FETAL EXTRAUTERINE SURVIVABILITY

Report of the Committee on
Fetal Extrauterine Survivability

to

The New York State
Task Force on Life
and the Law

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New York State Task Force on Life and the Law

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PREFACE

In March 1984, Governor Cuomo convened the New York State Task Force on Life and the Law. He charged the 25-member Task Force to develop recommendations for public policy in New York State on a host of issues arising from recent medical advances. These issues range from the determination of death and the withdrawal and withholding of life-sustaining treatment to organ transplantation and new reproductive technologies. For each issue, the Governor asked the Task Force to devise specific proposals or recommendations in the form of either legislation, regulation or a report.

In June 1986, Governor Cuomo requested the Task Force to conduct a medical inquiry to determine the stage of gestational development at which the fetus can survive outside the womb. Among the public, there was a growing perception that technology would soon push back the frontiers of fetal survivability to the moment of conception. This impression could play a role in shaping public policy in several areas.

In response to the Governor's request, the Task Force agreed that the inquiry should be undertaken by a group of prominent medical and scientific experts who would report their findings to the Task Force. Dr. Alan Fleischman, Director of the Division of Neonatology at Albert Einstein College of Medicine and a member of the Task Force, chaired a committee established to conduct the inquiry. He invited leading experts in the fields of reproductive biology, obstetrics, gynecology, fetal biology, and neonatology from across the State to serve as consultants to the Task Force committee.

The Committee met twice in the Fall of 1986. Each consultant was asked to prepare a short paper and presentation on his respective field of expertise. These papers formed the basis for a report circulated to each of the Committee members. At the end of the process, the Committee submitted its final product to the Task Force.

The Committee Report does not present an exhaustive review of the literature in fetal biology. Instead, the Committee close to proceed by calling upon leading medical and scientific experts in New York State to give the public the benefit of their expertise in a concise and straight-forward manner. The Report is a brief summary of informed opinion written for a general audience, not a formal review of the literature as might appear in a scientific or medical journal. In the interests of brevity, only a few of the leading references are cited in each section.

At its meeting in June 1987, the Task Force concluded that the Report provides valuable information and a framework for examining the current ability of medical science to extend the limits of fetal survivability. The Task Force releases the Report without comment about the ethical or social implications of the medical inquiry conducted by the Committee. It hopes, however, that a realistic understanding of fetal survivability will contribute to a more informed public discussion of these topics.

The consultants to the Committee are identified on the title page of the Report. The Task Force extends its gratitude to each consultant for contributing his expertise and participating in the meetings that led to a timely and objective report to the public

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I. INTRODUCTION

In the past decade, medical science has made great strides in the technology available to sustain newborns of decreasing gestational age. In the late 1970's, few newborns with extremely low birth weights, those born weighing between 500 and 1000 grams (approximately 24-28 weeks of gestational age), survived. A 1000 gram infant had approximately a ten percent chance of survival in 1970. Today a significant number of these infants live, with the survival rate approaching 80-90% near the 1000 gram mark. ([1, 2,3,4])

Likewise, the survival rate for smaller infants has also climbed. Approximately 25% of infants born weighing 500-750 grams now survive depending upon certain factors, including the level of care available. Extrauterine survivability, therefore, is a target that has shifted to earlier points in gestation as the medical techniques for treating newborns have improved.

Just as advances have occurred in the treatment of newborns, technological developments at the other end of the reproductive process have made it possible to fertilize human ova outside the body and to sustain the resulting embryo in the laboratory for as long as nine days.([5]) As a result of these advances, many lay persons writing on ethics and law have postulated the development of an artificial placenta and the ability to gestate a fetus completely outside the human body.

Public knowledge about the new reproductive technologies, particularly in vitro fertilization and embryo transfer, combined with advances in care for very premature newborns, have generated a false assumption that it may soon be possible to save virtually any fetus, regardless of gestational age. This public misperception may have implications for the formulation of public policy and the public response to issues such as abortion and medical advances to assist human reproduction.

II. THE PROBLEM

Issues concerning fetal extrauterine survivability relate to three broad areas of inquiry: (i) philosophical questions about the nature of personhood; (ii) ethical issues related to decisions about the fetus; and (iii) biological questions regarding fetal development. The Task Force Committee on Fetal Extrauterine Survivability was asked to address only the third set of questions related to fetal biological development. In particular, the Task Force asked the Committee to assess the gestational age at which a fetus can survive outside the womb given currently available medical technology. Although the threshold of survival has moved downward in the past decade, the question remains whether there is a physiological threshold that perinatal care cannot push back, even with more sophisticated application of present treatment methods.

The Committee has conducted this inquiry in the hope that its findings will inform the public discussion of sensitive issues related to fetal development and prevent the creation of policies founded on erroneous assumptions about present scientific capability. To accomplish its mandate, the Committee undertook four tasks: (i) assessment of the ability to sustain an early embryo outside the uterus; (ii) identification of the developmental characteristics of vital fetal organ systems and the potential for extrauterine function with medical support at given stages of gestation; (iii) a clinical review of data on gestational age, birth weight, and survival as reported in the most recent literature; and (iv) consideration of techniques to measure and predict fetal development in utero.

III. EMBRYO DEVELOPMENT OUTSIDE THE WOMB

The Committee first explored the current scientific ability to sustain the embryo outside the womb. Specifically, the Committee considered whether the technology is available to support total development in vitro or whether an artificial womb or placenta would be developed soon.

Methods currently exist to fertilize and grow an egg in the laboratory for at least seven days to the blastocyst stage, the point of development at which implantation in the uterine wall normally occurs for the human conceptus. For the first days following fertilization, the embryo is only a cluster of undifferentiated cells that are relatively easy to maintain in vitro. As the cells divide and multiply, they also advance in complexity. It becomes more difficult, and quickly impossible, to sustain them artificially/[5]^

This is true even for small rodents whose embryos have been grown in the laboratory for limited periods of development beyond the blastocyst stage. In the case of the mouse, it has been possible, although with low success rates, to support continued development of the blastocyst outside the womb for as long as ten days/[5]^

Scientists have not been able to reach even this stage with primate embryos because of differences in embryonic development. Most rodent embryos develop a large yolk sac that can act as an efficient organ of nutrient exchange in vitro. This sac is poorly developed in primates which depend on a placenta composed to a significant degree of maternal elements/[5]^

For human beings and other primates whose developmental biology is not conducive to prolonged laboratory growth, complete extrauterine development is not a realistic possibility in the foreseeable future; no technology exists to bridge the development gap between the three-day embryo culture and the 24th week of gestation/[5]^ While in vitro fertilization and the brief (2-3 days) laboratory culture of embryos have major therapeutic implications for infertile couples, the technology cannot reasonably be expected to permit complete extrauterine gestation or the development of an artificial placenta that would alter the threshold of fetal extrauterine survival in the near future.

IV. **FETAL ORGAN DEVELOPMENT**

The threshold of fetal survival *ex utero* relates to the gestational age at which the fetal organ systems are sufficiently developed to maintain the body's physiological balance. The Committee identified and examined the developmental biology of three organs essential to fetal survival: the brain, the kidneys, and the lungs. In relation to each organ, it sought to determine the critical points in fetal development that would permit survival with the aid of current technology.

A) Brain Development

The focal point of human brain development is the cerebral cortex, the portion of the brain required for cognition/[6]^ By 24-26 weeks of gestation, the cerebral cortex has received its full complement of neurons or nerve cells. However, the "window of development" for cognitive capacity is 28-34 weeks, during which time the connections between the neurons form so that the isolated cells can begin to function as a single, integrated unit. Failure to develop these structural connections results in mental impairment. By 38-40 weeks, the neural connections have formed and cortical development has advanced to a stage where the capacity for cognition exists/[6]^

Despite the crucial role of cortical function and the corresponding capacity for cognitive activity, it appears that cerebral development is not a determining factor in maintaining life through the critical 20-28 week period of gestation. If the brain receives appropriate oxygenation and other physiological support at this stage, life will be maintained. The immature brain, however, may hemorrhage. Such intracerebral vascular accidents in young pre-term infants can lead to death or significant neurological and neurobehavioral disorders, including cerebral palsy and mental retardation.® Nonetheless, if other organs adequately support and nourish the brain, it will continue to develop in a manner compatible with survival.

B) Renal Development

The kidneys are more critical determinants of fetal survival than the brain. A minimal level of renal development must occur in order for the fetus to survive outside the womb. During gestation, the placenta performs many of the kidneys’ functions except for the formation of urine, needed to provide adequate amniotic fluid. Once the fetus is outside the womb, the kidneys must assume their normal function to maintain fluid and electrolyte balance and to clear toxins from the blood.

The adequacy of renal function can be assessed by measuring the kidneys’ glomerular filtration rate (GFR), the rate at which the kidney excretes unneeded and toxic substances from the blood. At 24-26 weeks of gestation, the GFR is about 10% of what it will be at full-term (40 weeks gestation)/[7,8’9’]® Although the GFR increases over the first weeks of extrauterine life by a factor of two to four times, this can take longer in the very low birthweight (VLBW) baby.®

Theoretically it is possible to compensate for insufficient kidney function with dialysis or blood exchange transfusion. However, these interventions are technically difficult in VLBW infants and are often contraindicated by concurrent conditions such as respiratory failure. VLBW newborns often face multiple medical problems that cause greater physiological stress on the kidneys. For example, the asphyxia associated with lung immaturity makes the blood acidic, thereby increasing the level of kidney function needed to keep the blood balanced. Even if the kidneys of a VLBW newborn could meet normal physiological demands in the first weeks of life, they might be unable to compensate for the increased metabolic load caused by asphyxia/[11]^ Evidence suggests that some VLBW infants with asphyxia die because their kidneys are unable to handle the added activity[12]

Available information does not allow a precise determination of the gestational age at which renal function, limited by low GFR and other factors, is incompatible with survival. Studies of renal function in newborns with a gestational age of less than 26 weeks are practically nonexistent.

Although the maturational limitations in renal function are an important factor in the morbidity and mortality of VLBW infants with a gestational ageless than 26 weeks, renal function is generally not the sole determinant of survival—even down to 24 weeks of gestation. [7] In the earlier 20-24 week gestational period, inadequate kidney development potentially determines fetal survivability.

C) Lung Development

Adequate lung development is the most critical factor in making a successful transition from fetal to neonatal life. Before the lung can support normal respiratory function, several developments must occur. [13] First, the lungs must be able to absorb oxygen into the blood stream and eliminate carbon dioxide. Such gas exchange can only take place when the pulmonary air spaces in the lungs become juxtaposed to the pulmonary blood vessels. Second, the fetus must have the ability to produce surfactant, the phospholipid-protein complex that prevents collapse of the pulmonary air spaces. Third, and finally, the maturation of the neuromuscular system that controls breathing movements must be complete. This factor is the least important, however, because a mechanical respirator may substitute for spontaneous respiration.

The critical phase of lung development for extrauterine survival occurs at 20-28 weeks of gestation. During this period, it becomes possible for gas exchange to occur, and the cells responsible for manufacturing surfactant appear. Anatomically, gas exchange cannot occur until the air sac-capillary interfaces are sufficiently thin to permit the diffusion of oxygen. Precisely when this happens differs from fetus to fetus/[13]-[1]

Clinical experience and anatomic studies suggest that gas exchange is almost never possible before 23 weeks of gestation, but is not uncommon after 26 weeks [(3,14)] Thus, after 23 weeks of gestation the anatomic configuration necessary for gas exchange has developed, at least in some fetuses[(13)] The fetus begins to produce surfactant at a low level around 20 weeks of gestation, and the amount increases significantly near 34 weeks. Although the initial amount of surfactant produced is too low to keep the airways in the lungs open, it is possible to stimulate surfactant production artificially by administering hormones once the cells that secrete surfactant have developed [(13)]

By 34 weeks of gestation, the neuromuscular system needed to sustain breathing has developed sufficiently to maintain spontaneous respiration. Most infants cease having problems with muscle fatigue or apnea (temporary respiratory failure) at this time [(13)]

Over the past 25 years, remarkable strides have been made in the respiratory support of newborns. In fact, the judicious use of respirators now enables infants with surfactant deficiency and/or significant apnea to survive until these functions mature post-natally.

However, since many acute and chronic complications are associated with mechanical ventilation for newborns [(14)] the use of artificial surfactant may be preferable to treat selected cases of neonatal respiratory immaturity. To date, experience with this therapy is limited, but researchers have obtained promising results; the incidence and severity of neonatal respiratory distress has decreased while the number of VLBW infants that survive has increased [(15-18)]

Nevertheless, this therapy has not changed the lower boundary of gestational age at which newborns can survive.

It has not yet been determined whether providing surfactant to infants of less than 23-24 weeks will be beneficial. The fact that potential gas exchange sites are not yet present in the lungs of these infants suggests that surfactant would offer little benefit. For the same reason, the usefulness of mechanical respiratory assistance is also limited. Thus, the determinant of extrauterine survival based on lung function is anatomic-it depends upon the capacity of the fetal lung system to exchange carbon dioxide for oxygen at approximately 23-24 weeks of gestation/[13]^

Other experimental treatments now being used for infants 24-34 weeks of age also have the potential to lower the threshold of fetal survival. Two such modalities are antenatal maternal hormone therapy to enhance fetal maturation and extracorporeal membrane oxygenation (ECMO) that would act as an "artificial placenta" for gas exchange/[13]^ Antenatal maternal hormone therapy involves giving the woman hormones to accelerate fetal lung maturation in utero and increase survival when a premature delivery is anticipated. ECMO refers to a substitute means of oxygenating the blood prior to lung maturation-a concept similar to the way that dialysis replaces kidney function.

At present, no adequate studies have been conducted to determine the efficacy of hormone therapy in infants less than 28 weeks. ECMO has been utilized as a research modality in full-term infants but has not been successful in VLBW neonates. While it is theoretically possible that such therapies may shift the lower limit of fetal lung capability at some time in the future, these therapies have not been successfully applied to date to VLBW newborns and are not expected to lower fetal survivability in the foreseeable future. Fetal lung function therefore remains constrained by the anatomic immaturity of the fetus below 23-24 weeks of gestation [(13)]

D) Conclusions on Organ Development

The increasing ability over the past decade to save progressively younger neonates is primarily due to the ability to support and assist, at an earlier age the organs already present in the fetus. The developmental biology of the fetus however, has not changed. After reviewing the developmental biology of several crucial fetal organs, including the brain, the kidneys, and the lungs, the Committee concluded that a point exists before which the fetal organs are too immature to function, even with the assistance of sophisticated medical technology. This point in time is 23-24 weeks of gestation; prior to that time, fetal life cannot be maintained outside the womb.

V. **EPIDEMIOLOGIC DATA**

The Committee reviewed the literature and statistics about the six month survival rate of VLBW infants born between 1978 and 1984.^ The six month survival rate of 500-600 gram neonates (approximately 24 weeks of gestation was 5-10%; 600-700 gram neonates (approximately 25 weeks), 10-15%; 700-80 gram neonates (approximately 26 weeks) 25-45%; 800-900 gram neonates (approximately 27 weeks), 35-55%; and 900-1000 gram neonates (approximate! 28 weeks), 60-80%.[1,3,19,25]1

An extrapolation from these data, combined with current experience at on university hospital, yield a prediction that the average six month survival rate for infants in 1987 in the following categories would be: 500-600 grams, 15% 600-700 grams, 25%; 700-800 grams, 40%; 800-900 grams, 60%; 900-1000 grams

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1These are average figures for babies of different sex, race and place o birth (hospital vs. transfer to a hospital with neonatal intensive care unit).

80%[1] Other data suggest that these figures are somewhat higher than those currently seen at other major institutions but are within the same general range.

Neonates less than 24 weeks gestational age have close to a 0% survival rate. This rate is not expected to change in the future, despite the prediction of steadily increasing survival rates and decreasing morbidity in newborns over 500 grams. Just as mortality lessens with increasing birth weight or gestational age, so morbidity decreases as well.

Statistics about neonatal survival therefore confirm the prediction of fetal survival based on an analysis of fetal biological development; they support the conclusion that the threshold of fetal extrauterine survival is approximately 500 grams or 23-24 weeks of gestation. The Committee noted that there have been rare cases of neonates reported to be less than 500 grams or 23-24 weeks who survive. Such data should be viewed skeptically and evaluated carefully to determine if the infant is small for the given gestational age or the gestational age has not been assessed accurately.

VI. FETAL DEVELOPMENT: MEASUREMENT AND PREDICTION

Once the developmental biologist has defined the critical points in fetal organ development compatible with survival, the obstetrician and sonographer must determine whether those milestones of development have been reached. A variety of methods are available to assess the development of a fetus in utero. The methods, including ultrasound, correlate physical signs or measurements with the stage of fetal development, age, or weight since these latter indicators cannot be directly assessed. In an individual fetus, the relationship between measurements and development is not absolute. The relationship will hold, however, when compared statistically to the general fetal population.

Historically, physical parameters were used to estimate fetal development[26] Uterine growth, for instance, occurs at a uniform rate during the first 24 weeks of gestation and is related to gestational age rather than fetal size. Fetal heart sounds are first heard with an unenhanced stethoscope at 18-20 weeks of gestation. Quickening, the first perception by the pregnant woman of fetal movement on three successive days, as well as the appearance of the linea nigra (dark line) on the abdomen and the flattening of the umbilicus, provide further estimates of fetal age. The most accurate estimate of gestational age is dating by the woman's last menstrual period, at least for women with regular menstrual cycles who are followed from early in the pregnancy. While these physical findings can identify a nonviable or previable fetus, they cannot accurately determine when a fetus has reached a developmental stage at which the fetus can survive outside the womb [26]

Laboratory technology such as ultrasound provides the most accurate means to determine fetal age or weight/[27]) Estimates of fetal age or weight from ultrasound examinations are based upon a mathematical analysis of the relationship between actual age or weight and measured anatomic dimensions. Using this approach, either age or weight can be determined if the appropriate fetal dimensions are measured.

Fetal age estimates derived from ultrasound measurements consist of two parts-the predictive age and the age variability. In essence, there is a range of ages associated with any given ultrasound measurement of fetal size. This means that an age predicted by ultrasound is not necessarily the true age of a particular fetus. The actual age, however, can be found within an age range associated with the predicted age with a probability of 95%. The variability of the age estimate changes with the parameter being measured and increases with gestational age.

The variability associated with using a measurement of biparietal diameter (the traverse diameter of the fetal head at its widest point) to estimate fetal age is *+/-1.7* weeks at 18-24 weeks and + /- 2.2 weeks at 24-30 weeks[27] Although other body measurements can also be assessed by ultrasound, the likelihood of increased specificity for estimating gestational age between 18-30 weeks is small given currently available technology.

Fetal weight estimates obtained by using ultrasound are also variable. In one study of infants weighing 500-1000 grams, estimates of birthweight were within 10% of the actual neonatal weight in 92% of the cases.[(27)]

VII. CONCLUSIONS

Based on its analysis of current information about early embryonic development ex-utero, fetal biological development and survival studies, the Committee reached several conclusions/[28]^ First, scientific advances in embryology will not allow complete fetal development in vitro in the foreseeable future. Second, although advances in perinatology over the past decade have steadily reduced the age for fetal survival, a study of fetal biological development shows that an anatomic threshold of development occurs around 23-24 weeks of gestation (500 grams). Before this time, the fetal organs, especially the lungs, are not sufficiently developed to permit extrauterine survival even with the most sophisticated technology currently available.

While this threshold can be determined with some accuracy, the current capability to predict which intrauterine fetuses fall within the 23-24 week range has some variability. It remains more difficult to predict whether a particular fetus in utero at approximately 24 weeks will survive outside the womb than it is to identify the general age limit of fetal survivability.

Present epidemiologic data on the mortality of VLBW infants confirms that 23-24 weeks is the threshold of fetal survival. In the foreseeable future, it is likely that technological advances in the care of newborns will enhance survival at each gestational age above 24 weeks, but will not lower the threshold for fetal extrauterine survival.

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28. After the Committee completed its work, it became aware of a British report published in 1985 by the Royal College of Obstetricians and Gynaecologists that reached similar conclusions. In its "Report on Fetal Viability and Clinical Practice," a committee of representatives from the British Paediatric Association, the Royal College of General Practitioners, the Royal College of Midwives, the British Medical Association and the Royal College of Obstetricians and Gynaecologists concluded that 24 weeks is the gestational age at which a fetus can be considered viable. From their report it appears that the British adopted a practical compromise to competing views on fetal viability. Although the Task Force Committee reached nearly the same conclusion, its findings were based entirely on the data from current scientific literature and clinical practice.