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# Informed Consent as a Parent Involvement Model in the NICU

by Kleia R. Luckner and Irwin J. Weinfeld

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*The informed consent doctrine can be a viable model that ensures and enhances parental input in the decision-making process in the neonatal intensive care unit (NICU). Throughout medical history the purpose and practice of informed consent and patient disclosure has often been to encourage the patient to agree to what the physician wanted to do. A new understanding of this doctrine is necessary for both health care givers and patients, one that views informed consent as a process of mutual discovery, shared options, and dialogue.*

Achieving the appropriate level of parental involvement in the neonatal intensive care unit (NICU) is a difficult task. Finding that level rests to some extent on developing a working definition of "informed consent."

Parents and physicians often have differing perceptions of the meaning of this term. To parents, it most often connotes being given options by the health care professionals upon which informed decisions are made. Some physicians may perceive it to mean discussing the case with the parents, describing the technology involved, providing the results of diagnostic tests, and explaining the anticipated outcomes. Other physicians view informed consent as informing the parents, but slanting the information so the parents agree with the physician's plan of treatment. What results is a gap between parents and physicians regarding parental involvement. As the gap increases, so does the level of frustration among all parties, and the possibility of legal action by the parents. A more uniform understanding of informed consent could alleviate these problems.

## **Barriers to Parental Involvement in NICU Decision Making**

NICU professionals sometimes consider parents' involvement in decision making as inappropriate since it is the professionals who have the ex-

pert knowledge, the detachment, and the objectivity necessary to advocate for the baby's best interest (Harrison 1986, 167). Parents' informed choice, then, is a misnomer. For those who adhere to this thinking, it is inappropriate for parents to make the choice; these professionals view informing parents as explaining the consensus of opinion so that the parents will agree with the prescribed treatment or procedure. The principle of paternalism is invoked as justification for this view.

Frequently parents are presented with one strong recommendation, for example, "Unless we operate, the baby will die." Communications patterns may include euphemism such as "developmental delay" for mental retardation, or statistical and highly technical terms that leave parents

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confused. Furthermore, some physicians do not have the communication skills needed to convey the appropriate message to parents. Breaking bad news to parents is difficult and more so in emotionally charged situations regarding the potential death of an infant. Parental options and opinions are sometimes lost in the emotion of the situation.

In the NICU, many patients have complex medical problems requiring multiple medical consultants (cardiologists, surgeons, etc.) and ancil-

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lary paramedical services (respiratory therapists, social workers, educators, etc.). This scenario also hinders communication, causing delays in scheduling meetings and difficulty in obtaining a medical consensus. Without a physician coordinating the process, parents become frustrated, confused, and discouraged.

Complicating parent-physician communication are the complex ethical issues that often arise in the NICU environment. These issues include quality of life, viability, uncertainty of neonatal outcome, rights of parents versus the baby's rights, burden of care versus the benefit of care, and the allocation of limited resources. Physicians may be reluctant to actively involve parents in the decision-making process when such ethical issues are involved. Does the physician serve the patient's good or his right? Does he or she serve the patient's needs or the wishes expressed by the parents? Who does the physician serve (Friedman 1986, 169)

In addition to these issues, the NICU environment normally does not encourage continuous parent communication nor foster active involvement in the decision-making process. For ex-

ample, some decisions involving life-threatening situations require immediate answers and do not allow time to contact the family members to discuss the situation. Other barriers include: maintaining a consistent treatment and care plan with frequent changes in the nursing staff, marked variation in the ratio of health care professional to patients, and the lack of adequate space for regular parent/caregiver conferences.

Outside factors also add to the pressure for parents and physicians to communicate. Increased media coverage of unusual neonatal cases such as the birth of Siamese twins, heart transplants with anencephalic infants, and the numerous television shows about the successful outcomes of critically ill newborns add to the general public's interest in such cases. Families frequently use these well-publicized cases as a paradigm for their infant's own treatment plan. Increased dialogue regarding informed consent can create even more conflicts between the wishes of parents and the health care professions (Clark 1994, 100).

### **The History of Decision Making in the NICU**

The pendulum of parental involvement in the care of critically ill babies has swung widely from one side to the other, from excluding parents in the process, to increased involvement and interaction between the physician and parents, to favoring the parents' treatment decisions.

Twenty-five years ago the situation in "premature" nurseries was primitive by today's standards. Hyaline Membrane Disease was treated by an oxygen hood or utilization of adult respirators, now known to be inappropriate. Nutrition was administered by clysis (subcutaneous injection of fluid) or gavage feeding with hospital-prepared formula. Because of the fear of infection and contamination, parents could visit only occasionally and were required to dress in cover gowns, gloves and masks. Excluded from the NICU as well as the decision-making process, parents stood in the hall and viewed their sick newborns through a glass window.

During these years the physician was the deci-

sion maker with little open discussion; an obstetrician would make the decision about the viability of premature infants or severely deformed newborns. The "physicians knew the family, knew the family circumstances and often knew the parents' wishes. There was little or no open discussion" (Silverman 1992, 972).

Gradually it was recognized in neonatology that the bonding between parents and babies was necessary and essential. Health care professionals began encouraging parents to touch critically ill babies in their Isolettes and hold the babies when they became more stable. This phase in the history of NICUs saw increased visitation by parents, siblings and supportive relatives in the units as well as the development of more specific infant care activities performed by the parents. This non-medical interaction led to improved communication between the parents and health care professionals. NICUs established sessions in which parents learned methods of infant care and stimulation and other techniques for carrying for the baby at home.

### **Informed Consent Doctrine as a Model**

The informed consent doctrine is a viable model to enhance parental input into NICU decision making. Historically the informed consent law comes from the tort law of assault and battery. It is the legal doctrine protecting the right of each individual to be touched only when and in the way authorized (Schloendorff 1914). Routed in case law and ratified in over twenty-three states, informed consent is the procedure or process whereby patients consent or refuse a medical intervention based on information provided by the physicians regarding the nature and potential consequences of the proposed intervention, as well as a discussion of alternatives and their consequences (Purtilo 1993, 126).

Throughout much of medical history the purpose and practice of informed consent and patient disclosure have been to encourage the patient to agree to what the physician intended to do. However, informed consent is not a mere formality, a recital of options, or a signing of a form. Rather, it

is a process of mutual discovery, interaction and dialogue between the caregiver and the patient. Here the "informed" aspect is a genuine mutual and participatory process and not simply a one-way disclosure of information.

The participatory process itself includes several elements: the physician discloses the proposed treatment and alternatives, and the reasons for his choice; the patient is encouraged to ask questions about both the treatment and the physician's rationale; and finally, the questions are answered to the patient's satisfaction. In this model the physician engages in his usual patient-management thought process, but he does it with the patient, and in language understood by the patient. The problematic area in this disclosure process is determining what the physician should or must disclose to the patient.

### **Disclosure Requirements**

Courts have developed case-by-case lists of items required in disclosure. These items usually include: diagnosis; the nature and purpose of proposed treatment; risks and consequences of proposed treatment; probability that the proposed treatment will be successful; reasonable treatment alternatives; and the prognosis if the proposed treatment is not undertaken.

Of interest to physicians is the standard the courts use when evaluating the extent of the physician's disclosure. A major change took place in 1972 when the District of Columbia court in *Canterbury v. Spence* (1972) withdrew from the medical community the right to determine what must be disclosed to the patient. The Canterbury Court established the reasonable patient standard which reaffirmed the patient's right of self determination. In California's *Cobbs v Grant* (1972), the courts viewed the physician as a decision analyst who was to recommend a particular set of actions for the patient, based on his medical expertise. The standard, then, shifted in the early 1970s from the traditional standard based on customary practice in the physician's community to the more liberal standard based on what an average, reasonable patient would consider material

to the treatment decision.

### **The Physician Role in Informed Consent**

In the informed consent model, the physician practitioner provides expert information while the task of valuation falls directly on the patient. The claim that patients will not understand the specific information merely begs the question of why the information is not made understandable. This doctrine implies that there are a series of alternative treatments from which a patient or guardian may choose, determined by what is important to the patient. Yet physicians sometimes see only superior or inferior treatment options.

The eminent Justice Cardoza, in his landmark 1914 decision in *Schloendorff v. Society of New York Hospital* stated that "true consent of what happens to one's self is the informed exercise of a choice and this entails the opportunity to evaluate the options available and the risks attendant upon each." Since the present standard for disclosure is based upon what is material to the patient, this disclosure requirement imposes a duty on the physician to know the patient and identify which factors are important to him in making treatment decisions.

### **Informed Consent in NICU**

In the NICU environment, the implementation of informed consent carries its own challenges. Clearly, the NICU patient is unable to exercise informed choice; an infant must rely on his parents to make decisions in his best interest. An adult's right to consent or to refuse treatment is rooted in the common law principle of self-determination and the constitutional right of privacy. However, the child, because of his minor status, must of necessity be represented in treatment choices by an adult. The basis of child protection laws is the best interest of the child. In question is who should represent those best interests, parents or health care professionals.

The interests of the infant are almost always inextricably linked to those of the family. In defining and securing the child's best interest, the central role of the parents/family must be ac-

knowledged and supported. Occasionally this approach and the resulting parental decisions may risk violating moral or religious values of the professionals or possibly an existing law. There is no universally accepted consensus about what constitutes the best interests of the child; rarely can this be described abstractly by committees or by courts. Considerations of the meaning of "best interest" should include promoting "...the child's welfare which more specifically has been defined as: relief of suffering, preservation or restoration of functions and the extent and quality of life sustained that reasonable persons in similar circumstances would be likely to choose" (Jonsen 1992, 70). Only if the parents select a course of treatment that clearly sacrifices their child's best interests to fulfill their own needs should the physician intervene, invoking the principle of paternalism and trumping the parents' decision.

### **Informed Consent in Practice**

Physicians discharge the duty to obtain proper informed consent more in certain clinical situations. They are likely to present more information for a surgical procedure, for example, than to discuss withdrawal of ventilator support for an infant with multiple abnormalities. When discussing surgical or technical treatments, physicians frequently present many of the treatment options, along with the risks and benefits, and their recommendations, often colored by their own value systems. Frequently this process doesn't include adequate discussion of the parents' opinions and wishes. Conversely, when discussing a case that involves the limitation of treatment, physicians have a tendency to make brief presentations and turn over the total decision to the parents. When this is coupled with a lack of emotional support, an even greater burden of guilt and responsibility is placed on the parents.

### **Balancing Parents' and Physicians' Decisions**

Clearly a proper balance of power between parents and physician is necessary in the decision-making process. The balance can best be achieved by using the informed consent doctrine. The dialogue between parents and physicians inherent

in informed consent allows the parents to reject procedures being advocated more for the physician's benefit than the child's. Furthermore, this dialogue enhances the quality of the physician's own decisions as additional scrutiny

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is given to the treatment proposals. Dr. William Silverman, one of the earliest and most revered pioneers in neonatal medicine, alluded to this balance at the centennial meeting of the American Academy of Pediatric Society in 1988: "What happens when the wholehearted dedication of medical personnel to rescue weaklings is not matched by an equal commitment on the part of parents and the community?" Dr. Silverman draws the analogy to a song by Tom Lehrer: "Once the rockets are up, who cares where they come down? That's not my department says Werner von Braun" (Silverman 1989, 168).

### **Consequences of an Imbalance in Decision Making**

An improper balance between the power of the parents and physicians' authority can lead to a variety of undesirable consequences, as illustrated by the following example:

The parents of a very premature infant were frustrated with the physicians regarding the option to stop treatment. Their two-week-old infant, born twenty-eight weeks prematurely, had developed intraventricular hemorrhage with a potentially poor prognosis. The parents wanted to stop all medical treatment, including ventilator support, while several of the attending neonatologists disagreed, feeling that the situation was not hopeless. The family became angry at the nurses and physicians, constantly criticizing the staff. As a

result, several nurses refused to care for the infant. A member of the hospital pastoral care department was consulted and on one occasion a member of the hospital's security team was posted in the NICU to prevent a violent confrontation.

Ethical conflicts in health care can arise from clashes among two or more duties, two or more competing rights, or duties competing with rights (Putilo 1993, 39). In such cases both ethics committees and representatives from the hospital's patient representative and pastoral care department are available for consultation.

### **Suggestions for Implementing the Informed Consent Doctrine**

Since the informed consent process is the cornerstone of physician-patient communication, a broad definition should be utilized. For parents to provide consent, they must be informed of all aspects of the treatment plan, including alternatives. This requires adequate time for questions, discussions and sharing of opinions. It is a participatory process that needs continuous updating. Such an ongoing process takes time on the part of health care professionals. The following suggestions help facilitate this process.

*Meetings:* It is important for physicians and parents to meet on a regular basis and not only for life-threatening situations, pre-operative consent, or to deliver bad news. If possible, schedule meetings before the critical situation arises.

Many babies are born with potentially lethal anomalies involving ethical considerations in treatment decisions in the delivery room or the NICU. Most parents have no contact with the medical and nursing staff before the critically ill neonate is born. A meeting before birth should be scheduled, perhaps with a tour of the NICU, at which time treatment options are discussed. If a prenatal diagnosis cannot be made, then a meeting should be scheduled as soon as possible after the baby is admitted to the NICU.

Weekly meetings should be scheduled with the parents to review the baby's progress and to listen to the concerns of the parents. Special meet-

ings can be arranged when the situation changes.

When the physician meets with parents, an additional health care professional should be present, preferably someone the parents know. Frequently parents are more comfortable discussing their concerns with nurses, and nurses can verify and review the discussion with the family after the physician leaves.

When discussing concerns or problems with the family, ample time for reflection and repetition needs to be allowed. A meeting between the health care professionals and relatives, religious leaders, or other support persons to explain potential problems and answer questions is helpful in maintaining in a good physician/parent relationship.

*Health Care Team Leader:* In order to reduce the confusion associated with multiple medical and surgical consultants, one physician needs to be the primary physician of the team. This person, whether the primary physician, a medical or surgical consultant, or the neonatologist, coordinates the care, collects the medical options and discusses them with the family. The family, then, has only one physician with whom to interact, rather than a large team of physicians with different schedules, personalities and communication skills.

*Physician Education:* By being open to alternative suggestions, physicians learn how to communicate more effectively with the family. Many parents have extensive experience with a specific disease, particularly if that disease is genetic.

Private and religious organizations provide current information on specific topics such as alternatives to blood transfusions for Jehovah's witnesses.

Carefully evaluating parents' suggestions along with discussing the advantages and disadvantages of each encourages trust and indicates to the family that the physician is willing to explore alternatives.

Acceptance of information can transform a po-

tential conflict into a successful outcome, as illustrated by the following case:

A premature infant was born to a Jehovah Witness family who refused any blood transfusion on religious grounds. The neonatologist, anticipating a possible need for a transfusion and wanting to initiate the best treatment for his patient, obtained a court order allowing treatment. The parents then transferred the infant to another NICU. At the new hospital, the Jehovah Witness community leader presented to the physicians an extensive bibliography on a new blood stimulating agent. The risks and benefits of this new modality were discussed by the parents, physician and religious leader. The new drug was used, and the infant did not need a blood transfusion during his hospitalization.

*Parent Education:* The provision of adequate information to the parents enables them to make an informed decision by evaluating all their options.

General informational brochures and videos about the NICU for parents relieves some of the threat and stress of the NICU environment.

The availability of non-technical information about the disease itself, including the risks and the benefits of various alternatives to the proposed treatment, is helpful to parents.

Support groups provide parents a chance to learn from other parents.

### **Conflicts with Family and Physician**

Even with the successful utilization of broader informed consent doctrines, conflicts can still arise between family members and the physicians. In these cases, calling in an outside health care professional to meet with the family, e.g., a chaplain or social worker, can assist in determining the cause of the conflict. A second medical opinion can also be useful. Working with the hospital's ethics committee provides a forum for information to be shared and discussed. The family should be notified of the committee's meeting and be invited to share their concerns.

## Conclusion

Informed consent is a viable model to enhance parent/physician communication in the NICU. The model suggested in this article parallels the principles gathered by a group of parents, all of whom had infants in the NICU. In a recent article in *Pediatrics*, this group provided guidelines for professionals and explained the active role parents expected to play in the decision-making process. This active role is realized through the informed consent process. This comprehensive approach allows all avenues to be considered and allows parents and physicians to become partners in care decisions. Rather than being a mere document, informed consent becomes the cornerstone of the physician-patient communication.

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