both partners. This definition includes recognition of the fact that many couples are waiting longer to have babies and expecting to procreate in increasingly shorter periods of time.

PARENTS, CHILDREN, AND FAMILIES

The desire to have children and to become a parent is the reason infertile individuals seek treatment for their infertility or choose adoption. This report is about those who seek diagnosis and treat-

ment of their infertility—people whose motivations for having their own children vary. For some individuals, having children is an important feature of their life plans because of their own ex-

periences as children; their desire to have a link with the future or for emotional or genetic longevity; their desire to love, sustain, and endow specific members of the next generation with tangible and intangible resources; or as an inexplicable part of their love for each other.

For a subset of this group, a genetic tie (i.e., a blood relationship) to their children is extremely important. Some couples seek specific forms of infertility treatment in order that at least one of the parents is genetically related to the child. In addition, for some single men and women, reproductive techniques such as artificial insemination by donor may serve to circumvent not infertility but the lack of a partner of the opposite sex.

Children need nurturing to grow and thrive. A close bond with at least one adult is an essential feature of a healthy childhood, although the specific circumstances surrounding conception and birth can and do vary. Whether or not any variation in a natural event of human fertiliza-

tion and birth *ought* to occur is the ethical question that is the source of extensive debate about the use of the specific reproductive technologies examined in this report (see ch. 11).

It is not necessary to describe all the current social and demographic changes in families in order to focus on the procreative desires of couples who may vary in lifestyle, social status, or marital configuration. Many argue that the desire to procreate is a family centered desire by definition. Others argue that the desire to procreate can and should be distinguished from the creation of a family, in order to recognize that a couple can be a family unto itself, that a person might procreate for purposes apart from the creation or enlargement of his or her personal family, or that a person might, through adoption, create a family without procreation. Regardless of how a family is characterized by membership, form, or function, those seeking and providing treatment for infertility share a common interest in creating a new generation.

THE HUMAN REPRODUCTIVE PROCESS

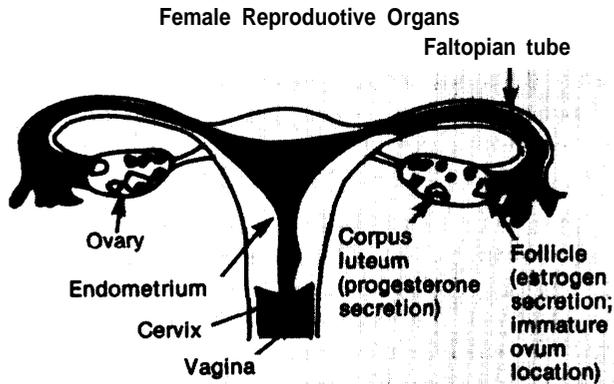
Attempts to create a family typically involve coitus and conception without medical assistance. Single individuals who choose to reproduce and parent alone must use reproductive technologies as a matter of necessity, but for most people, human reproduction is a natural lifecycle event. To understand the anatomic and physiological features of infertility, it is necessary to consider the conditions and processes of normal human reproduction. Many aspects of normal human reproduction are not well understood, and there are areas in which additional research is needed. It is also important to understand the process of fertilization and the early phases of embryonic and fetal development in order to appreciate the technical, legal, and ethical issues involved in the use of reproductive technologies.

Under normal circumstances, fertilization of an egg, implantation of an embryo, and maintenance of pregnancy depend on a series of complex and interrelated events:

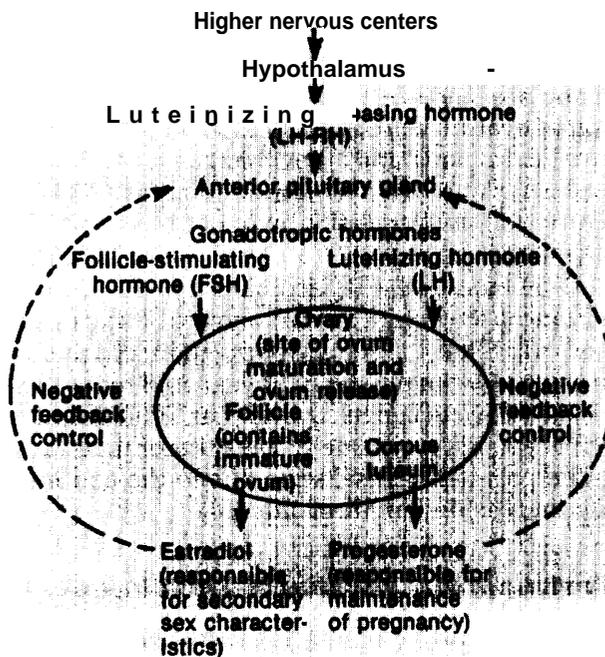
- The male must produce an adequate number of normal sperm and must be able to deposit them in the upper vagina at the appropriate time of the female cycle.
- The female must have at least one ovary and her ability to produce eggs (ovulatory mechanisms) must operate within a normal range of levels. Also, hormone levels must be sufficient to stimulate the production of normal cervical mucus near the time of ovulation and to later support implantation of the embryo and maintenance of pregnancy.
- The quality and quantity of cervical mucus must allow sperm to pass into the uterus.
- The oviducts must be open enough to allow fertilization as well as transport of the ovum from ovary to uterus. In addition, functioning tubal ciliary action is also required to assist sperm to travel up the fallopian tubes.
- The uterus must be capable of supporting implantation of the embryo and fetal growth throughout pregnancy (8).

In both men and women, the hypothalamus, an area at the base of the brain, orchestrates the body's reproductive function (see figures 2-1 and 2-2). It receives neural and hormonal input from other parts of the brain and endocrine glands, and responds to these stimuli by secreting luteinizing hormone releasing hormone (LH-RH, also

Figure 2-1.—The Female Reproductive System

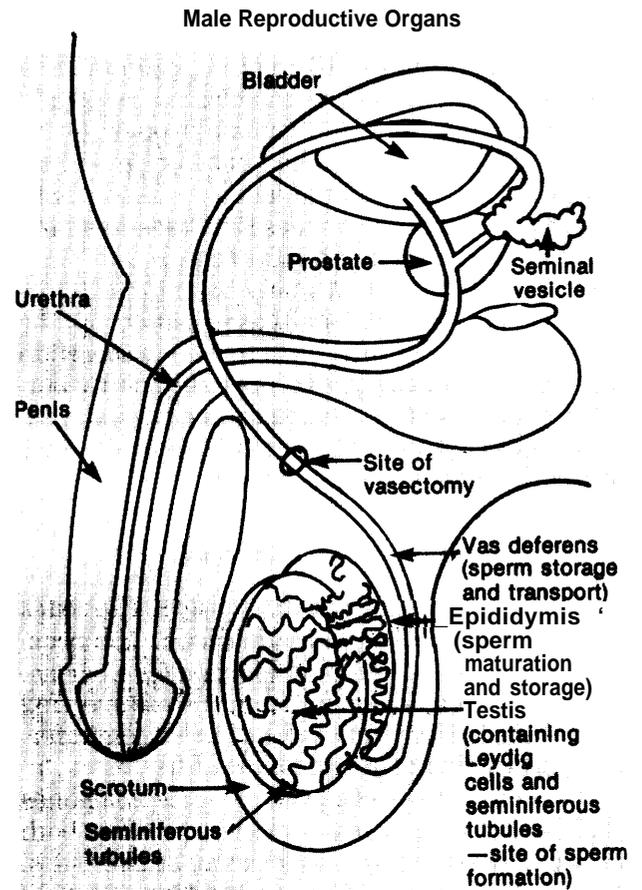


Hormones Involved in Female Reproduction

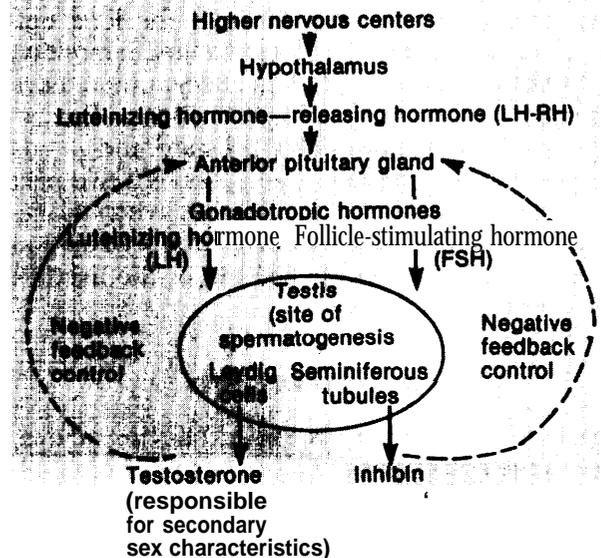


SOURCE: C. Djerassi, *The Politics of Contraception* (New York: Norton, 1980).

Figure 2-2.—The Male Reproductive System



Hormones Involved in Male Reproduction



SOURCE: C. Djerassi, *The Politics of Contraception* (New York: Norton, 1980).

known as gonadotropin releasing hormone or Gn-RH) and other hormones. LH-RH acts on the pituitary gland to promote secretion of two hormones, luteinizing hormone (LH) and follicle-stimulating hormone (FSH). Known as gonadotropins, LH and FSH direct hormone and gamete production by the testes and ovaries. The gonads release hormones in response to stimulation by LH and FSH, and these gonadal hormones feed back to modulate the activity of the hypothalamus and pituitary gland (11). A defect at any point in the hypothalamic-pituitary-gonadal axis will interrupt the normal pattern of reciprocal hormone secretion among these organs. It is through the central nervous system that psychological, emotional, sensory, and environmental stimuli can profoundly influence reproductive function.

Sperm Production

Sperm are produced continuously in the testes from puberty throughout adulthood. The process begins with division of sperm cells (spermatogonia), which, in combination with supporting (Sertoli) cells, make up the long, coiled seminiferous tubules that constitute most of the testes. Interspersed Leydig cells produce male hormones (androgens), notably testosterone, that affect both sperm production and male sex characteristics. Sperm production takes about 72 days. The final stages of sperm maturation take place as sperm exit the testis and pass through the long epididymis. Maturation involves changes in motility, metabolism, and morphology. Sperm then leave the body in the semen, a fluid consisting of secretions of the seminal vesicles, prostate, and glands adjacent to the urethra. Ejaculation is a two-part spinal reflex that involves emission, when the semen moves into the urethra, and ejaculation proper, when it is propelled out of the urethra at the time of orgasm.

Egg Production

The female germ cells, called oocytes or ova, are in the two ovaries. They number several million in the fetal stage, are fewer than 1 million at birth, and continue to decline markedly throughout life. Only about 400 to 500 oocytes are actually ovulated during the period of female

fertility. In contrast to the continuing renewal of germ cells throughout an adult male's life, no new oocytes are formed after the fetal stage in the female. Usually one oocyte matures each month in a follicle on the ovary's surface, and the follicles also produce estrogen. At ovulation, the follicle ruptures, and the oocyte is picked up by the oviduct and propelled down to the uterus. The ruptured follicle then changes to a yellowish protrusion on the ovary, called the corpus luteum, which begins to secrete another hormone, progesterone, in addition to continued estrogen production. The corpus luteum regresses if pregnancy does not occur. These hormonal changes prepare the uterus for a possible pregnancy, but if pregnancy does not occur, the uterine lining is sloughed off, producing the menstrual flow,

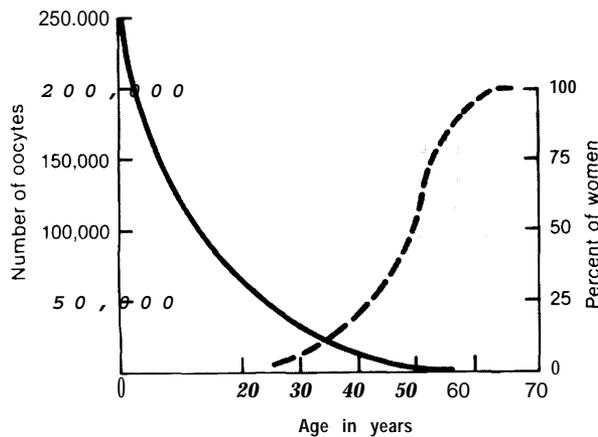
The female menstrual cycle averages 28 days and may range from 26 to 30 days, normally ending with menstrual flow unless pregnancy occurs. Variability in the length of the menstrual cycle typically results from varying duration of the preovulatory, or follicular, phase. It rarely results from variations in the time from ovulation to menstruation—the luteal phase—which usually takes about 14 days.

Menopause, the cessation of menstrual cyclicity, occurs when the ovary is virtually depleted of oocytes, and is marked by diminished production of ovarian estrogens, sudden body temperature fluctuations, and other changes over a longer term. It occurs, on average, at about age 50 (see figure 2-3), but ovulation may occur erratically during the preceding 2-to-10-year period (5). The study of menopause is becoming increasingly important as the number of women age 50 and older (currently half the female population) continues to grow. A woman who is 50 years old today can expect to live to age 89. By the year 2000, women will be spending a greater proportion of their lives in the postmenopausal state due to the continually increasing length of life (10).

Fertilization and Early Development

Human reproduction is characterized by relatively long intervals during which conception is impossible; in fact, fertilization can only take place within about 1 day following ovulation. Fertiliza-

Figure 2-3.—Relation Between Age, Oocyte Number, and Menopause



SOURCE Adapted from D R. Mattison, M.S. Nightingale, and K Shiromizu, "Effects of Toxic Substances on Female Reproduction." *Environmental Health Perspectives* 48:43-52, 1983

tion usually occurs in the oviduct. When a sperm and egg meet, the sperm penetrates the wall of the egg and the genetic material from the sperm and egg unite. The cell thus formed, containing DNA from both sperm and egg, is called a zygote.

The zygote begins to divide, first into two cells, then into four, then eight, and so on. The mass of cells in the earliest stages is called a conceptus. Cell division, or cleavage, continues as the early embryo passes down the oviduct and develops into a blastocyst through the next 3 or 4 days. The blastocyst is a fluid-filled sphere of cells, resembling a balloon. Most of the cells of the blastocyst are in the outer wall or trophoblast, which becomes the placenta. The fetus is derived from a small cluster of embryonic cells inside the sphere. The blastocyst starts to implant in the lining of the uterus about 6 to 7 days after ovulation, and at this point is referred to as an embryo. The terms preimplantation embryo and preembryo are sometimes used to describe the mass of dividing cells and the blastocyst up to 14 days after fertilization (1).

During the earliest stages of development, all the cells are more or less equivalent. Once more than 16 cells are present, the trophoblast cells start to become distinct from the internal cells that ultimately become the fetus. Small and difficult to detect at first, other differences become

more pronounced as cell division and growth continue, and they form the foundation for the later differentiation of tissues and organs.

During the second and third weeks after conception—about the time the first menstrual period is missed—the development of the three embryonic layers of cells (endoderm, mesoderm, and ectoderm) occurs as a group of cells called the primitive streak initiates the development of the nervous system. The primitive streak is also the first landmark that reveals the future symmetry of the human body.

The embryonic period takes place between the end of week 2 and weeks 8 to 9 after conception. This is a critical phase of development, during which cell differentiation proceeds at an accelerated pace. During this period, the brain, eyes, heart, upper and lower limbs, and other organs are formed. At 8 to 9 weeks after conception, the embryo makes the transition to a fetus, with most subsequent development taking the form of growth and specialization of organ function, rather than the formation of new organs. Highly complex systems, like the brain and nervous system, continue to develop long after the embryo has become a fetus, and even after birth. Table 2-2 summarizes the timing of embryonic and subsequent fetal development.

Embryonic loss is a normal part of the reproductive process. Only one-quarter to one-third of all embryos conceived become live-born infants. The remainder are lost at some stage between fertilization and the end of pregnancy, for example, prior to implantation. Data on these are hard to obtain, and estimates vary, because the loss of embryos is particularly high in the early stages, before clinical diagnosis of pregnancy is made (see figure 2-4). The time line in this figure represents what is currently conjectured to be the relative amount of reproductive loss among a population of 100 women at various stages of the reproductive cycle.

When pregnancy occurs, the ovarian corpus luteum is maintained by another hormone, human chorionic gonadotropin (hCG), secreted by the implanted embryo, and estrogen and progesterone continue to be produced. With the most sensitive laboratory tests, hCG can be detected in blood and

urine as early as 6 to 9 days after conception, soon after implantation of the primitive embryo into the uterine endometrium. Measurement of hCG in urine as an indicator of pregnancy is the basis

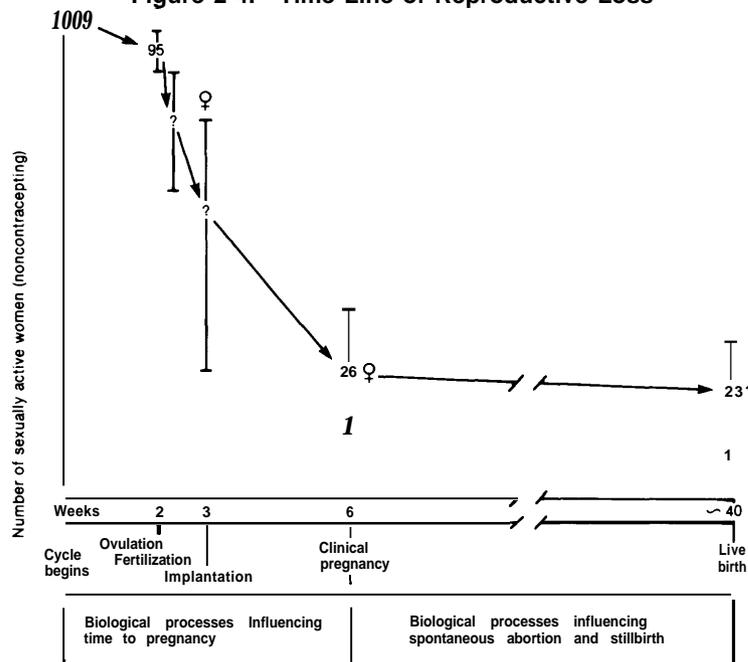
of over-the-counter home pregnancy tests; it is important to note, however, that elevated hCG levels can also be due to other factors, including cancer.

Table 2-2.—Stages of Embryonic and Fetal Development

Period	Time after conception	Stage	Time after conception
Embryo "Preembryo," "preimplantation embryo," or "conceptus" Embryonic	First week	Zygote	1 to 2 days
		Cleavage	2 to 4 days
		Blastocyst	4 to 6 days
		Implantation begins	7 days
	2 to 3 weeks	Primitive streak	7 to 8 days
		Gastrula	7 to 8 days
		Neurula	20 days
	3 to 5 weeks	Limb buds	21 to 29 days
		Heart beat	21 to 29 days
		Tail-bud	21 to 29 days
Complete embryo		35 to 37 days	
6 to 8 weeks	Body definition	42 to 56 days	
Fetus	9 to 40 weeks	First fetal	56 to 70 days
		Second fetal	70 to 140 days
		Third fetal	140 to 280 days

SOURCE: Office of Technology Assessment, 1988, adapted from R.H. Blank, *Redefining Human Life: Reproductive Technologies and Social Policy* (Boulder, CO: Westview Press, Inc., 1984).

Figure 2-4.—Time Line of Reproductive Loss



SOURCE: D.D. Baird, A.J. Wilcox, and C.R. Weinberg, "Use of Time to Pregnancy to Study Environmental Exposures," *American Journal of Epidemiology* 124:470-480, 1986.

PUBLIC UNDERSTANDING OF REPRODUCTION

Many Americans are misinformed about key aspects of the relationship between the timing of sex and pregnancy, according to the findings of a 1986 national telephone survey of 802 adults, split equally between men and women (7). (The results of this survey have a 95-percent confidence level, with error due to sampling and other random effects at plus or minus four percentage points.) About one-third of the public said they did not know what the term “ovulation” meant. Only 10 percent of those surveyed accurately described ovulation as the release of an egg from a woman’s ovary, while an additional 37 percent gave less specific descriptions that included mention of a woman’s egg. One-fourth (26 percent) of those surveyed believed that a woman could become pregnant 10 or more days a month. The largest subgroup to hold this incorrect belief were 18- to 24-year-olds (35 percent).

Americans revealed a great gap in knowledge when asked “How long does the woman’s egg live after it released from her ovary?” Slightly more than half (51 percent) said they did not know. A higher percentage of women (56 percent) than men (47 percent) said “don’t know” in response

to this question of the female reproductive system. The fertile life of the human egg is believed by scientists to be an average of about 24 hours.

Half (53 percent) of those surveyed believed that on average it takes 3 months or less of trying for a couple to conceive; the actual average is at least 4 months. Perhaps as a result of this underestimation of the time it takes the average couple to conceive, half (53 percent) of those surveyed felt a couple should seek medical advice if conception did not occur after 6 months or less of trying. An additional 28 percent said that medical advice should be sought after 6 to 12 months of trying (7).

Overall, the study found that Americans exhibit a definite lack of knowledge about many of the facts relating to fertility and reproduction. The low level of knowledge of the ovulation process as well as poor understanding of the basic facts about the male and female reproductive systems were generally consistent across demographic subgroups (7). These facets of the public’s misunderstanding and lack of information about human reproduction are an important aspect of the social context of this OTA study.

THE OTA STUDY

With this report, OTA assesses what it means in the late 1980s for some couples to conceive and form a family. Couples unable to conceive a child without assistance and those unable to conceive at all are faced with an array of technical and social means to assist reproduction. These procedures—some involving high technology and others involving ordinary technology—raise a host of novel issues in medicine, ethics, law, and economics. At times, they even require a new vocabulary (see box 2-B). The 13 chapters that follow describe methods of assisted conception and provide a comprehensive examination of the issues raised by their use.

Beyond the concerns of an individual couple lies perhaps the most difficult aspect of infertility prevention and treatment for public policy makers: the question of the government’s role with respect to assisted conception. In addressing this issue, policymakers are subjecting to public discussion sexual topics generally consigned to private conversation. Such discussion must be viewed in the context of a sizable level of public ignorance about human reproductive biology. A series of policy issues and associated options for congressional action are presented in this report in order to address the concerns of policy makers.

Box 2-B.— New Conceptions, New Vocabulary

Expectations and obligations created by the use of noncoital reproductive techniques are shared among the sperm or ovum donors, gestational mother, intended rearing parents, physicians, attorneys, commercial brokers, and resulting child. In many ways, the English language is inadequate to express all of these possible relationships. For example, the term “sperm donor” can be misleading when in fact a man sells his sperm; “sperm vendor” would be more accurate, but does not match common parlance.

“Surrogate mother” is a troubling term because of possible confusion over usage. The popular press appears to use the term to cover both women who carry to term an embryo to which they are genetically unrelated and women who are artificially inseminated with the sperm of a man who intends to be the rearing parent of the resulting child when the women themselves will not be rearing parents. The legal literature uses the term to refer almost exclusively to the latter situation, which in fact is far more common. “Surrogate gestational mother” is the term used in legal parlance to cover the former situation.

An additional problem stems from the possibly prejudicial use of the term “surrogate” in the context of a woman who is artificially inseminated (i.e., who is the genetic and gestational mother of the child). This genetic and gestational relationship embodies the traditional definition of “mother.” A woman’s prior agreement to relinquish a child does not diminish this fact, as can be seen in the context of prebirth adoption arrangements. The term “surrogate mother” may imply that the surrogate in this situation is somewhat less than a real mother. This is not true biologically and has not yet been determined legally,

For the purposes of this report, a woman with a genetic relationship to the child is called the “genetic mother” or “ovum donor,” as appropriate. The woman who is both genetically and gestationally the parent of a child is called the “mother.” In the interests of clarity, she may be referred to as the “surrogate mother” when describing surrogacy arrangements. If a woman carries to term a child to whom she is genetically unrelated, she is referred to as the “gestational mother”; again, in the interests of clarity she may be referred to as the “surrogate gestational mother” in the context of surrogacy arrangements. Regardless of their biological relation to a child, the persons who intend to raise the child are referred to as the “intended rearing parents.”

SOURCE: Office of Technology Assessment, 1988

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