

CHAPTER 14

*Using One Baby for Another**Babies Fae, Gabriel, and Theresa, Plus Separating Conjoined Twins*

This chapter discusses the 1984 case of Baby Fae, who briefly lived with a baboon's heart, the 1987 case of Baby Gabriel, an anencephalic baby whose heart went to another infant, Paul Holc, the 1992 case of the anencephalic Baby Theresa, whose parents wanted to donate her heart to another baby, and a series of cases about separating conjoined twins. All these cases raise issues about how dying babies are used in experimental medicine and about how one dying baby is used to help another.

The Case of Baby Fae, 1984

The infant known as Baby Fae was born at a hospital in Barstow, California, on October 14, 1984. Three weeks premature, she weighed five pounds. Noticing her pallor, the pediatrician transferred her to Loma Linda Hospital, a Seventh-Day Adventist facility near Riverside, California, about 60 miles from Los Angeles. Physicians there diagnosed her with hypoplastic left heart syndrome (HLHS).

Affecting one in 10,000 babies, HLHS leaves the normally powerful left side of the heart and aorta underdeveloped and thus too weak to pump blood. HLHS almost always kills infants within two weeks.

Fae's mother was 23-years-old, a Roman Catholic, unmarried, unemployed, and had no medical insurance; Fae's father was a 35-year-old laborer. The two had a son and had lived together for five years, but at Fae's birth, they were separated.

At Loma Linda, doctors told the mother that Fae would soon die; she was kept overnight in the hospital and then released. The mother had Fae baptized and took her to a motel to wait for her to die.

Transplantation of an organ from one species to another is a *xenograft*. Before this case, xenografts were rare and unpromising. In 1964, James Hardy implanted a chimpanzee heart into a 68-year-old man, who lived 90 minutes.¹ In 1977, Christiaan Barnard piggybacked a baboon heart next to the heart of a 25-year-old Italian woman, who lived 300 minutes; he later used the same technique to implant a chimpanzee heart in a 59-year-old man who lived less than four days. During the 1960s, Thomas Starzl and Keith Reemtsma performed six transplants each with simian (primate) kidneys and had better luck, but eventually abandoned the projects.² Baboon kidneys worked at best only two months. In 1975, a

British cardiologist connected veins and arteries of a dying one-year-old boy to a live baboon, neither of whom lived through the operation.

Leonard Bailey, the 41-year-old chief of pediatric surgery at Loma Linda, had been aggressively pursuing animal-to-human heart transplants for seven years. According to physician and critic Kenneth Stoller, during this period Bailey had performed "about 160 cross-species transplants, mostly on sheep and goats, none of whom survived more than six months."³ For the previous 14 months, Loma Linda's Institutional Review Board had been considering xenografts by Bailey, and it had recently granted him permission for five operations.

When Baby Fae first came to the hospital and options were discussed with her mother, Bailey was away at a convention. When he returned on October 16, he called Baby Fae's mother to discuss a xenograft.

On October 19, Baby Fae was readmitted to Loma Linda and placed on a respirator. The surgeon discussed the operation for several hours with Fae's mother, father, and grandmother. Fae's mother watched a slide show about the operation. Both parents then signed a consent form, which had been reviewed in great detail by the IRB; they later signed a second form.

Bailey's immunologist, Sandra Nehlsen-Cannarella, began antigen-typing tests to find the best match for Fae among potential baboon donors; these tests would take six days. Using Fae's reaction to her own blood and tissue as a control, Nehlsen-Cannarella tested the following beings for compatibility: Baby Fae's mother (finding a weak immune reaction), some lab workers (strong reaction), herself (strong reaction), three baboons (strong reaction), and three additional baboons (weak reaction). A baboon named Goobers had a "very, very weak" reaction, so she became the source of the xenograft.⁴

The fact that a baboon heart might be used at all indicates a common ancestor of humans and primates. There is considerable similarity between human blood and the blood of primates, thus we might expect to find some close matches between humans and primates. Moreover, one-third of humans have a preformed antibody against tissue from other humans. About 70 percent of humans also have a preformed antibody against baboon tissue; Baby Fae was among the 30 percent who did not. Bailey gave this fact considerable weight, arguing that ignorance about human-baboon matching explained Hardy's earlier failures with xenografts.

Yet other primates are closer to humans in evolution, so Bailey was once asked on a radio show why, in view of these facts about evolution, he had picked a baboon rather than a chimpanzee. He surprisingly replied, "Er, I find that difficult to answer. You see, I don't believe in evolution."⁵

On October 26, the tissue-typing tests arrived, and Baby Fae's heart was said to have started dying and her lungs to be swelling with fluid. Whether Fae was dying at this point is important: According to the hospital's spokesperson, a baboon heart was used because there was no time to find a compatible human heart, so the transplant had to take place right away.

The source, Goobers, was a nine-month-old female baboon, purchased from the Foundation for Biomedical Research in Texas. According to standard procedure, Bailey placed Fae on a heart-lung machine that lowered her blood temperature to 68 degrees. Meanwhile, Goobers was sedated, and Bailey excised her walnut-sized

heart. He then removed Fae's defective heart and replaced it with Goobers's healthy one.

Over the next four hours, he connected the transplanted heart and transplanted arteries. Then the heart-lung machine raised Fae's temperature to 98 degrees, and Goobers's heart began to beat spontaneously inside Fae.

On October 29, nurses weaned Fae from her respirator. On November 5, Bailey predicted that the animal heart would grow with Fae, and that she might celebrate her 20th birthday.

At the time, Christiaan Barnard predicted that soon medicine would have baboon farms for simian xenografts. Barney Clark's surgeon, William DeVries, said, "I really have sympathy for what [Bailey and his colleagues] are going through."⁶

Two weeks after surgery, Fae showed the first signs of rejection of the donor heart. Soon she deteriorated and went back on a respirator.

On November 15, Fae developed a heart blockage and renal failure; her physicians started closed-heart massage and dialysis. She then died, having lived 21 days with her baboon heart.

Bailey attempted no more xenografts, but other surgeons did. In 1992, Thomas Starzl at the University of Pittsburgh transplanted a baboon liver into a 35-year-old man with hepatitis B. He lived 70 days. The same year, a woman waiting for a human liver at Cedars Sinai Medical Center in Los Angeles received a pig liver as a bridge to a transplant, but died 32 hours later. In 1993, a man with hepatitis B received a baboon liver at the University of Pittsburgh; he was 62-years-old and near death at the time, and he died during the operation. Since 1905, baboon organs were transplanted to humans in 33 operations, but none succeeded.

Surgeons hope that transferring human genes into pigs will allow porcine xenografts, but none have worked to date. Even when drugs suppress immunorejection, a more lethal *hyperacute rejection* soon occurs in all xenografts.

ETHICAL ISSUES

Animal Donors and Animal Rights

Animal activists criticized Bailey: "This is medical sensationalism at the expense of Baby Fae, her family, and the baboon," said Lucy Shelton of People for the Ethical Treatment of Animals.⁷ Activists protested outside Loma Linda Hospital, claiming that Fae's life was not intrinsically worth more than Goobers's. The philosopher Tom Regan claimed the operation had "two victims:" Fae and Goobers.

Regan argues that beings who "have a life" have a *right* to life. He held that Goobers had a biographical life in that it mattered to her whether she would live or have her heart cut out: "Like us, Goobers was somebody, a distinct individual." Regan argued that all primates have equal moral value, so Goobers did not exist as Fae's resource:

Those people who seized [Goobers's] heart, even if they were motivated by their concern for Baby Fae, grievously violated Goobers's right to be treated with

respect. That she could do nothing to protest, and that many of us failed to recognize the transplant for the injustice that it was, does not diminish the wrong, a wrong settled before Baby Fae's sad death.⁸

Regan argued that even if human beings had obtained benefits in the past from using animals, such use was intrinsically wrong.

Other animal-rights philosophers emphasized that the difference between Baby Fae and Goobers, considering how young both were and what their individual potential might be, was not as great as the difference between Baby Fae and an anencephalic baby.⁹ Anencephalic babies lack potential cognitive ability, whereas Goobers has more cognition, agency, and consciousness than either such a baby or a healthy newborn.

Some philosophers contemplated the large breeding facility from which Goobers had been bought and offered the image of a similar facility supplying anencephalic babies as sources of organs. If this image is repugnant, they asked, why do we tolerate such a facility for primates, especially when such primates are *more like us* than severely retarded humans? Are we just in denial?

So why not use an anencephalic newborn as a donor? As we shall see, this logic prevailed in the later cases of Baby Gabriel and Baby Theresa.

Bailey retorted that animal lovers picketing his campus were "born of a luxurious society" and implied that only in California would surgeons have to confront such activists: "People in southern California have it so good that they can afford to worry about this type of issue."¹⁰ Moreover, "When it gets down to a human living or dying, there shouldn't be a question" of using an animal to save that human.

The director of Loma Linda's Center for Christian Bioethics agreed:

On an ethical scale, we will always place human beings ahead of subhumans, especially in a situation where people can be genuinely saved by animals. That is the story of mankind from the very beginning. Animals, for example, have always been used for food and clothing.¹¹

Of animal-rights activists, Fae's mother said, "They don't know what they're talking about."¹²

Alternative Treatment?

Was alternative treatment possible? One alternative to a xenograft for Fae was a human donor heart. Loma Linda claimed that the xenograft was necessary because Baby Fae was dying and no human heart was available. Bailey argued that it would be impossible to find a heart because the donor would have to be less than seven weeks old, and criteria for neonatal brain death were problematical ("You can have a flat EEG on a newborn, and yet the baby will survive").¹³

Most neonatal transplants come from anencephalic babies; and Bailey maintained that most parents of such infants would refuse to accept the fact that their baby was brain-dead, and would not agree to donate the baby's organs in time. He described the baboon heart as Baby Fae's "only chance to live."

An associate surgeon at Loma Linda defended Bailey:

It would have to be the sort of case where an infant fell out of a crib and was declared brain dead but the heart was okay. Then all these tests would have to be done to insure a proper matching. With Baby Fae, we had five days to do those tests, getting the best possible [animal] donor. With a human heart, we might not have been able to keep the recipient alive.¹⁴

In his memoirs, surgeon Thomas Starzl describes Paul Teraski as a “symbol of integrity” in the transplant community.¹⁵ Teraski, director of the Southern California Regional Organ Procurement Agency, said that an infant heart had been available *on the day* of Baby Fae’s xenograft. Teraski added, “I think that they [the Loma Linda team] did not make any effort to get a human infant heart because they were set on doing a baboon.”¹⁶

Bailey agreed that he didn’t look for a human heart:

We were not searching for a human heart. We were out to enter the whole new area of transplanting tissue-matched baboon hearts into newborns who are supported with antipressure drugs. I suppose that we could have used a human heart that was outsized and that was not tissue-matched, and that would have pacified some people, but it would have been very poor science. On the other hand, I suppose my belief that there are no newborn hearts available for transplantation was more opinion than data or science, but it is scientific to acknowledge that the whole area of determining brain death of newborns is very problematical.¹⁷

Another alternative existed. Pediatric surgeon William Norwood had developed surgery for HLHS that attempted to repair the left ventricle. He had performed his operation many times at Children’s Hospitals in Philadelphia, with a success rate of 40 percent. Bailey claimed that children did not do well enough after the Norwood procedure to justify this operation for Baby Fae. But given Bailey’s interest in xenografts, was he an impartial judge? Also, can you use the “poor science” retest and not believe in evolution?

Babies as Subjects of Research

For critics, what was objectionable about Bailey’s surgery was not that it was risky or experimental—after all, surgery can discover what is possible only by trying. What was objectionable was that Bailey used a baby, who could not consent. In the decades since the earlier attempts at xenografts, the only new developments had been cyclosporin and better tissue matching, and both could have been used in a consulting adult.

In addition to questions about whether using Fae made sense medically, a more general question is whether parents should volunteer children as research subjects in any circumstances. Protestant theologian Paul Ramsey argued that it is always wrong for parents to volunteer their children as subjects of *nontherapeutic* research:

If today we mean to give such weight to the research imperative, then we should not seek to give a principled justification of what we are doing with children. It is better to leave the research imperative in incorrigible conflict with the principle that protects the individual human person from being used for research purposes without

either his expressed or correctly construed consent. Some sorts of human experimentation should, in this alternative, be acknowledged to be “borderline situations” in which moral agents are under the necessity of doing wrong for the sake of the public good. Either way they do wrong. It is immoral not to do the research. It is also immoral to use children who cannot themselves consent and who ought not to be presumed to consent to research unrelated to their treatment. On this supposition research medicine, like politics, is a realm in which men have to “sin bravely.”¹⁸

Catholic theologian Richard McCormick demurred, holding that parents can volunteer children for “low-risk” nontherapeutic research.¹⁹ Based on the Roman Catholic tradition of natural law, he argued that just as adults should volunteer for low-risk, nontherapeutic research, infants should be volunteered for the same kind of research.

Interestingly, neither Ramsey nor McCormick uses the utilitarian justification of the greatest good for the greatest number. To many people, though, utilitarianism offers the most natural justification. If no one volunteered for such research, progress would halt, so for the general good, both adults and babies should participate. Because HLHS is a congenital defect of babies, how can treatment for it advance unless some HLHS babies participate in research?

Informed Consent

Many people wondered whether Bailey had carefully described the Norwood procedure to Fae’s mother. Was she informed that a human donor was available on the day of Fae’s surgery?

The crucial fact here is that Fae’s mother had no medical insurance. The xenograft was offered for free. Fae’s mother had no money for the Norwood procedure or for a human heart transplant. Costs for such a transplant can be \$250,000 with immunosuppressive drugs costing \$20,000 a year for life thereafter.

Bioethicist and University of Southern California law professor Alexander Capron summed up this criticism:

Doubts linger, not only about the adequacy of the information supplied to Baby Fae’s parents, but about whether their personal difficulties made it possible for them to choose freely, and whether the realization that their child was dying may have left them with the erroneous conclusion that consenting to the transplant was the only “right” thing to do.²⁰

In most respects, the mother’s poverty and lack of insurance rendered her consent meaningless. Faced with the death of her baby and no other realistic options, what else could she choose?

And was the mother informed about the probable outcome of the xenograft? Did Baby Fae’s mother understand that Bailey’s xenograft was a shot in the dark, unlikely to work, and a procedure that might merely extend her baby’s dying?

Historically, lack of informed consent was always a problem with xenografts. Boston University law professor George Annas emphasized that in previous attempts to implant animal hearts in humans, patients were poor, vulnerable, and rarely consented.

In 1963, Keith Reemtsma at Columbia University implanted chimpanzee kidneys in a 43-year-old African-American man who was dying of glomerulonephritis. In 1964, James Hardy at the University of Mississippi implanted a chimpanzee heart into a poor, deaf, mute man who was dying, was carried to the hospital unconscious, never consented to the operation, and survived for only two hours. These operations were experimental, not therapeutic, and were characterized by exploitation and lack of consent. Annas saw Baby Fae's case as a continuation of such practices. Calling Bailey the champion of the "anything goes" school of experimentation, he concluded:

This inadequately reviewed, inappropriately consented to, premature experiment on an impoverished, terminally ill newborn was unjustified. It differs from the xenograft experiments of the early 1960s only in the fact that there was prior review of the proposal by an IRB. But this distinction did not protect Baby Fae. She remained unprotected from ruthless experimentation in which her only role was that of victim.²¹

The Media

This case drew an enormous amount of attention from the media. True, Loma Linda tried to protect the family's privacy and confidentiality, but it and Bailey withheld more than identifying details. Their account of events leading up to the surgery was confusing; hospital spokespersons gave occasional misstatements of fact; and Loma Linda refused to release a copy of the consent form which Fae's parents had signed. Journalists complained about secrecy and the public's right to know.

This situation formed an interesting contrast to the case two years earlier of Barney Clark's artificial heart. Just as many reporters came to Loma Linda as to Utah, but they got much less information. William DeVries had held daily press briefings; Bailey held fewer. Reporters accused Loma Linda of ineptitude and said that aspects of the case begged for clarification.

While Bailey and Loma Linda were accused of reticence, they were also accused of publicity seeking, self-promotion, grandstanding, and adventurism.²² In contrast, Keith Reemtsma at Columbia University gave no news conferences until his patient had been discharged from the hospital and until he had prepared and submitted a scientific paper. Reemtsma argued:

Science and news are, in a sense, asymmetrical and sometimes antagonistic. News emphasizes uniqueness, the immediacy, the human interest, in a case such as [Baby Fae's]. Science emphasizes verification, controls, comparisons, and patterns.²³

Law professor Alex Capron argued similarly:

There was a time when the public learned of biomedical developments after they had been reviewed by, and generally reported to, the researchers' scientific and medical peers [a procedure that protected everyone's dignity and meant that the public would learn only of genuine advances] rather than merely being titillated by bizarre cases of as yet unproven import.²⁴

As we shall see below, this criticism also applies to separation of conjoined twins, which has almost never been done as part of a scientific protocol where results are carefully studied over decades.

Therapy or Research?

Was Fae's xenograft therapy or research? Was alternative treatment available? Did the xenograft have a chance to help Fae, or was she just one sacrifice among thousands on the altar of medical research?

A *therapeutic* procedure offers a patient a reasonable chance of benefit; a procedure which offers little chance is *research* and *experimental*. This medical distinction can be expressed in Kantian ethics as the difference between treating people as "ends in themselves" and using them as "mere means." Essayist Charles Krauthammer wrote:

Civilization hangs on the Kantian principle that human beings are to be treated as ends and not means. So much depends on that principle because there is no crime that cannot be, that has not been, committed in the name of the future against those who inhabit the present. Medical experimentation, which invokes the claims of the future, necessarily turns people into means.²⁵

Was Bailey's best scenario possible? Was there a probability that Fae could have lived to 20 with a baboon heart? At one point, Bailey phrased his claim differently, saying that Fae had a chance to "celebrate more than one birthday with her new heart."²⁶ Was this modest scenario possible?

Bailey claimed his operation had *therapeutic intent*:

I have always believed it would work, or I would not have attempted it. . . . There was always therapeutic intent. My dilemma has been educating the university and the medical profession.²⁷

He made these comments nine days after the operation, when Baby Fae was still alive and seemed to be doing well. He also said that xenografts might soon be preferable to human transplants.

Immunologist Nehlsen-Cannarella argued that, if a perfect match had been found with the best-matched lymphocytes, the operation could have been therapeutic. With such a perfect match, Fae could have accepted the heart.

Other surgeons castigated Bailey, rejecting the idea of *therapeutic intent* and saying that Bailey needed *therapeutic probability*. Almost any experimental surgery has a remote chance of being therapeutic, but that's not enough.

These surgeons also rejected Bailey's and Nehlsen-Cannarella's claim about tissue typing. In 1970, Paul Teraski had discovered that while tissue typing can improve transplants within families, it couldn't outside of families. Surgeons resisted Teraski's findings, but accepted the limitations his results suggested. Thomas Starzl wrote in 1992:

Twenty years later the only controversy is whether matching under all circumstances means enough to be given any consideration in the distribution of cadaver kidneys. By exposing the truth, Teraski had made it clear that the field of clinical transplantation could advance significantly only by the development of better

drugs and other treatment strategies, not by vainly hoping that the solution would be through tissue matching.²⁸

Most transplant surgeons agreed. The American expert on pediatric transplants, John Najarian at the University of Minnesota, said of the Baby Fae case: "There has never been a successful cross-species transplant. To try it now is merely to prolong the dying process."²⁹ He also said that Fae's death on November 15 was "reasonably close to what could be expected," because three weeks was about how long it usually takes for rejection to do its damage.

In a review of this case, the editor of *Journal of Heart Transplantation* concluded:

These clinical attempts demonstrated that the human body could acutely tolerate primate hearts, at least for a few days, but no evidence was found to suggest that these grafts could be accepted for prolonged periods of time with the available methods of immunosuppression. . . . Using presently available means of immunosuppression and immunomanipulation, there is no evidence that a vital organ can be transplanted from one species to another and result in prolonged survival of the recipient

From the experimental data and past clinical attempts, there is nothing to indicate that a human infant will tolerate a primate heart for months or years using today's means to induce and control tolerance. The Loma Linda surgical team has not informed the medical community, as yet, of any new evidence that might suggest the contrary.³⁰

The case against Baby Fae's transplant as therapy may be summed up as follows:

First, it had been known since 1970 that better antigen matches between donor and recipient would not improve transplants.

Second, even the best matches required long-term maintenance on cyclosporin. Bailey claimed that infants can be given larger dosages of cyclosporin than adults, but cyclosporin eventually produces toxic side effects.³¹ The autopsy on Baby Fae indicated that her kidneys were probably poisoned by the massive dosages of cyclosporin she received.

Third, Bailey argued that since an infant's immune system is not fully developed, babies might initially tolerate xenografts. But this is not certain; and even if it were true, an initial success would be followed by failure as the baby's immune system developed and rejected the xenograft.

Fourth, only one heart xenograft had been tried previously, and this had a disastrous result.

Fifth, Loma Linda was a small medical institution. In their zeal to perform a xenograft and be famous, the staff was blind to their own limitations.

Sixth, Bailey himself was an amateur: He had never performed a human heart transplant, and he had never published about xenografts.

Taking all this into account, Baby Fae had no chance of surviving one year, let alone reaching her 20th birthday. Thus the surgery was not therapeutic but experimental. *Nature* concluded that "the serious difficulty over [Bailey's] operation . . . is that it may have catered to the researchers' needs first and to the patient's only

second."³² In his essay in *Time*, Krauthammer said that Baby Fae had lived and died in the realm of experimentation:

Only the bravery was missing: no one would admit the violation. Bravery was instead fatuously ascribed to Baby Fae, a creature as incapable of bravery as she was of circulating her own blood. Whether this case was an advance in medical science awaits the examination of the record by the scientific community. That it was an adventure in medical ethics is already clear.³³

In a review of the case, the American Medical Association and top medical journals criticized Bailey, concluding that xenografts should be undertaken only as part of a systematic research program with controls in randomized clinical trials.³⁴

Baby Gabriel and Paul Holc, 1987

Like the Terri Schiavo case two decades later, the Baby Fae case received saturation coverage in the media, making Bailey and Loma Linda household names. When his xenograft program failed, Bailey tried to use his new fame to create a center for heart failure on infants with HLHS with donated hearts from anencephalic babies.

In 1987, surgeons and medical ethicists at a conference in Ontario, Canada, who were sympathetic to Bailey's goal (Bailey had been a resident in cardiac surgery in Ontario in 1974), created guidelines for using anencephalics as organ donors, guidelines called the *Ontario Protocol*.

The most important of its guidelines was that an anencephalic baby could become a donor only after being pronounced dead by the classical criteria of brain death. Another guideline was that the potential donor could not be expected to live more than one week; this standard was meant to ensure that the donor was born dying. At birth, an anencephalic was to be put on a respirator to preserve its organs, then taken off every six hours to see if it could breathe on its own. If a baby failed to breathe for three minutes, it could be declared brain-dead by three physicians independent of the transplant team.

It should be noted that the respirator is necessary in this protocol because the normal course of anencephaly is for the heart gradually to stop beating: this diminishes blood flow, so the organs become anoxic and start to deteriorate; by the time the brain stem is dead, the heart and kidneys are no longer useful for transplantation.

Because maintaining the brain stem may prevent a potential donor from becoming brain dead, the Ontario protocol was ill-conceived.

UCLA pediatric neurologist Allan Shewmon severely criticized the Ontario Protocol (he also criticized the idea of "minimally conscious state" in the Schiavo case). The leading authority on anencephaly, Shewmon held that anencephalic babies should not be used as donors at all because there was no consensus in neurology about determining brain death in them.³⁵

The Ontario protocol was not applied to a case until February 1988, though it had been in the news for some time before that.

In October 1987, a Canadian couple, Karen and Fred Schouten, learned after eight months of pregnancy that their fetus was anencephalic. They decided to

bring it to term and to donate its organs. When her heart began to fail after birth, the baby, a girl named Gabriel, was ventilated. The United Network for Organ Sharing (UNOS) was alerted, but no potential recipients were found in Canada or the northeastern United States.

Meanwhile, at Loma Linda Hospital, Bailey was working with another couple, Gordon and Paul Holc, also Canadian, whose eight-month fetus had HLHS and needed a heart transplant and who had come to Loma Linda because of the publicity it was receiving. The Schoutens and Gabriel flew to Loma Linda. There, the Holcs' baby, Paul, was prematurely delivered by cesarean section to get the donor heart. Three hours later, Gabriel Schouten's heart was excised and transplanted into Paul Holc's chest.

This was the first time a transplant from an anencephalic baby to another infant resulted in a baby who could grow up and lead a normal life. In gratitude to the Schoutens and to Bailey, the Holcs named their baby Paul Gabriel Bailey Holc. Karen Schouten later said that she felt good about her decision and how it had benefited Paul Holc: "Paul is very special to me because he has a part of our baby inside him. One day maybe I'll see him. I hope he comes to me when he's 30 years old and says, 'Hi. Guess what? I made it.'"³⁶

In 1994, NBC aired a TV movie about the case, which ended by showing the real Paul playing in first grade and hugging the real Karen Schouten. Paul Holc, aka "The Incredible Holc," turned 13 in 2000 and was healthy and doing well.

Perhaps waiting too long for a consensus, Bailey never applied the Ontario Protocol in the Schouten-Holc case. Its first application came at Loma Linda in 1988 with Michael and Brenda Winners and their anencephalic baby. That case had a sad result: No recipients were found.

This was the first of 12 unsuccessful attempts by Bailey to transplant organs from anencephalic babies to other babies.³⁷ Of these 12 potential donors, 10 lived beyond the one-week limit, one could not be matched to a recipient, and in the remaining case the physicians decided against a transplant. In 1988, Bailey suspended his transplant program. There was a de facto moratorium on transplants from anencephalics until the 1992 case of Baby Theresa raised the issue again.

Baby Theresa, 1992

In 1991 in Fort Lauderdale, Florida, Laura Campo and Justin Pearson—who were not married—conceived a child. Like Fae's mother, Laura had no medical insurance and did not see a physician until her 24th week of pregnancy. During her eighth month of pregnancy, she learned that her fetus was anencephalic.

Anencephaly is a congenital neurological disorder characterized by absence of the cerebrum and cerebellum, as well as the top of the skull, resulting in exposure of the brain stem.³⁸ However, anencephaly "does not mean the complete absence of the head or brain."³⁹ Because there is a brain stem, an electroencephalogram can be taken, and autonomic functions such as breathing and heartbeat may be present. Anencephalics do not meet Harvard criteria of brain death.

Because the diagnosis of anencephaly was made so late in Laura Campo's pregnancy, and because Laura's health was not in danger from the fetus, no legal

abortion could be performed. Like most mothers of anencephalic fetuses, Laura said that if she had known the diagnosis earlier, she would have aborted.

After hearing a talk show about organ donation from anencephalic babies, Laura decided to bring the fetus to term to serve as a source of organs.

Anencephaly occurs in one in 500 pregnancies. Over 95 percent identified prenatally are aborted. Of those carried to term, 60 percent are stillborn. Since an anencephalic is likely to have a swollen head (hydrocephalus), vaginal delivery may kill it, and Laura had a cesarean delivery to keep the organs healthy for transplantation.

Anencephaly is perhaps the most serious of all birth defects, because the baby essentially lacks the higher brain necessary for personhood. Anencephalics are born dying. There is no hope of growth into childhood or adulthood. The open skull is vulnerable to infection, and most anencephalics die within one week, though in rare cases some have lived for one year.⁴⁰

Anencephalics are the major potential source of donor organs for other babies born with congenital defects. When the recipient is an infant, a donor organ must be very small, and so an infant donor is needed. However, few infants are involved in accidents that leave them brain dead but with healthy organs. Babies who die as a result of abuse or from sudden infant death syndrome usually have damaged organs that are unsuitable for transplantation.

In the United States, 2,000 babies a year need organ transplants; this number includes 600 babies with HLHS, about 500 with liver failure, and another 500 with kidney failure. About 300 anencephalic babies are born alive each year.

Using anencephalics as organ donors has been possible since 1967. A few days after Christiaan Barnard's transplant, Adrian Kantrowitz transplanted a heart from an anencephalic baby into another infant, who died six hours later.⁴¹ Kantrowitz had almost performed a similar operation 18 months earlier, but he had to wait for the anencephalic donor's heart to stop beating, and then restart it, which proved impossible.

Laura Campo's baby girl was born on March 21, 1992, and named Theresa Ann Campo Pearson. Some physicians expected her to die within minutes, but she did not. Pictures of Theresa showed a beautiful baby wearing a pink knitted cap that covered the top half of her head. Underneath the cap were no skin, no skull, and no cerebrum. Removing the cap revealed the brain stem inside a partial skull.

Under Florida law, before Theresa's organs could be donated, she had to be declared brain dead. Like most states, Florida used the Harvard standard of brain death. The neonatologist said that unless Baby Theresa was declared brain dead, he would not remove the organs.

Laura Campo and Justin Pearson then asked Judge Estella Moriarty of the circuit court to rule Theresa brain dead so her organs could be donated. But Judge Moriarty correctly ruled against the couple: "[I am] unable to authorize someone to take your baby's life, however short—however unsatisfactory—to save another child. Death is a fact, not an opinion."⁴²

The couple appealed to Florida's District Court of Appeals, which affirmed Judge Moriarty's decision and which ended the case medically. On March 29, Theresa began to experience organ failure. At this point, the neonatologist said, "We had to tell the parents [that] all they were doing was prolonging the baby's

death."⁴³ The respirator was removed and Theresa died the next day. By that time, her organs were useless for transplantation.

On the day of their baby's death, Laura Campo and Justin Pearson appeared on television to plead for a change in Florida's laws regarding brain death. Laura Campo was upset and depressed, and it was questionable whether she should have been allowed to undergo the strain of being on the show (but that is a question of media ethics, isn't it, not medical ethics?). A calm, eloquent surgeon joined them and discussed the need for donor organs.

Even though Baby Theresa was dead, in September the Florida Supreme Court heard arguments in the case for purposes of public policy. It decided not to change the law and that anencephalic newborns should *not be* considered dead for organ donation.⁴⁴

ETHICAL ISSUES

Infants as Donors

The cases of Baby Theresa and Baby Gabriel raised basic questions about using such infants as sources of organs. Should any baby be used for the good of another baby? If so, what are the criteria?

One argument against using infants as organ donors is their vulnerability. In general, the more vulnerable people are, the less defensible it is to do something to them without their consent, and babies are considered the most vulnerable of all.

In this regard, a question of terminology arises. When an infant's organ is used as a transplant, who is giving what as a "gift"? Terms like donation and "the gift of life" seem to be inappropriate in this situation; since no baby ever consents to donate his or her organs, a baby cannot really be described as providing a gift.

More accurate terms are: "organ salvage," "organ transfer," "organ recovery," "organ reassignment," and so on. Such terms seem cold, and this connotation suggests why people resist using infants' organs as sources for other infants and why organ procurement agents prefer phrases such as "gift of life."

On the other hand, one possible argument in favor of using infants' organs for transplants would be analogous to McCormick's argument: Parents should choose for a child as the child ought to choose in adulthood. Another possible argument is utilitarian: Infants' organs should be used for transplant if that resulted in the greatest good for the greatest number.

Anencephalics and Brain Death

One vital question in the debate over anencephalics as donors has to do with brain death. Some critics have argued that there are no good criteria for brain death in infants, and whether or not this is true, brain death in anencephalic infants is unclear.

Anencephaly is a medical term describing a range of gross congenital brain deficits, all of which entail no chance of normal brain function but some of which do not entail immediate brain death.⁴⁵ The fact that most babies do not die the first week—and thus could not be donors under the Ontario guidelines—illustrates

this problem, because some kinds of anencephaly are something like persistent vegetative state (PVS); therefore, with maximal supportive care, some anencephalic infants could survive indefinitely. One critic said, "I have an uneasy feeling that what lurks behind the anencephalic issue is the vegetative state issue."⁴⁶

Some commentators have suggested creating a new category of legal brain death, or an exemption from the usual legal criteria of brain death, to allow for transfers of organs from anencephalic babies. Such a new category or exemption is needed for organ donation because anencephalic infants are neither dead nor about to die quickly enough, and allowing them to die naturally could destroy their organs.

So the question boils down to this: Should we change our criteria of brain death for infants to get more organs from other dying infants?

The parents of Baby Theresa hoped that their case would help create pressure for such an exemption in Florida. Disability advocates opposed changing the Florida law: "Treating anencephalics as dead equates them with 'nonpersons,' presenting a 'slippery slope' problem with regard to all other persons who lack cognition for whatever reason."⁴⁷

Two physicians considered a proposal to adopt a system used in Germany, where anencephalics are considered "brain-absent" and therefore brain-dead. They rejected this proposal for America:

Not only are the brains of such infants not completely absent, but there is also a remarkable heterogeneity of morphologic and functional features in the infants considered anencephalic. . . . The causes of the neural-tube defects, including anencephaly, are complex and multiple—a fact that confounds the issue and supports the concept that the condition is quite variable. It is worrisome, but not surprising, that the diagnosis of anencephaly is occasionally made in error. Indeed, too many errors have been made for the diagnosis to be considered reliable as a legal definition of death. We conclude that anencephalic infants are not brain-absent and that the condition is sufficiently variable that the establishment of a special category is not justified.⁴⁸

Another problem is that diagnosis of anencephaly, even as a range, is often problematic. Diagnosing brain size or brain function at birth is controversial (see Baby Jane Doe case). Will overzealous physicians and parents, wanting to bring some good out of a tragedy, declare babies anencephalic when they have some lesser defect—say, microcephaly? The media sometimes report cases of retarded children allegedly diagnosed as anencephalic who now function well.

A slippery slope might occur here: If borderline anencephalics can become a source of organs, there might be a tendency to use infants with closely related disorders such as atelencephaly (incomplete development of the brain) and lissencephaly (unusually small brain parts). It has been argued that "the slippery slope is real," because some physicians have proposed transplants from infants with defects less severe than anencephaly.⁴⁹ Judge Moriarty wrote in her medical review for her decision, "There has been a tendency by some parties and amici to confuse lethal anencephaly with these less serious conditions, even to the point of describing children as 'anencephalic' who have abnormal but otherwise intact skulls and who are several years of age."⁵⁰

Some critics have asked whether less was being done for anencephalic babies when these babies were seen as potential organ donors. Alex Capron described the situation as follows: "By far the most fundamental problem . . . was trying to sustain an anencephalic's liver, heart, and kidneys without temporarily giving life to its brain stem, the one organ that needed to die for transplant to begin."⁵¹

According to the Ontario Protocol, a potential anencephalic donor is to be maintained on a respirator, but periodically removed from the respirator to see if independent breathing will occur. Is this removal in the best interest of the infant? Is the anencephalic infant really being seen as a patient? Or as an organ source? (The Pittsburgh Protocol raises the same questions.)

A counterargument here is that with anencephaly, birth is not morally relevant. That is, most fetuses diagnosed as anencephalic are aborted (indeed, anencephaly is one of the best reasons for aborting a fetus during the second term), and the birth of an anencephalic does not make a moral difference. If abortion is appropriate in anencephaly, why should it be considered immoral to do less to prolong the life of an anencephalic who is a potential organ donor? It might be argued, along these lines, that since anencephalics almost always die a few days after birth, why not allow physicians to kill anencephalics painlessly and transplant their organs at the optimal time?

Another question concerns keeping an anencephalic fetus alive to be a later source of organs. There seems to be a real distinction between keeping a fetus alive for this purpose and simply using the organs of a baby who has accidentally become brain dead or who has unexpectedly been born anencephalic. Some critics say we shouldn't cross this line.

So how many anencephalic organ sources are we talking about? Most anencephalics are identified in utero and most are aborted. Of the approximately 650 anencephalics brought to term each year in the United States, about 60 percent will be stillborn. Of the approximately 300 anencephalics who are born alive and survive immediately after birth, about half will be possible donors of hearts, kidneys, and livers; the others will be unacceptable for various reasons, including organ malformation, low birth weight, and lack of consent by family. The number of possible donors would be further reduced after blood and tissue matching. Taking all this into account, one study estimates that *only about 30 recipients a year* would benefit from using anencephalics as sources of organs.⁵²

Given that serious problems exist about using anencephalics as organ sources, is this figure—30 babies a year—large enough? Would it justify changing our criteria of brain death? Most ethicists and doctors decided negatively: The numbers were too small for so big a change.

Costs and Opportunity Costs

In the Baby Fae case, many critics questioned whether so much money should be spent on a single case when the same amount of money could have done so much good for so many others. Although Loma Linda never revealed the cost of Fae's surgery and the associated treatment, it was probably at least \$500,000. Would it make sense to perform, say, 500 to a 1,000 such operations a year, at a cost of maybe

\$1 billion, while thousands of babies are born deformed because their mothers could not afford prenatal tests like amniocentesis and sonograms?

In the case of Baby Gabriel and Paul Holc, the surgery alone cost \$140,000; in addition, there were costs of flying everyone to Loma Linda and, for the Schoutens and the Ontario hospital, the cost of keeping Gabriel Schouten alive for a week. Consider that thousands of pregnant women in the United States get no prenatal care and that as a result, many babies are born with preventable defects. Isn't the system biased in favor of dramatic surgical cases and against these anonymous women and their children?

What about costs of separating conjoined twins in 14-hour operations with dozens of surgeons? Millions of dollars can easily be spent on one case. Why is so much free care given on these dramatic cases, while other babies are ignored? How many poor women with babies with HLHS go to motels to wait for their babies to die?

Criteria of Success in Surgery: Conjoined Twins

Separation of conjoined twins also raises issues about use of babies in risky surgery and about surgeons seeking fame. On any given day in any major children's hospital, surgeons operate on two desperately ill infants and no one notices. Spectacular surgery occurs, teams spend weeks nurturing each child back to health, but the public is indifferent.

Now make one change and have the two infants enter the hospital as conjoined twins, connected at the head, sternum, or pelvis, and everyone takes notice. Why is that?

Philosopher Alice Dregger argues that it's a modern freak show, the kind of thing that people once paid to see in exhibits.⁵³ In the 18th century, physicians paid such people to exhibit themselves. But as this philosopher and historian of science argues, at least back then such people got paid and were allowed to exhibit their bodies with dignity. Today, the only message they get is: "You're abnormal. We can surgically normalize you, even at risk of killing you. Be grateful."⁵⁴

Separating conjoined twins, especially adults, may often be a reach for fame by the hospital and by the surgical team, saying, "Hey. We can do this and nobody else can! We're the top dogs!" More charitably, it may be just another version of the rule of rescue: We can separate these two conjoined babies, give them separate lives, and feel good about doing so.

In lionizing these cases and their surgeons, the media often describe twins undergoing separation as "brave little fighters," the surgeons as "heroes," and the hospital as performing operations that are "medically necessary." But is this really so?

Johns Hopkins's Ben Carson became famous in 1987 for successfully separating seven-month-old German craniopagus twins (joined at the head and sharing part of the same brain). Since then, he has written several best-selling books about his surgeries on conjoined twins and his life.⁵⁵ In 1994, he and his team tried to separate seven-month-old South African craniopagus twins, who both died during the operation. In 1997, he traveled with a 50-member team to successfully separate

two Zambian craniopagus twins facing in opposite directions, who did not share any organs.⁵⁶

In 2003, he joined the team of surgeons separating Ladan and Laleh Bijani, the adult Iranian women who both died during the operation. Dregger criticizes what Carson said he told the twins in obtaining consent, that a 50 percent chance existed that one of them would die or be disabled from the surgery:

But as a leading expert in the field, Carson surely knew of the most comprehensive study of craniopagus separations, which had concluded that 'mortality and morbidity after surgical separation of craniopagus twins is horrendous: of the 60 infants operated on, 30 died, 17 were impaired, 6 were alive but ultimate status unknown, and only 7 were apparently normal.'⁵⁷

As Dregger points out, at their advanced age, experts agreed that their skulls had thickened and hardened, their brains had matured and were less resilient, thus making their chances of success even worse than the above dismal statistics.⁵⁸ Dregger wonders whether these women were given true information about the dismal prospects of the surgery.

In 2004, Carson attempted to separate the German craniopagus twins Lee and Tabea Block. His surgery was only partially successful, as Tabea died during the surgery.⁵⁹

Conjoined children can live and grow into late adulthood while conjoined. Eng and Chang lived into their 70s, each married and fathered several normal children.

But don't conjoined twins do better when separated to live separate, independent lives? "The problem with this question is that conjoined twins almost invariably state that, from their point of view, they don't need to be separated to be individuals, because they are *not* trapped or confined by their conjoinment."⁶⁰

Perhaps the most spectacular issue here is *how little is known about long-term survival for conjoined twins who were separated and about their subsequent quality of life.* As Dregger notes, the one extant study merely asked whether separated twins were later alive or dead, with no other questions asked. How can surgeons get informed consent without real data? The assumption always is: anything is better than living like this.

But is it? What is the resulting quality of life for survivors? In retrospect, what do the separated twins think of the operation? Would they do it for their own children, if they were conjoined? How many mourn the loss of a twin killed in the operation?

Some adult conjoined twins claim surgeons and parents are prejudiced against life as conjoined adults, thinking that their quality of life is so low that likelihood of death for one during surgery to free the other is preferable.⁶¹ Dregger calls these *sacrifice surgeries* and argues that they pose the most challenging ethical questions. Surely they raise the most controversial assumption of all: that a chance of normalcy for one is worth the death of the other.

In discussing separation of the conjoined twins Angela and Amy Lakeberg in 1993, Dregger writes, "Yet no matter how justified the ends, it is troubling to see surgeons actively cause the death of a child like Amy—who was obviously conscious and as entitled to the conjoined heart as her sister."⁶²

In August 2002, UCLA surgeons separated one-year-old Guatemalan craniopagus twins in a 22-hour operation. The story received saturation coverage nationwide, illustrating the rule of rescue. In July 2006, Dr. Carson announced he would separate 10-year-old craniopagus twins from Delhi, India.

Conclusion

There is an old saying in medicine: "Beware the surgeon with one case." That sums up many of the cases in this chapter and sums up a continuing ethical problem in surgery. As Alice Dregger states the problem, "Unlike drugs and many non-surgical medical procedures, surgeries, at least in the United States, are largely exempt from systematic review. There is little tradition or regulation in support of rigorous systematic review."⁶³

When experimental surgery is done, it should be in a well-conceived research design. One surgeon grandstanding for fame should not be allowed. Loma Linda's website still features the Baby Fae and Paul Holc cases. Should it be proud of Leonard Bailey and what happened there? Should Hopkins boast of separating conjoined twins? What's the opportunity cost of all this surgery?

FURTHER READING AND RESOURCES

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Classic Cases in Medical Ethics

*Accounts of the Cases
and Issues that Define
Medical Ethics*

FIFTH EDITION

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Preface

I first started writing this book for my students 20 years ago when I had already been teaching the emerging field of bioethics for 10 years. I wrote this book for them because existing texts failed to convey the excitement of real cases in bioethics. In this fifth edition, I tried to keep the good parts of past editions (“If it’s not broke, don’t fix it”) and to add to, or improve, them.

Every reviewer used some chapters and not others, so it was difficult to cut any chapter. I decided to edit every chapter, sometimes reducing the number of words by a third, while retaining the essence of each. In addition, I added relevant cases and new issues to each chapter.

Like previous editions, this edition was tested on my undergraduates and medical students during 2006. As in the past, my students freely told me of mistakes and biases, improving the book.

If we date the start of modern bioethics to the 1962 God Committee, we’re almost at half a century of bioethics. Professors today must both teach about new issues (face transplants) while showing how they build on previous cases (heart and hand transplants). And sometimes one issue ties them together: a desire to be first in surgery.

Personally, I believe that knowing about real cases and how they were resolved is real education in ethics for people who will one day make medical decisions. Like the spreading ripples of a stone in a pond, more and more cases build up spheres of knowledge that are as close as we can teach to what Aristotle called *phronesis* or practical wisdom.

As always, I would like to hear your comments and can be reached at my email address: pence@uab.edu.

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