

Study Title

Clinical Practices Regarding Extremely Premature Births in New York City Hospitals

Background information

Internationally, infant mortality rates (IMRs) are used by the World Health Organization in their assessment of countries' health status, and in 1996 IMR ranged from a low of 4 per 1000 live births in Singapore and Sweden to a high of 191 per 1000 live births in Niger. In the United States, health professionals use IMRs as an indicator of the status of maternal and infant health. Federal and State health agencies use IMRs to establish funding priorities. In New York City, IMRs are published by borough and by health district, and aid the Department in its assessment of the health needs of New York City communities.

In examining IMRs, it is evident that reporting practice is a major factor in determining trends in IMRs. Reporting is based on the clinical definition of live birth that is used by hospitals and health care professionals. When extremely low birth weight, non-viable infants are included among live births, the resulting IMR may be increased.

Though the definition of a live birth is fairly standard, there are some variations between states, as well as in the way health professionals at hospitals within a given city may interpret the definition. For the most part, these variations concern "infants on the threshold of viability", that is, extremely low birth weight (less than 500g), extremely premature (less than 24 weeks gestation) infants. Depending on their clinical practice, some hospitals may classify these infants as spontaneous or induced terminations, instead of as live births.

According to *New York State Public Health Law*, the following is the definition of a live birth:

"The complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy, which, after such separation, breathes or shows any other evidence of life such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached".

New York City's Health Code has essentially the same definition of live birth. This definition does not take into consideration birth weight or gestational age.

The "*Guidelines for Perinatal Care*", which is published jointly by the American Academy of Pediatrics (AAP) and the American College of Obstetricians and Gynecologists (ACOG), and the National Center for Health Statistics (a division of the Centers for Disease Control and Prevention) have the following definition for live birth:

"The complete expulsion or extraction from the mother of a product of human conception, irrespective of the duration of pregnancy, which, after such expulsion or extraction, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. Heartbeats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps."

This definition is the same as that in New York State Public Health Law, and in the New York City Health Code, except it has in addition the underlined section. The added section is included to help in the determination of ‘what should be considered a live birth’, but in fact it may introduce subjectivity. In the Guidelines for Perinatal Care ACOG recommends that all live births be recorded regardless of gestational age, birth weight or survival time.

The 20th edition of “*Williams Obstetrics*”, a very popular obstetrics text book, gives the following definition of live birth:

“Whenever the infant at or sometime after birth breathes spontaneously, or shows any other sign of life such as heartbeat or definite spontaneous movement of voluntary muscles.”

This definition also allows for some amount of subjectivity on the part of the clinician.

A recent investigation of infant mortality at a New York City hospital revealed that the hospital defined and reported live birth based on a clinical definition, which took into consideration viability based on birth weight and gestational age. Infants born at 25 weeks gestation or greater were considered viable, aggressively resuscitated, and reported as a live birth. Infants born at 22 weeks gestation or less were considered non-viable because they had no chance of survival. These infants were reported as spontaneous terminations irrespective of evidence of life (as defined in the definition of live birth), and given only comfort care. The products of induced terminations were reported as such regardless of evidence of life. Infants born at 23-24 weeks gestation were in the “gray zone”. The management of these infants was based on clinical practice and the parents’ wishes. This hospital’s clinicians stated that their practices were based on clinical practices as reported in medical literature.

During a site visit to the hospital by the New York City Department of Health’s Office of Vital Statistics regarding another issue, the hospital staff were educated regarding the definition of a live birth as described in the New York City Health Code. After the site visit, the hospital changed its reporting practice to comply with this legal definition of live birth. The change in reporting practice caused the number of neonatal infant deaths reported for infants weighting less than 1000g to increase by 214% from one year to the next.

This investigation raised the question of whether or not the clinical practices of other New York City hospitals are in compliance with the New York City Health Code definition of live birth. We are interested in exploring the practices of other hospitals in the City regarding their definition of viability, and whether their criteria for reporting live birth is based on viability as indicated by gestational age and/or birth weight.

Objectives

The objectives of this study are to:

1. Determine hospitals’ definition of newborn viability and of live births.
2. Determine the impact of these definitions on infant mortality rates in New York City.
3. Explore the attitudes of clinicians regarding the management of extremely premature, and extremely low birth weight infants.

Hypothesis

The reporting of live births by hospitals is based on individual hospital's clinical definition of viability, and not on the New York City Health Code. This practice contributes to an underestimate of the infant mortality rate in New York City.

Methods

Data

Information will be collected from all hospitals in New York City with labor and delivery facilities using anonymous survey questionnaires. Birth centers will be excluded on the assumption that they are unlikely to have significant numbers of infants on the threshold of viability. See attached survey questionnaires.

Population

For each hospital defined above the information will be gathered from the chief of obstetrics and gynecology, and the chief of the neonatal intensive care unit (for hospitals where there is a neonatal intensive care unit), or their respective designees.

Mechanism

Contact will be initiated via a letter to the person that we wish to survey. This letter will give some background information to explain why the survey was initiated, a brief overview of the purpose of the survey, and indicate the intended use of the results. In this letter permission will be request to conduct a telephone interviews with these individuals. The letter will be followed by a telephone contact to set up a time for the telephone survey. At this follow-up telephone call, respondents will have the option to answer the survey questions or make an appointment to participate in the survey at another time. Efforts will be made to interview the entire target population. Up to 4 telephone calls will be made to set up the telephone survey.

At least 2 surveys will be completed for each hospital, one to be completed by the chief of the neonatal intensive care unit (NICU) or his/her designee, and one to be completed by the chief of obstetrics and gynecology (OBGYN) or his/her designee. At the hospital's request other clinical personnel serving in an administrative capacity at the hospital may be interviewed. Two slightly different survey instruments will be used, one designed for NICU personnel, and the other designed for an OBGYN.

The data will be entered into an Epi-Info database.

Analysis

Statistical analysis will be conducted on the data to determine the extent of the variation among hospitals. We will determine the average gestational age and birth weight at which clinicians deem aggressive therapy appropriate. We will also estimate the extent to which hospitals' reporting practices as described affect citywide infant mortality rates.

Expected Results

We expect to find that not all hospitals in New York City report as live births infants on the threshold of viability that live for a very short period of time, including such infants that are the result of an induced termination. However we anticipate that most hospitals have similar practices regarding the management of these infants.

Human Subjects Protection (risks and benefits)

The data will be gathered from each hospital's chief of OBGYN, and chief of the NICU (for hospitals that have a NICU).

The data is not intended to expose hospital practices, or to penalize hospitals for not strictly abiding by the New York City Health Code definitions. The data will be used for research purposes only. This will be stated during the initial phone conversation, and reiterated prior to conducting the telephone survey. In addition, no identifying information will be collected on the individuals supplying this information.

Each hospital will be assigned a number code for tracking and follow-up purposes, and to ensure that the names of hospitals are not recorded anywhere on the survey instrument or in the analysis. Only the investigators will have access to the password-locked computer file with information linking the number code to the hospital name and address, and the name, telephone and fax number of the hospital contact.

The data will be kept strictly confidential in password protected computers, with access limited to the investigators and the staff of the Health Information Services (HIS) Unit responsible for setting up the database protection. All hard copies and computers will be housed at the Office of Family Health at New York City Department of Health. This is a passcode-locked Office, which is not open to the public. In addition, the data will not be shared with individuals who are not directly involved in the project, and only aggregate data will be presented in any report published or presentation made based on this study.