Title
Symbiosis of nurse and machine through fuzzy logic

Author
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Publication Date
1993

Peer reviewed|Thesis/dissertation

Symbiosis of Nurse and Machine Through Fuzzy Logic: Improved Specificity of a New Neonatal Pulse Oximeter Alarm

by

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DISSERTATION

Submitted in partial satisfaction of the requirements for the degree of

DOCTOR OF PHILOSOPHY

in

Nursing

in the

GRADUATE DIVISION

of the

UNIVERSITY OF CALIFORNIA

San Francisco

[redacted]

Symbiosis of Nurse and Machine Through Fuzzy Logic: Improved Specificity of a New Neonatal Pulse Oximeter Alarm

by

Elena Marie Bosque

SYMBIOSIS OF NURSE AND MACHINE THROUGH FUZZY LOGIC: IMPROVED SPECIFICITY OF A NEW NEONATAL PULSE OXIMETER ALARM

Elena Marie Bosque, R.N., Ph.D.

University of California, San Francisco, 1992

ABSTRACT

Non-invasive pulse oximeters are used by nurses to monitor oxygenation in >600 NICU's in the USA for >80% of mechanically ventilated infants. Motion causes false alarms up to 29% of the time, resulting in poor specificity. I developed a fuzzy logic computer prototype alarm system using fuzzy sets of desaturation, within limits, and artifact. The purpose of this study was to compare the new (NEW) vs. conventional (OLD) alarm systems to test the hypothesis that a neonatal pulse oximeter alarm system based on fuzzy logic will have equivalent sensitivity and improved specificity vs. the OLD alarm system. Thirty-eight infants were enrolled with a mean (range) study weight of 1495g (470-3390). Oxygen saturation signals (Nellcor N200) were collected for 1 hour per infant on a strip chart recorder and saved on a computer. Reference (REF) signals were simultaneously recorded from a second pulse oximeter and transcutaneous O_2 monitor. If an alarm persisted, each 30 second interval was considered a separate event. The NEW vs. OLD alarms were compared to the REF for 919 alarm events. There were 451 new alarm events, with a mean of 12.1 (range 1-36) new events per subject, and the others were persistent alarms. Oxygen desaturation was defined as transcutaneous $PO_2<40$ torr and $SaO_2<85\%$ for the REF.

		Oxygen Desaturation	No Oxygen Desaturation
OLD	Desat Alarm	197	508
	Pulse Search	2	212
NEW	Desat Alarm	199	333
	Within Limits	0	129
	Artifact Alarm	0	258

	Sensitivity	Specificity	Pos.Pred.Value	Neg.Pred.Value
NEW	1.0	0.54	0.37	1.0

The NEW alarm system had 34% fewer false positive alarms ($p<.001$). The NEW fuzzy logic alarm system has equivalent sensitivity and improved specificity vs. the OLD alarm system. When used to monitor oxygenation in infants, this system with fewer false alarms may decrease the "Cry Wolf Syndrome", and represents a symbiosis between nurse and machine.

Dedicated to Ruth Cleona Hoeschen Bosque
(1926-1992)

My mother

Acknowledgements

I have been fortunate in my career, especially through my 12 year employment in the intensive care nursery at California Pacific Medical Center (formerly Children's Hospital at San Francisco). Dr. June Brady enthusiastically supported the idea for my first research study in 1982, and since that time, I have had access to many resources and opportunities which have made this dissertation work possible. My present position as research associate in the same intensive care nursery has complemented and enriched my academic education. The friendship, encouragement, ideas, and insightful suggestions from the neonatologists, Drs. Terri Slagle, Kathleen Lewis, Toshiko Hirata, and especially, Steven Goldman, have been critical to the clinical value of this work. Dr. Goldman analyzed the pulse oximeter tracings in a pilot study to determine the amount of artifact when the signal drops to baseline. Also, he raised important questions about the performance of the reference transcutaneous electrode.

From the University of California at San Francisco, Dr. Julien Hoffman offered continual interest and statistical guidance, as he has done so, generously, for years. Dr. John Severinghaus gratiously answered questions related to my concern about the transcutaneous oxygen electrode as a reference and suggested that I use a second pulse oximeter as well. Dr. Patricia Benner greatly influenced my choice of the phenomenological perspective of the conceptual framework, which provided the link between neonatal primary nursing theory and an application of fuzzy logic to a technological innovation. Cheryl Barbic has helped for three years by coordinating communication, meetings, and paper flow to my professors in the Family Health Nursing Department.

Melva Averhart, the Nurse Manager of the Newborn Intensive Care Unit supported my work and the development of the Primary Nursing Program which I began with Sheila Watson, RN, in the mid-1980's. These experiences have profoundly influenced my ideas of the future potential of the nursing profession in the intensive care nursery. Karen Connich, RN, AA, Barbara Earnhardt, RN, BA, Eileen Prendiville, RN, BS, and Ruthie Tolleson, RN, BS, are expert nurses whose interviews provided me with data and ideas for my conceptual framework of Neonatal Primary Nursing. All of the intensive care nursery nurses teased me and called me "Busy Bosque" but helped me with my work, and assured me that I was helping the profession with my academic and professional goals. Indeed, I wonder if I would have had the ideas for this work if I had not felt the respect from colleagues and co-workers, familiarity with the environment and instrumentation, and freedom to create.

In particular, I thank the following nurses from the Newborn Intensive Care Nursery (NBICU) at the California Pacific Medical Center for their participation in this study: Dina Novello, Diane Howard, Lydia Vasovich, Donna Hansen Caldwell, Lena Moore, Jizell Albright, Barbara Nelson, Jason Mass, Camille Bohanon, Diane Ziola, Sondra Geller, Lee Ann Stohlman, Marjorie Ward, Terri Hupfer, Norma Romano, Lisa Lyons, Kathy Cooper, Linda Blide, Sandra Wong, Helen Ho, Jackie Beattie, Ruthie Tolleson, Bonnie Fimbres, and Lourdes Durham. I am grateful to the families in the NBICU who, in spite of their own concerns, participated in the study, to benefit others in the future.

Dr. Dyanne Affonso has been interested in my professional development since we met while collaborating on a study of prolonged skin to skin contact

between mothers and premature infants in the intensive care nursery. Her suggestions about my academic studies and multidisciplinary research have been unselfish, astute, and given at critical times. I am grateful for her advice and have learned much from her about the politics of science. I have been impressed by her work and how she has organized a complicated program to measure the effect of an intervention that should have positive benefits for the highest-risk perinatal populations in the United States. She is open to new ideas, and eagerly welcomed the idea of mulitdisciplinary work for nurse scientists to advance our profession.

I met Dr. Ida Martinson when I began my doctoral program. I consider her a role model of how to conduct a career-long program of studies that evolves and becomes richer without losing the focus or passion for the phenomenon of interest. My ideas about advocacy of the primary nurse were influenced by her work with parents dealing with dying, death, or chronic illnesses of their child. She groomed me for the qualifying exam and dissertation defense processes, demystified them, and therefore made them interesting, constructive, and enjoyable experiences for all those involved.

Dr. Sheldon Baumrind has shown interest in this project since its inception. With his work on signal analysis and innovative technology in dentistry, he made many valuable suggestions when I was first developing my ideas about how to construct a prototype. What I found most provocative of all of my discussions with Dr. Baumrind were his questions and ideas about the philosophical and legal implications of having machines make decisions for humans, especially in the hospital environment. I went on to read more in that area of thinking and include my thoughts in the chapter about the evolution of fuzzy logic.

I had no idea as I nervously called Dr. Lotfi Zadeh that I would receive such warm and generous support and guidance from him. He welcomed me into the world of computer science, with his many invitations to classes, conferences, student presentations, and teas at his home, where I met international students who were interested in my project and from whom I learned much. His respect and invitation of my opinions, while attending computer science forums alien to me, gave me confidence. His invaluable referrals brought me into contact with artificial intelligence experts and computer scientists around the world, and enabled me to see my idea become developed into a computer prototype. Dr. Zadeh provided me with the quintessential multidisciplinary doctoral studies experience that I will never forget.

One of the most important referrals that Dr. Zadeh made was to Jill Barnes, BS, who was, at the time, a computer programmer returning to U.C. Berkeley to receive her baccalaureate degree. Her help to me went beyond that of her honors class project requirement. Jill helped me to buy my computer and formatted the data acquisition and fuzzy logic programs. She was patient with my many, basic questions about computers and programming and has hung in there during my various computer crises to this day, even though she is now enrolled at the University of California, Los Angeles in the Computer Science Masters of Science Program . Not only was a prototype alarm system produced as an outcome of this working relationship, but so was a friendship that will last.

Another member of the "team" is a man whom I hope to meet in person some day. Dr. William Siler, an artificial intelligence programmer, was also referred to me by Dr. Zadeh. We worked together via mail, telephone, and facsimile to write the fuzzy logic pulse oximeter alarm system program. Dr. Siler and I communicated well together but it did seem like magic to me that he produced the successful program so quickly after I sent him the fuzzy sets, variables, and some sample data from babies! I am very grateful to him for his kindness and expertise.

The last member of the "team" is my brother, Dan Bosque, an electrical engineer. Dan could always fix anything and loved to solve problems, so I was very happy that he wanted to work on this project. Dan, along with Jill, helped me to purchase the appropriate computer and programs to create the system that would collect saturations signals. Dan purchased and installed the analog-digital converter and built a cable to connect it to the pulse oximeter. His love and support for me started a long time before my PhD dissertation....

My other brothers also leant their talents to this project. I did not hesitate to call Kevin Bosque, a business computer analyst, whenever I had questions about the computer files, commands, etc... Even my third brother, Bill Bosque, Jr., gave me legal advice when I had questions. My sister-in-laws, Amy and Rosemary, cheerfully put up with the "absentee aunt". My father always told me that I could accomplish anything that I desired and worked hard all his life to provide me with an excellent education and a happy home. I have been very lucky.

My beloved mother died on March 19, 1992 of cancer. I was never so glad that I am a nurse as I was in the past year. My mother's unfortunate illness made me remember the intrinsic value of the most basic of nursing skills, and caring. I think that the best professional compliment that I will ever receive came when my mother looked at me, in a new way, one day while I was caring for her, and told me sincerely, "You are a good nurse".

I met Lisle Gatenby during my first year in the PhD Program. You know what they say about boyfriends of nursing students...."You have to feel sorry for them!" Lisle listens to all of my woes, understands and remembers everything that I tell him about my project, and knew exactly how many subjects I had entered at any given time. He carries my books, posters, computers, etc... to conferences and says that he will act as "bouncer" if anyone asks too challenging a question! I had better be nice to him after all this is over! The doctorate program made these last 3 years fulfilling ones for me but Lisle made them sweet.

A few weeks ago someone asked me how did I accomplish everything, work full-time, take care of my mother, and keep up with my professional and personal responsibilities. I was asked what had been sacrificed. I had to respond that I gave up much of my time with my girlfriends. And so I will finally acknowledge those who are such close friends that it will be easy to catch up with them when this is done, I hope! Thank you Gina, Nina, Tina, Annie, Anna, Amanda, Brandee, Lori, Laura, Sandy, Sheila, Mary Teresa, and the rest.

This dissertation has been supported by the following sources of funding: A Predoctoral Fellowship Award from the American Heart Association, California Affiliate, a research grant from the Organization for Obstetric, Gynecologic, & Neonatal Nurses (NAACOG), the Hill-Rom Company, Inc., Astro-Med, Inc., and a UCSF Graduate Research Award.

My doctoral education has been very rich, valuable, and momentous for me. Students always thank those around them who offered support and assistance. In

my case, my meaning is literal when I say that I could not have done this without them.

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Chapter 1

The Problem

Introduction

An infant cannot ring a bell for the nurse. An infant cannot speak to make his or her needs known and exists in a relatively defenseless and vulnerable state. This vulnerability is more pronounced when the infant is premature or ill and dependent upon highly technological life-support equipment.

Imagine what it must be like for parents who never knew of an intensive care nursery, who had dreamt of the perfect infant, to find their premature or sick infant in such an alien environment. The bright lights, noises, seemingly life-saving knobs, wires, tubes, and many people obscure the sight of their tiny baby in the isolette. These sights and sounds can make parents feel overwhelmed and physically ill (Harrison, & Kositsky, 1983).

A primary nurse, who consistently cares for the infant and family in the intensive care nursery, sometimes for months, will be in a position to understand the infant's comfort needs, behavioral cues, physiological symptom patterns, and medical plans (Schrader & Fischer, 1987). The expert primary nurse, who has embodied knowledge of the infant, will begin to act intuitively on behalf of the infant as an advocate (Benner, 1984; Benner & Tanner, 1987; Gadow, 1989). The nurse who knows the infant well can appropriately blend technology with personal knowledge about the infant to make clinical decisions, instead of relying solely on monitors and numbers. From a phenomenological perspective, machines used routinely can become an extension of the nurse and can result in a type of symbiotic relationship (Ihde, 1975; Merleau-Ponty, 1962; Polanyi, 1966).

The expert neonatal nurse will manipulate the environment to protect and benefit the vulnerable infant and parents. One form of this advocacy involves efforts on the nurse's part to actively select (if available) or lobby for technological monitoring devices which are better for the infant and family in terms of accuracy, reliability, safety, ease of use, and effects on the neonatal environment. One such monitoring device used in intensive care nurseries is the pulse oximeter.

The pulse oximeter is a spectrophotometric device which measures oxygen saturation by differentiating light absorbances of reduced and oxygenated hemoglobin during arterial pulsations through the use of a computer program (Yoshiga, Shimada & Tanaka, 1980). It is an attractive monitor for neonatal nurses because it measures oxygenation non-invasively and continuously. Although the reliability of the pulse oximeter is well established in adult (Severinghaus & Naifeh, 1987; Yelderman & New, 1983), pediatric (Fanconi et al., 1985; Swedlow & Stern, 1983) and neonatal (Bucher et al., 1989; Hay, Brockway, & Eyzaguirre, 1989; Jennis & Peabody, 1987) populations, in all of these studies the correlating arterial blood gases were obtained while the subjects were quiet and when the oximeter pulse rate was equal to the cardiac monitor heart rate. In the intensive care nursery, all but the paralyzed or moribund infants kick and cause interference to the pulsations sensed by the pulse oximeter, which causes the alarm to sound falsely (Harbold, 1989; Spyr & Preach, 1990). Motion artifact has been estimated to occur 12-29% of the time, resulting in poor specificity (Barrington, Finer & Ryan, 1988). Motion artifact has been identified consistently as a limitation of the pulse oximeter when used in neonates (Blanchette, Dziodzio, & Harris, 1991; Hay, Thilo, & Curlander, 1991; Salyer, 1991; Severinghaus & Kelleher; 1992; Welch, DeCesare,

& Hess, 1990). This frequent, excessive sounding of alarms may be overstimulating for infants and parents and dangerous if it causes a "Cry Wolf Syndrome" pattern of behavior among nurses, which could result in hypoxia or hyperoxia.

During a study of physiological measures of prolonged skin to skin contact between mother and premature infant in a tertiary level nursery (Bosque et al., 1988), I observed and recorded many hours of oxygen saturation signals. I observed characteristic differences in the patterns of the slopes of the saturation tracings when there was a true desaturation versus when there was motion artifact. I had the idea of developing an alarm system based on slope differentiation and then I read an article about fuzzy logic. I felt that fuzzy logic was applicable to my idea of developing a new alarm system for the neonatal pulse oximeter because it solved the practical problems as well as supported my conceptual framework for neonatal primary nursing.

Statement of the Problem

The problem to be studied was the testing of a new computer prototype neonatal pulse oximeter alarm system for equivalent sensitivity and improved specificity compared to the conventional alarm system.

Purpose of the Study

The purpose of this study was to work with experts from other disciplines to develop a prototype computer alarm system based on fuzzy logic for the neonatal pulse oximeter. The new (NEW) vs. conventional (OLD) neonatal alarm systems for the pulse oximeter were compared by testing them on data collected from infants in a tertiary level nursery. The application of fuzzy logic to a neonatal pulse oximeter alarm system would also theoretically support the conceptual model of Neonatal Primary Nursing.

Significance

Non-invasive pulse oximeters are being used by nurses in >600 intensive care nurseries in the United States, for more than 80% of mechanically ventilated infants (Sayler, 1991). Pulse oximeters are just one of many technological devices being used in intensive care nurseries in an attempt to accurately measure and carefully monitor the level of oxygenation in infants.

The practice of administering oxygen to infants was begun in the late 1930's. It was given to treat the neonatal respiratory depression resulting from narcotics administered to the mother and to prevent brain damage and death in premature infants (Meiks, 1937; Silverman, 1988). By the 1940's, the practice of administering high concentrations of oxygen was widespread, in spite of the identification of the blinding disease of retrolental fibroplasia by Theodore Terry, in 1941 (Patz, 1968). Many investigations were performed around the world to discover the cause of retrolental fibroplasia. Although the cause was thought to be multifactorial, enough evidence emerged by 1953, implicating the role of oxygen, to warrant investigators at the National Institutes of Health to identify the need for a randomized controlled trial (Silverman, 1988).

The dramatic results of that study, associating high concentrations of oxygen with retrolentral fibroplasia, caused physicians to limit the amount of oxygen they administered to infants within a year of the publication in 1954 (Lucey & Dangman, 1984). The indiscriminate restriction of oxygen then lead to increased neonatal mortality and increased incidence of spastic diplegia (Avery & Oppenheimer, 1960;

McDonald, 1963). These tragic discoveries about the consequences of oxygen therapy lead to efforts to develop methods of monitoring oxygenation, beginning with sampling from an umbilical arterial catheter, in the mid-1960's (Kitterman, Phibbs, & Tooley, 1970).

Other identified consequences of neonatal oxygen toxicity are changes in the pulmonary epithelium when oxygen is accompanied by positive pressure ventilation, resulting in bronchopulmonary dysplasia (BPD) (Boat, 1979; Northway, Bosan & Porter, 1967). Bronchopulmonary dysplasia is the major cause of significant morbidity among survivors of respiratory distress syndrome (Edwards, Dyer, & Northway, 1977). The relationship of oxygen toxicity to the etiology of this disorder is complicated by the finding that in severe cases of BPD, minor decreases in inspired oxygen results in increases in pulmonary vascular resistance and venous admixture (Halliday, Dumpit, & Brady, 1980).

Since the publication, in 1954, of the association of retrolental fibroplasia in premature infants with high concentrations of inspired oxygen, efforts have been made to develop accurate methods of measurement of oxygenation in infants (Lucey & Dangman, 1984). Approximately 5-20% of low birthweight infants who survive intensive nursery care have long-term sequalae of neurodevelopmental disorders, blindness, or chronic respiratory problems (Fitzhardinge, 1987). Injury resulting from hyperoxia as well as delay in tissue growth and disrupted organ function resulting from hypoxia have led investigators and clinicians to seek methods of measurement to provide the optimum level of oxygen to the infant in need of it (Kalhan & Denne, 1990).

Chapter 2

Literature Review: Primary Nursing

Meleis' (1985) tentative suggestion of the development of the nursing discipline as "a convolutionary process" (p. 63) can be supported by a review of primary nursing. The features of circular paths, retracing of steps, detours, and crises that Meleis added to the evolutionary process of discipline development, well characterize the knowledge generation related to the concept of primary nursing. At the conclusion of Giovannetti's (1986) beautiful and scathing critique of mostly inadequate evaluative studies, she encouraged nurses to proceed with a philosophical inquiry before measuring the effects of primary nursing by scientific means. Before entering upon such philosophical inquiry about neonatal primary nursing, it is necessary to review the literature and identify gaps in knowledge.

The purpose of this paper is to review the literature about primary nursing with a substantive focus on neonatal primary nursing. The work of major contributors will be summarized and common terms will be defined. Concepts arising from the voluminous descriptive and anecdotal articles will be identified. A table will be introduced in which major critical points are summarized about evaluative studies. Strengths and weaknesses of this work will be addressed. Gaps in knowledge will be identified, particularly with regard to the paucity of neonatal primary nursing literature. Finally, ideas for future work will be suggested.

Major Contributors

Manthey (1970, 1973, 1980) is generally credited with the development of the system of primary nursing. While working at the University of Minnesota Hospital in the late1960's, Manthey developed and implemented primary nursing as an alternative to team nursing. Four main characteristics of this system of care were twenty-four hour accountability, case-method assignment, direct communciation among care-givers, and the role of head nurse as facilitator (Manthey, 1980). Manthey consulted internationally and her system has been adopted and advocated widely around the world. Recently, she has addressed the relevant issues of how the system of primary nursing can be maintained during a nursing shortage as well as financial health care crisis (Manthey, 1988; Manthey, 1989).

Marram (1974) extended the concept of primary nursing into a philosophy of care. She believed that the patient, and not tasks, is the central focus of nursing and that accountability is of paramount importance. She criticized team nursing as being prohibitive of continuous care because of too many complex channels of communication. Marram's (1974) description of primary nursing is thorough, concrete and often used in articles when primary nursing is defined. Some of her characteristics include complete individualized care, twenty-four hour accountability achieved through written or verbal communication, consistency of patient assignment, multidisciplinary coordination of care, and the primary nurse identified as the patient's nurse. Finally, Marram (1971) was one of the first investigators to study the cost efficiency of primary nursing.

Ciske (1974) was a committee member who, with Manthey, planned the implementation of primary nursing at the University of Minnesota Hospital in the late 1960's. She has consulted with others who wished to implement primary nursing. Her contribution is her work analyzing selected processes occurring during primary nursing. She has written about accountability (Ciske,1979) and peer contracting (Ciske, 1983). Although these are predominantly anecdotal accounts, some definition of terms and concept analyses were accomplished.

Hegyvary (1977) analyzed the innovation of primary nursing and came to the conclusion that its development is part of the evolution of the nursing practice towards professionalism. She identified evolutionary stages as the era of individual responsibility for nursing (case method), the era of responsibility for tasks (functional nursing), the era of care through others (team nursing), and now the new face of individual accountability (primary nursing)

Others have made significant specific contributions to knowledge development, albeit, not necessarily in favor of primary nursing. Betz (1981) associated the rising popularity of primary nursing and accountability to the national development of consumerism. He performed comparative cost and quality analyses and found primary nursing to cost more than team nursing (Betz, 1980; Betz, 1981).

Shukla's (1981, 1982, 1983; Shukla & Turner, 1984) series of well-controlled, well-designed studies demonstrated that primary nursing costs more with no demonstrated benefit in terms of productivity, patient, or nurse satisfaction. One may still criticize the validity of the design to answer the question, "Is primary nursing worth it?", but Shukla's studies addressed many of the methodological issues lacking in previous studies.

Giovannetti (1980, 1981; Young, Giovannetti, & Lewison, 1981) also attempted to control for extraneous variables in answering efficacy questions about primary nursing, although she identified limitations in her own studies. Her critique of previous work (1986) highlights the necessity for philosophical inquiry and an unbiased, scientific approach before we will be able to make advancements in knowledge development related to the concept of primary nursing.

Definition of Common Terms

Primary nursing will be defined as a delivery system designed to allocate twenty-four hour responsibility for each patient's care to one individual nurse and to assign this nurse to the actual provision of her patient's physical care wherever possible (Manthey, 1980). The key concepts related to primary nursing are identified as accountability, advocacy, assertiveness, authority, autonomy, collaboration, continuity, communication, commitment, and coordination (Watts & O'Leary, 1980).

In the literature various models of nursing care delivery are mentioned and are defined according to Hegyvary (1977):

Team nursing provides care to a group of patients by coordinating the registered nurses, vocational nurses, and aides, under the supervision of the team leader.

Modular nursing care involves a geographic assignment of patients that encourages continuity of care by organizing a group of staff to work with a group of patients, usually about 10-12 patients per module.

Total patient care is a case method approach for organizing care so that nurses are responsible for total care of a patient for their shifts only.

Primary care refers to primary nursing, involving twenty-four hour accountability. The primary nurse may work with associate nurses, who work consistently with the patient but follow the plan of the primary nurse. Betz (1981) emphasized the distinction between primary nursing, as defined, and primary care in the medical sense as the first practitioner who sees a patient as he/she enters the health care system. The latter definition and meaning is not used in the care modalities studied.

Categories of Analysis and Summary of Descriptive Literature

In a review of the literature by Young, Giovannetti, Lewison, and Thoms (1981), over 150 articles about primary nursing were identified, with 80% of these being non-research based. Computer and manual searches of the years 1985-1990 by the present author resulted in over 140 articles about primary nursing, with 90% being non-research based. No article dedicated entirely to concept analysis could be found.

In the various primary nursing review articles, different categories have been used to organize the publications reviewed. Hegyvary (1982) divided publications into formative and summative work. Young, Giovannetti, Lewison, and Thoms (1981) used descriptive, descriptive-evaluative, and research-based classifications. Giovannetti (1986) used evaluative and explorative non-comparative, assessment of perceptual outcomes, quality of care, and multiple outcomes to divide her review of solely research-based studies. Finally, Macdonald (1988) used descriptive, formative, and summative catagories to organize her review.

The substance of the most recent descriptive literature to date has not changed from that summarized by Young, Giovannetti, Lewison, and Thoms (1981) or Macdonald (1988). It remains to include anecdotal accounts, case reports, definitions of primary nursing, factors leading to its implementation, support for it, and can be organized by the themes identified by Macdonald (1988) as "Is it worth trying?", "Here's what we did", and "Is it worth it?" (p. 797). The slight contemporary variations in content center around support for primary nursing during times of nursing shortages and financial constraints (Manthey, 1988; Manthey, 1989), implementation in different clinical settings (Bethea, 1985; Haff et al., 1988; Jones, 1986; Mileur, 1987) or in other countries (Bowers, 1989).

Review of Evaluative Literature

The review of the summative, research-based, or evaluative literature is summarized in Appendix A. Articles are listed in chronological order, key features are identified, and critical comments are included. These studies have been chosed for review because the methods and measures were easily discernible. This review is not all inclusive, but is representative of the best scientific work on the concept of primary nursing to date.

Many of the authors have produced multiple studies or descriptive aritcles about primary nursing, while others have been involved in only a single published study. Only a few of the authors used any kind of conceptual framework beyond a basic definition of primary nursing. These efforts at concept development will be discussed.

The outcome variables measured were related to quality of care, patient satisfaction, job satisfaction, and cost. Quality of care was sometimes measured in terms of patient satisfaction, anxiety, stress, tranquility, vitality, personal control, nursing documentation, and health outcomes. In other studies, patient satisfaction was identified as a separate variable, independent of quality of care. Job satisfaction was measured specifically, as well as by measuring turnover rates. Cost was measured by audit methods with varying definitions of the variables sought.

The following tools were used in one or more studies for the outcome variables identified. Reliability and validity of the use of these tools in the populations studied was not addressed in all of the studies.

Quality of Care

Audits of charts and acuity systems

Direct Observation of nurses working with patients

Geriatric Residents' Goals Scale (Cornbleth,1978)

Health Status Dimension Scale (Horn & Swain, 1977)

Interview

Life Satisfaction Scale (Neugarten, Havighirst, & Tobin, 1961)

Nursing Dependency Scale (Garraway et al., 1980)

Patient Service Checklist (Hall et al., 1975)

Personal Control Rating Scale (Zeigler & Reid, 1979)

Phaneuf Nursing Audit (Phaneuf, 1972)

Quality of Care Assessment Tool (Medicus System, 1983)

Quality Patient Care Scale (Wandelt & Ager, 1970)

Questionnaire (self-developed)

Risser Patient Satisfaction Scale (Risser, 1975)

Slater Nursing Competencies Scale (Slater, 1967)

State-Trait Anxiety Inventory (Spielberger & Diaz-Guerrero, 1976)

Stress Evaluation Tool (Volicer, 1973)

Tranquility/Agitation Scale (Morris & Sherwood, 1975)

Vitality Rating Scale (Zeigler & Reid, 1979)

Patient Satisfaction

Interview

Questionnaire (self-developed)

Risser Patient Satisfaction Scale (Risser, 1975)

State-Trait Anxiety Inventory (Spielberger & Diaz-Guerrero, 1976)

Job Satisfaction

Interview

Job Descriptive Index (Smith, Kendall & Hulin, 1969)

Job Satisfaction Questionnaire (Dyer, 1967)

Job Satisfaction Questionnaire (Munson & Heda, 1974)

Job Satisfaction Scale (Herzberg, Mauser, and Snyderman, 1959)

Questionnaire (self-developed)

Work Satisfaction Scale (Brayfield & Rothe, 1951)

Cost

Audits in which the following variables were measured:

Length of stay

Total cost of hospitalization

Cost/RN hour

Cost/patient day

Cost/nursing hour

Weaknesses and Strengths of the Studies

Many methodological problems exist in the studies of primary nursing. The existence of these weaknesses provide explanation for the lack of theoretical development of this phenomenon which so obviously intrigues many nurses. Probably more precisely, the lack of theoretical and conceptual work preceding experimental design may explain the failure of primary nursing to be widely implemented and accepted.

The methodological problems encountered in this review were absence of a conceptual framework and true experimental design including randomization, a control group, control of extraneous variables, and use of a reliable and valid tool to answer the research question. There were problems in design and selection which represent threats to validity, when subjects volunteered (Blair et al., 1982), patient populations differed (Carlsen & Malley, 1981), nurse's characteristics were not matched or addressed (Daeffler, 1975; Felton, 1975; Parasuraman, 1982), or there were problems of maturation and history (Wilson & Dawson, 1989). There were problems with measurement, analysis, and interpretation, when without established reliability and validity of tools and without statistical methods, conclus Neonatal Primary Nursingmary nursing (Betz, 1981; Collins, 1975;

Daeffler, 1975; Hegedus, 1979; Joiner, Johnson, & Corkrean, 1981; Jones, 1975; Marram, 1974; Marram et al.,1976; Wilson & Dawson, 1989).

In some studies, based upon a result of a significant difference in parts of tools, or in some measures when multiple measures were used, conclusions were reached in support of primary nursing (Alexander, Weisman, & Chase, 1981; Carlsen & Malley, 1981; Collins, 1976; Culpepper et al., 1986; Hegedus, 1980; Sellick, Russell, & Beckmann, 1983; Streckel, Barnfather, & Owens, 1980; Wilson & Dawson, 1989). In one study, there was a loss of data and the authors still concluded in favor of primary nursing (Pearson, Durant & Puntor, 1988). In other studies also affected by varying methodological problems, results were found lacking support for primary nursing (Betz, 1981; Betz, Dickerson & Wyatt, 1980; Blair, Sparger, Walts, & Thompson, 1982; Cassata, 1973; Giovanetti, 1980; Giovanetti, 1981; Glandon, Colbert & Thomasman, 1989; Humera & O'Connell; 1981; Mills, 1979; Parasuraman, 1982; Shukla, 1981; Shukla, 1982; Shukla, 1983; Shukla & Turner, 1984; Young, Giovanetti & Lewison, 1981). Finally, one must ask the question about external validity, and were the tools chosen or developed truly able to measure the effect of primary nursing? Was primary nursing accurately operationalized?

In spite of the many problems, strengths were identified in particular aspects of studies and it is possible to see attempts to overcome methodological and conceptual problems. The strengths will be discussed in terms of evidence of randomization, conceptual framework, operationalization of the concept, control of extraneous variables, and use of observation as a method to measure primary nursing.

Some evidence of randomization could be found. Random sampling of patients (Mayer, 1982; Steckel, Barnfather, & Owens, 1980), random sampling of observation periods (Betz, Dickerson & Wyatt, 1980), random assignment of patients to study units (Jones, 1975; Mills, 1979; Pearson, Durant & Punton, 1988), and randomization of head nurses (Chavigny & Lewis, 1984) were methods used. In some studies, although randomization was not accomplished, attempts were made to match characteristics of patients or nurses (Giovannetti, 1980; Giovannetti, 1981; Humera & O'Connell, 1981; Marram et al., 1976; Shukla, 1981; Shukla, 1982; Shulka, 1983; Shukla & Turner, 1984). However, these methods must be scrutinized. In the study by Marram, Flynn, Abaravich, and Carey (1976) certain demographic characteristics were matched between the primary nurses and team nurses, except for seniority. Although primary nursing was concluded to be more cost effective, this difference could be explained by the increased seniority of the team nurses.

A few of the investigators used some conceptual or theoretical framework as part of their studies. Mills (1979) wrote about the theory of nursing care delivery systems and the effects on perceptions of patients and nurses. Joiner, Johnson, & Corkrean (1981) included motivational and job design theory as the theoretical basis for their research question and choice of tool. Ventura et al. (1982) demonstrated some very basic concept analysis in their research aim of attempting to measure key concepts of primary nursing. Culpepper et al. (1986) used concepts of innovation and nursing process as a basis for their primary nursing quality of care study. Reed (1988) examined the philosophy of primary nursing and its relation to quality of care and job satisfaction using the Hackman and Lawler (1971) model of job satisfaction as a theoretical basis for the study.

Mayer (1982) made attempts at both concept analysis and operationalization of primary nursing. She identified one operational definition of primary nursing as the patient's ability to identify the primary nurse by name. She randomly selected patients on primary nursing units and compared the results of a patient satisfaction scale of groups of patients who did versus did not identify the primary nurse by name. Her conclusions were in favor of primary nursing. Mayer's study represents one of the few attempts at concept development and operationalization of the concept, using methods which control for extraneous variables.

Other attempts at operationalization of the concept and ensuring external validity involved the observation of nurses working with patients (Betz, Dickerson, & Wyatt, 1980; Giovanetti, 1980; Giovanetti, 1981; Humera & O'Connell, 1981). In all of these studies, many samples or long-term observation was performed and interrater reliability was established. The results in all but the Betz, Dickerson, and Wyatt (1980) study showed that the primary nurses spent equal or less time with the patients and the conclusions were that primary nursing was not supported. In the study by Betz, Dickerson, and Wyatt (1980) the authors observed that the primary nurses cared for patients with higher acuity scores as an explanation for the higher cost of primary nursing.

The use of observation methods will help to measure the essence of primary nursing, but investigators must clarify conceptual frameworks, propositions, and assumptions before making conclusions. Possibly a primary nurse who knows a patient well may spend less time and deliver better care. Methods of measurement, to date, have been inadequate because assumptions about the process of primary nursing have not been identified. In that case, conclusions must be made cautiously.

Other studies deserve mention because of particular salient features. Collins (1975) was one of the first investigators to raise the question about the effect of educational preparation on the nurse's perception and practice of primary nursing. In the survey of 19 hospitals by Haussman, Hegyvary, and Newman (1976), structural characteristics of nursing units were described in an attempt to answer the question of "Is primary nursing a philosophy or an administrative and structural mode of care?". Chavigny and Lewis (1984) concluded from their study that the preparation of the nurse may be more important that the mode of care. Culpepper et al. (1986) used three sets of post-tests to control for the "novelty" effect of a new innovation but found timing not to affect nurse perceptions. Glandon, Colbert, and Thomasma (1989) found that small primary care units with high percentages of registered nurses cost more than other modes of care, but failed to distinguish the higher cost as attributable to primary nursing or the cost of registered nurses. In all of these studies, investigators addressed the issues of confounding variables and difficulties of operationalization of the concept of primary nursing.

Review of Neonatal Literature

Almost no articles exist in the neonatal literature specifically about primary nursing. In many general neonatal articles primary nursing is advocated under the assumption that it is beneficial for the care of fragile, sick or premature infants and their families (Blackburn, 1982; Blackburn, 1983; Schraeder, 1980; Schraeder & Fischer, 1987; Thornton, Barry, & Dal Santo, 1984).

Bethea (1985) wrote a thorough description of an experience of implementation of primary nursing in an intensive care nursery, focusing on processes of interaction between the primary nurse and others, particularly the parents. Smith (1987), a nurse and parent of a premature baby, wrote a moving account of her bad experience in an intensive care nursery where primary nursing was not implemented and highly recommended its use. Shields and Tenorio (1988) wrote a case report about a chronically ill infant born prematurely who was dying from respiratory and nutritional problems until primary nursing was instituted in a pediatric intensive care unit. They included a weight chart showing dramatic weight gain immediately after primary nursing began, and described respiratory and developmental improvements.

The only study related to neonatal primary nursing is one by Als et al. (1986) in which individualized behavioral and environmental care for very low birthweight infants was shown to result in improved developmental outcome. To implement the independent variable of developmental intervention, primary nursing was instituted and infants received the intervention from the primary nurse. In a time series design, the control infants were sampled from the time before primary nursing was implemented. It is unclear whether the beneficial results reported were the result of the developmental intervention or from primary nursing.

The neonatal articles represent a miniscule version of the knowledge development of primary nursing, in general. These early efforts demonstrate fervent support for the phenomenon and assumption of benefit, include case and anecdotal reports, and already present problems of confounding variables in the one study involving primary nursing.

Gaps in Knowledge

Based on this review of the literature, the obvious gaps in knowledge related to primary nursing are the absence of conceptual and theoretical work, operationalization of concepts, development of propositions and assumptions, selection of measures appropriate to the research question, and justified interpretations of results. There exists a paucity of literature about neonatal primary nursing, indicating need for conceptual development, as well as work about processes and outcome. In both the adult and neonatal primary nursing literature, there have been a few descriptive and no controlled studies of the effect of primary nursing on physiological variables.

Conclusion

Situation-producing theory that can guide practice and constitute nursing as a discipline has its roots in practical wisdom (Dickoff & James, 1968). Dickoff and James warned nurse theorists and researchers not to overlook the abundance of rich resources which may be in an unsophisticated form. Silva (1977) emphasized the importance of being creative in the approach to a research question and the appropriate choice of method to avoid meaningless results for the sake of the claim that the "scientific method" was used.

The work accomplished in the study of primary nursing seems befuddled with difficulties and circular progress. However, this work cannot be ignored because it can provide the basis for elegant concept development and application of appropriate methods of theory-testing. At this time, the goal for nurse scientists interested in the concept of primary nursing should be to develop appropriate methods that will test theory and capture the truth. Those interested in the new area of neonatal primary nursing can learn from the efforts of others.

Chapter 3

Conceptual Framework: Neonatal Primary Nursing

In the past forty years, the development of medical technology has led to improvements in survival rates for premature and sick infants (Hodgeman, 1988), but not without its physical, emotional, and financial costs for the families (Blackburn, 1982). In the past ten years, investigators have described the effect of the physical and social environment of the intensive care nursery on the infant born at risk for developmental problems, and on the family (Beckwith & Cohen, 1980; Blackburn, 1983; Danford, 1983; Gorski, 1980; Gottfried, Wallace-Lande, Sherman-Brown, King, & Coen, 1981; Gottfried, Hodgeman, & Brown, 1984; Long, Philips, & Lucey, 1980; Norris, Campbell, & Brenkert, 1982). Interventions to ameliorate the stress on the infant and to promote the interactions between mother and infant have been described or investigated (Affonso, Walhberg, & Persson, 1989; Alset al., 1986; Anderson, 1989; Blackburn, 1983; Bosque et al., 1988; Thornton, Berry, & Dal Santo, 1984).

Central to discussions about supportive interventions is the role of a nurse who consistently cares for the baby and mother, the primary nurse (Als et al., 1986; Bethea, 1985; Medoff-Cooper & Schraeder, 1982; Thornton, et al., 1984). In spite of its importance, little is known about the concept of neonatal primary nursing. The purpose of this chapter is to analyze the concept of neonatal primary nursing in terms of the related concepts of intimacy, trust, intuitive knowing, and advocacy. The analysis will include

- A description of the phenomenon and explanation of its relationship to the nursing domain.

•An identification and definition of central and related concepts.

•A statement of antecedents and consequences.

•A presentation of exemplar and contrary cases.

Once analyzed, the concept of neonatal primary nursing will be related to interactional attachment theory. Assumptions, propositions, theoretical relationships, and goals for the framework will be presented, and a descriptive explanatory model for neonatal primary nursing will be suggested. This conceptual model provides the theoretical support for blending of intuition with technology or the symbiosis of nurse and machine.

Description of the Phenomenon

Imagine what it must be like for a parents who never knew of an intensive care nursery to find their sick or premature infant in such an alien environment. In a teaching hospital, there are so many different kinds of physicians and nurses every shift that, often, a mother does not know who she can approach with the simple question, "How is my baby doing today?"

It is not surprising that a mother's face will brighten when she sees that the nurse who usually takes care of her infant, is at her infant's isolette again. The phenomenon of the lengthy, intimate relationship of a consistent (primary) nurse with an infant and mother will be described in terms of characteristics of the relationship between **primary nurse and infant, primary nurse and mother**, and for the **nurse** him or herself. These descriptive characteristics were obtained from unpublished observations, data, and interviews with expert primary nurses and mothers. A few examples are presented below.

Primary Nurse and Infant: Observations

•The primary nurse focused on the whole versus parts. The infant is seen as a person. The primary nurse attempts to make life normal for the infant in the intensive care nursery.

•Primary nurses more easily became frustrated if physicians or other nurses did not respond to their concerns about a change in physiological variables or a need for a change in the plan of care.

•The primary nurses attempted to predict and identify problems such as hypoxemia, infection, seizures, need for medications, or best techniques for feeding and providing comfort more often than others.

Comments from Primary Nurses

•"The primary nurse knows the infant and his or her personality, and so knows how to handle behavior, e. g. how to interpret a cry, how to manage irritability, how to position for best oxygenation, without attempting "trial and error" methods of nursing care" (Connich, 1989, Earnhardt, 1989, Prendiville, 1989, Tolleson, 1989).

•The primary nurse knows the infant "like a mother, or like the mother would if she could" (Earnhardt, 1989), "like a pseudo-parent"(Tolleson, 1989), or "like a surrogate mother" (Connich, 1989).

•"A sick child represents a central, sensitive portion of a mother's life. To take care of someone else's child establishes an intimate relationship with them" (Connich, 1989).

Primary Nurse and Mother: Observations

•The primary nurses had more time to talk and listen to the mother because they already knew the infants, and their care-taking tasks were organized.

•Primary nurses gave mothers more control over the nursery environment, by involving them in care and establishing routines and rituals. These nurses were confident in encouraging the mothers to become involved because they knew what the infants could tolerate. These mothers began to take over care of their infants without asking permission.

•After discharge, mothers continued to communicate with primary nurses. Mothers made special efforts to thank primary nurses, continued to call with questions, and socialized with them.

The Primary Nurse: Observations

•Primary nurses felt a greater sense of commitment and involvement with the infant and family than did others who knew them less well. Primary nurses attended patient care and family conferences more often than others.

•Mothers became dependent upon the primary nurses. They asked for explanations, if the primary nurses were not caring for their infants because of assignment problems. Primary nurses informed mothers of their vacations, and often continued to communicate with them even if not caring for the infants.

Comments from Primary Nurses

•"It is easier to take care of an infant if one is the primary nurse. Ones knows what to expect" (Connich, 1989).

•"There is burn-out with primary nursing, but caring overcomes that" (Connich, 1989).

•"The primary nurse becomes an advocate for the baby" (Connich, 1989, Earnhardt, 1989, Tolleson, 1989, Prendiville, 1989). "A baby cannot ring a bell for the nurse. The primary nurse must make his needs known" (Connich, 1989).

Relevance to the Nursing Domain

Neonatal primary nursing is central to the domain of nursing because it includes the concepts of person, health-illness, nursing actions, and environment, as defined by Flaskerud and Halloran (1980). The applicability of these concepts can be specifically related to neonatal primary nursing.

The primary nurse helps the mother and infant overcome or adapt to health problems that threaten normal development. The nursing actions of the primary nurse are to support the mother in her recovery from health problems related to the pregnancy, labor and delivery, and to help her to adapt to physical and emotional problems related to having an infant in the intensive care nursery. The primary nurse also acts to prevent and treat the infant's health problems, give support against the effects of the environment, and promote normal infant development. The environment will be defined as the intensive care nursery, which affects both mother and infant. Friedmann (1989) proposed a new working definition of family nursing in which family members can be seen as individual clients, dyadic, triadic clients, or together as a family system, depending upon the situation. In the analysis of the concept of neonatal primary nursing, infant and mother will be viewed both as individuals and as a dyad, in relation to the primary nurse.

Identification and Definition of Concepts

The central concept of analysis is neonatal primary nursing. Manthey (1973, 1980) identified five basic principles of primary nursing:

1. Twenty-four hour per day responsibility for nursing-care decision-making.
2. Nursing assignments based on skills needed by patients.
3. Care planner as caregiver.
4. Direct communication between caregivers.
5. Head nurse as facilitator of primary nursing.

Many qualitative and quantitative descriptions of the effect of primary nursing in numerous patient care setting can be found in the literature. The variables studied have focused on issues of patient satisfaction, nursing practice, staff morale, and cost, with varying results. In spite of this plentitude of investigation in other specialty areas, there has been very little study of neonatal primary nursing. Although neonatal primary nursing is highly promoted (Harrison & Kositsky, 1983; Schraeder & Fischer, 1987; Thornton et al., 1984), only a few articles could be found in which neonatal primary nursing was explicitly described or tested (Als et al., 1986; Bethea, 1985; Schraeder, 1980).

In Bethea's (1985) and Schraeder's (1980) articles, their experiences with primary nursing was described and guidelines for implementation were suggested. Their suggestions supported Manthey's (1973, 1980) general principles. They described how the primary nurse can intervene on behalf of the infant because he or she knows the infant well. Furthermore, they saw better discharge teaching and parental support as the goal of primary nursing.

In Als and associates' (1986) study of the effects of protective developmental intervention technique for preterm infants, primary nurses implemented the experimental care. Their role was considered integral to the design of the study because the independent variable of developmental intervention relied upon the nurses' observation of the infants' physiological and behavioral cues, the nurses' alteration of care-giving practices in response to those cues, and observations of the infants' feedback. Emphasis was placed on the infants' individualized developmental care plan. The results of this long-term follow-up study indicated that infants in the experimental group had shorter times on respirators, increased inspired oxygen, earlier normalized feeding behavior, and better behavioral regulation scores at one and nine months corrected age. However, these results were attributed to the developmental intervention and not to the primary nursing that was supported by the design of the study.

The related concepts that repeatedly have emerged from observations of the phenomenon are intimacy, trust, intuitive knowing, and advocacy. They will be defined and related to the concept of neonatal primary nursing. Patterns among these related concepts will be identified. Neonatal primary nursing is an important intervention because of the vulnerability of the infant and family.

Vulnerability

Infants are vulnerable because they cannot speak for themselves. Although it seems logical that parents would become the advocates for their infant because of their close relationship, this is not always possible because of the parents' own vulnerability. The time surrounding the birth of a premature or sick infant is such an emotionally and physically critical period, and they are in a highly technological environment which may seem foreign and frightening to them. Many parents need help to process the information presented to them and adapt to the unexpected situation.

Penticuff (1988) presented an argument for allowing "reasonable parents" to have major input into treatment decisions for infants in intensive care nurseries, based on a model for "reasonableness standards". Included in the model is the assumption that infants are unable to make decisions for themselves and require a guardian to decide for them. A "bonded guardian", or someone with a prior relationship (e.g. throughout pregnancy) and affectional ties with the infant should make the decisions because they should be interested in the welfare of the infant above other concerns. The guardian should be able to comprehend relevant facts and make rational decisions.

Penticuff suggested that communication and education must be improved between health care professionals and parents, before parents will be able to understand enough to help make these difficult decisions. This approach is still controversial, yet emphasizes that the vulnerable infant must have someone to advocate for him or her to help parents overcome the physical, technical, psychological, and emotional barriers of the intensive care nursery (Griffin, 1990). The inability of the infant to speak has also been the stimulus for the development of many of the advanced monitoring systems in the intensive care nursery.

Intimacy

Intimacy is defined as "close acquaintance; deep and exact knowledge" (Overton, 1943, p. 566). Benner and Wrubel (1989) explained that embodied knowledge enables us to move through situations and encounter situations in terms of meaning and in rapid, nonreflective ways. The body was described as continuous with the person. Accomplished skills are like extensions of the body. Such propositions about knowledge acquisition assume a close relationship.

> To be intimate means to be close, and I must make it clear at the outset that I am treating this literally. In my terms, the act of intimacy occurs whenever two individuals come into bodily contact. (Morris, 1971, p. 9)

Kelley et al. (1983) defined a close relationship as "one of strong, frequent, and diverse interdependence that lasts over a considerable period of time" (p. 38). They defined the properties of the term "close" as "...frequency, duration, diversity, intensity. Close relationships are commonly believed to be characterized by strong positive emotion and high affective involvement" (p. 38). Huston and Burgess (1979) include in their explanation of a close relationship, factors such as shared norms about communication, responsibility, attitudes of liking, love, or trust, and beliefs about the uniqueness and importance of the relationship.

These definitions and descriptions of intimacy can be seen as applicable to the concept of neonatal primary nursing, based on the stated observations of the phenomenon. Intimacy could be seen between the primary nurses and infants because of the frequent, continual, physical contact over a duration of weeks to months. The strong, intense, affective involvement was evident in the primary nurses' descriptions of their feelings toward the infants who they came to know.

Intimacy can also be attributed to the relationship between the primary nurse and mother. Although actual physical touching is not frequently seen as an integral part of the their relationship, it could be observed at certain times. During crises when the mothers were crying or grieving, the primary nurses were usually the people to physically comfort them. During teaching, the primary nurse could be seen touching the mother when helping her position the infant for breast-feeding, when guiding the mother's hands during skill åcquistion, or when reassuring her. Finally, a very close physical relationship persisted continually for months when the primary nurse and mother could be observed standing next to one another, often with shoulders touching, while they watched the infant together.

The affective relationship between primary nurse and mother was certainly strong, frequent, and normally, positive. There were shared norms of communication, since the primary nurse was the consistent person who translated the medical information. The primary nurse could understand the mother's fears and concerns as they related to the context of the intensive care environment, a place which most relatives and friends cannot comprehend. There was a shared responsibility of taking care of the infant. As long as the nurse continually affirmed the mother's role and involved her, most mothers acknowledged the primary nurse's participation in the responsibility of caring for the infant.

The characteristic of interdependence, related to intimacy, is the most subtle one to attribute to neonatal primary nursing. The dependency of both infant and mother on the primary nurse can easily be observed and acknowledged by nurses and mothers, but how is the primary nurse dependent on the dyad? It is the contention of this author that the primary nurse is dependent on the infant and mother for professional satisfaction, that pride that remains long after the infant goes home.

Trust

The intimacy seen between primary nurse and infant, or mother, cannot occur without trust. Trust is defined as

> confidence or faith, especially in another's integrity or right principles; object of such trust or reliance; that which is confided or entrusted (to another); state of being entrusted; hence, charge or custody; reliance on something future as if it were present and real; hence, hope. (Overton, 1943)

Kelley and associates (1983) described self-disclosure and revealing of intimate facts as manifestations of trust. Richardson (1987) suggested that a nurse should be honest and accepting of the patients' behavior to win their trust. Beard (1982), in her study of the relationship of interpersonal trust with risk factors of coronary heart disease, defined trust as "an expectancy held by an individual or group that the word, promise, or verbal or written statement of another individual or group can be relied on" (p. 26).

Based on these definitions and descriptions, trust can be related to the concept of neonatal primary nursing. The primary nurse feels responsible for the infant who relies upon him or her. One could say that the primary nurse has custody or takes care of his or her charge, the infant. One might even suggest that the infant could have confidence, faith, or expectations that the primary nurse, who gives care in a consistent way, will meet future physical and emotional needs. The support of this suggestion lies in the speculative observation that certain infants have smoother physiological responses when the nurses care for them consistently and in the adaption of theories of reciprocity of early mother-infant interactions (Brazelton, Kozlowski, & Main, 1974; Sander, 1962; Tulman, 1981).

Evidence of the mother's trust in the neonatal primary nurse is more obvious. The interviewed primary nurses' statements about the mothers expecting them to be caring for their infants is a reflection of trust. With continual communication as the mothers and primary nurses became acquainted, the mothers could be observed revealing more intimate details of their lives and revealing their true fears and concerns, only to the primary nurses.

Intuitive knowing

Schraeder and Fischer (1987) defined intuitive perception as "the immediate knowing of something without the conscious use of reason" (p. 47). Agan (1987) described the theme of knowing that emerged from nurses' interviews. He wrote, "the theme of knowing in an intuitive, sensing, or psychic way relates to both interpersonal and universal/spiritual connection" (p. 66). One of the nurses who he interviewed explained, "a lot of what we consider to be psychic knowledge is subconscious knowing, it is that we're taking in information we're not aware of consciously" (p. 67). Swanson-Kauffman and Schonwald (1986) stated "The phenomenological researcher intuits the other's reality by being open to identifying with the other's self and considering the other's reality as a possible reality for herself" (p. 102).

Benner and Wrubel's (1989) explanation of embodied knowledge proposed that our bodies as well as our minds are knowers and that the body is continous with the person. They suggested that accomplished skills are like the extensions of the body. Finally, they state that "the skilled habitual body is acquired over time" (p. 44).

The primary nurse becomes very comfortable with the infant's body after consistently caring for the infant. Based upon the various definitions of intuitive knowledge, it is reasonable to assume that a nurse who continually cares for an infant, over time, will acquire intuitive knowledge. If one adopts the phenomenologist's view, the meaning of the experience for the infant can be appreciated by the primary nurse, who opens up to the reality of the infant's existence in the intensive care nursery. This embodiment becomes important when the primary nurse must advocate for the infant's needs.

The evidence of intuitive knowledge related to neonatal primary nursing was apparent in the interviews when nurses spoke of being in-tuned with the baby, just knowing what was wrong, being able to assess problems based on knowledge of the baby, the nurses' attempts at predicting physiological and behavioral responses, and how they felt comfortable making clinical decisions based on their knowledge of the baby. During the observations the primary nurses seemed to handle the babies less often and were more comfortable integrating the information from the monitors with their personal knowledge of the babies. They seemed to react more appropriately to alarms, knowing sooner which ones were false versus potentially true ones. The primary nurse's ability to intuit knowledge about the mother could also be seen as a function of the nurse's openness to the mother's reality and as a function of time.

Advocacy

An advocate is "one who pleads the cause of another" (Overton, 1943, p. 12). Kohnke (1982) stated that this dictionary definition applies to the situation that exists when the client "is very young or unconscious, when he is not present to defend himself, or when he is not able to act in his own behalf" Kohnke added, however, that for clients who can speak, the role of the nurse advocate is to "inform the client and support him in whatever decision he makes" (p. 2).

Copp (1986) defined advocacy as "pleading for the vulnerable" (p. 259). Gadow defined existential advocacy as "the nurse's interaction with the patient in determining the personal meaning that the experience is to have for that individual" (Gadow, 1979, p. 85). Curtin (1979) emphasized the nurse's special position to advocate for vulnerable persons. Because of relationships with patients over a sustained period of time and exposure to intimate emotional and physical details, nurses acquire knowledge of the person as a distinct and unique human being. This holistic, fundamental type of advocacy is "human advocacy" (p. 4).

Patients who cannot speak represent the greatest challenge for nurses. If nursing's moral principle of regarding all patients as subjects and not objects is to succeed, then the nurse must be able to advocate for the silent patient incapable of autonomy and self-determination (Gadow, 1989). The solution to achievement of subjectivity with the silent patient is through continual, close, physical involvement. Over time and with experience through physical caring, the nurse will gain knowledge about the patient's world and experiences. This type of knowledge acquired through repetitive, close physical involvement is called embodied knowledge (Merleau-Ponty, 1962). The patient's body will cease to be an object as the nurse gains embodied knowledge of the patient. The nurse who has embodied experience with a patient is in the best moral position to give a voice to the patient's wishes and needs when they cannot be otherwise expressed (Gadow, 1989).

Evidence exists from the observations and interviews that advocacy is related to neonatal primary nursing. All of the nurses used the word "advocacy" to describe their representation of the infant and mother. They expressed that after caring for an infant and mother over time, the patient was seen as a person, versus an object. They spoke of their ability to interpret behavior and express their concerns to physicians and nurses about changes in physiological variables. They spoke of their ability to represent the infant and mother at patient care and parent conferences. Finally, the nurses advocated for the mother, even though she could speak, in that they informed her by explaining and translating medical information, supported her decisions, and communicated her wishes to others about the care of her infant.

Antecedents and Consequences

Identification of antecedents and consequences of the concept of neonatal primary nursing, can be accomplished in relation to the associated concepts and the patterns seen among them (Walker & Avant, 1988). It was observed that for the close relationship between a nurse and infant or a nurse and mother to occur, the antecedants of intimacy and trust were necessary. Intimacy and trust were demonstrated over time.

When intimacy and trust were evident, then the nurses called themselves primary nurses, and mothers would seek out the specific nurses. Other antecedents to the concept of primary nursing were consistent assignment of the baby to the primary nurse, and a mutual attraction between nurse with infant and mother, which led the nurse to ask for the assignment again, or led the mother to ask the nurse to care for the infant again.

When intimacy and trust were evident, the consequences of intuitive knowledge and advocacy became apparent. Other consequences were the mothers' more frequent expression of their concerns, and later, of their feeling comfortable taking care of their infants. Discharge teaching was accomplished and reinforced before the day of discharge and mothers expressed feelings of having some control over the environment.

The other consequence for the primary nurses was their impressions that primary nursing gave them more satisfaction with their job and was a retention factor. Demonstrations of pride by their behavior, and respect from other nurses and physicians could be observed, as well as evidence of the emotional drain of primary nursing.

Exemplar Case

Barbara E. had taken care of a very low birth weight infant for months. During this time the infant had had severe respiratory distress syndrome, bronchopulmonary dysplasia, pulmonary interstitial emphysema, multiple infections, and an intraventricular hemorrhage. Barbara had written and continually updated an extensive, individualized care plan, been involved in patient care and parent conferences, and was consulted with by nurses and physicians because of her knowledge of the infant.

The infant's twin had gone home but this infant was deteriorating. Barbara knew the mother very well, having spent so much time with her, and was concerned about her because it was apparent that the infant was going to die soon from respiratory failure. Barbara left word with other nurses that she was to be called when death became imminent.

She was called at 2:00 A.M. and arrived minutes after the infant died. She supported the mother while she held the infant, supported her while she cried, reminisced about the life that the family had had with the infant, and sat with her in silence until dawn arrived. During these hours Barbara was not charting, cleaning the bedside, or even taking care of the body. She was present with the mother, accepting of her behavior, and helping her to see meaning in the short life that she had had with her infant. The mother felt comfortable with Barbara because she knew her, and she knew that Barbara had cared about her baby.

Contrary Case

A nurse who had never before worked in a certain intensive care nursery was giving report to another nurse who had never worked there before. The charge nurse, who knew the infant well, could hear them discussing the feeding schedule, intravenous fluid rate, and timing of suctioning and medications, in a depersonalized manner, when the heart rate alarm sounded. The charge nurse saw that the infant was experiencing a bradycardic episode and alerted the two nurses. By the time they looked, the infant's heart rate had increased, although he was still slightly oxygen desaturated.

When the charge nurse asked the nurses to intervene, the nurse who was about to leave, said "That was not a true bradycardia. This baby hasn't brady'd all day. The baby probably isn't desaturated either. The pulse oximter probe probably isn't picking up the pulse because the baby is moving around" (Anonymous, 1988).

These nurses did not know that the infant had had a history of apnea and bradycardia because they had not encountered it themselves. They were slower to intervene than the charge nurse, who knew the infant, because they were trying out other possible explanations for the sounding of alarms.

Theory of Interactional Attachment

Explanation of the interactional theory of maternal attachment may serve as an account of the ability of the primary nurse, acting as a surrogate for the mother, to respond to the infant's behavioral and physiological cues. The controversies regarding this view will be discussed.

Maternal attachment "develops through the reciprocal interaction between the mother and her infant" (Tulman, 1981, p. 13). Sander (1962) proposed that a mother's sense of competence increases with her ability to read her infant's behavioral cues. The interactional theory of maternal attachment assumes that the infant is an active, rather than a passive agent in this process. For infants to be active agents, they must possess certain capacities for interaction at birth.

Investigators have suggested that newborn term infants have the capability to cope with and shape their environment, and interact with their caretakers (Brazelton, Kozlowski, & Main, 1974; Brazelton, 1979; Korner, 1973). Others have described similar capabilities of the ill or premature infant (Als, et al., 1986; Blackburn, 1983; Gorski, 1980; Long et al., 1980).

It is the hypothesis of this author that the neonatal primary nurse, giving surrogate support to the infant, when the mother cannot, participates in physical and behavioral interactions with the infant, which, over time, allow him/her to read the cues of the infant, as suggested by Gorski (1980). The proposed consequences of this interaction are attachment between primary nurse and infant, the gaining of intuitive knowledge about the infant, and the nurse's increased sense of competence about his or her professional care-giving skills.

This is a controversial view because neonatal nurses have been educated to avoid speech or actions that might threaten the mother's perception of maternal role, which might have negative consequences on role attainment, and could ultimately lead to child abuse (Millor, 1981). Furthermore, much emphasis has been placed on professional behavior, and avoiding perpetuation of the historical images of nurses with nurturing qualities, like mothers. However, a professional use of self has been recommended (Carper, 1978), and primary nursing has been advocated as a means of decreasing stress for the mother, who feels relieved to know that someone who knows her infant well is taking care of him or her (Bethea, 1985; Schraeder & Fischer, 1987; Thornton, et al., 1984).

During the observations of the phenomena, both nurses and mothers used the terms surrogate mother and pseudo-mother. This hypothesis is, by no means, meant to minimize the critical role of the mother in the care of her infant in the intensive care nursery. It is, rather, meant to validate and explain the relationship between the primary nurse and infant, a relationship which has, as one of its goal, the support of the mother's role.

Propositions

The following propositions, in relation to the previous discussion of the concepts, and interactional attachment theories, are stated:

1. The primary nurse becomes attracted to a certain infant and mother, and begins to care for them consistently.

2. Consistent caring increases the attachment between the primary nurse and infant and primary nurse and mother.

3. Consistent caring for an infant and mother involves intimacy and builds trust.

4. When intimacy and trust are evident, the primary nurse gains intuitive knowledge about the infant and mother.

5. The primary nurse, who is attached to the infant and mother, and who has intuitive knowledge about them, advocates for them.

6. The primary nurse attempts to predict and intervene regarding the infant's physiological and behavioral idiosyncrasies, blending intuition with technological information.

7. The primary nurse will be able to "fine-tune" interventions (e.g. oxygen delivery, feeding, etc...), in response to physiological and behavioral cues, better than others who do not know the infant as well.

8. The mother who has a primary nurse will feel a greater sense of control in the intensive care nursery environment.

9. The mother who has a primary nurse will have an improved sense of competance and confidence in care-taking skills at the time of discharge.

Assumptions

The assumptions related to these propositions are stated:

1. Primary nursing is occurring beyond just consistent assignment.

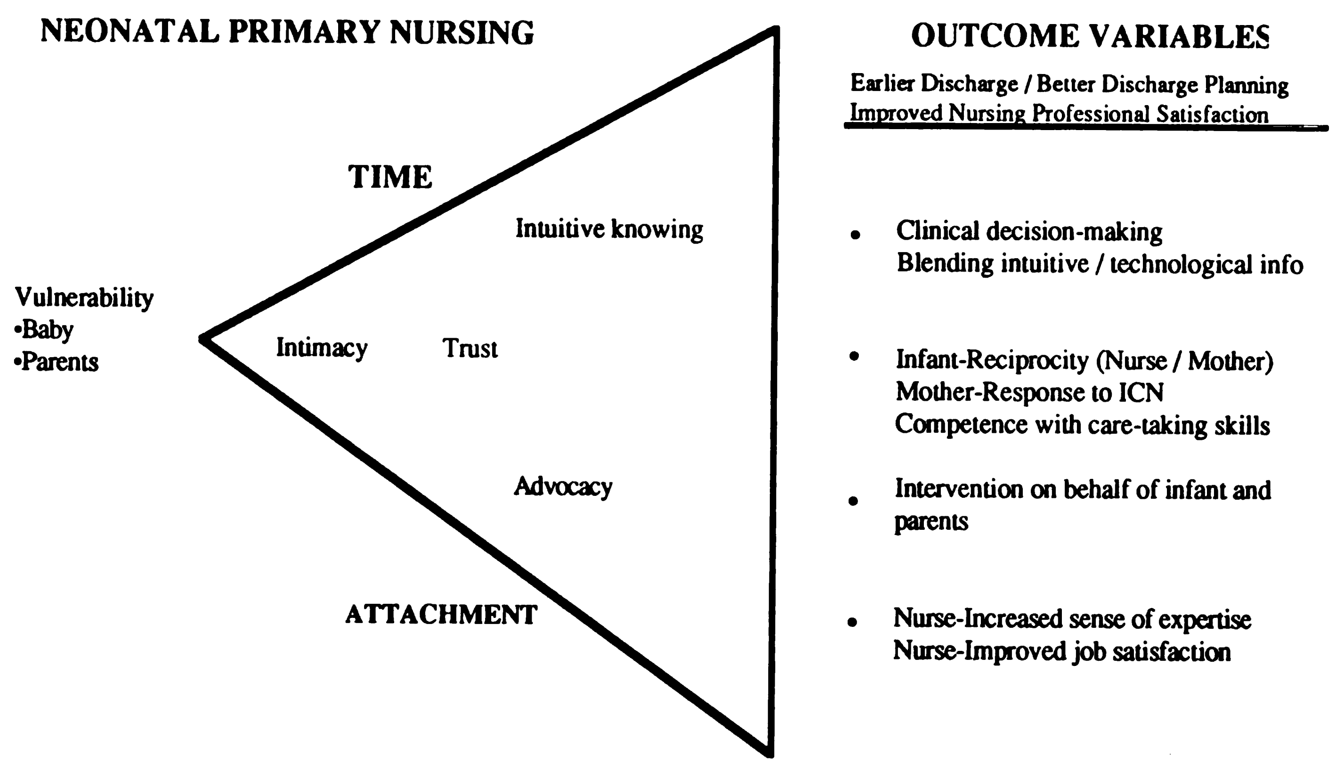
2. The primary nurse is an expert nurse, as defined by Benner (1984).

3. The infant is an active participant in an interactive process with his or her caretaker.

4. The primary nurse can be viewed as a surrogate caretaker, during a critical time period, for the purposes of explanation of his or her attachment.
5. The family, i.e. infant and mother, can be viewed as a person in the context of nursing's domain, as defined by Flaskerud and Halloran (1980).
6. The mother will be the focus of parenting interactions. The father's role is not meant to be neglected, but cannot be addressed in the scope of this analysis.

Figure 1.

Neonatal Primary Nursing
A Conceptual Framework
Elena Bosque, RN, MS



The key element in this model (Figure 1) of neonatal primary nursing is time. Laszewski (1981) wrote about primary nursing and advocacy, "Time spent with the patient builds insight into individual needs" (p. 29). Schraeder and Fischer (1987) interviewed a nurse who spoke of the infants, "You know them when you work with them day in and day out. They become like your own." Time spent with the infant and mother is integral to the functioning of this model, which is supported by interactional attachment theories.

Theoretical Relationships

The relationships among the concepts and important features belonging to the neonatal primary nursing framework will be described. The structure and linkages among the parts of the model in Figure 1 will be explained. The description will support the propositions that arise from the framework.

The vulnerability of a relatively helpless infant or parents who are overwhelmed and lack the expertise to control the events in the highly technological intensive care nursery environment motivates their attachment to a consistently assigned nurse. A nurse who perceives professional, altruistic, and personal benefits of caring for an infant and family consistently will be motivated to make the arrangements for consistent assignment. This nature of the illnesses of infants in the intensive care nursery, which require them to remain there for weeks or months, promote the intimate relationships between nurse and infant and nurse and mother. And so, this intimacy develops over time.

The element of vulnerability is placed at the narrow point in the structure of the model because at that time little is known about the members of the neonatal primary nursing relationship. If certain features are lacking (e.g. consistent assignment over time or attachment), then intimacy may never develop. This can be seen for the infants who do not stay for long in the intensive care nursery. They receive proper nursing care, but they may not have primary nurses. This situation may not affect them adversely since they are generally not the sickest infants.

The interactional attachment theories include time as a catalyst (Brazelton, Kozlowski, & Main, 1974; Brazelton, 1979; Korner, 1974; Sander, 1962; Tulman, 1981). With time, attachment deepens, and accounts for the events which occur later in the process. Based on the attachment theories, the trust grown out of consistent caring and a reciprocal relationship will enable behavioral and physiological responses of mother and infant to be seen by the nurse. Again, with time, the nurse will be exposed to patterns of responses. In the conceptual model, the concept of trust is placed slightly ahead of the consequences of intuitive knowing and advocacy because it seems that some time must pass after trust has been established so that the patterns of responses can be experienced.

In the section where the concepts of intuitive knowing and advocacy were defined, a phenomenological perspective have been adopted. Both intuitive knowing and advocacy can be explained by this perspective, and both concepts require a physical and emotional closeness between nurse and infant or mother. Merleau-Ponty's (1962) idea of embodied knowledge, Polanyi's (1966) idea of accomplished skills as extension of the body, and Benner and Wrubel's (1989) encorporation of these ideas into the practice of nursing are used as theoretical support for two different processes of the model, which lead to the outcome variables.

As advocate, the nurse is compelled to intervene on behalf of the infant and parents, in ways different from a nurse who does not have the same type of relationship. Intervention may be measured theoretically, quantitatively (e.g. one could count and describe the types of interventions) or qualitatively, as has been done by Benner and Wrubel (1989).

The phenomenological perspective may also explain how the primary nurse uses the intuitive knowledge gained from the relationship. In the highly technological intensive care nursery environment, the nurse is trained to use available information produced by various monitors and machines. The neonatal primary nurse will blend intuitive knowledge with that supplied by technological devices to make clinical decisions. The primary nurse who advocates for the infant and family in an environment which constantly poses an iatrogenic threat will select or lobby for machines and equipment which are most beneficial and least hazardous, e.g. a pulse oximeter with an alarm which differentiates between true desaturation and motion artifact. In this disseration, this outcome variable will be tested theoretically. Later, a pulse oximeter will be used to test this outcome measure by recording the oxygen saturation "swings" of babies cared for by primary versus rotating nurses. The hypothesis of this future study would be that the primary nurse would blend intuitive with technological knowledge to fine-tune the changes in inspired oxygen with fewer resultant "swings" in oxygen saturation.

The relationship between the primary nurse and infant or mother will result in outcomes that may be measured physiologically or in terms of behavior or perceptions. The reciprocity between infant and primary nurse may measured quantitatively or qualitatively. Reciprocity could be demonstrated in terms of positive physiological responses such as minimal oxygen requirements during feeding, increased growth, shortened hospital stay, optimal developmental progress, etc... The interactions could also be measured quantitatively or qualitatively through observation, videotape, or with standardized tools. Mothers' responses to the perinatal experience with or without a primary nurse may be measured with standardized tools or with qualitative methods such as phenomenology or grounded theory.

Neonatal primary nursing has implications and produces outcomes for nurses, themselves. The nurses' sense of expertise, feeling of job satisfaction, and other measures of professional or personal effects of the system of nursing care may be measured quantitatively or qualitatively.

The propositions and theoretical relationships have been broadly stated because of the many implications for research related to the concept of neonatal primary nursing. The structure of the model for neonatal primary nursing has an open shape where the outcome variables are described because it represents the many effects on the family and the nurse that can be tested. In this dissertation, the two outcome variables related to clinical decision-making through the use of monitors, and the primary nurse's intervention of behalf of infant and parents will be tested theoretically when a new pulse oximeter alarm system is validated quantitatively.

Walker and Avant (1988) stated that conceptual frameworks need not always be tested empirically. Theoretical testing is valid if the consensus of reviewers is that concepts are well-defined and logically ordered, relationships and linkages are explained and parsimony is present. Rigorous theoretical testing can lead to empirical testing. The development and testing of a new alarm system for the pulse oximeter will theoretically test the neonatal primary nursing conceptual framework.

Goals of the Conceptual Framework

The goals of the neonatal primary nursing conceptual framework are earlier discharge to home, away from the potentially harmful intensive care nursery environment, better "discharge planning", and improved professional satisfaction for nurses. Bethea (1985) and Schraeder (1980) identified improved discharge planning as outcomes of neonatal primary nursing. The term "discharge planning" includes as measureable outcomes: demonstrated and perceived maternal competence with care-taking skills, perception of support, quality of maternal-infant interaction, and infant developmental outcome.

Many qualitative and quantitative methods have been used to measure professional satisfaction. The results of improved professional satisfaction have implications for nursing retention, health care system economics, and the professionalism of nursing.

Conclusion

Although Walker and Avant (1988) state that conceptual frameworks may be tested theoretically, Dickoff and James (1968) plead for prescriptive theory development leading to research and practice. In this dissertation, two outcome variables will be tested theoretically but results of this work will produce a means of testing other propositions empicically, using a triangulation of methods.

A test of this model or propositions would significantly contribute to theoretical nursing since the concept of primary nursing has never been analyzed or its propositions tested. These propositions need to be tested since financial crises in the health care system threaten the role of the professional nurse, as well as existing systems for the delivery of nursing care.

Most importantly, these propositions need to be tested because they relate to the quality of care of the sick or premature infant and mother. Carper (1978) wrote "The nurse in the therapeutic use of self rejects approaching the patient-client as a object and strives instead to actualize an authentic personal relationship between two persons" (p. 256). Meleis (1987) challenged nurses to focus our efforts on developing knowledge related to the domain of nursing. Her plea for a "passion for substance" (p. 17) can be answered through future investigation of the phenomena of neonatal primary nursing, which applauds the therapeutic use of self of nurses in an intimate relationship that brings respect and actualization to the persons they serve.

Chapter 4

Conceptual Framework: Symbiosis of Nurse and Machine Through Fuzzy Logic

After the introduction of mechanical ventilation with continuous positive airway pressure in the late 1960's (Gregory, 1971), mortality rates for premature infants dramatically improved (Thompson and Reynolds, 1977). This new medical therapy was accompanied by multiple monitoring devices and specialized nurses and physicians. The old premature nursery was transformed into the modern neonatal intensive care unit. Fear of a repetition of the retrolental fibroplasia (RLF) tragedies of the 1940-50's which resulted in blindness and cerebral palsy, before controlled studies were performed, led to further development of monitoring devices (Cone, 1985).

In the intensive care nursery, there are monitors with alarms for heart rate, respiratory rate, central and peripheral blood pressure, baby's temperature, incubator temperature, waterbed heating pad temperature, intravenous fluid pumps, mechanical ventilator pressures, compressed oxygen and air pressure, incubator and ventilator oxygen concentration, as well as alarms for emergency situations in the delivery rooms. In an effort to carefully assess oxygen and carbon dioxide levels, various monitors, with alarms, have been developed and it is possible to find an infant wearing a pulse oximeter, as well as transcutaneous oxygen and carbon dioxide electrodes, simultaneously.

During these same twenty years when the highly technological intensive care nursery was evolving, much work has been done in the area of artificial intelligence (AI) computer programming. The goal of AI scientists has been to impart to computers, rules which would enable them to perceive and understand meanings and to problem-solve and make decisions. Many of these early efforts were supported financially by the United States Defense Department and scientists believed that computers with artificial intelligence could replace human beings in certain endevours (Dreyfus & Dreyfus, 1979). Because of this work and the increasingly technological nature of the intensive care nursery, some timely questions arise. Can a machine can replace the monitoring and decision-making functions of an expert nurse in the intensive care nursery, or in contrast, can the "intelligence" of monitors be improved to assist nurses, who are experts in their "domain"?

Progress and Problems with Artificial Intelligence

"One might say that cognitive science has a very long past but a relatively short history." (Gardner, 1985, p. 9) Artificial intelligence, one branch of cognitive science, is not a new phenomenon. It has its roots in ancient Greek philosophy with Plato's love of explicit principles and definitions and Aristotle's insistence on logical thinking and his development of the syllogism. The syllogism, although dependent upon assumptions, was the basis for modern linear system theory (Dreyfus & Dreyfus, 1986; Durant, 1955).

Seventeenth century philosophers and mathematicians, although each influenced by different schools of thought, imparted the values that truth and knowledge could be gained from objective observations of nature. Bacon introduced the scientific method of inquiry by encouraging observers to doubt and test their observations. He believed that we can know the phenomena by knowing their laws and properties, discovered through investigation. Descartes' belief that any problem could be reduced to discrete elements and explained in terms of rules led to an intolerance of imprecision and a value that all truth could be defined in terms of what is quantifiable. Pascal, who unlike his contemporaries, believed in trusting emotions and intuition, nevertheless built a calculator that could combine simple elements. Leibniz is credited with inventing binary numbers, the basis for the concept of the binary ("on/off") logic. The ideas of these men provided the philosophical and technical bases for the development of digital computers and artificial intelligence (Durant, 1955; Kuhn, 1977).

The early work in artificial intelligence was stimulated by reactions to the Behavioristic view of man that predominated the 1920's and 1930's as well as discoveries in the physical and living sciences that made questioning the enigma of the human mind feasible. Examples of pioneering work that paved the way for developments in artificial intelligence was Gottlob Frege's manipulation of abstract symbols to show that arithmetic could be reduced to logic in the late 1800's, Bertrand Russell and Alfred North Whitehead's reduction of basic arithmetic laws to logical propositions in the early 1900's, Alan Turing's tape coding calculator, and John von Neumann's development of stored memory for Turing's calculator in the 1930's (Gardner, 1985).

In the late 1930's, a digital computer was designed by Claude Shannon from complicated series of "on/off" switches and manipulated quantifiable symbols (Gardner, 1985). By the end of the 1950's researchers such as Alan Newell and Herbert Simon saw that the symbols could represent facts, and rules could be programmed to described relationships among the facts. They believed that computers could be used to simulate logical thinking and began to call these computers logic machines. It was thought that these computers, if programmed with enough data and rules, could solve problems, read stories, recognize patterns, and interpret language. Newell and Simon wrote "...Man is to be modeled as a digital computer" (Newell and Simon, 1972, p.5) and it was this epistemological belief that dominated the early work in artificial intelligence, in an effort to investigate the relationship between human thought and machine thought.

Gevarter (1984) identified the two goals of artificial intelligence as making machines more useful and understanding intelligence. Artificial intelligence (AI) differs from conventional computer programming in that AI uses primarily symbolic versus numeric processes, includes heuristic (implicit solution steps such as decision trees) versus explicit algorithmic steps, has a control structure separate from domain knowledge, and accepts sometimes satisfactory or incorrect answers. These features are necessary for the "intelligent" program to apply logic to a presented problem and find a solution.

<u>Neural Network</u>

The concept of a neural network, a type of AI, was developed by Warren McCulloch and Walter Pitts in the early 1940's (Gardner, 1985). They conceived of the analogy between the neurons of the human brain and its logic with linear binary electrical signals passing (or not) through a circuit. This idea was attractive to some AI researchers because if human thought could be described via principles of logic, and if this process could be translated into an electrical one, then the human brain could be thought of as a powerful computer. With a neural network program, connections which would result in successful "behavior" would reproduce that behavior the next time the problem was introduced and similarity recognition, or a type of problem-solving memory, could be achieved.

Expert Systems

Many early researchers claimed that computer intelligence would exceed human intelligence by the year 2000. As the problems such as multiple word senses, syntactic ambiguities, and difficult searches in broad domains were identified in the 1950-60's, lessons were learned and expert systems were developed (Gevarter, 1984).

> An expert system is an intelligent computer program that uses knowledge and inference procedures to solve problems that are difficult enough to require significant human expertise for their solution. The knowledge necessary to perform at such a level, plus the inference procedures used, can be thought of as a model of the expertise of the best practitioners of the field. (Feigenbaum, in Gevarter, 1984, p. 71)

Expert systems, also known as "knowledge-based systems" were seen as an answer to many of the early problems encountered in AI work. Before expert systems were developed, complex questions tended to require searches of broad data bases that expanded exponentially because of the number of parameters involved. An expert system focuses on a narrow field of expertise and obtains its knowledge base from an expert in the field, a "domain expert" (Wallich, 1986). It was assumed that the judgement rules of the domain expert could be imparted to the knowledge-base of the computer (Gevarter, 1984).

Limitations of Artificial Intelligence

By the 1970's, the limitations of artificial intelligence were identified. The early AI goals that a computer could be designed in twenty years to understand, reason, solve problems, and plan as well as (or better than) a human were seen as overambitious, excessive, and even dangerous. Some felt that certain experiences and tasks should be left to humans (Weizenbaum, 1976).

The lack of progress in AI work was attributed to the assumptions that all human intelligence could be described in logical terms. What was lacking in some of the early game-playing, linguistic, and problem-solving programs were the human capacities for fringe consciousness, ambiguity tolerance, commonsense understanding, adaptation to changing relevance, and embodied knowledge (Dreyfus, 1972; Dreyfus & Dreyfus, 1986).

> The attempt to capture human, temporal, situated, continuously changing *know-how* in a computer as static, de-situated, discrete *knowing that* has become known as the frame problem. (Dreyfus & Dreyfus, 1986, p. 82)

The phenomenological view that humans understand a phenomenon by contextual, cultural, practical, embodied, life meaning and not by rules (Heidegger, 1927/1962; Merleau-Ponty, 1962; Polanyi, 1966) was contrary to the linear, inferential, and logical underpinnings of AI. While Dreyfus' (1986) competent human skilled performer uses rules and a proficient performer still analyzes, an expert acts reflexively, without thinking of rules. The expert discriminates and associates knowledge and experience holistically to problem-solve. Sometimes this commonsense, intuitive understanding defies logic. When experts are forced to explain how they made a decision so that logic can be programmed into a computer, then they begin thinking like a competent performer, and so does the computer (Dreyfus, 1972; Dreyfus & Dreyfus, 1986).

The early AI efforts did not result in computers that could translate language, win a chess game, or give psychological advice. The early data bases were so broad that the heuristic searches were time-consuming and the results often disappointing because the decision rules were defined for limited contexts. The meanings were defined so literally that a conversation with a computer was successful only on the most simple level.

Some achievements have been recognized. The neural network could be programmed to search information within certain categories, or heuristic nets, identify system errors in logic and recognize pattern similarities. However, for neural networks to solve real-world problems, they must be able to generalize responses based on contextual demands that may be slightly different from the past problems (Gardner, 1987; Schank, 1986).

The development of expert systems has solved some of the early AI problems because facts and rules within a specific and limited expert domain are programmed so there is improved precision and speed, although blindness to contextual, situational elements persists (Wallich, 1986). The idea that expert systems could replace educators has been criticized because of the inability to inpart true expert intuition into computers (Dreyfus & Dreyfus, 1986). However, expert systems have been successfully used as teaching tools. An example of this is the MYCIN medical diagnostic program at Stanford University that is used to help physicians in training think of possible diagnoses, but do not replace the physician or the educator (Dreyfus & Dreyfus, 1986; Gardner, 1986).

Finally, the value of expert systems has been acknowledged when they empower the experts to make better use of their human wisdom.

> "If we fail to put logic machines in their proper place, as aids to human beings with expert intuition, then we shall end up servants supplying data to our competent machines." (Dreyfus & Dreyfus, 1986, p. 206)

What emerged was an expert system that could assist humans in everyday practices because it could handle the contextual ambiguities of real life.

The Emergence of Fuzzy Logic

> Unlike traditional logical systems, fuzzy logic is aimed at providing a model for modes of reasoning which are approximate rather than exact. In this perspective, the importance of fuzzy logic derives from the fact that almost all of human reasoning--and especially commonsense reasoning--is approximate in nature. (Zadeh, 1990)

Fuzzy logic has its roots in the introduction of quantum mechanics, with its inherent ambiguities, and in the work done on fuzzy systems by Lukaciewicz in the1920's (Johnson, 1990; Schwartz, 1990). In 1965, Dr. Lotfi Zadeh realized that many concepts without sharply defined boundaries could not be defined by conventional linear system theory. He published a paper on fuzzy sets, in which he theorized that ambiguous, slowly-varying variables could be defined in terms of continuous degrees of membership in a set or class or concept (Zadeh, 1990).

For example, in describing the concept of age (e.g. youth or middle-age), various ages grouped around a point on a zero-to-one continuum could be members of a set with the label of very young. Some of those ages will also be members of the adjacent set with the label of young. Some ages within the young set will also be members of the not young set, etc... Within each set, a given age will have a certain degree of membership to that set. The degree of membership of the variable (e.g. a certain age) is weighted by determining how experts judge the degree of membership in the set (e.g. middle-age or old age) This may pertain to concepts such as height, weight, amount, color, light, heat, etc... (Zadeh, 1984)

With conventional computer logic, the circuitry rules are rigid in a series of if/then statements. The number of variables and the order in which they are considered require much programming information and memory, and often result in inaccuracies because of the difficulty of borderline cases. With fuzzy logic,the rules are similar except that the solution will be expressed as a probability. The system assigns a value proportional to the extent that the data meets the rule (Schwartz, 1990; Zadeh, 1973, 1990). Fuzzy probabilities are perceptions of liklihood, such as "very likely, unlikely, not very likely, etc..." (Zadeh, 1984).

For example, a light meter based on fuzzy logic can better sense the location and distance of an object because probabilities of the subject being located in any place in any quadrant with varying degrees of light are weighted, instead of applying rules to discrete conditions which may not fit the reality (e.g. The subject may be overlapping two quadrants and the light may be of varying quality). Linguistic variables are ordinary language terms that are used to represent a particular fuzzy set in a given problem, such as "large", "small", "medium", or "OK". Fuzzy sets are sets that do not have a crisply defined membership, but rather allow objects or variables to have grades of membership from 0 to 1 (Zadeh, 1984).

Domain experts are consulted to determine the class of membership functions for the input variables (Schwartz, 1990). For example, the experts would determine how much light constitutes the set of "dim light". The results of the system are based, not on the programmed judgement rules of experts, which would reduce the computer knowledge to competency (Dreyfus & Dreyfus, 1986), but on actual expert judgements much like content validity analyses.

Fuzzy logic is not meant to be applied to systems requiring precision such "precision machining or precise robot positioning" (Haavind, 1989, p. 147). With the development of the fuzzy chip by Togai and Watanabe at Bell Telephone Laboratories in 1985, fuzzy logic has been used in many everyday, consumer products which require interpolative reasoning, when a degree of uncertainty exists and information is incomplete. The inference rules of fuzzy logic programs allow the computer to identify similarities between the interpolated data entered and its programmed fuzzy predicates. This reduces the number of "if/then" rules in the knowledge base (Zadeh, 1990). Fuzzy systems are considered by some to be a blend of neural systems and expert systems, allowing both vague and precise information to be processed simultaneously (Schwartz, 1990).

Fuzzy logic programs applied to heating/cooling and camera focusing systems require 25 rules whereas conventional AI programs would require more than 300 rules. Fuzzy logic programs require less chip memory and less time to develop. A change in the program only requires a simple change in the software. These attributes and most importantly, the fact that fuzzy logic has improved the efficiency of machine functions, explain the recent success of Japanese commercial applications such as the subway system in Sendai, Japan, video camcorders, camera light meters, air conditioners, washing machines, auto transmissions, rice cookers, vacuum cleaners, and televisions (Armstrong & Gross, 1990).

Although developed in the United States, fuzzy logic has been slow to gain popularity here and was initially criticized. Some of Zadeh's colleagues were skeptical and hostile when he presented his theory 25 years ago. One colleague said

> Fuzzy theory is wrong, wrong, and pernicious. What we need is more logical thinking, not less. The danger of fuzzy theory is that it will encourage the sort of imprecise thinking that has brought us so much trouble. (Zadeh, 1990)

The reticence to accept fuzzy logic has been attributed to the Western Aristotilian orientation to science versus the Asian tradition of holism (Johnson, 1990; Zadeh, 1990). That is why fuzzy logic is considered a non-conventional type of artificial intelligence.

Parallel Development in the Study of Decision-Making in Nursing

Revolutionary discoveries are made by scientists who are part of and committed to the prevailing tradition but who recognize that something is wrong or missing with existing knowledge or beliefs (Kuhn, 1959; 1977). The revolutions that result from divergent achievements will have common features in any scientific community (Kuhn, 1962). If we assume that nursing is a scientific discipline, then we can see parallel development in the development of artificial intelligence and the study of decision-making in nursing.

Nursing's "capitulation to scientism" (Chenault, 1964, p. 32) became evident in the 1950's and 1960's. It has been attributed to the nursing community's efforts to be recognized as a profession and a discipline in the era of the prevailing rationalistic view of knowledge development (Gerrity, 1987).

Since the 1970's, in an effort to provide rationale for nursing practice, nurses have developed formal, standardized taxonomies to describe and prescribe nursing diagnoses and interventions (Bulechek & McCloskey, 1987; Kim & Moritz, 1982; Henderson, 1978). The need to objectify and quantify is evident in reports of development of tools that measure perceptions of clinical decision-making (Jenkins, 1985; Joseph, Matrone, & Osborne, 1988) and the use of statistics to analyze problem-solving style during simulated (Holzemer, 1986) and actual (Joseph, Matrone, & Osborne, 1988) situations. Decision-making approaches and influential factors have been described (Baumann & Bourbonnais, 1982; Corcoran, 1986; Thompson & Sutton, 1985) for educational purposes, or simply because "the use of a systematic and objective decision process would be important" (MacLean, 1989, p. 74). Information processing and expert systems theories have been used as a basis for analysis of clinical decision-making for educational purposes. Expert system programs have been developed for computer-assisted decision-making, nursing diagnosis, and care-planning with the promises that they will save time and money (Chase, 1988; Jones, 1988; Probst & Rush, 1990; Putzier et al, 1985; Sinclair, 1990).

The study of intuition in clinical decision-making has emerged from a different perspective. One could argue that the holistic, non-rational, subjective knowledge that is now often called intuition, was valued during the first half of this century because of early written descriptions of nurses' creative solutions, imagination, instinct, and awareness of patients' feelings (Rew & Barrow, 1987). However, the term was only used once in the literature from 1900-1985 (Rew and Barrow, 1987) and it has been stated in an article in which intuition is supported, that "In general, nurses are individuals who prefer sensing and whose least developed process is intuition (Gerrity, 1987; p. 67).

The concept of intuitive expertise gained popularity in the 1980's. Like Zadeh's observations about the inadequacies of linear systems theory, nurse scientists realized that the existing rationalistic approaches to the study of clinical decision-making could not explain how correct decisions were made in the face of ambiguous or meager data (Benner & Tanner, 1987; Rew, 1986; Rew & Barrow, 1987; Schraeder & Fischer, 1986).

Benner's work describing novice to expert clinical nursing practice was based on the Dreyfus & Dreyfus (1980) model of skill acquisition (Benner, 1984). Benner's underlying philosophical approach was phenomenological, describing how a nurse gains expertise through experience. Expert performance of skills and clinical judgements, or embodied intelligence, allows the nurse to see patterns within complex clinical information.

> It is the unique, remarkable capacity of the body to cope with vague, "fuzzy" information and regions of influence and tension that makes possible the human capacity to function in ambiguous, underdetermined situations (Benner & Wrubel, 1989, p.53)

The novice must solve problems using theory and rules but with actual practice the nurse tests theory and the approach changes. An expert makes decisions based on, not rules, but intuitive, embodied knowledge. Benner (1983) used nurses' stories of memorable cases and Heideggerian interpretive methods to describe the phenomenon because of the belief that expertise cannot be reduced to a description of decision-making rules.

Although the importance of cues, pattern recognition, and categorizations have been related to intuitive knowledge, it is the holistic gestalt, the gut feelings, and the subtle falling out of patterns which are more often characterized. Qualitative methods have been used in the study of intuitive decision-making in an effort to capture the immediate, holistic, and experiential nature of this phenomenon (Benner, 1984; Pyles & Stern, 1983; Rew, 1986; Young, 1987).

Symbiosis of Nurse and Machine

To value the role of intuitive knowledge in clinical decision-making need not diminish the benefits of technology. Schraeder and Fischer (1987), in a study of intuitive knowledge in the neonatal intensive care nursery, stressed that both biomedical and intuitive knowledge should be valued in nursing practice. Ford (1990) explored the possibility of how computers and technology can transform nursing negatively if they limit thinking and creativity or positively if they promote expediency, efficiency, and precision.

In a study of the impact of machines on critical care work, nurses reported that in their roles as "guardians of the patient", they acted as coordinators of machines and patient care. "Being the "coordinator" required that the nurse be proficient in machine use and have input into machine use" (McConnell, 1990, p. 51). The nurses in McConnell's study (1990) advocated for their critical care patients by selecting machines for use for specific patients, making suggestions about the selection of machines for the unit, as well as participating in machine design. The nurse is responsible for both the technical and psychosocial aspects of patient care, balancing machines and human response in health care (Curtin, 1984). From a phenomenological perspective, machines can become an extension of a person and can result in a type of symbiotic relationship (Ihde, 1975; Merleau-Ponty, 1962; Polanyi, 1966).

The "Cry Wolf" Response to False Alarms

Because of motion artifact when used in neonatal populations, pulse oximeters have many false alarms resulting in low specificity for detecting hypoxemia and hyperoxemia (Blanchette, Dziodzio, & Harris, 1991; Bucher et al., 1989; Harbold, 1989; Hay, Thilo, & Curlander, 1991; Salyer, 1991; Severinghaus & Kelleher; 1992; Spyr & Preach, 1990; Welch, DeCesare, & Hess, 1990). Motion artifact has been estimated to occur up to 29% of the time (Barrington, Finer, & Ryan, 1988). This frequent, excessive sounding of alarms may be dangerous if it causes a "Cry Wolf Syndrome" pattern of behavior among nurses.

> In most cases caregivers have become deafened in their response to a true SpO2 alarm condition, most commonly silencing the alarm without evaluating the infant's condition. To reduce the frequency of alarms, some institutions have sedated the infants, restrained the monitored limb, broadened the alarm set points, or reduced the update time of the monitor to dampen the response (for example, 15-second display average). None of these maneuvers should be considered clinically acceptable because they each present the infant with an added risk. (Kopotic et al, 1987)

The expert primary nurse will readily differentiate between motion artifact and true events at a glance based on intuitive knowledge of clinical attributes, but tends to ignore the alarms during periods when the infant is moving. The novice nurse or the nurse who does not know the infant well, who tends to approach any alarm in the same deliberative fashion, may become overwhelmed by the false alarms and may eventually completely fail to respond if he or she is preoccupied with other demands. This is similar to the children's tale of the "Boy Who Cried Wolf", in which the boy so often cried "Wolf!" to tease his companions when there was no wolf, that they did not respond to his cries the day the wolf attacked him.

Hypothesis: Fuzzy Logic for a Neonatal Pulse Oximeter Alarm

The theoretical hypothesis is that the expert neonatal primary nurse, who is responsible for manipulation of the environment of the vulnerable baby and parents, would choose to use and lobby for a pulse oximeter with improved specificity over one with many false alarms, if the sensitivity to true events was equivalent. The empirical hypothesis is that a pulse oximeter alarm, with a program design based on fuzzy logic, will be more specific and equally sensitive when compared to the present alarm system.

Definition of Terms

The fuzzy logic program includes fuzzy sets, linguistic variables, associated values, and components of the decision process including sets of goals, constraints, and a performance function resulting in the decision set. The linguistic variables and associated values related to the oxygen saturation signal were determined by Elena Bosque, the domain expert:

Fuzzy Set / Concept	Linguistic Variable	Associated Numerical Values
Level O_2 saturation	High	≥95%
	Medium	85-95%
	Low	<85%
Rate of Change	Precipitous	≤1 sec
	Fast	1-2 sec

	Slow	>2 sec
Degree of Jaggedness	Not very	$\leq$1 mm paper
	Moderately	1-3 mm paper
	Very	>3 mm paper

These variables were translated into voltages (from 0-1 volts), and our discussions resulted in the determination of the "confidence" values, which represents the estimate of degree of membership of a variable within the fuzzy set. The fuzzy logic program was written by Dr. William Siler and resulted in the following input data:

Data file: (name of file)

Sampling rate: 10/sec

Sample points per points processed: 1 (so every point was processed, 1 / 0.1 sec)

SaO_2 for 0.5 confidence desaturation: 0.85 (low limit for level of SaO2)

SaO_2 for confidence 0.5 high O2: 0.95 (high limit for level of SaO2)

Rate for confidence 1 medium: 0.05 (rate of change=SaO_2/sampling interval)

Rate for confidence 1 high: 5 (rate of change=SaO_2/sampling interval)

Rate scale factor for plot: 5

Weight for last point input: 0.1

Length of line between points: 1

The sets of goals and constraints are related to fuzzy unions of the linguistic variables from the fuzzy sets arising from the oxygen saturation tracings. The performance functions results in the decision set with the linguistic variable of desaturation (traces red on computer screen with alarm sound alternating between

512 and 602 Herz), normal saturation (a white tracing with no sound), oversaturation (High O2 traces blue with pulses of sound at 444 Herz), and artifact (Momentary artifact produces small circles with short pulse of sound at 256 Herz, while continuous artifact traces blue, with an alarm sounding at 256 Herz).

Fuzzy Logic and Neonatal Primary Nursing

How does the development of a new alarm system for a pulse oximeter relate to the conceptual framework of neonatal primary nursing? The conceptual framework of neonatal primary nursing has a broad set of outcome measures than can be tested by a triangulation of methods. The application of fuzzy logic tests two areas of the framework, theoretically.

Fuzzy logic depends on the input of domain experts who judge the degree of membership of variables in a fuzzy set. This judgement is holistic and does not require the expert to reduce decision-making to a set of rules which would only reflect "competancy". Intuitive expert knowledge cannot be reduced to parts (Dreyfus & Dreyfus, 1986). By placing value on the domain expert's knowledge for programming purposes, one mimics the process of decision-making of the expert primary nurse. The theoretical and methodological choice of use of fuzzy logic supports the process of neonatal primary nursing and the outcome involving clinical decision-making and blending of intuitive with technological information.

The testing of the new alarm system and demonstration of improved specificity theoretically tests the process of neonatal primary nursing and the outcome involving the nurse's intervention on behalf of the infant and parents. Based on unpublished observations, it can be assumed that primary nurses will advocate for the family and use or lobby for a pulse oximeter with fewer false alarms to protect the infant from noise and the potentially deleterious effects of the "Cry Wolf Syndrome".

Summary

The progress in the studies of artificial intelligence and decision-making in nursing have had similar courses in the search for alternative approaches to the rationalistic view of knowledge development. A phenomenological view of embodied intelligence allows for a symbiosis of intuition and rationalism, or in this case, nurse and machine. Development of computer programs that better approximate human interpolative thought can aid, although not replace, the expert primary nurse.

The study of information technology has been identified as a nursing research priority by the National Center for Nursing Research (Moritz, 1990). Emphasis for future work has been placed on determining the best techniques for eliciting specific types of knowledge and development of methods for transforming this information into efficient computer algorithms to produce clinically relevant expert systems for nurses (Thompson, Ryan, & Kitzman, 1990). If nurses are allowed to participate in the development and testing of expert systems in their domain, then we may be able to avoid the "Cry Wolf Syndrome" of the neonatal pulse oximeter.

Chapter 5

Methodology

Research Design

The design used in this study was that of diagnostic observational testing to determine how well the OLD vs. NEW neonatal pulse oximeter alarm system could predict oxygen desaturation (Hulley & Cummings, 1988). The dichotomous predictor variable was the test result (alarm, or no alarm). The outcome variable was the presence or absence of the disease (desaturation or no desaturation) as determined by the references (second pulse oximeter and transcutaneous oxygen monitor), which were substitutes for a gold standard.

Description of the Research Setting

All studies were performed in the intensive care nursery (NBICU) at California Pacific Medical Center, California Campus (Formerly Children's Hospital of San Francisco). The tertiary level nursery has 20 beds for maximum level care and a separate 8 bed transitional care nursery for stable, growing premature infants. There are approximately 400 admissions per year to the intensive care nursery. A 150 ft^2 pulmonary function lab is adjacent to the NBICU, where equipment is tested and maintained. Much of the required equipment was available for use, including the recorder, pulse oximeter, transcutaneous monitor, cardiorespiratory monitor, electrodes, and pulse oximeters probes that the infants already had. The computer, analog-digital converter, related computer cables, parts, programs, and discs, and second pulse oximeter probes were purchased with research grant funds. The recorder paper was donated.

Sample

Human Subjects Assurance

The study was approved by the human research committees at both California Pacific Medical Center and at the University of California, San Francisco. After parents saw their infant and the preliminary admission activities settled down, parents were approached for their consent to participate in the study. They were not approached if the infant was in critical condition or moribund. Written consent was obtained from a parent before the infant was enrolled in the study (Appendix B). Written consent was obtained from the infant's primary nurse before descriptive data was obtained (Appendix C).

Sample Selection

Based on power analysis of expected means and standard deviations, with an alpha of 0.05 and beta of 0.20, 35 (2-tailed test) or 38 (1-tailed test) preterm or term infants requiring a pulse oximeter were to be enrolled in the study. The expected differences were determined from results of a preliminary study done to calculate the amount of extreme artifact of the pulse oximeter when the oxygen saturation tracing falls to baseline (Bosque & Goldman, 1992). We found from 25 studies of 19 infants in the ICN that 4 (range 0-20) percent of the time extreme artifact occurred. This was a gross underestimate of entire time of neonatal pulse oximeter artifact but was an important description because it provided data about the minimal type of artifact that could be differentiated by the NEW alarm system.

Infants of any size and gestational age were eligible for the study. Our preliminary study showed a positive correlation between increasing weight and amount of artifact ($y=0.002x-1.202$, $r^2=0.39$, $p=0.001$) so we did not limit the weight or gestational age of eligible infants. Infants were eligible whether or not they were intubated, required any kind of ventilatory support, or had an umbilical arterial catheter, as long as they required a pulse oximeter. Infants were ineligible if they were receiving a paralyzing agent (e.g. Pavulon), had congential anomalies that affected movement, or were critically ill or dying.

Data Collection Methods

Techniques

Diagnostic testing is a type of observational study. Once the fuzzy logic prototype alarm system was developed, oxygen saturation signals from infants were collected onto the computer. Simultaneously, the principle investigator recorded the signals and observed the main pulse oximeter and marked alarm events for one hour per infant.

Instruments

Pulse oximeter

A pulse oximeter (Nellcor® N200) was used. The pulse oximeter is a monitor for continuously measuring arterial oxygen saturation. The measurement is made through an adhesive sensor (Nellcor® N25) attached to a finger or foot of the infant. Also, a new type of probe (Nellcor® RF10) has recently been available to be used on flat surfaces and its design is based on the properties of reflectance.

On the front panel of the oximeter, oxygen saturation and pulse rate values are displayed numerically and a bargraph of light emitting diodes indicate pulse amplitude. The displays are updated with each heart beat. Alarm limits can be set for low oxygen saturation and high and low pulse rate. The percent saturation range is 0-100% or 50-100%. The pulse rate range is 0-250 beats per minute. The wavelength measurements used are 660 nm and 920 nm. The sample averaging rate used was 2-3 seconds. The pulse amplitude is 350 ± 70 millivolts. Analog outputs are 0-1 volts or 0-10 volts.

The validity and reliability of the Nellcor® pulse oximeter in infants was demonstrated (y=0.7x+27.2; r=0.9) in a study of 26 premature newborns with 177 paired measurements of SaO_2 measured by pulse oximeter and by a Instrumentation Laboratory 282 co-oximeter (Jennis & Peabody, 1987), as well as by others (Deckardt & Steward, 1984). No calibration of this instrument is required.

Transcutaneous oxygen monitor

A transcutaneous oxygen monitor (TCM 2, Radiometer®) was used as a reference. The transcutaneous oxygen monitor measures the partial pressure of oxygen as it diffuses across the skin from vessels dilated by mild heat. The transcutaneous oxygen monitor has a Clark electrode, heating element, adhesive ring, and cable. The validity and reliability was demonstrated in a comparison of 159 paired determinations of arterial PO_2 and transcutaneous PO_2 in 30 sick infants with r=0.983 (Peabody et al., 1978). During normal use, performance of the transcutaneous oxygen monitor has been shown to be affected by increases in temperature, hydrogen ion concentration, amount of fetal hemoglobin, poor perfusion, or thickened skin in older infants (Bancalari, & Flynn, 1988, Delivoria-Papadopoulos; Roncevic, & Oski, 1971). This instrument requires calibration with known gases before each use.

Cardio-respiratory Monitor

Heart rate, electrocardiograph, and respiration (via thoracic impedance) signals were collected using a small, double-channel cardio-respiratory neonatal monitor (78213C, 78212C, Hewlett-Packard).

Recorder

An eight-channel digital recorder (MT-9500, Astro-Med, Inc.) was used to collect continuously, electrocardiograph, respiration, oxygen saturation from the main and reference oximeters, and transcutaneous oxygen monitor signals onto paper. The analog signals were transmitted through cables connecting the monitors to back of the recorder via 15-pin D-shell connectors. Pre-amplifiers conditioned the signals in the 0-1 or 0-10 millivolt range. The recorder has a clock and the time is recorded onto the paper continually. When an event button is pushed, a line is marked onto the paper. The paper speed is variable, but was set at 60 mm/min for all of the studies. No calibration is required.

Computer and Programs

A PC 386 (CGS Electronics) computer (40MB, 25 herz) and a math co-processor (387 DX, Intel) was used. An analog-digital converter (PC-LPM-16, National Instruments) and a data acquistion program (Daqware, Ni-Daq™Dos, National Instruments) were installed to allow for the pulse oximeter signal to be collected into a file on the computer. After data collection from an infant, each Daqware data file of signals was formatted to prepare it for application of the fuzzy logic alarm program. The fuzzy logic prototype alarm system program is another file on the computer, which is applied to the signal data in the Daqware file when commanded. On the computer screen, the Daqware file of data looks exactly like a paper recording of oxygen saturation signals over time. The fuzzy logic prototype alarm system program applied to that data looks exactly the same, except for the addition of audible alarms and color indicators of saturation status.

Fuzzy Logic Alarm System Prototype Program

The fuzzy logic alarm system was written by Dr. William Siler using Quick Basic 4.5 (Microsoft ®). As the domain expert, I sent Dr. Siler fuzzy sets, linguistic variables, associated values (described in Chapter 3) and talked to him about my ideas and goals for the system. I also sent him three sets of signal data on computer files from infants, deliberately capturing various situations including different types of true desaturation and artifact signal slopes to demonstrate my ideas for the fuzzy sets. After a number of communications to clarify my meanings and goals for the decision set, the fuzzy logic program was sent and ready for use. The entire program is include in the Appendix D.

Nurses' Questionnaire

A questionnaire was developed to collect descriptive data from primary nurses about the infant's idiosyncracies related to oxygenation and interventions. The nurses were asked to guess the SaO_2 and PO_2 of the arterial blood gas, if one was obtained, and asked to guess the amount of artifact for the study infant and in general. The content of the questionnaire was based on a preliminary study (Bosque & Goldman, 1992) and from observations of primary nursing (Appendix E).

Procedure

After informed consent was received from a parent and primary nurse, the instrumentation was brought to the infant's bedside, connected to the computer and recorder, and calibrated. The pulse oximeters were switched so that the signal output was 0-1 volts and so the oxygen saturation output was 50-100%. The transcutaneous oxygen monitor was calibrated with room air oxygen from 0-160 torr. The pre-amplifiers on the recorder were set so that the pulse oximeter oxygen saturation signals of 50-100% and transcutaneous oxygen signal of 0-160 torr reached the full span of 40 mm/channel on paper. The electrocardiograph and respiration signals were conditioned to obtain a large tracing to fill the 40mm span on the recorder paper.

The primary nurse was consulted to help determine the best time to begin to capture some intervention (e.g.suctioning, feeding, or handling). At the appropriate time, the main oximeter probe and references were applied. The transcutaneous oxygen probe was applied to abdomen or back, avoiding the ribs and right upper quadrant of the chest, and allowed to equilibrate for 15 minutes before data collection began. By convention, the main and reference probes were applied to the ipsilateral surfaces of the right foot and right hand, respectively. If an intravenous catheter was present in the right foot or right hand, then the left foot or left hand was used. When a reflectance oximeter probe was used, it was applied to the head or back.

Electrocardiograms, respirations, and signals from the two oximeters and transcutaneous oxygen monitor were recorded continuously onto the recorder for one hour surrounding an intervention. At the beginning of the hour, when the instrumention was ready, the data acquisition program start button on the computer and event marker on the recorder were pushed simultaneously to indicate the beginning of data collection. An electrical signal event marker on the recorder was pushed each time the desaturation or pulse search alarms sounded on the OLD alarm system, and pushed twice when it ended. All nursing, medical, or parenting activities were noted on the recorder. The period of time including an intervention was chosen as the study period to attempt to capture a "naturalistic" occurrence of oxygen desaturation related to suction, feeding, or handling, as well as artifact.

Fifteen minutes after recording began, an arterial blood gas was obtained (if an umbilical artery catheter was present) while the infant was quiet, not moving, and the oximeter pulse rate equalled the cardiac monitor heart rate. Arterial oxygen partial pressure was be measured on a Corning model 168 pH/blood gas analyzer. Arterial oxygen saturation was calculated. An event marker indicated the time that the blood sample was obtained and measurement of oxygen saturation from the catheter was noted simultaneously. The nurse guessed the SaO_2 and PO_2 without looking at the pulse oximeter or transcutaneous oxygen monitor. These variables were included for descriptive data.

The oxygen saturation signal was transmitted two ways: the conventional alarm system signal (OLD) was transmitted to a data acquistion program on a PC 386 computer with a math co-processor via an analog-digital converter, and the other was transmitted to a digital recorder. The reference pulse oximeter signal was also transmitted to the digital recorder. After the data collection time was completed, the data acquistion program was stopped and an event was marked simultaneously on the recorder. The data was saved in a file on the computer and the recorder tracing was labelled and stored.

Demographic data was collected for the infants (Appendix F) and nurses (Appendix E). Information about infants' ventilatory requirements, arterial blood gas results, temperature, and blood transfusion history was collected. Primary nurses were asked to complete a brief questionnaire about the infant's idiosyncracies related to oxygenation and handling. They were asked to estimate the percent time of artifact for the infant studied and for all infants in the ICN.

Data Analysis

After data collection was completed, the Daqware data acquisition files were formatted to remove characters incompatible with the fuzzy logic alarm system program. After a data file was prepared, the fuzzy logic alarm system program was applied to it, frame by frame. The time length was 30 seconds for each screen frame of the computer data in the fuzzy logic alarm system program. That frame was matched for each 30 second period of recorder tracing. Every alarm or pulse search event on the recorder tracing was matched to the corresponding frame of the fuzzy logic alarm program on the computer and analyzed. If the event lasted longer than one second, then the point of lowest oxygen saturation of the main pulse oximeter was selected for analysis for that frame. Since the beginning and end of the alarm event was noted on the tracing, each 30 second period was analyzed during the time an alarm sounded.

For each event a decision was made for the OLD alarm, NEW alarm, and references (REF), and entered into a statistical program (Statview™II, Abacus Concepts, Inc.). The actual values of the pulse oximeter and transcutaneous monitors were entered for each event. Definitions for the conditions were determined before the data collection began.

Conditions

OLD: YES: If a pulse search or desaturation alarm sounded.

NO: No was never selected for the OLD alarm by definition because every event was initiated by an alarm of the OLD system.

NEW: YES: Yes was chosen if the NEW fuzzy logic alarm indicated desaturation at the time of the event, even if it also indicated artifact at the same time.

NO: No was chosen if the NEW fuzzy logic alarm indicated artifact or within limits of saturation, at the time of the event.

REF: YES: If both the reference pulse oximeter $SaO_2 < 85\%$ AND the transcutaneous PO_2 was < 40 torr.

NO: If either the reference pulse oximeter $SaO_2 \geq 85\%$ OR the transcutaneous PO_2 was ≥ 40 torr.

The limits of 85-95% for normal saturation were selected as outside limits used in research and practice (Comer, 1992). The transcutaneous reference value was selected 30 seconds after the event. This time period of delay in the transcutaneous oxygen signal was selected based on data from studies of arterial oxygen tension and transcutaneous oxygen tension (Conway et al., 1976; Horbar et al., 1987; Le Souef et al., 1978; Poet et al., 1991). The value of 40 torr as an indication of hypoxemia was selected because it is the lower limit used in clinical care and has been used in studies of transcutaneous oxygen and pulse oximetry (Hay, Brockway, & Eyzaguirre, 1989; Horbar et al., 1987). Artifact or falling off was defined for the transcutaneous oxygen monitor as a value >130 torr at the time an oxygen saturation <95% (Barrington, Finer, & Ryan, 1988).

The amount of true and false alarms of the OLD and NEW alarm systems were compared with the references. Based on those comparisons, the following situations were determined for the OLD and NEW alarms, for each event: True-positive, true-negative, false-positive, false-negative. Sensitivity, specificity, positive-predictive value, and negative-predictive value were determined for both the OLD and NEW alarm systems.

Comparisons of estimates and arterial blood gas results were analyzed by a one factor analysis of variance with repeated measures using an alpha of 0.05. 'The nurses' descriptive data was summarized and analyzed using thematic categorization.

Chapter 6

Results

Sample Characteristics

Thirty-eight infants were studied. There were 23 (60%) males and 15 (40%) females. Mean ± S.D. birth weight was 1451 ± 763 (range 550-3500) grams. Study weight was 1495 ± 740 (range 470-3390) grams. Infants were studied on day 11 ± 15 (range 2-78) of life. Study length was 67 ± 18 minutes.

Infant's study temperature was 36.9 ± .34 °C in an ambient temperature of 34.2 ± 2.5 °C. Thirty-one (82%) of the infants were being cared for in isolettes, 2 (6%) were on open tables with radiant warmers, and 5 (12%) were in basinettes.

At the time of the study, 13 (34%) infants were breathing room air and 23 (66%) infants were receiving ventilatory support.

Ventilatory Support

Type of Ventilatory Support	Number of Infants (%)
Room Air	13 (34)
Ventilator	12 (32)
Mask CPAP *	5 (13)
Nasal CPAP	4 (11)
Isolette Oxygen	2 (5)
Oxygen per Nasal Cannula	2 (5)

*CPAP-Continuous positive airway pressure

The infants in room air had the pulse oximeter monitor because of histories of apnea, bradycardia, or oxygen desaturation. The peak inspiratory pressure of infants on ventilators was 20 ± 6 (range 14-38) cm H_2O, the end-expiratory pressure or continuous positive airway pressure was 3.75 ± .45 (range 3-4) cm H_2O, and the rate was 26.08 ± 10.6 (range 12-50) breaths/min. The oxygen requirements during the study are listed for all infants, independent of type of ventilation.

Oxygen Requirements During the Study

Time	Mean ± S.D.	Range
Start FIO2	.26 ± .08	.21-.52
End FIO2	.27 ± .1	.21-.60
High FIO2	.32 ± .14	.21-.70
Low FIO2	.24 ± .07	.21-.52

The position of the main and reference pulse oximeter probes is shown below.

Positon of Main Pulse Oximeter Probe

Position	Number (%)
Right Foot	26 (68)
Left Foot	8 (21)
Left Hand	4 (11)

Position of Reference Pulse Oximeter Probes

Position	Number (%) *
Right Hand	17 (46)
Left Hand	8 (22)
Head (Reflectance Probe)	7 (19)
Right Foot	3 (8)
Left Foot	1 (3)
Back (Reflectance Probe)	1 (3)

*One infant was studied with only the TCM as reference.

Sixteen (43%) of the infants had received blood transfusions while 22 (57%) had not. The infants received 1.1 ± 3.0 (range 0-17) transfusions.

Analysis of Hypothesis

From the 38 infants studied, 941 alarm events were recorded and analyzed. Because of technical problems, of either the reference pulse oximeter or transcutaneous oxygen electrode, 22 events were excluded from the analysis. Of the 919 alarm events, 451 (49%) events were new ones and the rest were events that persisted for longer than 30 seconds. Each infant had 12.2 ± 7.7 (range 1-36) new alarm events per study period. These events were initiated by both desaturation and pulse search alarms of the main pulse oximeter probe and the OLD alarm system. There were 727 (77%) oxygen desaturation and 214 (23%) pulse search alarms. For each event, the OLD and NEW alarms were compared with the references and the presence or absence of oxygen desaturation was determined.

		Oxygen Desaturation	No Oxygen Desaturation
OLD	Desat Alarm	197	508
	Pulse Search	2	212
NEW	Desat Alarm	199	333
	Within Limits	0	129
	Artifact Alarm	0	258

For each event, the number of true-positive, true-negative, false-positive, and false-negative situations were identified. From these results, sensitivity, specificity, positive-predictive value, and negative-predictive value were determined for the NEW alarm system (Hulley & Cummings, 1988).

Sensitivity = The proportion of patients with the condition who have a positive test.

True-Positive / True-Positive + False-Negative

Specificity = The proportion of patients without the condition who have a negative test.

True-Negative / True-Negative + False-Positive

Positive Predictive Value = The liklihood that someone with a positive result actually has the condition.

True-Positive / True-Positive + False-Positive

Negative Predictive Value = The liklihood that someone with a negative result actually is free of the condition.

True-Negative / True-Negative + False-Negative

	Sensitivity	Specificity	Pos.Pred.Value	Neg.Pred.Value
NEW	1.0	0.54	0.37	1.0

Other Findings

Arterial blood gases were obtained from umbilical artery catheters in 13 (34%) of the 38 infants. Blood gases were not drawn from the others because they did not have arterial catheters in place.

Arterial Blood Gas Results

Result	Mean ± S. D.
pH	7.34 ± .05
CO_2	42 ± 9
Base Excess	-2.73 ± 3.52

ABG SaO_2	83 ± 8*
Main Pulse Oximeter SaO_2	90 ± 13
Reference Pulse Oximeter SaO_2	91 ± 7*
RN SaO_2	92 ± 5*
ABG PaO_2	53 ± 10**
$TcPO_2$	60 ± 8**
RN PaO_2	59 ± 9

*$p<0.05$ RN vs. ABG SaO_2, Ref vs. ABG SaO_2

**$p<0.05$ ABG PaO_2 vs. $TcPO_2$

Descriptive Data From Nurses

Descriptive data was obtained from 32 of 38 nurses caring for the infants' studied. Six questionnaires were not completed because of busy assignments. None of the nurses refused to participate in the study. The number of years as a nurse was 13 ± 7.5 (range 3-29) years. The number of years working in the intensive care nursery was 11 ± 7 (range 2.5-28) years.

The nurses estimated that their baby experienced artifact 30 ± 27 (range 0-90) percent of the time. They estimated that, in general, babies in the nursery experience artifact 41 ± 19 (range 5-90) percent of the time.

The responses to the questions indicated that nurses felt that they knew the infants well and expressed a protective quality in their care. The themes relating to the caring activities that emerged from this analysis were identified as establishing personhood, protecting, and identifying physiological patterns. The individual responses to the questions are listed in the Appendix G.

Establishing Personhood

Even with these few questions, the nurses established the infant's personhood, especially with the answers to the question about idiosyncracies. The nurses spoke about the babies' preferences and needs. One nurse spoke for the baby and showed that she was treating him "like a baby" when she said, "Likes his pacifier. We are planning his first bath. He seems hungry. He would like to be in prone position if not for umbilical arterial catheter." In total, the responses were varied and even extreme, sometimes. It was clear that the nurses were speaking about very different babies.

Protecting

The primary nurses were quite emphatic at times in their protection of the infant. In response to the question about idiosyncracies, one nurse wrote, "Needs minimal handling!" The nurses performed individualized interventions to prevent or minimize oxygen desaturation for each particular infant. One nurse wrote in response to the question about how the infant tolerated suctioning, "Tolerates moderately if oxygen increased 20% and increase oxygen after suctioning too." while another wrote, "Desats. Requires increased oxygen 1-2%.". Another nurse wrote, "Needs increase oxygen and increase in hand-bagging rate.

Identifying Physiological Patterns

The responses to the questions about handling and idiosyncracies showed how the nurses identified physiological and behavioral patterns. Again, there was a particular nature to the responses indicating that each baby was different. The observations of subtle physiological responses are those discernable after repeated, continual contact with the infant. One nurse wrote, " Jittery and agitates easily.

After handling, calms but may desaturate." With time, the nurses could identify infants who could tolerate handling. "Sats remain 89-92 with handling. Handles well." "Tolerates handling well for size, gestation." "Tolerates well." They could identify babies who could tolerate handling contingent upon certain circumstances. "No desaturation unless nasal CPAP falls off, then heart rate decreases." "Doesn't need oxygen increased unless agitated." Finally, nurses could identify babies who did experience oxygen desaturation, and even suggested the cause. "Better now, but she still desaturates." "Desaturates with noise. At 81%, increase oxygen 1-2%." "Poorly. Desats with general care."

Chapter 7

Meaning of Findings in Relation to Hypothesis

False Alarms and Artifact

The mean (range) number of new alarm events per subject was 12.1 (1-36), so the alarm and artifact events were spread over the sample population and the results are not just the product of a few probes incorrectly applied. By design, if an alarm persisted, each 30 second interval was considered a separate event. The Nellcor® pulse oximeter is designed to alarm again in 30 seconds after it was silenced if an alarm condition persists. If one includes both new and persistent alarms, then 919 alarms in 38 infants represents 24 new or persistent alarms/hour.

Five hundred eight out of 919 (55%) alarms with the OLD alarm system versus 333/919 (36%) with the NEW alarm system were false. The NEW fuzzy logic was able to reduce the number of false alarms by 34% ($p<0.001$). These rates of artifact are much higher than reported in the one study of artifact found in the literature.

In one study, computerized recordings of pulse oximeter, electrocardiogram, and movement signals were analyzed to calculate the percentage of time that the pulse oximeter heart rate was >10 beat/min different from the cardiac monitor heart rate for at least 10 seconds, causing the saturation to read zero or fall inaccurately (Barrington, Finer, & Ryan, 1988). The results indicated that motion artifact occurs up to 29% of the time, depending on the type of pulse oximeter and signal averaging system used. Twenty-two infants were studied for 7 days. Birth weights ranged from 650-2000g but neither mean weights nor study weights were given so it was difficult to know whether mostly small or large infants were studied, which could affect the amount of artifact measured. It was not clear whether the duration of these events was measured continuously (only percentages and no raw data was presented) or if an event during a two minute epoch was divided by the total number of epochs. Also, an "inaccurate" oxygen saturation (meaning mild artifact versus when the reading drops to zero) was not defined but was included in the artifact results.

In the present study, the definitions of artifact for the reference oximeter and transcutaneous oxygen electrodes were conservative ones. If either reference met the hypoxemia criteria, then the event would be identified as true desaturation. This type of analysis would not overestimate the amount of artifact. In the preliminary study (Bosque & Goldman, 1992), extreme artifact (when the saturation signal instantaneously drops to baseline) occurred 4 (range 0-20) percent of the time, which was similar to the results reported by Barrington, Finer, & Ryan (1988). The fuzzy logic alarm system identified momentary as well as prolonged artifact whenever the variables met the criteria in the "artifact" fuzzy set, so the amount of artifact measured should be more than previously possible to measure.

The fuzzy logic prototype pulse oximeter alarm system has equivalent sensitivity and improved specificity when compared with a conventional pulse oximeter alarm system so the hypothesis was supported. The elegance and versatility of fuzzy logic theory, the talent of the artificial intelligence expert, and appropriate judgement of the domain expert is demonstrated by the fact that no revisions have been made to the original program that was used for this study. Observation of the fuzzy logic alarm program, when applied to the sample data, was revealing and may indicate how the program can be improved.

Although the NEW fuzzy logic alarm identified 387 true-negative situations, therefore improving the specificity of the system, there were still 333 false-positive situations, resulting in false alarms. Although the ideal system would have few false-positives and few false-negatives, it might not be possible to design such a system for the pulse oximeter. The fuzzy logic alarm program was conservative and descriptive in that it identified both artifact and oxygen desaturation, even if they occurred simultaneously. Sometimes the alarms were false because the infant was not actually oxygen desaturated. The fuzzy logic program might be improved to correctly identify these situations. Other times, both artifact and oxygen desaturation conditions were true. Very low birthweight infants often would kick and move, or be handled and move, first causing artifact, and then desaturate while they were moving or being handled. It will be a challenge to program the fuzzy logic alarm to discriminate between saturation and desaturation when artifact is occurring simultaneously, without creating any false-negative situations, that is, missing a true event of oxygen desaturation.

Eliminated Data

The NEW fuzzy logic alarm system had 22 false-negative events. Because of the concern about missing true episodes of oxygen desaturation, each event was reviewed. All of the 22 false-negative events could be attributed to problems with either the reference pulse oximeter or transcutaneous oxygen monitor. For example, the reference oxygen saturation signal was characteristic of artifact, e.g. rapid rate of change down to baseline, and the transcutaneous oxygen monitor had fallen off. Since the reference oximeter at baseline represented 50% saturation, then the event was designated as "true desaturation", therefore producing the false-negative identification, even if the NEW system showed artifact. Problems with the indirect references could be ameliorated by the use of a gold standard such as an indwelling umbilical arterial catheter with an electrode to measure oxygen tension. After consultation with a statistician, these events were excluded from the analysis because of the technical problems.

Pulse Search Alarms

The pulse search alarms were included in the analysis because they often precede a desaturation alarm on the OLD alarm system. They accounted for 23% of all of the recorded events. When the pulse search alarms were excluded and the oxygen desaturation alarms were analyzed separately, the NEW alarm system still had equivalent sensitivity and improved specificity. The specificity of the NEW system dropped from 0.54 to 0.37, but is still a significant improvement over a specificity of 0 for the OLD system.

Arterial Blood Gases

The analysis of variance of the estimates and measures of oxygen saturation and oxygen tension at the time of the arterial blood gas indicated that there was no signficant difference between the nurses' estimates of oxygen saturation and the oxygen saturation as measured by the main or reference pulse oximeter. There were differences between the nurses's estimates versus the calculation of oxygen saturation from the blood gas. There was no significant difference between nurses' estimates of oxygen tension and that measured by either blood gas or transcutaneous oxygen monitor. In terms of clinical relevance, all of the estimates and measurements were close and the mean values were within normal limits (except for calculated blood gas oxygen saturation which was 83%). In general, these results support the proposition that a neonatal primary nurse can make accurate assessments by blending intuition with physiological data. However, that hypothesis cannot be proven until a study is designed with neonatal primary nursing as an intervention, a control group, and when blood gas oxygen saturation is measured with a co-oximeter and not calculated, as was done in this study.

Nurses' Descriptive Data

The descriptive data supports the neonatal primary nursing conceptual framework and the appropriate use of nurses as domain experts for the development of technology. The themes that emerged from the nurses' responses to questions about the infants' idiosyncracies in relation to activities and oxygenation were identified as establishing personhood, protecting, and identifying physiological patterns. The nurses' spoke of the infants as persons with quirks and preferences, e.g. "Prefers minimal handling." Sometimes it seemed as if they were speaking of older children when they made statements like, "Doesn't like wet diaper. Needs heat lamp. Likes to be tucked in." They were specific in their descriptions of the infants' needs during suctioning and handling, reflecting the pattern recognition and "fine-tuning" that occurs when a nurse consistently cares for an infant. It was clear in the summary of responses that they were speaking about many different infants with, if not unique, at least distinct needs.

The nurses who were questioned had much neonatal nursing experience. One might argue that an expert nurse can make assessments of the infant as well as a primary nurse. The expert nurse's identification of patterns and situations may be reflexive, but it is the intimate, continual relationship between primary nurse and infant that allows for the very specific plans of care, the attribution of personhood, and the urge for advocacy and protectionism. In the future, this proposition can be proven in a randomized study of primary versus rotating expert nurses.

The nurses' estimates of the percent of alarms which are artifact were variable. Their mean estimate of 41 percent was between the amount of up to 29% by Barrington et al. (1988) and 75% (including pulse search alarms) or 68% (excluding pulse search alarms) in the present study. The nurses' estmates ranged from 0-90%, which certainly was consistent with measurements of extreme or total artifact from both studies. Because of the way the data was analyzed in this study, that is, comparing the value of the diagnostic testing for the total number of events, the nurses' estimates of artifact for their primary babies were not compared to the actual amount for each infant. This will be done in a future study, when continuous amount of artifact (in seconds) can be measured, as opposed to counting the number of new or persistent events every 30 seconds, as was done in this study.

Significance

Non-invasive pulse oximeters are used by nurses to monitor oxygenation in >600 NICU's in the USA for >80% of mechanically ventilated infants (Salyer, 1991). The results of this study are significant because they indicate that a fuzzy logic computer chip could be placed in a neonatal pulse oximeter and decrease by 46% the number of false alarms that nurses and other staff members will hear. Instead, they would hear another audible indicator (an "alert") of artifact, and they should assess and monitor the infant until the movement or condition subsides. Motion artifact has been identified in many articles as a limitation of the pulse oximeter (Blanchette, Dziodzio, & Harris, 1991; Hay, Thilo, & Curlander, 1991; Salyer, 1991; Severinghaus & Kelleher; 1992; Welch, DeCesare, & Hess, 1990).

Although motion artifact itself will not be eliminated, the false alarms and "Cry Wolf Syndrome" that results from the motion artifact may be eliminated by an alarm system that provides more discriminating information to those caring for and protecting the vulnerable infant.

Limitations

The main and reference probes were not always consistently placed. The reasons for variations in protocol were presence of an intravenous catheter, lesions or abrasions of the skin, need for particular positioning and requests not to move the infant to place the probe, requests to use an existing probe placement to ensure minimal handling. The reflectance probes were used as they became available because of their potential for placement of flat surfaces and non-appendages, therefore possibly ameliorating all motion artifact to become an ideal reference (Severinghaus & Kelleher, 1992). In fact, if they had worked as promoted, there would be little need for the NEW alarm system because there would be no artifact to differentiate. However, the reflectance probes did not consistently work, depending on the size of the infant, unique curvature of the head, and probably other unknown factors.

A true gold standard would be an indwelling oxygen electrode attached to an umbilical artery catheter. The next protocol has already been approved to study infants with oxygen tension catheters in place and test the fuzzy logic alarm system. It will be difficult to enroll large infants because if they are sick enough to need an umbilical artery catheter then they are usually medically paralyzed to minimize their oxygen consumption and prevent them from resisting the ventilator. Also, it is difficult to obtain consent from parents around the birth but before an umbilical artery catheter is placed because they are either unavailable or overwhelmed with frightening information. The best time to obtain consent from parents is before birth if they are in the hospital to prevent labor. Because of the difficulty in enrolling large infants and large numbers of infants, indirect references were used in the present study.

There was concern about blunting of the transcutaneous oxygen monitor signal. If signal blunting does exist then oxygen tension may drop and desaturation may exist but the transcutaneous oxygen signal may not change fast enough to capture it. This would result in inaccurate true-negative events of the NEW alarm system and an inaccurate improvement of specificity. If signal blunting did exist, then the reference pulse oximeter would support a determination of desaturation while the transcutaneous oxygen monitor was within normal limits.

In the present study design, the reference determination was "desaturation" if both the reference pulse oximeter and transcutaneous oxygen monitor were below defined limits. Blunting should not have affected the analysis of the present study, unless the reference oximeter probe had artifact, the transcutaneous oxygen signal was the one used to determine the event, the infant was desaturated, but blunting was occurring. In studies of and articles about transcutaneous oxygen monitors and their limitations, signal delay was described but not blunting (Conway et all, 1976; Horbar et al., 1987; Le Souef et al., 1978; Poet et al., 1991; Southall et al., 1987).

Southhall et al. (1987) compared transcutaneous oxygen and arterial oxygen in 60 instances from 23 infants and found 1.67 ± 1.73 kPa absolute difference in values. There were 10 differences >2.67 kPa and 3 differences >5.33 kPa, but about half of the transcutaneous oxygen values that were different were underestimates of PaO_2. Since it was not stated otherwise, it is assumed that the samples were obtained simultaneously, and blunting was not identified as a problem, although it might have been a cause of the overestimates of arterial oxygen levels. Transcutaneous oxygen monitor overestimates of arterial oxygen comprised about 10% of the results. The question about blunting can be answered in a study using an umbilical artery catheter with an oxygen electrode.

The amount of fetal hemoglobin may have affected some of the results of this study, when oxgyen levels were near the defined levels of oxygen desaturation. Jennis & Peabody (1987) found that infants with >75% fetal hemoglobin had 3.6% difference in between measured oxygen saturation and pulse oximeter saturation values. Those with <50% fetal hemoglobin had less than a 0.5% difference in oxygen saturation values. In the normal term infant, the transition from fetal to adult hemoglobin takes place within 3 to 6 months, but is affected by the level of 2,3-diphosphoglyerate, gestation, and rate of blood withdrawal and replacement (Delivoria-Papadopoulos, Roncevic, & Oski, 1971; Ryan et al., 1986).

None of the infants in the present study received an exchange transfusion, and at the time of the study the number of transfusions was only 1.1 ± 3.0, but the range was 0-17 transfusions, so some infants had received more than others. During the study, the effect of fetal hemoglobin seemed to be present because sometimes the transcutaneous oxygen (torr) was in the high 40's at the time the oximeter alarm sounded and oxygen saturation was <85%. Other times the transcutaneous oxygen (torr) was in the mid 30's before the saturation was <85%. These differences affected the analysis because the predetermined definitions of hypoxemia were used and not changed for individual infants. In future studies, these differences may be explained by the measurement of fetal hemoglobin. Infants may require individual definitions of hypoxemia based on amount of fetal hemoglobin. However, this issue remains controversial.

The most obvious limitation is that the principal investigator collected and analyzed the data herself. The development of a computer program to analyze all of the signals would be ideal. However, many subtle observations were made during data collection and analysis that will be shared with the artificial intelligence programmer to improve the fuzzy logic alarm system and will be incorporated into the designs of future studies.

Future Research and Implications for Nursing

A study has been approved of the OLD versus NEW alarm systems with the use of an umbilical artery oxygen electrode and measurement of oxygen saturation and fetal hemoglobin with a co-oximeter. A computer program could be designed to analyze the signals and measured total amount of artifact continuously. This study will validate the results of the present one and will answer questions about performance of the transcutaneous oxygen monitor as a reference, and about the effect of fetal hemoglobin.

> In the past two decades, advances in technology have resulted in the availability of new equipment and procedures for use in the assessment of patients. Until scientific documentation validating these advances is available, nursing care must be based on proven methods. Guidelines, policies, procedures, and protocols must be developed for the use of technology such as electronic fetal monitoring, pulse oximetry, and hemodynamic monitoring in

> the care of women and neonates. The Committee on Practice supports innovation that involves the use of technological advances in the nursing assessment of patients. The use of such equipment and procedures, however, does not replace "hands-on care" of the patient by the nursing staff. Nursing process must remain the foundation for the provision of nursing care.
> (NAACOG Committee on Practice, September 1991)

The development of an improved alarm system for the pulse oximeter is worthless unless behavior is changed that positively affects the care of the infants. A future study should include one in which the behavior of nurses and other caretakers is observed and measured to determine if they respond more appropriately with an alarm system that differentiates conditions more specifically. The effect of infants' oxygenation in relation to the use of the OLD versus NEW alarm system could be measured.

To determine if primary nurses' knowledge of the infant affects defined outcome variables, such as use of technology, ventilation or oxygenation requirements, amount of oxygen "swings", length of hospitalization, maternal comfort with caretaking skills, or professional satisfaction, a randomized controlled study must be performed in a setting where the study goals and design are supported. If the propostions about the positive effects of primary nursing are proven, then there would be many physiological, psychological, and economic benefits for the infant and family.

Summary

The NEW fuzzy logic alarm system has equivalent sensitivity, and improved specificity, positive and negative predictive values versus the OLD alarm system.

When used by nurses to monitor oxygenation in sick and premature infants, this system with fewer false alarms may decrease the "Cry Wolf Syndrome", and represents a symbiosis between nurse and machine.

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Appendix A

Review of Evaluative Literature About Primary Nursing

Author	Variables	Design	Measures	Results	Conclusion	COMMENT
Cassata (1973)	Pt/Ns perceptions satisfaction	Comparison PN vs Team	Interview Questionnaire	Few differences	New mode of care created dissatisfaction	Reliability & validity of tools not addressed.
Marram (1974)	Pt/Ns/MD/admn perceptions	Comparison PN/Team/ Functional/Case	Interview Questionnarie	Inc. % PN & pts satisfied	PN satisfying mode of care for pts and nurses	No reliab/valid of tools. No stats used to compare.
Collins (1975)	Qual Care Staffing costs Job satisfaction Pt satisfaction	Comparison PN vs Team in 2 hospitals	Audit Observation Job sat questnr Pt sat interview	Inc. qual PN No cost diff Inconclusive satis results	High qual care with PN	Looked at education diffs. No valid/reliab
Daeffler (1975)	Pt satisfaction Report omission of care	Comparison 1 PN vs 5 Team units	Questionnaire Checklist	Diff in 20% items in favor of PN	PN leads to improved pt satisfaction	No reliab/valid No comparabil. of groups
Felton (1975)	Qual Care	Comparison PN vs Team in Peds	Qual Pt Care Scale(Wnd/Agr) Slater Competnc Phaneuf Audit	Higher scores for PN	Higher qual care scores with PN	No reliab/valid No comparabil. of groups
Jones (1975)	Complications Length of stay Cost Pt attitudes	Comparison PN vs Team Transplant Unit	Self-developed tool	Stat results unclear	Better qual Fewer complic Dec. cost with PN	No reliab/valid Random assign of pts to grps
Haussman, Hegyvary, & Newman (1976)	Structural char. of mode of care in 19 hospitals	Survey	Questionnaire	Hi scores for small units, many RNs, using PN	Support for PN	Diff. definitions of PN/hosp. Survey-No causal relation
Marram, Flynn, Abaravich & Carey (1976)	Cost Ns satisfaction Pt satisfaction Qual Care	Comparison PN vs Team	Questionnaires	Same qual at lower cost, in %.	PN is cost efficient	No reliab/valid Matched grps Cost diff-inc senior team ns's

Review of Evaluative Literature About Primary Nursing

Author	Variables	Design	Measures	Results	Conclusion	COMMENT
Hymovich (1977)	Perception of pt, ns, MD, administrators	Time series Pre-test/Post-test in Peds	Questionnaire	No difference	None	No stat test Relied on %
Kent (1977)	Qual Care Ns satisfaction	Comparison PN (12) vs Team (5) vs Case Method Units (3)	Qual Care Tool, Collins (1975) Job satis tool-self develop	Inc qual & job satis data for PN	Higher qual & job satis for PN	No reliab/valid Interrater reliab OK
Eichorn & Frevert (1979)	Qual Care	Time Series Pre-test/Post-test on 4 Units	Qual Pt Care Scale (Wan & Ager)	Diff scores in 2 units	Inc qual with PN	No mention prev mode of care or pt selection. Reliab addressd.
Hegedus (1979)	Pt. stress	Time Series Pre-test/Post-test	Stress Evaluation tool (Volicer, 1973)	Dec stress score for PN	Dec stress with PN	No reliab/valid Head Ns selected pts.
Mills (1979)	Perceptions of pt & ns	Experimental Random assign 3 PN vs 3 Team Units	Questionnaire	Inc.perceptions of authority, autonomy, acctabil with PN	Influence of PN not easily discernible	Difference in pre-test responses between grps.
Betz, Dickerson, & Wyatt (1980)	Cost	Time-series Pre-test/Post-test	Pt classification Cost Qual/Medicus System	Higher cost PN	Higher acuity of PN unit so higher cost PN	Random observations No data shown for conclusion
Giovannetti (1980; 1981)	Qual Care Cost Nsg time Pt & ns satisf	Comparison PN vs Team	Observation Job desc. Index (Smith, 1969) Audit/Interview	Results favored Team	PN not supported	Grps equival Rel/valid OK
Hegedus (1980)	Qual Care Ns satisfaction	Time-series Pre-test/Post-test	Job Satis Tool (Herzbrg, 1959) Qual Care Scale	Trend supported PN Not stat signif	PN implemented	Rel/valid addressed

Review of Evaluative Literature About Primary Nursing

Author	Variables	Design	Measures	Results	Conclusion	COMMENT
Steckel, Barnfather, & Owens (1980)	Qual Care Outcome	Comparison PNvsTotal Pt CarevsTeam	Qual Care Scale (Wandelt, 1970) Health Stat Scale (Horn, 1977)	Inc qual PN & TPC Units No diff outcome	Individ.care, continuity of care inc. qual	Stratified random sampling used to select pts.
Alexander, Weisman, & Chase (1981)	Ns perceptions Job turnover	Comparison PN vs Functional Unit	Questionnaire Job Desc Index Wk Satis Scale (Brayfld, 1951)	No diff job satis Varying results job turnover	Varying results support PN	Relia/valid OK
Betz (1981)	Job satis Job turnover	Comparison 3 PN vs 3 Team	Job Desc Index (Herzbrg, 1959)	Dec job satis PN Higher turnover	PN not supported	No reliab/valid No stat tests used
Carlsen & Malley (1981)	Job satis	Comparison 300 PN vs Team Ns's on 27 units	Job Satis Quest (Munson, 1974)	Inc absenteeism & turnover of PN	PN more accountable so inc turnover	No reliab/valid Gps not equival. <54% responded
Humera & O'Connell (1981)	Qual Care	Time series Pre-test/Post-test	Direct Observation for 5 days	No diff time or qual of ns/pt interaction	PN not supported	Equival grps Observers trained Interrater OK
Joiner, Johnson, Corkrean (1981)	Motivating Potential Job satis Pay satis	Comparison PNvsTotal Pt CarevsTeam	Questionnaire	Higher motiv scores PN No higher satis	PN role more enriched	No reliab/valid Grps different
Sellick, Russell, Beckmann (1983)	Pt satisfaction Ns satisfaction	Comparison 1 PN vs 1 Functional Unit	Questionnaire	Diff in few satis items	PN inc pt/ns satisfaction	No reliab/valid Conclusion based on few items
Shukla (1981, 82, 83) Shukla & Turner (1984)	Qual Care Cost Pt satisfacation Ns satis, trnovr	Comparison PN vs Team	Qual Care Scale Slater Comptncy Direct Observe	PN inc cost Dec prodctvty No diff pt satis	PN not supported	Rel/valid OK Grps matched

Review of Evaluative Literature About Primary Nursing

Author	Variables	Design	Measures	Results	Conclusion	COMMENT
Young, Giovannetti & Lewison (1981)	Qual Care Job satis Nsg time	Comparison 1 PN vs 1 Team	Observation Wk sampling Job Desc Index Audits	Higher PN qual audit score	PN not supported	Question valid of qual care audit
Blair, Sparger, Walts, & Thompson (1982)	Pt satisfaction Ns satisfaction Pt anxiety	Time series Pre-test/Post-test in 2 ER's	Job Satis Scale Risser Pt Sat Scl State-trait Anxiety Scale	No diff pt satis Inc job satis Dec pt anxiety	PN supported	Diff pre-test Ns/pt voluntr No rel/valid Measurd X3wks
Mayer (1982)	Pt satisfaction	Comparison Pts knew vs not know name of PN	Risser Pt Satis Scale	7/8 questions sign. diff in favor of PN	PN supported	Operationalize PN Random select Rel/valid OK
Parasuraman (1982)	Job stress Job satis	Comparison 300 PN vs Team nurses	Questionnaire	Inc stress PN	PN not supported	Grps not equivl. Rel/valid OK Looked at shift differences
Ventura (1982)	Pt satisfaction	Comparison 1 PN vs 1 Team	Risser Pt Satis Scale	No diff pt satis	Not able measure PN with pt satis	Rel/valid OK
Chavigny & Lewis (1984)	Qual Care Pt satis Cost Job satis	Cohort design PN vs Team	Observation Audit Questionnaire	PN less pt contact PN inc stress	PN prep may be more impt than mode of care	Head nurse randomized
Culpepper, Richie, Sinclair, et al. (1986)	Qual Care	Time series Pre-test/Post-test on 22 units	Medicus Qual Assessment tool	5/8 qual scores improved Post-tests vary	Inc qual PN No effect from timing of adoption of PN	3 sets post-tests to control for novelty effect Rel/valid OK
Pearson, Durant, & Punton (1988)	Qual Care	Comparison PN vs Functional	Phaneuf Audit Pt. Service Chk Life satis scale	Higher scores PN	Higher qual PN	Random assign No reliab/valid Loss of data

Review of Evaluative Literature About Primary Nursing

Author	Variables	Design	Measures	Results	Conclusion	COMMENT
Reed (1988)	Qual Care Philosophy of care Job satisfaction	Comparison 1 PN vs 1 Team	Qual Care Scale Phaneuf Audit Phil Care Quest Job Desc Index	Inc scores qual & job satis PN Diff phil scores	Inc qual PN Inc job satis PN Coherent philos PN	Grps not equiv No rel/valid
Glandon, Colbert, & Thomasma (1989)	Cost	Compare various modes of care in 392 units in 62 hospitals	Nsg cost RN cost	Costs varied Highest/sm unit with RN's	Not one best mode of care in terms of cost	No random select RN or PN costs?
Wilson & Dawson (1989)	Pt well-being Nsp practice Staff morale Cost	Cross-over design in 2 geriatr units PN vs team	Tranq/Agit Scle Vitality Scale Pers Contrl Scle Geriatr Goals	Diff nsg pract & pt well-being PN No diff morale/cost	PN has benefits	Diff pt pops Sim ns stafng patterns Prbs/Maturation

California Pacific Medical Center

Reliability and Validity of a New Pulse Oximeter Alarm System for Neonates

Permission to Include My Child in a Research Study

Principal Investigator: Elena Bosque, RN, MS

By signing this consent form, I agree to have my baby, ______________, participate in a study to test a new alarm system for my baby's pulse oximeter, the monitor which measures the oxygen in my baby's blood. My baby's participation depends upon my continuing consent. I understand that I may refuse or I may withdraw my consent at any time without in any way changing my baby's care.

WHY IS THE STUDY BEING CONDUCTED?

The pulse oximeter measures very accurately how much the blood is saturated with oxygen when babies are not moving. Most babies still kick and move, even when they are sick or very premature. This movement causes the pulse oximeter to have false alarms, which may be dangerous if they happen so often that they are confused with the "true alarms". False alarms are estimated to occur up to 29% of the time. When the pulse oximeter is hooked up to a machine that continuously records the tracing of the amount of oxygen onto paper, it can be seen that there are characteristic changes in the tracings during times of false alarms. These tracings are different from those that occur during true desaturations, when the oxygen concentration is low in the baby's blood. Based on these observations, the investigator has worked with computer scientists to apply a new computer science theory to improve the program that runs the alarm system for the pulse oximeter.

The new alarm system would include one "alert" which would sound when the baby is moving and so the nurse should not trust the machine at that time. Another "alarm" would sound when the oxygen is low in the blood. If this new alarm system works, it would better indicate what is happening with the baby, and decrease the chance that people become overwhelmed by false alarms and ignore them. This study would test an early computer model of this new alarm system and compare it with the present one.

WHAT HAPPENS TO MY BABY AND OTHER STUDY PARTICIPANTS?

After I have given consent to have my baby participate in this study, the measuring instruments will be assembled and calibrated at my baby's bedside. My investigator will show me the equipment before the study begins. The information from my baby's monitors will begin to be recorded 30 minutes before a scheduled time for suctioning of the tube in my baby's throat. All nursing, medical, or parenting activities will be noted on the recorder. The transcutaneous oxygen monitor will be calibrated and placed on my baby's skin. As soon as my baby is quiet and not moving, a small blood sample will be obtained to check the amount of oxygen in my baby's blood. The amount of oxygen measured by the pulse oximeter will be recorded continuously for the remainder of the hour, including during the time of the suctioning event. The suctioning event was selected for the study period because it is a time during which my baby is likely to experience changes in oxygen and probably will be moving, so that the alarm systems can be tested.

My baby's primary nurse will be asked to answer a questionnaire regarding an estimation of the infant's saturation at the time of the blood gas measurement and about my baby's idiosyncrasies related to oxygenation. The primary nurse will be questioned again about idiosyncrasies related to oxygenation two weeks after the study day.

WHAT ARE THE RISKS OF THIS STUDY?

My baby will not experience any measurements that he or she would not experience anyway because of health care needs. There are no known risks of this study for my baby.

WHAT ARE THE BENEFITS OF THIS STUDY?

There are no direct benefits to my child.

HOW WILL THE STUDY AFFECT MY BABY'S MEDICAL CARE?

Except as stated in this consent form, this study will not in any way affect the care my child normally receives.

HOW CONFIDENTIAL ARE MY BABY'S MEDICAL RECORDS?

The nurse conducting this study and any other person whom I allow (by this signed consent form) will have access to my baby's records. All records will be treated confidentially and in the event of publication of this study, individual identities will not be disclosed.

WHAT HAPPENS IF MY BABY IS INJURED OR HARMED IN SOME WAY BY THE STUDY?

I understand that California Pacific Medical Center and/or the investigators have no special program that provides compensations for medical treatment if any complications arise from participation in this study.

WHERE DO I GO WITH QUESTIONS?

Elena Bosque, RN, will answer any questions I may have about my baby's participation in this study. I may reach her at (415) 750-6211 (a 24-hour number).

WILL I BE TOLD WHAT THE STUDY LEARNED?

Yes, I will be advised of any significant new findings developed during the course of the research, if I request the information. I will be sent a written summary of the research study after its completion if I provide my address at the time my baby is enrolled into the study.

I have been given a copy of this consent form and the Experimental Subjects Bill of Rights and I have read and understood them.

PARENT'S SIGNATURE_________________________________ DATE________

WITNESS SIGNATURE_________________________________ DATE________

(11/91)

California Pacific Medical Center

Reliability and Validity of a New Pulse Oximeter Alarm System for Neonates

Permission to Include Me, a Neonatal Primary Nurse, in a Research Study

Principal Investigator: Elena Bosque, RN, MS

By signing this consent form, I, _______________, agree to participate in a study to test a new alarm system for a neonatal pulse oximeter. I understand that I may refuse or I may withdraw my consent at any time.

WHY IS THE STUDY BEING CONDUCTED?

The pulse oximeter measures very accurately how much the blood is saturated with oxygen when babies are not moving. Most babies still kick and move, even when they are sick or very premature. This movement causes the pulse oximeter to have false alarms, which may be dangerous if they happen so often that they are confused with the "true alarms". False alarms are estimated to occur up to 29% of the time. When the pulse oximeter is hooked up to a machine that continuously records the tracing of the amount of oxygen onto paper, it can be seen that there are characteristic changes in the tracings during times of false alarms. These tracings are different from those that occur during true desaturations, when the oxygen concentration is low in the baby's blood. Based on these observations, the investigator has worked with computer scientists to apply a new computer science theory to improve the program that runs the alarm system for the pulse oximeter.

The new alarm system would include one "alert" which would sound when the baby is moving and so the nurse should not trust the machine at that time. Another "alarm" would sound when the oxygen is low in the blood. If this new alarm system works, it would better indicate what is happening with the baby, and decrease the chance that people become overwhelmed by false alarms and ignore them. This study would test an early computer model of this new alarm system and compare it with the present one.

WHAT HAPPENS TO ME?

On the day that the computer prototype alarm system will be compared with the conventional pulse oximeter alarm system of the baby for whom I am the primary nurse, I will be asked to answer a one-page quesitonnaire. I will be asked to answer questions regarding an estimation of the baby's saturation at the time of the blood gas measurement and about the baby's idiosyncrasies related to oxygenation. I will be questioned again about idiosyncrasies related to oxygenation two weeks after the study day. The questionnaire responses will provide descriptive data about nurses' intuition and assessment of oxygenation in babies with whom they care for continually.

WHAT ARE THE RISKS OF THIS STUDY?

There are no known risks of this study for me.

WHAT ARE THE BENEFITS OF THIS STUDY?

There are no direct benefits for me.

HOW CONFIDENTIAL ARE MY RESPONSES TO THE QUESTIONS ASKED?

The nurse conducting this study will have access to my questionnaire responses. All records will be treated confidentially and in the event of publication of this study, individual identities will not be disclosed.

WHAT HAPPENS IF I AM INJURED OR HARMED IN SOME WAY BY THE STUDY?

I understand that California Pacific Medical Center and/or the investigators have no special program that provides compensations for medical treatment if any complications arise from participation in this study.

WHERE DO I GO WITH QUESTIONS?

Elena Bosque, RN, will answer any questions I may have about my participation in this study. I may reach her at (415) 750-6211 (a 24-hour number).

WILL I BE TOLD WHAT THE STUDY LEARNED?

Yes, I will be advised of any significant new findings developed during the course of the research, if I request the information. I will be sent a written summary of the research study after its completion if I provide my address at the time I am enrolled into the study.

I have been given a copy of this consent form and the Experimental Subjects Bill of Rights and I have read and understood them.

SUBJECT'S SIGNATURE_________________________________ DATE_________

WITNESS SIGNATURE__________________________________ DATE________

(11/91)

```
REM ROUTINE TO PLOT BOSQUE GRAPHS
REM BOSQUE.BAS
REM 02-13-92 WS

REM Colors: 0 = black, 1 = blue, 2 = red, 3 = white (default)

REM Fuzzy sets:
REM RATE.HIGH, RATE.MEDIUM, RATE.LOW
REM DESAT.YES, DESAT.NO, DESAT.HIGH
REM oldDESAT.YES, oldDESAT.NO
REM ARTIFACT.YES, ARTIFACT.NO
REM oldARTIFACT.YES, oldARTIFACT.NO

REM Fuzzy logic operators

REM Fuzzy AND

DEF FNFZAND (A, B)
IF A < B THEN C = A ELSE C = B
FNFZAND = C
END DEF

REM Fuzzy OR

DEF FNFZOR (A, B)
IF A > B THEN C = A ELSE C = B
FNFZOR = C
END DEF

REM Fuzzy NOT

DEF FNFZNOT (A)
FNFZNOT = 1 - A
END DEF

REM Input run parameters from keyboard

INPUT "Data file"; FILE$
INPUT "Samples per computed point"; DX
INPUT "SAO2 at 0.5 confidence desaturation YES"; desat
desat = desat * 2 - 1
INPUT "SA02 at 0.5 confidence O2 HIGH"; HIGHO2
HIGHO2 = HIGHO2 * 2 - 1
INPUT "Rate at confidence 1 rate MEDIUM"; testRATE.MEDIUM
INPUT "Rate at confidence 1 rate HIGH"; testRATE.HIGH
INPUT "Rate multiplier for plot"; MPY
INPUT "Weight of last sample for moving average (0-1)"; WT
INPUT "Length of line between points in pixels"; PIX

REM Initialize file, screen

ON ERROR GOTO NOFILE
OPEN FILE$ FOR INPUT AS 1
SCREEN 1
COLOR 0, 1
WINDOW (0, 0)-(300, 1.25)
LINECOLOR = 3

REM Initialize program variables
```

BOSQUE.BAS
2/13/92

jram BOSQUE (source code BOSQUE.BAS, executable module BOSQUE.EXE) .a preliminary fuzzy alarm system for a neonatal pulse oximeter.

ne program may be simply executed by entering (at the DOS prompt)

bosque < ting.inp (wangfeng.inp, gonzalez.inp)

although this redirection of the input makes it impossible to use the end-of-frame options described below.

Normal input, on entering BOSQUE at the DOS prompt, is:

DATA FILE (ting.dat, wangfeng.dat or gonzalez.dat)
SAMPLE POINTS PER POINTS PROCESSED (permits reducing the sampling rate if desired. I use a value of 1, so that every point is processed.)
SAO2 FOR .5 CONFIDENCE DESATURATION (I use 0.85) Threshold / Degree of Jaggedness
SAO2 FOR CONFIDENCE ,5 HIGH O2 (I use .95)
RATE FOR CONFIDENCE 1 MEDIUM (I use 0.05) } Rate of Change
RATE FOR CONFIDENCE 1 HIGH (I use 0.5)
RATE SCALE FACTOR FOR PLOT (I use 5)
WEIGHT FOR LAST POINT INPUT (I use 0.1)
LENGTH OF LINE BETWEEN POINTS (I use 1)

Output includes the original SAO2 wave, scaled to read from 0.5 (bottom) to 1.1 (top). Lines are drawn across the screen at SAO2 values of 0.5 (bottom), 0.75 (middle) and 1.0 (toward the top). Also plotted is the rate of change of SAO2, plotted with zero at the 0.5 SAO2 line.

Actions are these:

HIGH O2: Turns traces blue, pulses of sound at 440 Herz.

MOMENTARY ARTIFACT: small circle drawn on SAO2 and RATE traces, short pulse of sound at 256 herz.

CONTINUOUS ARTIFACT: traces blue, sound at 256 Herz.

DESATURATION: traces red, sound alternates between 512 and 602 Herz.

While the program is running, key presses execute some run-time options at the end of a frame. Pressing the P key causes a pause at the end of a frame (Hit any key to continue); the Q key enables quitting the program (press any key to quit); the H key toggles the sound signal for high O2; the U key increases the level required for high and medium rate fuzzification, making the system less sensitive to artifacts; the D key decreases these levels, making the system more sensitive to artifacts.

If is is desired simply to view the data, run program PLOTIT.

The program language is Quick Basic 4.5, by Microsoft.

READ.ME

```
INPUT #1, JUNK, SAO21
REM old moving average
MA1 = SAO21
REM Fuzzy set for artifacts on last point
oldARTIFACT.YES = 0
oldARTIFACT.NO = 1
REM Fuzzy set for desaturation on last point
oldDESAT.YES = 0
oldDESAT.NO = 1
REM numerical value of last rate
RATE1 = 0
REM enables, disables sound warning for high O2
SOUNDHI$ = "Y"

ON ERROR GOTO FINISH

REM Start loop over screen frames

FOR FRAME = 0 TO 1000
  PRINT "Frame"; FRAME
  REM Tick marks
  FOR X = 0 TO 1.21 STEP .1
      LINE (0, X)-(3, X)
  NEXT X
  FOR X = 0 TO 1.21 STEP .2
      LINE (3, X)-(6, X)
  NEXT X
  LINE (6, .5)-(300, .5)
  LINE (6, 1)-(300, 1)

  REM Loop over points in a frame

  FOR I = PIX TO 300 STEP PIX
    REM Input extra samples (if any) and sample to be used
    FOR J = 1 TO DX
      INPUT #1, JUNK, SAO22
    NEXT J
    REM Plot original data
    LINE (I - PIX, SAO21)-(I, SAO22), LINECOLOR

    REM Get moving average
    MA2 = (1 - WT) * MA1 + WT * SAO22

    REM Plot moving average of SAO2
    REM LINE (I - PIX, MA1)-(I, MA2), 2

    REM Plot unsmoothed rate
    RATE2 = (SAO22 - MA1) / DX
    LINE (I - PIX, RATE1 * MPY + .5)-(I, RATE2 * MPY + .5), LINECOLOR
    REM Get absolute value of RATE2 for later tests
    ABSRATE = ABS(RATE2)

    REM Fuzzify SAO2 into fuzzy set DESAT

    REM get desaturation confidence similarly
    IF MA2 > 2 * desat - 1 THEN
      DESAT.YES = (1 - MA2) / (2 * (1 - desat))
      DESAT.NO = FNFZNOT(DESAT.YES)
    ELSE
      DESAT.YES = 1
```

```
    DESAT.NO = FNFZNOT(DESAT.YES)
  END IF
  IF MA2 > 2 * HIGHO2 - 1 THEN
    DESAT.HIGH = (MA2 - (2 * HIGHO2 - 1)) / (1 - (2 * HIGHO2 - 1))
  ELSE
    DESAT.HIGH = 0
  END IF

  REM Fuzzify rate into fuzzy set ARTifact
  REM Triangular membership functions

  IF ABSRATE > testRATE.HIGH THEN
    RATE.HIGH = 1
    RATE.MEDIUM = 0
    RATE.LOW = 0
  ELSEIF ABSRATE > testRATE.MEDIUM THEN
    RATE.HIGH = (ABSRATE - testRATE.MEDIUM) / (testRATE.HIGH - testRATE.MED)
    RATE.MEDIUM = FNFZNOT(RATE.HIGH)
    RATE.LOW = 0
  ELSE
    RATE.HIGH = 0
    RATE.MEDIUM = (ABSRATE - testRATE.LOW) / (testRATE.MEDIUM)
    RATE.LOW = FNFZNOT(RATE.MEDIUM)
  END IF

  REM Existence of artifact depends on last and current status
  REM Rule: if (old artifact and desat) or (rate HIGH) then
  REM       current artifact

  ARTIFACT.YES = FNFZOR(RATE.HIGH, FNFZAND(oldARTIFACT.YES, DESAT.YES))
  ARTIFACT.NO = FNFZNOT(ARTIFACT.YES)

  REM Rule: if rate medium then give artifact warning only

  WARN = RATE.MEDIUM
  IF WARN > .5 THEN
    SOUND 256, .5
    CIRCLE (I, RATE2 * MPY + .5), 3, 1
    CIRCLE (I, SAO22), 3, 1
    REM Reset moving average
    MA2 = SAO22
  END IF

  REM Rule: if artifact then take action

  IF ARTIFACT.YES > .5 THEN
    REM Reset moving average
    MA2 = SAO22
    LINECOLOR = 1
    REM CIRCLE (I, SAO22), 3
    SOUND 256, .5
  ELSE
    LINECOLOR = 3
  END IF

  REM Now O2 level tests
  REM Rule: if O2 level high then give warning
  REM       else restore warning line color

  IF DESAT.HIGH > .5 THEN
```

```
    LINECOLOR = 1
    IF I MOD 50 = 0 AND SOUNDHI$ = "Y" THEN SOUND 440, .5
  ELSEIF ARTIFACT.NO > .5 THEN
    LINECOLOR = 3
  END IF

  REM Now if in desaturation, be sure we are not in an artifact
  REM Rule: if O2 level in desaturation and no artifact then
  REM       reset confidence in DESAT.YES

  DESAT.YES = FNFZAND(DESAT.YES, ARTIFACT.NO)

  REM Rule: if still in desaturation, then -- (consequence more rules)

  IF DESAT.YES > .5 THEN
    REM If desaturation, make sure it has held up long enough

    REM Rule: if not previously desaturated set desat time to zero,
    REM       else increment desat time
    IF oldDESAT.NO > .5 THEN
      TDESAT = 0
    ELSE
      TDESAT = TDESAT + DX
    END IF

    REM Rule: if desat time > 2 seconds then issue warning
    IF TDESAT > 20 THEN
      REM Signal desaturation
      LINECOLOR = 2
      REM Sound alternating tones
      IF TDESAT MOD 40 < 20 THEN
        SOUND 602, .25
      ELSE
        SOUND 512, .25
      END IF
    END IF: REM End if desat time > 2 seconds
  END IF: REM End if now in desaturation

  REM Reset old values
  SAO21 = SAO22
  MA1 = MA2
  RATE1 = RATE2
  oldDESAT.YES = DESAT.YES
  oldDESAT.NO = DESAT.NO
  oldARTIFACT.YES = ARTIFACT.YES
  oldARTIFACT.NO = ARTIFACT.NO

NEXT I

REM If key pressed, honor it:
REM Q stop; P pause; U up slope; D down slope; H = toggle high warn sound

A$ = UCASE$(INKEY$)
IF A$ = "Q" THEN
  GOTO FINISH
ELSEIF A$ = "P" THEN
  DO: LOOP WHILE INKEY$ = ""
ELSEIF A$ = "U" THEN
  testRATE.MEDIUM = testRATE.MEDIUM * 1.2
  testRATE.HIGH = testRATE.HIGH * 1.2
```

```
  ELSEIF A$ = "D" THEN
    testRATE.MEDIUM = testRATE.MEDIUM / 1.2
    testRATE.HIGH = testRATE.HIGH / 1.2
  ELSEIF A$ = "H" THEN
    IF SOUNDHI$ = "Y" THEN
      SOUNDHI$ = "N"
    ELSE
      SOUNDHI$ = "Y"
    END IF
  END IF

  CLS
NEXT FRAME

FINISH:
DO: LOOP WHILE INKEY$ = ""
SCREEN 0
WIDTH 80
PRINT "Plotted"; 300 * FRAME / PIX + I / PIX; "points."
END

NOFILE:
DO: LOOP WHILE INKEY$ = ""
SCREEN 0
WIDTH 80
PRINT "END OF DATA"
END
```

California Pacific Medical Center

Symbiosis of Nurse and Machine Through Fuzzy Logic: Reliability and Validity of a New Pulse Oximeter Alarm System for Neonates

Demographics and Data from Nurses

Name______________Birthdate__________# years as RN______#years in ICN______

Date of questionnaire____________Name of Baby______________Baby's Study #______

At time of ABG, estimated PaO_2____________________SaO_2____________________

At the time of the ABG, describe how this baby looks to you.______________________

In terms of oxygenation, how does this baby react to suctioning?____________________

In terms of oxygenation, how does this baby react to handling?_____________________

Can you describe any other of this baby's idiosyncracies related to oxygenation, ventilation, and nursing, medical, or parenting activities and care?____________________________

Do you think that this baby's pulse oximeter has a lot of motion artifact? Yes____No____

What percent of the time do you think this baby has motion artifact?_______________%

How much pulse oximeter motion artifact do you think there is in general?__________%

Appendix F

California Pacific Medical Center

Symbiosis of Nurse and Machine Through Fuzzy Logic:
Reliability and Validity of a New Pulse Oximeter Alarm System for Neonates

Demographics and Data from Infants

Name___________ **Study Number**________ **MR#**____________ **Birthdate**_________

Sex_____________ **Birth Weight**_________ **Study Date**________ **Study Weight**_________

Baby's Temp__________**Isolette Temp**___________**Transfused? No**______**Yes**______**#**_____

Start FiO2________ **End FiO2**____________ **Hi FiO2**__________ **Low FiO2**___________

STUDY TIMES: Start_______ **ABG**_______ **Suction**_______ **End**________

ABG GOLD Time______ **FiO2**________ **pH/CO_2/BE**__________

Pa O_2..........._**ABG SaO2**______ **Co-Ox SaO2**______ **Main Pulse Ox SaO2**_____

Ref Pulse Ox SaO2_______ **TCPO2**__________

# ALARM SIGNALS: Time	OLD (Y/N)	NEW (Y/N)	SAT (Y= <85%/N= ≥85%)

Artifact: _________**sec/**__________**total time =** ___________**% Artifact**

Appendix G

Responses to Nurses' Questionnaire

At the time of the ABG, describe how this baby looks to you?

•Pink, quiet, not agitated.

•Pink, then dusky.

•Pink, well perfused.

•Pink before ABG, then dusky.

•Pink, well perfused, cool.

•Calm, pink, rapid respiratory rate, mild retractions.

•Pink, active but not agitated.

•Pink, calm, not breathing over ventilator.

•Pink, very deep red blood.

•Pink, retractions, tachypneic.

•Pink, jaundiced, quiet, moderate retractions.

In terms of oxygenation, how does this baby react to suctioning?

•OK, drops to 80's.

•Not good. Must increase oxygen 10-30%.

•Desats. Requires increased oxygen 0.1-0.2%.

•Required increased oxygen by 20%. Tolerates suctioning fair, not great.

•Very well. Requires increase in oxygen 10-30%.

•Requires oxygen increase 10%.

•Requires oxygen increase to .25. No desats or brady's. Can wean back to 0.21.

•Tolerates moderately if oxygen increased 20% and increase oxygen after suctioning too.

•OK in 40%. Can dial down after. Good recuperation after suctioning.

•Suction orally on mask CPAP. Needs blow-by oxygen.

•Needs increase oxygen and increase in hand-bagging rate.

In terms of oxygenation, how does this baby react to handling?

•Terribly.

•Prefers minimal handling. Desats with prolong handling.

•Requires oxygen increased sometimes.

•Requires oxygen increased 5-10%.

•Sats remain 95-100%.

•Desats and has apneas with handling.

•Jittery and agitates easily. After handling, calms but may desaturate.

•Poorly. Desats with general care.

•Sats remain 89-92 with handling. Handles well.

•Does well.

•Tolerates handling well for size, gestation.

•Rarely desaturates.

•Needs increased oxygen to keep within saturation limits.

•Tolerates well. No desaturation unless nasal CPAP falls off, then heart rate decreases.

•Does not desaturate, but there is some artifact.

•No color change but desats to 80's.

•Doesn't need oxygen increased unless agitated.

•Better now, but she still desaturates.

•Does OK. Normal response to handling.

•Tolerates handling well.

•Fine. No color change. No sat change.

Can you describe any other of this baby's idiosyncracies related to oxygenation, ventilation, and nursing, medical, or parenting activities and care?

•Doesn't like blood draw.

•Needs minimal handling!

•Desaturates with noise. At 81%, increase oxygen 0.1-0.2.

•Fairly stable when alone.

•Doesn't like wet diaper. Needs heat lamp. Likes to be tucked in.

•Desatuates with nippling.

•Not labile. Tolerates handling if a little extra oxygen is given.

•Fewer apneas and desaturations since blood transfusion. Apneas require mild stimulation and oxygen. Vagal response occurs with passing of the oral gastic tube.

•Swallows air when agitated, even with oral-gastic tube in place.

•Does not brady with handling, but desaturates when restless.

•More stable in prone position. Sats stay 91-92% with activity.

•Holds breath for feeds, desaturates, and requires stimulation.

•Consistent oxygen requirements. Requires room air for 8 hours at a time, then needs 0.1 liter for 3-4 hours.

•Need to group activities together and increase oxygen.

•If oxygen increased before activities, and activities grouped together, then does fairly well.

•Quiet. Has apnea and bradycardias but no desats, even with apnea.

•Tolerates off nasal CPAP for 10 minutes but not during weighing at night.

•Circumoral cyanosis when crying. Better at coordinating nippling and breathing. Fewer desats.

•Yesterday required increased oxygen for handling but not today. Cranky and irritable. He doesn't like nasal CPAP.

•Has periodic breathing. Brady's to 50-60 bpm with desaturation to 79-80%, occasionally associated with apnea.

•Stable with handling. If having brady's to 40-80 bpm, he's still breathing and pink.

•Nipples well. No desats.

•Likes his pacifier. We are planning his first bath. He seems hungry. He would like to be in prone position if not for umbilical arterial catheter.

•Likes hard nipple when agitated, otherwise gets gavage-fed.

•Calm, quiet last 2 days. She's been on her side, cuddled with rolls.

•Brady's a lot. Propping head to prevent obstruction. Does fine with oral gastric tube placement.

•Desats occasionally during gavage feeding but self-resolved. Oximeter is sensitive to movement.

•Increased lability with feedings. Desats don't appear to follow any pattern.

•Quiet and sleeping well. No problem with feeding or handling.

Sixteen of 30 nurses (53%) felt that the infants for whom they were caring experienced motion artifact of the pulse oximeter. They guessed that the infant for whom they were caring experienced pulse oximeter motion artifact 30 ± 27 (range 0-90) percent of the time. In general, they guessed that pulse oximeter motion artifact occurred 41 ± 19 (range 5-90) percent of the time.