VII.

FETAL VIABILITY AND DEATH

The definitions of fetal viability and death present important issues in the conduct of research on the fetus. Accordingly, the Commission contracted for two studies in this area: the first, a medical study to define fetal viability and death based on present capabilities of medical technology; the second, an analysis of ethical and philosophical as well as scientific considerations in defining fetal viability and death.

The first study was conducted under contract with Columbia University, Richard Behrman, M.D., Principal Investigator. It included (1) a survey of the changes over the last 10 years in survival rates of premature infants and the advances in technology that have contributed to improved survival; (2) an assessment of the present state of medical technology designed to sustain premature infants; and (3) based on the foregoing, a recommendation for guidelines for use by physicians in determining whether a fetus, delivered spontaneously or by induced abortion, is viable, nonviable or dead. Consultation with representatives of professional societies in pediatrics and obstetrics, surveys of selected newborn intensive care units in the United States and Canada, statistical surveys and literature reviews were employed in carrying out this charge.

Assessment of changes in survival of premature infants relied primarily on data from New York City and from geographically dispersed infant intensive care units, as no national or international data broken down by weight group under 2500 grams were available. New York data showed a 4.5 percent increase in survival rate (26 percent reduction in mortality) of all infants under 2500 grams for the period covering the years 1962 to 1971. The improvement was primarily in the lower weight groups: 68 percent increase in survival rate under 1000 grams, 20 percent increase from 1001 to 1500 grams, and 6 percent from 1501 to 2000 grams. Infants cared for in intensive care units showed an even greater improvement in survival.
Many innovations in caring for the fetus in utero and the delivered pre-
mature infant were introduced in the last decade. The large number of these
innovations, and their introduction at different times in different centers,
generally made it impossible to establish a direct correlation between a given
technologic innovation and a change in infant survival. One exception, where
such a correlation may be made, is the effect on survival of monitoring fetal
heart rate and acid-base balance during labor. At Los Angeles County USC
Medical Center, monitoring was introduced as a routine procedure for high risk
obstetrical patients in 1970; low risk patients were unmonitored. Between 1970
and 1973, the intrapartum death rate of infants weighing more than 1500 grams
decreased 64 percent, and the fetal death rate became lower for the monitored
high risk women than in the unmonitored low risk women. Comparable results
were obtained in New York City at Columbia Presbyterian Medical Center, where
over 90 percent of the monitoring was done on high risk ward patients, primar-
illy black, poor or Spanish-speaking; the low risk private patients were unmoni-
tored. Following introduction of monitoring, the high risk monitored patients
had 10 percent fewer fetal deaths, 14 percent fewer perinatal deaths, and
37 percent fewer intrapartum fetal deaths than the unmonitored low risk private
patients.

Overall improvement in premature survival may be traced more generally
to the gradual adoption of other innovations. For example, the improved rates
during the years 1967 through 1969 may be related to advances first introduced
during the years 1964 through 1966, which included amniocentesis for intrauterine
diagnosis of infants severely affected with erythroblastosis; fetal transfusion
in utero; reorganization of premature nurseries into intensive care centers;
extensive monitoring of gases and other substances in blood, and of vital signs,
with more aggressive attention to correction of abnormal values; hand ventilation
with ambu bags; regulation of the thermal environment; and greater density of
nursing personnel. Increases in survival in the period 1970 to 1973 may be cor-
related with a constellation of advances in the years 1968 through 1970. These
included extensive study of amniotic fluid in managing high risk pregnancies;
fetal heart rate and uterine pressure monitoring during labor; improved infant
transport systems and referral to intensive care units; major advances in design
and techniques for use of infant respirators; total intravenous alimentation;
and use of phototherapy for jaundice. Numerous other innovations have been introduced, but these are the major advances that have come into widespread use.

Impact of these changes on survival is reflected in data from University College Hospital in London, where survival rate of infants 1001 to 1500 grams was a steady 45 to 50 percent during the 1950's and early 1960's. During the period 1966 to 1970, the survival rate increased to 70 percent. Equally significant is an indication of decreased morbidity. During the 1950's and 1960's, the handicap rate for infants weighing less than 1500 grams at birth ranged from 33 percent to 60 percent. A recent study evaluating the outcome of such infants born from 1966 to 1970 indicated that 90.5 percent had no detectable handicap.

Despite these advances in the technology of caring for premature infants, there remain limits beyond which the best care cannot result in survival. To ascertain the present limits, surveys were conducted of vital statistics of the United States (including individual states) and Quebec, the medical literature, and 27 major centers with obstetric services and special intensive care units for premature infants. These centers represent the optimal care that present medical technology can provide. Despite differences in data base from various sources, two facts emerged clearly: probability of survival of infants weighing less than 750 grams was extremely small, and no cases were found from any documentable source of any infant surviving with a birth weight below 600 grams at a gestational age of 24 weeks or less. Some rare cases were documented of infants surviving with birth weights below 600 grams, but in each instance, the gestational age exceeded 24 weeks, and the cases thus represented more mature infants who for various reasons were small-for-dates. Other rare cases were documented of infants born before 25 weeks gestational age who survived, but in each instance birth weight exceeded 600 grams. Thus, on an empirical basis the current limits of viability are clear: there is no unambiguous documentation that an infant born weighing less than 601 grams at a gestational age of 24 weeks or less has ever survived.

The concept of viability implies a prediction as to whether a delivered fetus is capable of survival. A prematurely delivered fetus is viable when a minimal number of independently sustained, basic, integrative physiologic functions are present. The sum of these functions must support the inference that
the fetus is able to increase in tissue mass (growth) and increase the number, complexity and coordination of basic physiologic functions (development) as a self-sustaining organism. This development must be independent of any connection with the mother and supported only by generally accepted medical treatments. If these coordinated functions are not present, the fetus is nonviable. This may be the case even though some signs of life are apparent.

The following functions, taken together, constitute the minimal number of basic integrative physiologic functions to support an inference of viability:

1. Perfusion of tissues with adequate oxygen and prevention of increasing accumulation of carbon dioxide and/or lactic and other organic acids. This function consists of the following components:
   
   (a) inflation of the lungs with oxygen,
   
   (b) transfer of oxygen across the alveolar membranes into the circulation and elimination of carbon dioxide from the circulation into the expired gas, and
   
   (c) Cardiac contractions of sufficient strength and regularity to distribute oxygenated blood to tissues and organs throughout the body, and to eliminate organic acids from those tissues and organs.

2. Neurologic regulation of the components of the cardio-respiratory perfusion function, of the capacity to ingest nutrients, and of spontaneous and reflex muscle movements.

These functions in the prematurely delivered fetus cannot at present be assessed separately in a consistent, reliable and exact manner. The absence of the sum of these functions, however, can be assessed indirectly in a reasonable and reliable manner by measurement of weight and an estimation of gestational age. Thus, organisms of less than 601 grams at delivery and gestational age of 24 weeks or less are at present nonviable; signs of life such as a beating heart, spontaneous respiratory movement, pulsation of the umbilical cord and spontaneous movement of voluntary muscles are not adequate in themselves to be used to determine the existence of basic integrative functions.

A weight of 601 grams or more and gestational age over 24 weeks may indicate that the minimal basic functions necessary for independent growth and
development are present. Such a prematurely delivered fetus may be considered at least possibly viable. At these weights and gestational ages, a sign of life such as a beating heart, spontaneous respiratory movement, pulsation of the umbilical cord or spontaneous movement of voluntary muscles indicates possible viability.

Prediction of extrauterine viability of the fetus while it is still in utero takes on an additional dimension of complexity. The fetus in utero, in the absence of clear signs that death has occurred, is always at least potentially viable as long as it remains in the uterus. However, it cannot be weighed, size assessments based on uterine size are inaccurate, and estimates of gestational age based on menstrual history are often inexact. The best medical technology can provide at present is an index of gestational age based on measurement of head size, using ultrasound. In the best hands, this technique is accurate within ±1 week at 20-26 weeks. Relating gestational age to fetal weight, and taking into account the range of error and normal variation, an estimated gestational age of 22 weeks or less by ultrasound would virtually eliminate the possibility of fetal weight above 600 grams and actual gestational age greater than 24 weeks. Such an estimate would permit the prediction that if such a fetus were outside the uterus, it would be nonviable.

Employing present technology, therefore, research on the fetus in utero, undertaken before an abortion to occur not later than 22 weeks gestational age as estimated by ultrasound, would not impact on a fetus with a chance for survival after the abortion. Any reduction of the 22 week limit would provide an additional safeguard.

Whatever the boundaries are for viability, there is always a chance that a viable infant may be born after a prediction of nonviability by gestational age. When this occurs, the premature infant clearly must be cared for in accord with accepted medical practice. Further, these criteria for viability are based on current technology, which is subject to change. Accordingly, the criteria should be reviewed periodically.

Death of the delivered fetus is judged to have occurred when there is a cessation of the minimal basic integrative physiologic functions which, considered together, may result in self-sustained extrauterine growth and development. The
absence of all of the following signs indicates the cessation of these minimal basic integrative physiologic functions:

(1) heart beat,
(2) spontaneous respiratory movements,
(3) spontaneous movement of voluntary muscles, and
(4) pulsation of the umbilical cord.

Approaching the same issues of fetal viability and death from the viewpoint of a physician-scientist and philosopher, Dr. Leon Kass, in an essay prepared for the Commission, came to conclusions similar to those reached by Dr. Behrman on criteria for determining death and defining fetal viability (though Dr. Kass was more conservative on the latter). In clarifying the terminology, Dr. Kass distinguished between the terms "viable" and "nonviable" (which refer to states of a living fetus) and "alive" and "dead" (which refer to mutually exclusive conditions of the organism independent of its stage of development). The terms "viable" and "nonviable" are predictive of future outcome, which is dependent on the fetal stage of development and relation to the environment. Thus, the determination of viability is influenced by whether the fetus is inside or outside the uterus, and by the technology available for sustaining life. A fetus that is alive inside the uterus is always at least potentially viable; the same fetus outside the uterus may be viable or nonviable.

As criteria for determining death, Dr. Kass suggested that a fetus be considered dead if, based on ordinary procedures of medical practice, it has experienced an irreversible cessation of spontaneous circulatory and respiratory functions and an irreversible cessation of spontaneous central nervous functions. These criteria are evidenced on examination of the fetus by absence of the following:

(1) spontaneous muscular movement,
(2) response to external stimuli,
(3) elicitable reflexes,
(4) spontaneous respiration, and
(5) spontaneous heart function manifested by heartbeat and pulse.
These criteria differ from those suggested by Dr. Behrman only by the addition of (2) and (3). Dr. Kass advised that the presence of any one of these functions is a sign that the fetus is alive (again in agreement with Dr. Behrman), and he further suggested that use of the EEG is unnecessary in making the diagnosis of death. Finally, he recommended that the fetus in utero be considered alive until proved dead, and that the fetus being aborted be presumed alive until examination reveals it to be dead.

A viable fetus was defined by Dr. Kass as one that has reached the stage of development at which it is able to sustain itself outside the mother's body. In suggesting criteria for fetal viability based on present technology, Dr. Kass supported use of essentially the same physiologic criteria as suggested by Dr. Behrman, but would not rely upon weight or gestational age to indicate the presence of these integrated functions in the delivered fetus. He suggested that the delivered fetus should be considered viable in the presence of all five of the functions listed above (the absence of which is definitive of death). Of these, respiratory activity is the sine qua non of viability. Following delivery of the fetus, adequate time should be allowed to assess the presence of life and determine viability before research involving the fetus can be considered. This evaluation should be made by the delivering obstetrician, and then only if he is not himself likely to be engaged in subsequent research involving the fetus.

It is more difficult to determine whether the fetus in utero would be viable, if delivered, and, due to the possibility of error, Dr. Kass advised caution. He suggested that viability of the fetus in utero be evaluated according to gestational age. The fetus in utero is potentially viable before 20 weeks gestational age, but nonviable if removed from the uterus. It should be considered viable after the age of 28 weeks. Accurate evaluation of the viability of a fetus in utero between 20 and 28 weeks gestational age is not possible; such a fetus should be presumed viable if a heartbeat is audible using a stethoscope. The fetus which is to be aborted before the heartbeat is audible should be regarded as potentially viable until the abortion procedure is actually in progress, after which it may be considered nonviable.