

How Can We Evaluate Safety and Effectiveness?

During the 1960s and 1970s, two British researchers, in the field of reproductive health, Robert Edwards and Patrick Steptoe, developed the science and technology of in vitro fertilization (IVF). Their work led to the birth of the first “test tube baby,” Louise Brown, on July 28, 1978. More than 4 million babies have since been born through IVF.

When Brown was born, there was a wave of public concerns about the prospect of IVF being used in “baby factories” to mass-produce new humans. These concerns have proved to be unfounded. However, some people remain uncomfortable with technologies that interfere with the natural processes of conception and childbirth. Many reproductive technologies also raise a number of difficult ethical and moral questions. For example:



Laboratory storage of frozen sperm in liquid nitrogen



- Many reproductive technologies involve gathering and fertilizing several eggs. Only one or a few of the resulting zygotes may be implanted and carried to term. The rest are destroyed. What rights does a zygote have?
- What rights should gamete donors and surrogate parents have? Should they have any rights as a parent? Should a gamete donor have the right to remain anonymous?
- Couples using certain technologies can select the biological sex of their babies. Zygotes also can be tested for certain genetic disorders before implantation. Should people be able to “design” their babies?

Questions such as these do not have easy answers, and they require input from all members of society. Some questions will be settled, to some extent, through legislation and the courts. While scientists and technologists can help to answer moral and ethical questions, they are better situated to evaluate reproductive technologies based on factors that can be tested and assessed.

Scenario

People who seek to enhance their ability to conceive or to prevent conception require advice from qualified health professionals to determine the best course of action for their particular situations and needs. Many factors are involved in making this determination. **Two of these are the safety of any given technology and its effectiveness. These factors, safety and effectiveness, require further elaboration to clarify their meaning. For example, to what or to whom does safety refer? Is it the person undergoing treatment, the embryo/fetus, or both? What does effectiveness mean, and how is it to be quantified or assessed? How reliable is the method or methods used to quantify or assess it?** Imagine that you are part of a working group that has been tasked with the responsibility to determine the safety and effectiveness of various reproductive technologies. Some of these are aimed at enhancing conception, and others are aimed at preventing it. The chart outlines these technologies.

Selected Technologies for Enhancing Conception	Selected Technologies for Preventing Conception
<ul style="list-style-type: none"> • artificial insemination • assisted hatching (also called laser assisted hatching) • gamete intrafallopian transfer (GIFT) • in vitro fertilization (IVF) • intrauterine insemination (IUI) • surrogacy • microsurgical epididymal sperm aspiration (MESA) • tubal embryo transfer (TET) • zygote intrafallopian transfer (ZIFT) 	<ul style="list-style-type: none"> • condoms • fertility awareness methods • intrauterine device (IUD) • lactational amenorrhea (LAM) • oral contraceptives—pills that contain both estrogen and progestin (synthetic progesterone) • progestin-only contraceptives • spermicides • tubal ligation • vasectomy

Research one of the technologies in the table and create a list of risks and benefits.

Technology:	
Risks	Benefits

1. Create a definition for the word “safety” as it applies to reproductive technologies.

2. Create a definition for the word “effectiveness” as it applies to reproductive technologies.
