Public Health and the Law

The Baby Doe Regulations: Governmental Intervention in Neonatal Rescue Medicine

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The quandary of rescue medicine is nowhere as grave and disputable as in the neonatal intensive care unit. Advances in medical technology provide the possibility, sometimes even the probability, that infants who would have surely died in the past can have their lives prolonged. Most frequently decisions regarding the treatment of such handicapped or critically ill infants are made by their parents and the attending physician. The outer limits of parental authority regarding treatment decisions for their children are vague, and the role the state should play in protecting the rights of infants seems uncertain.

Governmental intervention in treatment decisions involving newborns has generally been limited to cases involving alleged child abuse or neglect. The most notorious of these have involved the withholding of life saving corrective surgery from Down Syndrome children. One, an unnamed baby born at Johns Hopkins with duodenal atresia and not treated, was the subject of a film, "Who Shall Survive?", that has been widely used in schools and hospitals for the past decade. The child starved to death. The other, known as "Baby Doe", died in Bloomington, Indiana on April 15, 1982 at the age of six days, following a court-approved decision that routine life-saving surgery need not be performed to save his life. The infant had a tracheoesophageal fistula which was not repaired; instead the child was medicated with phenobarbital and morphine. There is no transcript, and the court's basis for affirming the parents' decision is not known. Both of these children should have been treated, and the public was properly outraged that they were not.

On the strength of the Bloomington, Indiana case, the US Department of Health and Human Services (HHS) wrote a letter to approximately 7,000 hospitals on May 18, 1982, putting them on notice that it was "unlawful [under sec. 504 of the Rehabilitation Act of 1973] for a recipient of Federal financial assistance to withhold from a handicapped infant nutritional sustenance of medical or surgical treatment required to correct a life-threatening condition if: 1) the withholding is based on the fact that the infant is handicapped; and 2) the handicap does not render treatment or nutritional sustenance contraindicated." The penalty for noncompliance was the possible loss of federal funds. In announcing the policy, then Secretary Richard Schweiker said: "The President has instructed me to make absolutely clear to health care providers in this nation that federal law does not allow medical discrimination against handicapped infants."[1]

This policy statement is the focal point of a nationwide political, legal, medical, and ethical debate which continues to this day: what is the proper role of government regarding medical treatment of handicapped infants? About ten months after the letter was sent, and shortly after the tenth anniversary of the US Supreme Court's abortion decision, the White House instructed HHS to issue more detailed follow-up regulations. In emergency regulations published in March 1983, HHS required the substance of the May 1982 letter to be displayed conspicuously in each delivery ward, maternity ward, pediatric ward, nursery, and intensive care nursery (see Figure 1). Included in the notice was a toll-free, 24-hour a day "hotline" number that individuals with knowledge of any handicapped infant being discriminatorily denied food or customary medical care were encouraged to call. HHS officials were given authority to take "immediate remedial action" to protect the infant, and hospitals were required to provide access to their premises and medical records to agency investigators.[2]

The American Academy of Pediatrics and others brought suit against HHS and its new Secretary, Margaret Heckler, to enjoin the "interim final rule" on March 18, four days before it was to become effective. In early April 1983, US District Court Judge Gerhard Gesell found the regulation invalid because HHS had failed to follow the Administrative Procedures Act in promulgating it. Judge Gesell also added some personal comments on the regulation, noting that he saw its primary purpose as requiring "physicians treating newborns to take into account wholly medical risk-benefit considerations and to prevent parents from having any influence upon decisions as to whether further medical treatment is desirable." He noted further that without a definition of the "customary medical care" required by the regulation, it is "virtually without meaning beyond its intrinsic *in terrorem* effect."[3,4]

Instead of pressing an appeal of Judge Gesell's ruling, the Administration reissued the regulations in early July 1983, as proposed rules, giving interested parties 60 days to comment on them. Unfortunately, the Administration's revisions dealt almost exclusively with the procedure, and tended to ignore or gloss over the central and problematic substantive issue of the proper government role in this arena.

In fact, the July Baby Doe proposal was *identical* with the March original, with four exceptions:

This is the first of a three-part series on governmental regulation involving the treatment of handicapped newborns. Part 2 in July will deal with the case of "Baby Jane Doe"; the final column in August will deal with alternative methods of decision-making.

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NOTICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office for Civil Rights

DISCRIMINATORY FAILURE TO FEED AND CARE FOR HANDICAPPED INFANTS IN THIS FACILITY IS PROHIBITED BY FEDERAL LAW. SECTION 504 OF THE REHABILITATION ACT OF 1973 STATES THAT

"NO OTHERWISE QUALIFIED HANDICAPPED INDIVIDUAL SHALL, SOLELY BY REASON OF HANDICAP, BE EXCLUDED FROM PARTICIPATION IN, BE DENIED THE BENEFITS OF, OR BE SUBJECTED TO DISCRIMINATION UNDER ANY PROGRAM OR ACTIVITY RECEIVING FEDERAL FINANCIAL ASSISTANCE."

Any person having knowledge that a handicapped infant is being discriminatorily denied food or customary medical care should immediately contact:

Handicapped Infant Hotline
U.S. Department of Health and Human Services
Washington, D.C. 20201
Phone 800-368-1019 (Available 24 hours a day) - TTY Capability

In Washington, D.C. call 863-0100

OR

Your State Child Protective Agency

Federal Law prohibits retaliation or intimidation against any person who provides information about possible violations of the Rehabilitation Act of 1973.

Identity of callers will be held confidential.

Failure to feed and care for infants may also violate the criminal and civil laws of your state.

FIGURE 1—Notice to be Displayed in Each Delivery Ward, Maternity Ward, Pediatric Ward, Nursery and Intensive Care Nursery of Hospitals

- The hotline notice now need only be posted at "each nurse's station";
- The minimum size requirement for the notice was reduced to 8.5 by 11 inches;
- The state child protective agency's phone number had to be added to the poster; and, most significantly,
- An entirely new section mandated that each state's child protective services agency establish procedures designed "to prevent medical neglect of handicapped infants."[5,6]

HHS received 16,739 comments (many based on letter-writing campaigns by "right to life" organizations) on its July proposal, of which it categorized 97.5 per cent as supportive. This aggregate precisely reflected the breakdown of the 322 nurses who responded, but 72 per cent of 141 pediatricians opposed the regulations, as did 77 per cent of hospital officials and health-related organizations. HHS took at least some of these comments into account in issuing the final regulation on January 12, 1984.[7]

Only two substantive changes were made from the March and July versions: 1) The substance of the required notice was changed to require that "nourishment and *medically beneficial treatment (as determined with respect for reasonable medical judgments)* should not be withheld from handicapped infants solely on the basis of their present or anticipated mental or physical impairments." (emphasis added); and 2) the size ("no smaller than 5 by 7 inches") and the location ("where nurses . . . will see it") of the notice was changed; and an alternative notice of compliance adopted.[7]

The first change responded to the most conspicuous deficiency of the original regulation: that it provided no guidance at all to physicians as to their legal obligations but instead mandated that they follow "custom." But this, of course, remains a central problem in the neonatal setting. Because the alternative treatments for extreme prematurity and other now treatable conditions are new, no "medical custom" has been defined. Accordingly, the original regulations offered no useful guidance to physicians. As Judge Gessel argued, they instead had the effect of frightening the physician into always treating everything, thereby often "over treating" at the expense of increased suffering on the part of incurable and dying infants.[3] Surgeon General C. Everett Koop had earlier argued that it was not the Administration's intention to prolong the dying process, and the "medically beneficial" amendment is apparently aimed at making this clearer. Of course, what "medically beneficial" treatment is begs the question of the criteria used to judge such treatment, including the extent to which quality of life judgments can be used by parents and physicians in determining "medical benefit."

The second set of changes is cosmetic. Reducing the size of the notice and having it placed where family members are unlikely to see it responds to the affront many physicians and hospital administrators felt in being forced to post the original notice in a more public place without altering the substance of the rule.

The only meaningful novelty in the January 1984 regulation refers to Infant Care Review Committees (ICRC). Many commentators, including the President's Bioethics Commis-

sion, had suggested some form of internal ethical review committee to help sensitize the hospital staff to ethical problems and act as an advisory board when called upon. Some even suggested that this committee take the place of the hotline and federal investigative intervention.[7]

The regulation "encourages" hospitals to set up such committees to aid HHS policy enforcers and investigators. No hospital is required to have such a committee. However, if it does, the regulations contain an "advisory" model ICRC made up of at least seven members, including a physician, nurse, hospital administrator, lawyer, lay member, disabled group representative, and a member of the institution's medical staff "who shall serve as chairperson." The model sees this group developing treatment guidelines "for the management of specific types of cases or diagnoses, for example, spina bifida, and procedures to be followed in such recurring circumstances as, for example, brain death and parental refusal to consent to life-saving treatment." The ICRC must also review specific cases brought to it by those involved in the treatment decision. In reviewing treatment termination cases, the committee must appoint one member to act as an advocate for the infant "to ensure that all considerations in favor of the provision of life-sustaining treatment are fully evaluated and considered by the ICRC."[7]

The model is heavily weighted in favor of continued treatment. If the family refuses consent, but the ICRC disagrees with the family (whether or not the family is supported by the physician), the ICRC is expected to recommend to the hospital that a court or child protective agency be notified. The model committee must also retrospectively review the records of all cases "involving withholding or termination of medical or surgical care to infants . . ." In the Appendix to the regulations HHS makes it clear that it sees the ICRC as its local investigatory arm, noting that its investigators will make immediate contact with the ICRC when a complaint is made to get the ICRC's side of the case, and further that HHS "may require a subsequent written report of the ICRC's findings, accompanied by pertinent records and documentation."[7]

The final regulations retain the substance and thus the problems of the original proposal, and more than the suggested "model ethics committee" is required to move forward the quest for better care of the handicapped.

The final regulations took effect on February 13, 1984. In the meantime, a case destined to join the Johns Hopkins and Bloomington, Indiana cases, the case of "Baby Jane Doe" was being played out in the New York courts.

REFERENCES

1. Fost N: Putting hospitals on notice. Hastings Center Report, August 1982; 5–8.
2. 48 *Federal Register* 9630–9632, March 7, 1983.
3. *American Academy of Pediatrics v. Heckler*, 561 F.Supp. 395 (D.D.C. 1983).
4. Annas GJ: Disconnecting the baby doe hotline. Hastings Center Report, June 1983; 14–16.
5. 48 *Federal Register* 30846–30852, July 5, 1983.
6. Annas GJ: Baby doe redux: doctors as child abusers. Hastings Center Report, October 1983; 26–27.
7. 49 *Federal Register* 1622–1654, January 12, 1984.

World Hemophilia AIDS Center Established

The World Hemophilia AIDS Center (WHAC), an international clearinghouse of information about acquired immune deficiency syndrome (AIDS) and hemophilia, has been established at Orthopaedic Hospital, Los Angeles, California. WHAC, established under the auspices of the World Federation of Hemophilia and Orthopaedic Hospital, will serve as an international case surveillance center for AIDS or suspected AIDS cases in hemophilia patients. The Center also will distribute information about AIDS to concerned individuals and to organizations.

For further information, contact Shelby L. Dietrich, MD, World Hemophilia AIDS Center, Orthopaedic Hospital, 2400 South Flower, Los Angeles, CA 90007, 213/742-1354.