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Pilot Usability Study of UI Prototype for Collaborative Adaptative Decision Support in Neonatal Intensive Care Unit

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PILOT USABILITY STUDY OF UI PROTOTYPE FOR COLLABORATIVE ADAPTATIVE DECISION SUPPORT IN NEONTATAL INTENSIVE CARE UNIT

Submitted by

Lan Yang, B.A.Sc.

A thesis submitted to the Faculty of Graduate and Postdoctoral Studies in partial fufillment of the requirements for the degree of

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Abstract

Pilot Usability Study of UI Prototype for Collaborative Adaptive Decision Support in NICU

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2005

This thesis presents the usability evaluation of the user-interface prototype of the PArents Decision Support (PADS) framework. The PADS framework is the first decision support system to address ethical decision-making in Neonatal Intensive Care Unit (NICU). But due to the historical resistance of information systems by clinical staffs, does this system have the potential of being accepted into the NICU? We took the user-centric evaluation approach by rapid prototyping and conducting a pilot study with clinical users to assess whether this prototype satisfies basic usability requirements. Our results indicated that all of the clinical evaluators found the prototype moderately easy or very easy to use, as well as being consistent with the concepts and terminologies used in their clinical practices. Based on those results, we conclude that the UI prototype satisfied the usability objects we set out and that the PADS framework's requirements has partially been validated.

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Contents

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Glossary of Terms and Acronyms

ANN: Artificial Neural Network is a computational method that uses artificial intelligence to learn by past experience and to classify current cases according learned patterns

Architecture: Highest level concept of a system in its environment [IEEE, 1999]

BPD (Bronco-pulmonary dysplasia): a form of chronic lung disease often occurring in extremely premature infants

CDSS (Clinical Decision Support System): A collection of tools and methods to improve the decision-making process often encountered in clinical environments

CRIB (Clinical Risk Index for Babies): a clinical scoring method for evaluating the severity of a baby's condition

CHEO (Children's Hospital of Eastern Ontario): located in Ottawa, Ontario, Canada

Epidemiology: The branch of medicine that deals with the study of the causes, distribution, and control of disease in population

HIS (Hospital Information System): A network of computers that provide information services and data housing for hospitals

ISI (Illness Severity Indices): A scoring system used to measure, compare, and classify the state of health of individuals

IVH: Intraventricular Hemorrhage is the bleeding into the normal fluid spaces within the brain of the very underweight babies. IVH is also referred to bleeding in areas near the ventricles even if the blood is not within them. The extent of IVH is graded I, II, III, IV

Medical Informatics: Medical Informatics combines the disciplines of medicine and information technology to support the health care delivery process and improve the quality of care delivered, through initiatives such as CDSSs.

MIRG: Medical Information-technology Research Group is a research group situated in Ottawa, Canada

MIS: Medical Information Systems

NICU: Neonatal Intensive Care Unit provides specialized care to high-risk infants

Ontology: An explicit formal specification of how to represent the objects, concepts and other entities that are assumed to exist in some area of interest and the relationships that holds among them

NEC (Necrotizing Enterocolitis): An inflammation causing injury to the bowel of the extremely premature baby

PADS (PArents Decision Support): A combination of computer processes and human process that enables parents to make an informed decision regarding the selective non-treatment of a neonate

PVL (Periventricular Leukomalacia): Softening of the brain near the ventricles due to tissue death

ROP (Retinopathy of Prematurity): An abnormal growth of blood vessels in the eye of the extremely premature baby, causing infant blindness

SNAP, SNAPPE, SNAPPE-II: Score for Neonatal Acute Physiology and SNAP Perinatal Extension is a method of scoring newborn illness severity and mortality risk

UML (Unified Modeling Language): A language for visualising, specifying, constructing and documenting the artefacts of a software intensive system

Use Case: A UML term describing interactions between actors and the system; the complete set of use cases describes the system functionalities

XML (eXtensible Markup Language): As defined in XML 1.0, XML is a standard from the W3C that provides tagging of information content within documents. XML offers a means for representing content in a format that is both human and machine readable.

VLBW (Very Low Birth Weight): Neonate who weigh less than 1500 grams at birth

Chapter 1 Introduction

1.1 Overview

Computing technology holds enormous potential to improve medical care through electronic medical records, communication between physicians and patients, information sharing among health care providers, and rapid access to reliable real-time medical information. Potential benefits of medical information infrastructures include reduced wait-time, improved process efficacy, better quality of care, and patient empowerment [Sittig & Stead, 1994]. Those benefits would be valuable to a variety of clinical specialties, from ambulatory settings [Johnston *et al.*, 2003] to primary care. Of particular interest to this work is the Neonatal Intensive Care Unit (NICU), where critical healthcare is provided for the very most vulnerable and unpredictable neonates born at the margin of viability.

Clinical studies have shown the survival rate of extremely premature and very low birth weight infants has been rising for the past 30 years [Tyson, 2003]. Since the number of preterm birth and low birth weight have actually risen [Johnston, 2001], the reduction of mortality indicates that more previously hopeless neonates are being given a chance at life. These successes are mainly attributed to the increasing sophistication of neonatal medical technology [Cole, 2004; Horbar *et al.*, 1995]. The survival rates improvement is particularly pronounced among the extremely premature and the extremely low birth weight babies [Horbar *et al.*, 1995]. However, epidemiological studies have shown that improved survival rate is *not* associated with similar improvement in morbidity rates [Penticuff, 2003]. In other words, while more infants survive the trauma of a high risk birth, these infants are often sustaining serious or even severe life-long disease and illness.

Due to the uncertainty and long-term risks associated with the health of these critically ill newborns, the use of life-sustaining medical care must be questioned and examined before administration [Cuttini, 2001]. Are there infants so malformed and premature that aggressive intensive care is merely prolonging the process of dying? What are the long-term outcomes of those patients? Historical evidence has shown that indiscriminate use of aggressive care, some even against the parents wishes, could result in tragic outcomes [Richardson, 2001]. The proper usage of the power of medicine requires the controls in the manners of planning, management, strategies, and risk analysis.

The Medical Information-technology Research Group (MIRG) of University of Ottawa has recognized the shortage of research in this area. We advocate the appropriate use of engineering methods to solve clinical medical problems and demonstrated the performance of artificial intelligence tools in predicating clinically significant outcomes [Frize *et al,* 2001; Ennett *et al.*, 2003; Walker *et al.* 2001, Tong *et al.*, 2002]. Frize et al identified "a critical need to provide physicians with more accurate estimations of the likelihood of infant surviving, the estimated duration of artificial ventilation, and length of stay (LOS) in NICU" [Frize *et al.*, 2003]. Not only do we recognize the need to advance methods of predication and classification, we are also well aware of the special needs of our clinical users and have taken into consideration the needs of physicians in their interaction with our software [Liu, 2001]. In 2003, Frize et al, suggested the potential of using a two-method approach to support ethical decision in NICU such that the neonatologist can make a decision with reliable quality information to avoid potential adverse outcomes [Frize *et al.*, 2003]. Yang, Frize *et al.* then expanded on this work by developing a conceptual architecture, called the PArents Decision Support (PADS) tool [Yang & Frize, 2004; Frize *et al.*, 2005]. Based on this premises, our work here is to conduct the initial feasibility study. Being a pilot study, this work evaluates whether a group of clinical users find the concepts of such a system, manifested through a limited UI prototype, acceptable and useable.

The PADS architecture developed by MIRG is a system that provides a set of tools that allows physicians, allied healthcare team, and parents to collaborate in the decision. The goal of PADS is to seamlessly integrate computerized tools into existing clinical procedures such that the efficacy of decision-making can be improved with minimal disturbance and effort to learn new technology. It is a well-documented fact that, historically, attempts to bring information and knowledge management technology into the medical profession has met with consistent resistance and barriers [Altman, 1998]. The decision problem domain that we wish to address is one with significant amount of ambivalence and complexity. Therefore, before we can pursue further research on this topic, we need to establish a proof of concept – that the conceptual architecture of PADS has a reasonable chance of being successfully accepted and eventually being integrated into the clinical decision-making procedure.

Up to this point, we have yet to find a closely matched research premises as ours. However, some comparable computer-aided decision support in NICU as well as other clinical environments has been studied by various projects such as the NEONATE project [Ewing *et al*, 2003] and the commercial product Baby CareLink® [Safran, 2000]. However, our work differs in that we approach the problem from an engineering perspective. We strive to use state-of-the-art engineering technology and methodology to approach the problem. Through this work, we will address the integration issues of clinical processes, artificial-intelligence methods, group collaboration, and personal decision-making from a systems perspective. We also suggest that the appropriate decision support system has the potential to be accepted and incorporated into clinical process, thus will be possible to make an impact on the ethical decision-making process in NICU.

1.2 Motivation and Significance of Research

Since our research is based on the confluence of engineering and medicine, with an evaluation method adapted from software usability testing, we will describe our motivation from those three perspectives, and summarize with the multidisciplinary studies perspective.

1.2.1 Engineering Perspective

Rapid progress in microprocessors, telecommunication, application development, and knowledge management provide engineers with unprecedented tools to aid in the innovative methods for solving old problems, such as provision of better health and delivery of healthcare. Engineering has effected every major industry – from banking and finance to education and research, and the examination of problems in the medical fields is long overdue. This delay has resulted in a widening gap between medicine and healthcare management. With the maturity of communication technology and knowledge management, it is time to examine potential solutions for this pressing problem.

There exists a pressing need to reform the ailing healthcare system in Canada [Rother, 2003]. Major research agencies, such as the Natural Sciences and Engineering Research Council (NSERC), acknowledge the need to apply information technologies on clinical workflow and processes, and literature shows evidence that the hospital information systems (HIS) is already surging in US healthcare systems [Patel *et al.*, 2002]. The major overhaul of current healthcare infrastructure is inevitable. In alignment with those goals, we justify the use of our group's core technologies to augment the ethical decision-making process in neonatal care provision. As an engineering problem, conducting a usability study is useful for assessing if our proposed solution actually meets basic constraints to eventually provide benefits.

Another primary motivation for this research is to extend the current tools developed by MIRG for clinical use. MIRG has been conducting research on the estimation of clinical outcomes for neonates for the past two years. Our software can effectively predict outcomes that could potentially provide significant support to decision-making and help reach their goals. However, there are considerable challenges before the realization of those goals, such as process integration issues, technology limitations, and social barriers. One of the objectives of this research is to validate this prediction technology. If this technology is mature enough, it becomes desirable to apply the results to clinical practice. The most immediately visible usage case would be the integration of these results to critical treatment selection and decision. In effect, the machine intelligence must be aggregated with the human intelligence, since this is what makes the approach useable.

1.2.2 Healthcare Perspective

Before discussing the technical challenges in integration of machine and human intelligence, it is insightful to justify the existence of clinical decision support system in hospital environment. Currently, researchers in the healthcare field are well aware of the problems that plague current clinical processes. There is no shortage of literature in medical journals on the topics of treatment decision support and healthcare management. Healthcare professionals are concerned current deficiencies and are looking for methods to deliver of better patient care throughout the healthcare environment, from diagnosis to chronic care management to genetic drugs and therapy. Some branches of medicine that has evolved from past research include telemedicine, evidence-based medicine, and problem-based medicine.

The NICU is a very good example of a clinical environment where medical technology has grown phenomenally. Since 1970's, when the world hailed the wonders of scientific discoveries and its first clinical products, the 'miracle babies' [Richardson, 2001], there has been a relentless push from

scientific community and the rest of society alike to foster new progress. It was race to see how far humans can push the limits of nature and their own survivability. In the past few years, advancements in in-vitro fertility, obstetrics, neonatology, and perinatology have also led to the birth and survival of the increasingly vulnerable and fragile. Recall that, however, Darwin has asserted his well accepted theory of evolution - survival of the fittest [Darwin, 1859]. It follows that, associated with the positive effect of providing more infants with a chance of life, there are some very serious underlining negative implications of the power of modern NICU medicine.

As mentioned in the overview, while neonatal intensive care is very effective at reducing mortality, outcome for the patients remains uncertain and variable. It is a well recognized fact that extremely premature (<= 25 weeks of gestation at birth) or extremely underweight (<= 1000 grams at birth) neonates are likely to sustain diseases and long-term disabilities that could severely limit the quality of life [Allen *et al.*, 1993]. A significant percentage of NICU graduates suffer from neurological damage that leads to long term adverse outcomes [Wood *et al.*, 2000]. Due to their fragile nature, neonates often develop additional complications after prolonged exposure to aggressive care - treatment as innocuous as oxygen therapy can lead to retinopathy of prematurity (ROP), or infant blindness [Ward & Beachy, 2003]. That is to say, while neonatal medicine has successfully improved the number of life, the quality of life has yet to be significant improved. Despite these risks, in western philosophy, it is the medical principle of benevolence that governs the care of this vulnerable population – that every infant should be given as much a chance at life as possible [Cole, 2000].

In most cases, treatment withdrawal decisions have to be made under a great deal of uncertainty. As Dr. Robin Walker of CHEO explains: in the current healthcare setting, the best a physician can provide in terms of concrete evidence regarding the outcome of a premature infant of less than 24 weeks gestation

is to inform parents that their child has a 50% chance of being mentally and/or physically handicapped [Walker 2001]. Our physicians need more accurate and specific prediction method. By knowing the optimal amount of information, enforced with sound professional judgment, physicians are better equipped to form the best decision for the infant.

Not only are these decisions uncertain, but by their nature, they are associated with ethical weight as well. The ethical principles that come into conflict are mostly parent autonomy and benevolence. While each case is unique and individual, experts and clinical studies results show that shared-decision making is a recommended practice model for these ethically challenging questions [Carter, 2003], since most parents have been found to appreciate active participation in treatment decisions [Penticuff, 2003], in some study, parents have responded well to web application design to increase their ability to have influence the decision for their child [Safran, 2003]. This recommendation is not merely popular in North America, but in other major developed countries as well [William *et al.*, 2004].

Shared information, then, needs to be acquired from relevant sources and disseminated to both physician and parents to ensure a partnership on reaching a multilateral decision on the proposed intervention. However, parents are under exceptionally stressful circumstances; thus, it is understandable and foreseeable that parents will have difficulty coping with the learning necessary to effectively participate in the decision making.

From the healthcare perspective, there are certain rules and guidelines that can be used for decision support. But with today's emphasis on shared decision and patient empowerment, a more patient-specific, collaborative, and adaptive, system is need.

1.2.3 Usability Perspective

In the field of neonatology and other clinical fields, the potential benefits of clinical decision support systems (CDSS) are well recognized. However, it seems that while they work well in principle, seldom do CDSS make it into clinical usage, and when they do, they often fail, causing the users to become frustrated and unwilling to try again. While the concepts of human factoring are understood in the fields of medicine, they do not understand the necessity to rigorously and scientifically evaluate the qualitative constraints on software, as well as how to consistently improve upon existing basis. Past failures in implementing clinical software suggests that more incorporation of usability engineering techniques could possibly help avoid potential resistance and barriers to an evolutional change in clinical practice. In fact, usability testing should probably be made standard procedure amongst interdisciplinary systems and solutions.

As research suggests, the long overdue arrival of computers in the hospital environment is primarily due to the resistance from physicians and clinical staff. Therefore the usability study not only serves as a pilot study to evaluate a slice of our system concept, but also serves as a mean to familiarize physicians with the potential reality of using such systems in daily routine. In this manner, we can adjust the system according to the clinical user's feedback, and in turn, clinical users can adjust some of the existing bias they may have regarding computers. We believe such an effort would cause the research effort to spiral vertically, and in each iteration, closing a finger's width of the historical gap that lies between medicine and engineering.

1.2.3 Multidisciplinary Perspective

This research holds significance due to unique multi-disciplinary nature, and its applicability to other similar endeavors. In fact, it would be interesting to see whether a usability study should be the de facto

pilot evaluation method for most multi-disciplinary research, since it is a simple method for measuring the potential effect of a multi-disciplinary research idea. In later chapter 3, we will see that different fields have different names for the same ontology, which manifest itself as a difficulty of running this evaluation – specifying the naming and definition for entities when there are so many competing perspectives on the same issue.

1.3 Thesis Objectives

The primary objective of this thesis is to evaluate a user-interface prototype that demonstrate core system concept through a selective subset of functionalities. Through this study, we wish to determine whether the prototype can satisfy basic usability requirements (defined in chapter 5) for an ethical decision support tool in NICU. In addition, we show and document the initial response to PADS, such that we can test whether it would be worthwhile to continue along this research direction. In order to achieve this central objective, this thesis has the following secondary objectives:

1. **Define functional and non-functional requirements:** An integral component to evaluation is to develop an accurate set of requirements according to the needs of users and the organization. Use-cases will be defined. We also need to state the non-functional requirements - usability requirements. These requirements are not defined prior to conception of this thesis, but will be developed based on analysis and synthesis from existing literature. We will also explicitly state the subset of key requirements that will be used in our prototype validation.

2. **Describe system architecture**: this objective will abstractly describe the conceptual framework. This will include high-level discussion on the context, data needs, components, and integration

process that makes up the PADS system. We will also suggest how the system may be implemented.

3. **Design UI**: this provides the prototypes (mock-up and functional) and the rationale for our UI design. We also provide rationale for our prototyping methodology as well as some of the risks and challenges.

4. **Conduct Usability Testing of PADS-III prototype**: we evaluate the prototype to assess whether our target users find the user-interface learnable and easy-to-use, thus meeting the usability requirements previously defined. We also attempt to validate some requirements using a questionnaire.

5. **Evaluate and analyze:** this employs common evaluation methods such as statistical testing of results data, and qualitative analysis of user feedback. It is also our intention to analyze the response to infer whether such a concept can be acceptable in NICU and whether such a system is sustainable in NICU.

1.4 Thesis Outline

This dissertation is divided into nine chapters as follows:

Chapter 2: Medical Background covers the relevant medical, ethical, and clinical concepts that are necessary to develop an understanding and appreciation of the context of this problem. Because this

work spans multiple traditional fields, this chapter will introduce basic clinical concepts that are used in the subsequent chapters.

Chapter 3: State of Art Review provides a summary of work in our Medical Information Research Group (MIRG), the state-of-the-art research of decision support, with a concentration on its usage in healthcare. Different types of CDSSs are described, and examples of tools are compared. There will be a focus on papers that present or evaluate user-interfaces for decision support.

Chapter 4: Problem Statement provides a description of the engineering problem to be solved, including an analysis of the information presented in Chapter 3 and justifies that the study being conducted solves a significant problem in an original manner. This includes a description of potential applications for this work.

Chapter 5: Software requirements present a gathering of all requirements, including definition of use cases.

Chapter 6: High level Architecture is an overview of architecture, which set the context of our usability study. We also suggest how such a system maybe implemented.

Chapter 7: UI Design describes how we design the user interface and describe some of the prototyping work.

Chapter 8: Usability Evaluation describes our method, observation, result, and analysis for pilot usability testing. Standard measures using usability questions are presented, along with a discussion of the challenges and impact of the framework on the clinical process. Here, we also attempt to validate the requirements using a questionnaire.

Chapter 9: Conclusion summarizes the main contributions, limitations and a presentation of future work to build upon this research.

Chapter 2 Medical Background

2.1 NICU Summary

In order to gain a sense of the NICU environment and the problems that we are attempting to solve, the following section describes significance of the NICU, clinical decisions that are made, decision makers and informers, and the user of decision aids.

2.1.1 Significance of NICU

The motivation for a specialized Neonatal Intensive Care Unit (NICU) is to provide specialized care for infants who have to be hospitalized upon birth. Over the past thirty years, the effectiveness of NICUs and neonatal medicine is evident through the continuous improvement of survivability, particularly for preterm babies born at the limits of viability, as demonstrated in figure 2-A [William, 2004; Richardson *et al*, 2001]. The tiniest baby to have survived the trauma of birth is documented at 300 grams [learnersonline, 2004].

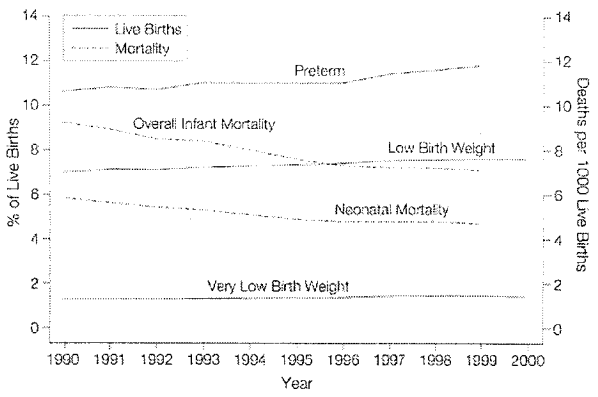

Figure 2-A: Rates of infant birth weight and mortality [Richardson, 2001]

In the United States, approximately 470,000 babies (~12%) are born prematurely [Mueller, 2003] every year. The rate of low weight births and the rate of birth defects have not declined since the 1970's [Carter, 2003], and the pre-term birth rate has increased steadily, as observed in figure 2-A. In Canada, preterm rates also display increasing trend, rising from 6.3% in 1981 to 7.5% to 2003 [Daily, 2004]. These shifts are attributed to changes in the frequency of multiple births, obstetrical intervention, and the use of ultrasound-based estimates of gestational age [Joesph *et al.*, 1998]. In addition, the establishment of In Vitro Fertilization (IVF) programs contributes to NICU admission rate, as birth by older, higher-risk couples have a tendency towards high-risk pregnancies [Sloane, 2004]. Now more than ever, the demand for NICU services is increasing, and those patients admitted to NICU are staying longer [William, 2004]. Based on these observations, the need of NICU services is likely to increase in the next ten years.

2.1.2 Clinical Decisions

Upon admission, the parents and the infant are often considered a patient unit – consisting of distinct individuals who work towards achieving the common health goal – recovery of mother and child. After the initial activities of hospitalizations have been completed, depending on the conditions, changes, and other clinical factors, the neonatologist will identify whether or not there is a need to discuss the possibility of limiting aggressive care. In certain cases, if the infant is displaying unequivocal signs of catastrophic outcomes, the physician will make the decision. On the other hand, there have been cases where very unlikely babies have survived against all odds and grown into healthy adulthood. There is always a great deal of uncertainty in choosing treatments for hospitalized neonates, and physicians have to exercise keen judgment and diligence in initiating the decision process for selective non-treatment.

2.1.3 Decision Makers and Informants

We mentioned previously the role of the physician in NICU. In traditional paternalistic medicine, neonatologist would be the sole decision makers for the treatment selection for the infant. Nowadays, a shift towards patient empowerment have promoted the involvement of parents through informed consent – where they passively agree or disagree to their physician's recommendation – to informed decision, where the parents actively participates in weighing the options and choosing the one they deem to be yield the most optimal result for their family.

Other roles that occur during decision making are those of clinical nurse specialists, attending nurses, pharmacist, specialists, social workers, and even ethicist. These practitioners are collectively known as allied health team (AHT). They act as informants to the decision-makers. In the case of social worker of ethicist, their role is also to listen to the parents and members of the AHT to help them through any issues they may be concerned or conflicted about.

2.1.4 Use of Decision Aids

Clinical procedures use a variety of indices and tests to sift information from raw data. Some examples of decision aids under current use are illness severity indices, and logistic regression analysis models to estimate factors such as mortality for patients with bronco-pulmonary disease. An important limitation of these tools is that they are designed by and useful for population estimation; clinical problem solving, however, is case-based. That is, each individual case differs enough to render prognosis based on group norms to be inaccurate in almost every case. Computerized methods, with their ability to handle large quantities of information and producing case-specific results could potentially solve the said problem.

However, the use of computerized decision aids in NICU is not very prevalent, even amongst the most technologically advanced hospitals. The most common form of computerized CDSS is rule-engines integrated with physician order entry system (CPOE) [Gordon, 2004]. We've identified several types of NICU computerized and non-computerized aids; these are the BabyCareLink ® [Safran, 2000], the NEONATE project [Ewing *et al.*, 2000], and Neonatal Case Management [Carter *et al.*, 1999], each of these will be discussed in sections. The role of computer in electronic health management falls mainly under the categories of medical record, communication, knowledge base and decision support. Computerized Physician Order Entry tools are often mentioned [Blumenfeld, 2003]. Diagnosis and prognosis are classification problems that have captured the interested of AI scientists. However, there is little evidence that such type of tools exist in clinical practice. Altman attributes this phenomenon to the physicians' resistance to computers taking away the 'fun of problem solving' and challenging their clinical expertise [Altman, 1999]. There is also the possibility that in the past, computer technology was cumbersome to bring to the bedside, where it was most important to have access to data.

2.1.4.1 BabyCareLink ®

The **BabyCareLink** ® tool is the only commercially deployed tools found through Internet and journal search. Developed through a joint research effort by the Harvard Medical School and the Beth Israel Deaconess medical Centre, this tool is built around the concept that decision-making is a knowledge intensive process in NICU and provisions of tools improves this critical clinical procedure even for vulnerable population. It uses a web application interface to provide parents with varying background and education level a method to increase their participation and their saying in making healthcare decision for their infant [Safran, 2003]. The CareLink architecture is based on the distribution of host computer to each participating family, which then allows access to the server-side patient database. The architecture accounts for components such as security and user authentication, confidentiality,

maintainability, extensible database design, and the concept of classifying users for access control. The tool also attempts to manage the relationship between users, infants, and family, maintaining user status and preference, syndicating dynamic content according to user and patient status. Their evaluation method includes randomized controlled trial with parents in control and intervention groups through tracking the frequency and length of videoconferencing for each family. Initial results indicate the system to be robust and scaleable [Gray J *et al.*, 2000]. Figure 2-B shows the web-based interface courtesy of [Gray *et al.*, 1998.]

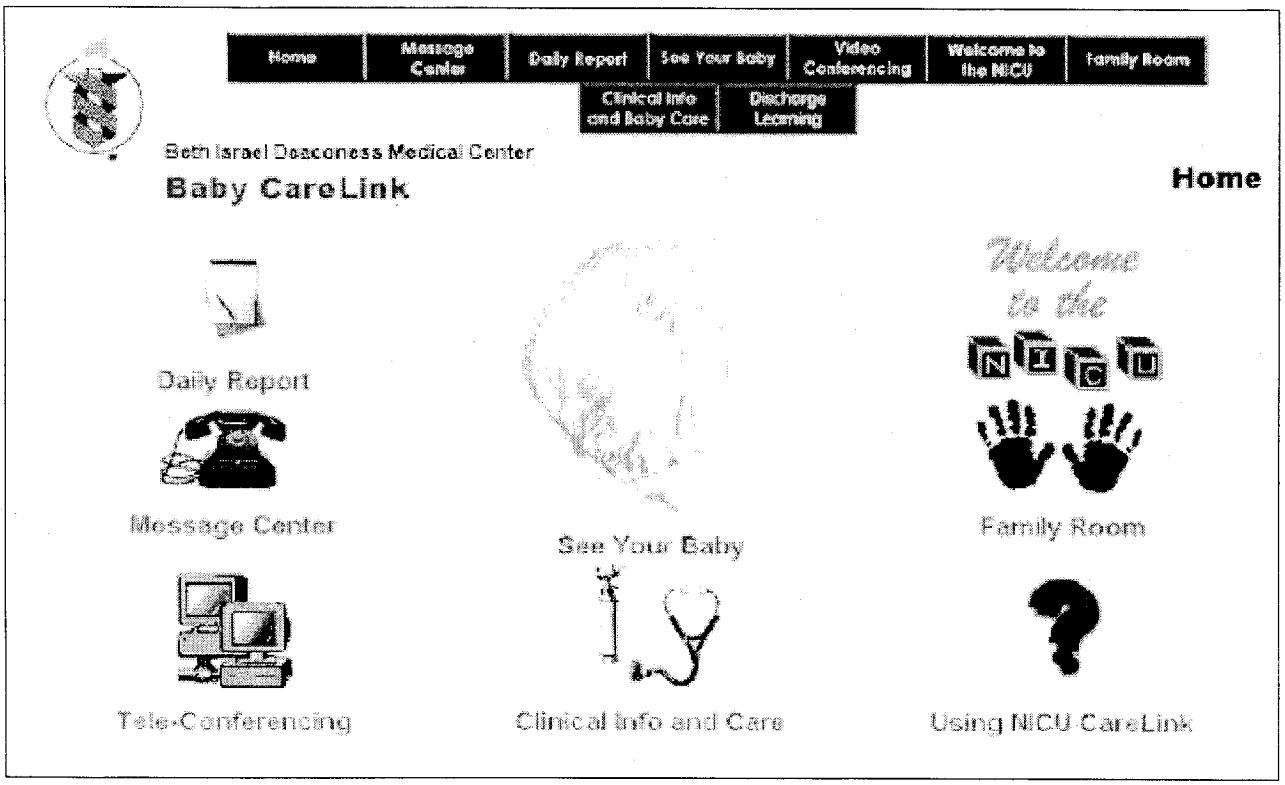

Figure 2-B: Baby CareLink ® [Gray *et al.* 1998]

2.1.4.2 Neonatal Case Management Tool

The **Neonatal Case Management Tool** is developed for the high risk neonates who are difficult and expensive to manage due to the complexity and incremental nature of NICU medicine, varying patterns

of care amongst NICUs, difficulty of the problem of having to withdraw or limit treatment, and the rapidly changing status of neonates. According to Carter *et al.*, the key to managing this population requires three aspects: data, clinical expertise, and integrated management process [Carter *et al.*, 1999]. This tool is a process flow chart that is assimilated by physicians only.

2.1.4.3 NEONATE and other projects

The NEONATE project was a research study run by clinical cognitive engineering group in an effort to develop decision support for NICU staff at the Simpson Centre for Reproductive Health, Edinburgh, U.K [Ewing *et al.*, 2003]. The study attempted to organize the lexicon of terms terminologies to reflect the data and communication that occur in NICU [Ewing, 2000]. These concepts are then used to design user-interfaces which allow specialists to document the clinical activities. Other projects, such as MARY, use computerization as a mean to provide trend graphs or reports [Alberdi *et al.*, 2000]. In summary, there were few computerized decision support tool in use in NICU. In terms of interfacing, the most comparable system would be the BabyCareLink ® tool. The only major difference is this tool doesn't acknowledge the need to make difficult and critical decisions that requires the maintenance and enhancement of traditional physician-parent interaction. That is to say, parents will most likely stay within close proximity of their baby should there be the need to make critical life-affecting decisions.

2.2 Shortcomings of NICU system

Given current medical and technological environment, major challenges exist in the modern NICU. These are medical challenges and information challenges. Since we are concerned about the usability of our decision support system, we will dwell more on the second challenge.

2.2.1 Lack of improvement in morbidity

First, preventing the adverse neurodevelopmental outcomes of extremely high-risk population remains a major challenge [Msall, 2004]. In the largest population-based study, nearly half of survivors had a disability in one or more domain at 30 month corrected age [Wood et al, 2000]. Second, many patients who suffer through the pain and discomfort of aggressive treatment eventually die in NICU [Alexander, 2003]. Predicting the likelihood of impairment in an individual is inaccurate, despite the availability of the most sophisticated equipment [Saigal, 2001]. The need for better methods of prognostication is justified based on two cases: first, to improve the cost-effectiveness of the expensive NICU treatments, and second, to minimize prolonged pain and suffering caused by futile treatment.

2.2.2 Unequal distribution of knowledge and documentation

In order to realize the hope for patient empowerment and taking control of their own healthcare, parents must be able to access the knowledge and assimilate the knowledge on their own accord. Parents do not have a simple method of accessing the knowledge is concentrated in the physicians and the various members of the AHT, patient data records, and medical literature. Parents may request to see the infant's health charts, but accessing this information is inconvenient and cumbersome. In addition, not all the information exchanged during verbal discussion is available for parents, resulting in the loss of knowledge. Some inquisitive parents may seek out information from the Internet, but they also should realize the Internet is an unreliable source at best and the information needs to be explained to them in context of their problem.

2.2.3 Lack of structure and consistency

As mentioned previously, one of the reasons for examining managed care is due to the variability between different NICU on their pattern and quality care [Carter, 1999]. A sound process and data structure not only ensure consistency and avoid poor decision making, but it also ensure the patients and

physician engage in repeatable process that can be evolutionally improved upon. Overall, we believe the NICU needs a management mechanism to control the delivery of healthcare.

2.3 Attributes of NICU Decisions

From the moment the patient is hospitalized, the physician and parents must be prepared for a potentially long and tortuous path, where the infant's condition may change on daily basis and decisions have to be made accordingly. Some of the decisions, such as how much surfactant to administer, is purely medical, and is expectedly left up to the physician to decide. The other types are value and preference sensitive decisions that require the participation of parents. This section defines the decision that we are interested in as a healthcare problem.

2.3.1 A Difficult decision

The most difficult decision a parent might face in NICU is the possibility of having to withdraw or limit the aggressive treatment on their infant. These decisions are inherently difficult due to their ethical implications. Often, it is difficulty reaching a consensus due to the varying principles between the decision makers. Sometimes, selecting between the alternatives is difficult because of the major implications of the outcomes, and the grey area that exist between the ultimatums. Even when there are no ethical conflicts, just the mere fact that the parents have the burden of deciding whether their newborn dies is difficult enough. The graveness of the outcomes makes the decision much more difficult, and the parents may be emotionally charged, ethically challenged, and fundamentally ambivalent. In addition to this, the factors of religious belief and values and principles also come into play in this type of decision, which adds another dimension of difficulty to the task.

2.3.2 Uncertainty

Patient condition changes daily, which exacerbates the complexity of the decision. Some research findings reveal clinical statistics that can provide guidance on choosing an alternative. However, decisions to withdraw aggressive treatment can hardly be based on epidemiological findings alone. In addition, the decision requires making trade-offs between near and long-term outcomes and between quantity of life verses the quality of life, which are unfortunately all uncertain for sometimes prolonged periods of time. In certain cases, learning disabilities do not become apparent until the early school years. The need to juggle the risk and the probability is not an easy task even for the most-trained professional, and must more difficult for the untrained, traumatized parents. Such decisions are often associated with time variability, over-confidence, misinterpretation, and unrealistic expectation.

2.3.3 Group decision making

The need for shared decision raises the point that the decision-making is in fact a group process. While it is understood that the recommendation for withdrawing treatment decision varies between countries and often between centers in the same country [Cuttini *et al.*, 2001], however, a best practice recommendation is that such a decision must be made based on a parent-physician partnership; this is based on historical reasons. Early success of neonatal intensive care led many clinicians and the general public to boundless optimism and unreasonable expectations, which resulted in tragic cases of aggressive care against parents' wishes [McCormick, 1980; McCarton, 1997]. Opposition from various forces, including parents' advocacy groups, presidential commissions, and ethics committees, pushed towards parents' autonomy and shared decision-making [Harrison, 1993]. In response to social pressure, the medical community acknowledges the negative effects of indiscriminant treatment of neonates, and the potential for long-term suffering [Carter, 2003]. Current guidelines suggest shifting away from medical paternalism [Yu, 2002] and recommends that the treatment planning of neonates should opt for an explicit decision process and parental involvement. Rempel [2004] stated that

"although advances in technology have enabled diagnosis, health care professionals must elicit each parent's particular perspective, be cognizant of their professional influence, and actively support parents". This view is shared by many others as well [Wood, 2000; Vohr, 2003]. However, Ruland asserts that without systems to facilitate shared-decision making as part of clinical practice, it is difficult to include parent's perspective, values, and preference into patient care [Ruland, 2004].

2.3.4 Medical complexity

Non-treatment selection is an active choice to forgo aggressive treatment in cases of very grave outcomes. This alternative is only plausible if the infant is given a very poor prognosis. To understand how physicians arrive at prognosis requires understanding of a myriad of medical concepts, including congenital defects, symptoms development, complications, and long-term implications. Clinical situations in which withdrawal of aggressive treatments is considered are: (1) when death is inevitable, (2) when conditions indicate extremely poor prognosis or future quality of life, and (3) when survival is accompanied by ongoing pain and suffering, repeated hospitalization, and invasive treatment, and early death in childhood [Allen, 1999; Boyle, 2004]. In each case, the reason why the patient might be consider to be undergoing futile treatment is different, and the parents must assimilate those medical concept before they can make an informed choice. Short-term complications that often arise are listed in table 2-A indicates the complexity and progression of medical disease that ensues after birth around 25 weeks.

Table 2-1 Short-term complication with approximate timeline for detection and description

Timeline – survival to	Disease Monitoring	Description
1st day	Hypernatremia	Inchoate skin allows permit evaporative loses and poses additional stress on the immature lungs fluctuations in fluid and electrolyte equilibrium
3rd day	Patent ductus arteriosus	Substantial adaptation and the weaning of ventilator and blood pressure support reveals the evidence of PDA, affecting about 40% infants of less than 1000 g.

	Intraventricular hemorrhage (IVH)	Intraventricular and intraparenchymal hemorrhages caused by vulnerability of the cerebral germinal matrix. While incidences of IVH have fallen over the past decade, the cause remains uncertain. Possible explanations range from failure of cerebral arterial auto regulation to venous infarction, to more recent evidence suggesting remote damage from circulating cytokines.
2nd week	Bronchopulmonary dysplasia (BPD)	Cause by the cumulative pulmonary barotraumas and oxygen toxicity, early chronic lung disease is defined as a persistent oxygen requirement by 36 postmenstrual (i.e. corrected gestational) age.
3rd week	Necrotizing enterocolitis (NEC)	Life-threatening gut injury of unknown cause that affects 6% to 10 % of extremely premature infants. About half of NEC cases progress to perforation or gangrenous bowel and require surgical intervention.
4th week	Periventricular Leukomalacia (PVL)	Cranial ultrasound routinely scans for this disease, which is diagnosed in 3% to 4% of extremely low gestational age newborns. PVL is the strongest single predictor of later cerebral palsy. Its causes stem possibly from pypoxic-ischemic events and overlaps of early appearance of IVH, but it may be undetectable until several weeks have elapsed.
31 to 32 postmenstrual age	Retinopathy of Prematurity (ROP)	ROP is a fibroproliferative disease of the retina that can lead to scarring, retinal traction and detachment, and in some cases, blindness. While the cause is uncertain, its incidence and severity are closely linked to gestational age.

Survival increases with each passing week, rising from 0% at 22 weeks to 25% at 23 weeks, and reaching 95% by 25 weeks [Wood *et al.*, 2000]. Even after the most dangerous part of the infant's course has passed, the full outcome, such as motor disability and learning disabilities will not be known for years. Even more subtle effects on behavior and personality may take much more time to recognize. Unfortunately, long-term outcome of the high-risk graduates are not adequately known due to the difficulty in tracking longitudinal studies of patient and taking account the new development in treatment and individualized care. Wood has comprehensively studied extremely premature cohorts in U.K and found about half of survivors born at 24 to 25 weeks have some major disability, including cerebral palsy, cognitive impairment, or severe neurosensory impairment [Wood *et al*, 2001].

In summary, the decision-making in NICU is a complex process, drawing on a myriad of medical information, personal value systems, and dynamic parent-professional interaction. When a consensus has been reached by the NICU staff that selective non-treatment is an appropriate option to present to the parents, one or more family meetings would be required to discuss and reach a consensus on the matter. These meetings usually involve parents, the attending neonatologist, a nurse specialist, and a social worker. The medical teams actively elicit the parent's perspective, communicate the neonatologist's empathy and commitment, and help the parents reach an appropriate decision.

Chapter 3 State of the Art Review

3.1 Decision Support Systems

Decision Support Systems (DSSs) are a set of interrelated components, infrastructure, and process that facilitates information and knowledge aggregation, management, and dissemination for decision-makers to better perform their tasks and reach their objective. Commercially available DSSs have applications in mostly banking, finance, investment, manufacturing and other business-driven models. In research, the appeal of DSS is not limited to cost analysis and optimization, but can be extended to any case analysis or scenario modeling. There has been an increasing interest in developing DSS target to other industries, especially healthcare fields. Recent examples are emergency call center's triage system that supports the operating nurse during phone interaction with a client [Latimer *et al.*, 1998]. In the following section, we'll describe briefly the various types of DSS framework in the business model, and the different clinical decision support.

3.1.1 Business Applications

Business and administration is one of the fields that initiated the science of decision support. It follows that the DSSs for business decisions have been in development for a much longer time than clinical DS, and are thus much more mature than clinical DSS. In the following section, we will describe some business decision support system (BDSS), focusing on the transferable architecture or aspects that could be applied in clinical usage. The potential transferability is corroborated by the research evidence that using CDSS manage healthcare can reduce costs. Indeed, many BDSS tools have main objectives of optimizing return and minimizing cost. However, we will also stress that BDSS and CDSS have fundamentally different goals, and care should be taken not to simply plug one system into the other

context. The BDSS we investigated considers non-conventional criteria into the decision modeling, such as cognitive processes and ethics.

3.1.1.1 Cognitive model

In business process, focus has been shifted from primary objectives of cost-effectives to include other "critical success factors" to cater to changing business needs [Chen & Lee, 2002]. Chen & Lee proposes a cognitive approach to decision support. They suggest this conceptual model has the benefits of reducing cognitive biases in decision making, since cognitive orientation or mental models plays critical role in decision-making under uncertainty and lack of structure, which is the case of many business problems that have largely gone unexamined. This model is suppose to remove factors that undermine the selection process, such as over-simplification, immediate recall, prior hypothesis bias, reasoning by analogy, and overconfidence. The proposed architecture is based on three modes of operation: retrospective, introspective, and prospective. The functions of each mode of operation are listed in Table 3-1, an abridged version adapted from [Chen & Lee, 2003, p. 5]. In essence, Chen & Lee are building the concept of internal and reflection rumination into the decision support framework, perhaps adopted from Clarence's technique as featured in movie classic "It's a wonderful life" [Capra, 1946] or the Ghosts of Past, Present, and Future as appeared in "A Christmas Carol" [Dickens, 1843].

Table 3-1: Summary of the three-mode conceptual model, adapted from [Chen & Lee, 2002]

Supporting mode	Description	DSS supporting functions	Possible cognitive aid
Retrospective	- Recall similar experiences and cases past - Analogical rationalization	Case Memory - aid storage, retrieval, and management of personal experiences and cases	- memory aid - reduce availability bias - analogical cases aid creative thinking
Introspective	- Reflect on and examine the assumptions and belief system	Cognitive Mapping - aid graphical representation of assumptions/belief systems (cognitive maps) - deduce the impact of specific construct through inferences - manage and manipulate belief system	- state and examine explicit and implicit assumptions - overcome blind spots - increase self-assurance
Prospective	- envision future state of business environment - understand possible consequences of decision	Scenario Building - aid multiple scenario construction process - assist multiple scenarios management and manipulation	- Reduce overconfidence - Reduce anchoring effect - Reduce availability bias - Change frame of reference

3.1.1.2 Ethical model

Robbins *et al.* investigated the potentials for ethical decision support with decision-aid technology [Robbins *et al.*, 2004]. In their work, they developed a web-based decision aid that was designed to help student work through and solve a case that presented ethical dilemmas. To achieve this, they first defined "solving a problem ethically" as the discernable use of well-defined ethical theories in decision-making. The underlying principle was to reduce ambiguity for people when using ethical theories, and thereby helping them during ethical problem solving and decision-making. The decision aid was based

on the principles of three theories: (1) the Theory of Reasoned Action [Ajzen & Fishbein, 1980], (2) a situational ethics model [Banerjee et al., 1998], and (3) a theory of marketing ethics [Hunt, 1986]. By implementing a small prototype and evaluating with a sample size of 87 students, the investigators obtained results, such as the inclusion of certain key words and the length of the answer that demonstrated a web-based decision aid was able to effectively influence the process of students trying to solve an ethical decision problem. The goal of the aid was not to minimize mental exertion, but to cause student to exert *more* mental effort, which would ideally lead to a more complete and effectively better solution. While the results obtained were inconclusive, this study presented an exploratory study of decision aid applied to ethical problem, with several exemplary aspects that can be applied to this work. For instance, the inclusion of several ethical theories, such as normative beliefs that may be new to the user, is a good example of supported learning. Another aspect that presents good experimental design is the focus on effectiveness, and not efficiency in decision making. Making an ethical choice should not involve how fast the choice can be made, but how consistent is the decision with the user's values and believes, the social norms, and the deontology.

3.1.2 Clinical Application

The application of DSS in the clinical environment can be categorized under the following categories: diagnostics, prognostics, value clarification, and treatment selection. Section 3.1.2.1 to 3.1.2.4 demonstrates conceptual frameworks or specific examples that apply to each type of medical decision.

3.1.2.1 Early Decision Support

Early computer scientists were captivated by the problems presented by clinical diagnostic decision. The diagnosis process is, in a sense, an ideal process to model using artificial intelligence. Early AIs were designed to emulate the brain of an expert when presented with an esoteric problem. Systems such as MYCIN [Buchanan & Shortliffe, 1984], CASNET [Kulikowski and Weiss, 1983], PIP [Szolovitis &

Pauker, 1975], and Internist-I [Miller, 1982] displayed deducing capabilities comparable to their human counterparts. Despite their in-vitro success, clinical users rejected them, finding them laborious and cumbersome to use. In addition, physicians reflected they do not need system to help with diagnosis [Altman, 1999]. The developers failed to recognize that the medical profession is one with a great deal of established traditions and as a group are suspicious to changes. This feature of the healthcare environment emerges again and again in future efforts to introduce technology to medicine.

3.1.2.2 Prognostic Decision Support

Since then, knowledge representation, automatic data acquisition, and distributed data analyses have advanced phenomenally. Researchers identified that more integrated applications are necessary in order to improve the delivery of medicine and healthcare, especially in areas such as following-up patient's cases and responding to their evolution intelligently. Systems that support the delivery of cost-effective, high quality care become the mandate. Five years ago, Sims has recommended maximizing the use of *evidence-adaptive* clinical decision support systems that can incorporate new evidence-based guideline knowledge as it becomes known [Sims, 2000]. More recent frameworks are focused on the "need to extend our previous guideline adherence scoring method to allow for *uncertainty in belief* or *ambiguity* about the quality of physician's behavior under these variances [Advani, 2002]." The concept of decision support is derived from information technology and knowledge management. Those two technologies, along with the maturing of Internet development, are playing an increasingly significant role for systems to manage medical records, knowledge sources, decision support and education [Kahn & De La Cruz 1998].

Szolovits suggests uncertainty in medicine should be dealt with systematically, by methods such as reducing uncertainty, or accept uncertainty into decision process [Szolovits, 1995]. Uncertainty in

prognostication has resulted in the development of prognostic decision models [Abu-Hanna & Lucas, 2001]. Various methods has been suggested, include statistical methods, machine learning methods, and AI methods. Statistical methods use a quantitative and probabilistic approach; examples are simple decision rules based on the categorization of scoring index, Baye's rule, and logistic linear regression. The medical statistic field has the most experience with developing these types of models. . Artificial intelligence methods, such as artificial neural networks (ANN), Case Based Reasoning (CBR), and Bayesian networks have captured a great deal of attention due to its advantages over conventional computation and manual analysis [Partidge *et al.*, 1996]. Machine learning algorithms, such as genetic algorithms, are emerging methods that also deserve some attention for solving prognosis problems [Abu-Hanna & Lucas, 2001]. Researchers acknowledge the possibility that these methods may be combined to create complementary effects at estimation.

3.1.2.3 Value Sensitive Decision Support

This type of CDSS is used to help patients decide on what is important to them. One of the leaders of this research field is O'Connor's Ottawa Decision Support Framework (ODSF). O'Connor's work is well recognized as the standard methodology for development of clinical decision aids [O'Connor *et al.*, 2002]. The ODSF promotes the sharing of deciding power between patient and physician. By utilizing the decision aid, patients can gain a better understanding of their own values and believes and use this knowledge to guide them in their treatment selection. This method has been evaluated and demonstrates consistent improvement in efficacy [O'Connor *et al.*, 2003].

Given the difficulty of making healthcare decision in today's world of options, the decision makers – the parents and neonatologist – face significant *decisional conflict.* Decisional conflict is the uncertainty about which course of action to take when choosing among mutually exclusive alternatives involving

risk, loss, regret or challenge to personal values [O'Connor, 2001]. O'Connor has investigated several clinical decisions (e.g. selection of hormone therapy for post-menopausal women) that are value-sensitive and ambivalent, such as choosing hormone therapies, and made recommendation that decision conflict must be recognized and attempts must be made to minimize this interference. O'Connor defines modifiable factors contributing to decisional conflict: a) knowledge deficits regarding the options, potential outcomes and complications; b) unrealistic expectations or perceived likelihood of outcomes; c) unclear values or personal importance of the consequences of each option; and d) inadequate support for decision making [O'Connor, 2002]. Fortunately, these factors can be 'modified' by providing appropriate counseling and coaching in deliberation and communication. O'Connor repeatedly demonstrated that decision conflict is a measurable attribute that should be reduced through the appropriate use of decision aids.

Another decision paradigm that has focused on the needs of patients is the shared decision framework. Ruland & Bakken's framework [Ruland & Bakken, 2003] is closely based on ODSF, but extends the development method to include standardized evaluation methods which are discussed in section 3.3.2. Shared decision model is a recommended practice model, especially under circumstances where outcomes are uncertain, clinical evidence is inconclusive, stakes are high, or the decision is associated with a range of personal values, which are characteristic of treatment withdraw decisions in NICU. Ruland's work highlights the importance of informatics tools to support difficult decisions that requires multi-participant collaboration [Ruland, 2003], in areas of risk communication and comprehension. Literature has repeatedly demonstrated the limitations of human cognitive abilities to assimilate numerical information and make decisions consistently based on numbers [Wologhin, 1999]. Ruland suggests using Informatics tools in the following ways to improve shared decision making:

- **Interactive tutorial to improve risk comprehension** for parents to avoid fallacies and obtain better understanding of data on risks and benefits as well as the potential harm of the alternatives.

- **Multiple, individualized format** to convey risk information according to individual needs as a measure against framing (a concept related to various reaction to simple changes in format of identical numbers) and sequencing biases. People's interpretation of numerical information is dependent on several factors, including mentality, characteristics such as age, education, and recent experience of illness or social context.

- **Individualized risk calculations** that includes estimations on outcomes. A common approach to decision aids is the use of group-based risk estimations; however, there are arguments that individualized risk profiles may be better performing that average-based data. Informatics tools can retrieve and meta-analyze this data from multiple disparate databases to discover new individual-based probabilities, rather than the traditional average group-based statistics.

- **Assistance in reaching the actual decision** such that the highest preferred expected outcome is achieved. Informatics tools can assist in this computation by including decision analysis techniques in shared decision making models.

- **Automatic updates of evidence** such that the clinical decision is always made with respect to adequate representation of the salient elements. Decision aid should be based on information from systematic reviews that include the latest validated evidence about available medical findings.

- **Different preference-elicitation techniques and formats** to augment communication between patient and physicians. Informatics tools allow electronic presentation in a variety of formats, tailored information about options and outcomes, and guided tools to elicit personal importance on various aspects of the decision to be made.

3.1.2.4 Collaborative Decision Support

In face of uncertainty and personal factors, shared-decision making is recommended as a good practice model. However shared-decisions and collaboration is associated with the challenges of group work. A huge body of literature exists on topic of group decision process. However, in the clinical domain, very few decision support tools addresses the need to distribute knowledge between patient and physician, as well as the necessity of collaboration between clinical staffs. Karacapilidis and Papadias [2001 and 1998] introduce HERMES as a Collaborative Decision Support System (CDSS) that supports argumentative discourse in multi-agent decision making. The work was motivated by the facilitation of solving ill-structured problems by a set of decision makers working together as a team through the use of an interactive computer-base system [Kreamer and King, 1988]. The main objective of this abstract tool is to augment the effectiveness of decision groups through the interactive sharing of information between group members and the computer. The tools was adapted to a medical domain in the work of [Karacapilidis & Papadias, 2001], where physicians simulate discussion on a cancer patient's treatment. As explained by Karacapilidis and Papadias, their approach focused on supporting decision-making not only through efficiently structuring the discussion, but also by providing reasoning mechanisms for it. In the words of the authors, HERMES was developed to be a "generic active system that efficiently captures users' rational, stimulates knowledge elicitation and argumentation on the issues under consideration, while it constantly (and automatically) checks for inconsistencies among users' preferences and considers the whole set of the argumentation items asserted to update the discourse

status". Consensus-building activities include collaboratively considering alternative understandings of the problem, competing interests, priorities and constraints. Additional features that the authors considered necessary for real CDM applications include remote and distributed information retrieval to help users justify their arguments in order to reach consensus. Other ongoing research is the Argument Builder Tool (ABT) that, using suggestions and automatic querying of Case-Based Reasoning tools, to help users construct robust arguments. The authors note that such techniques have been particularly useful in the CDM domain, due to their similarity to the human cognitive process in evaluating future results based on past experiences.

3.2 User Interfaces of Clinical Decision Support

Since the most important operation of CDS tools is interacting with human users, the user interface (UI) design becomes a key feature of the system that could significantly impact the ability for the system to perform according to expectations. In this section, we examine the various user-interfaces to gain ideas for our own design.

3.2.1 Web-based CDSS

These days, majority of software is built on web-based platforms [Kinney, 2003; Catley *et al.*, 2004]. A large number of CDSS are also designed to be browser based. There are several potential advantages, but the most immediate benefit is improved accessibility, interoperability, and easy integration with remote and wireless devices. [Kinney, 2003], [Warren *et al.*, 2002], and [Gray *et al.*, 1998] are all examples of clinical decision support software with browser based UI. In [Kinney, 2003], a CDSS to save costs and to improve scheduling of vestibular patients was implemented using HTML and ASP (via MS Frontpage ®). Patients were essentially provided login and password that allowed them to access a simple static webpage that displayed a graphical decision tree, as depicted in Figure 3-A.

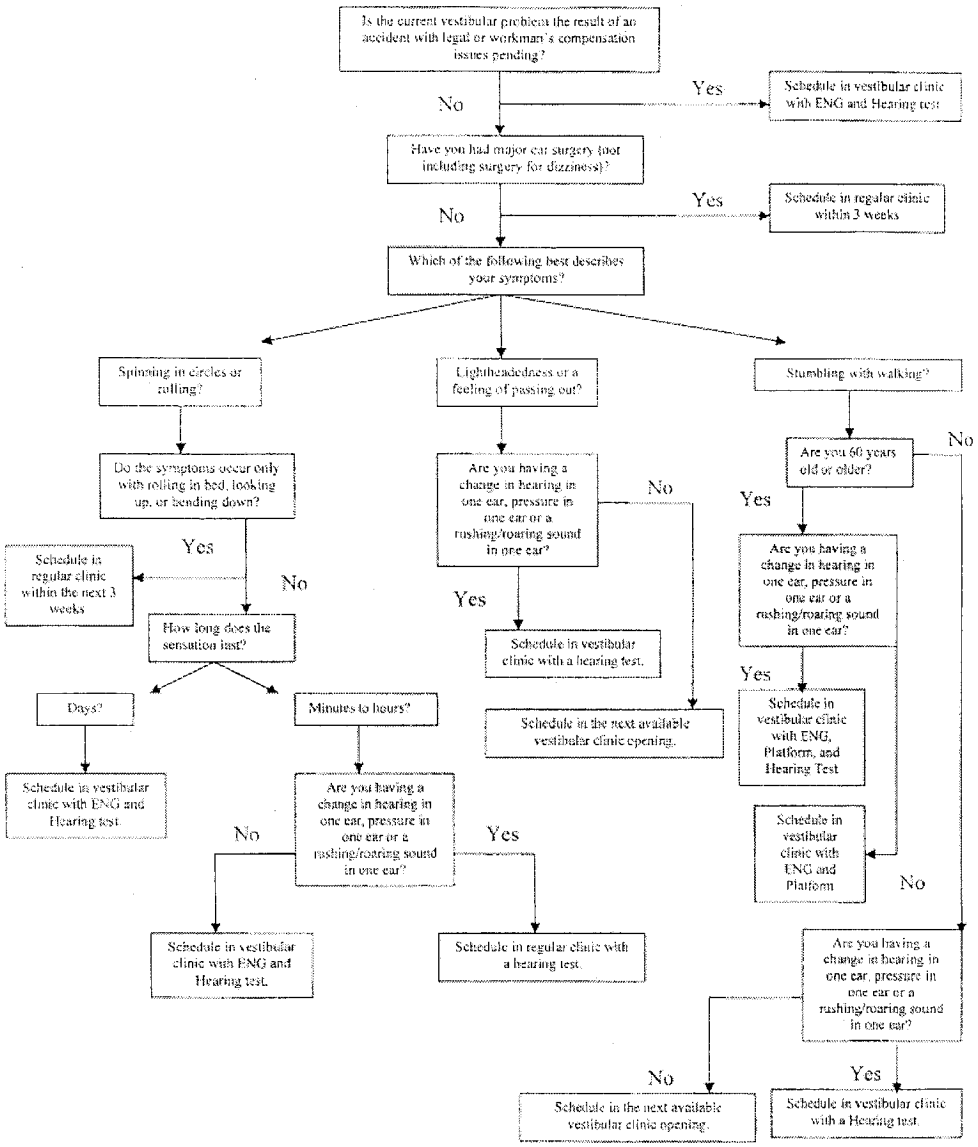

Fig 1. Decision tree for vestibular assessment.

Figure 3-A: Decision Tree for Vestibular patients [Kinney, 2003]

A more complex example of UI for clinical decision support software is found in [Warren, 2002]. Warren *et al.* presented the Care Plan On-Line (CPOL) system, which is a model for chronic disease management. The interface rationale for CPOL was based on constrained adaptation of user interface while passively aiding user actions. The model incorporates concepts of efficiency, managed care, and common health record architectures. The CPOL system is designed to support GPs in chronic

management of patients with 12 month treatment plans. The UI design concentrated on user control, flexibility, user task, integration of workflow and decision support. The designers were very aware of the needs and attitudes of the user cohort and designed the interface to match their users' requirements. The interface is organized around a central patient object (Figure 3-B). Using familiar metaphors such as tabs, the interface seeks to be intuitive and easy to use by physicians.

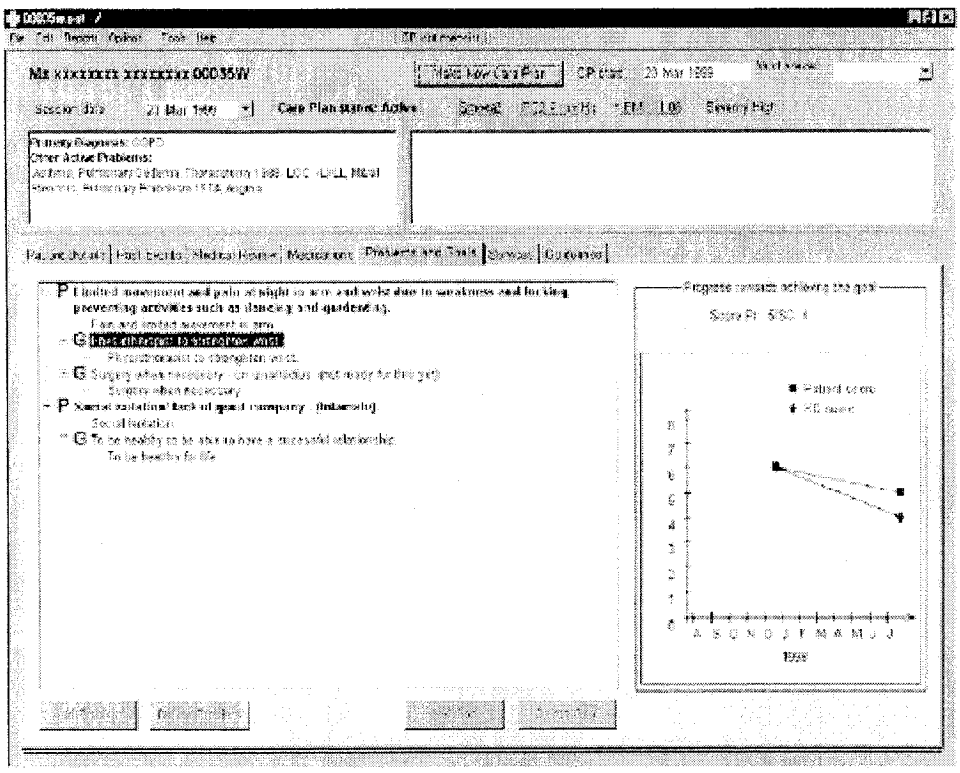

Figure 3-B CPOL main screen, showing Problem and Goal tab [Warren *et al.*, 2002]

The only web-based tool that we found had UI designed for parent user is the BabyCareLink ® tool we have briefly mentioned in section 2.1.4.1. Please refer to Figure 2-B. In addition, this tool had a flash demo existing at www.cstlink.com.

3.2.2 Collaboration-based CDSS

As mentioned in section 3.1.2.4, [Karacapilidis & Papadias, 2001] is a DSS that can be used in any environment where argumentative discourse precedes consensus. A web-based prototype was constructed and exemplified using a case from the medical decision domain – selecting amongst intervention options for patients with various tumor-related symptoms, as illustrated in figure 3-E.

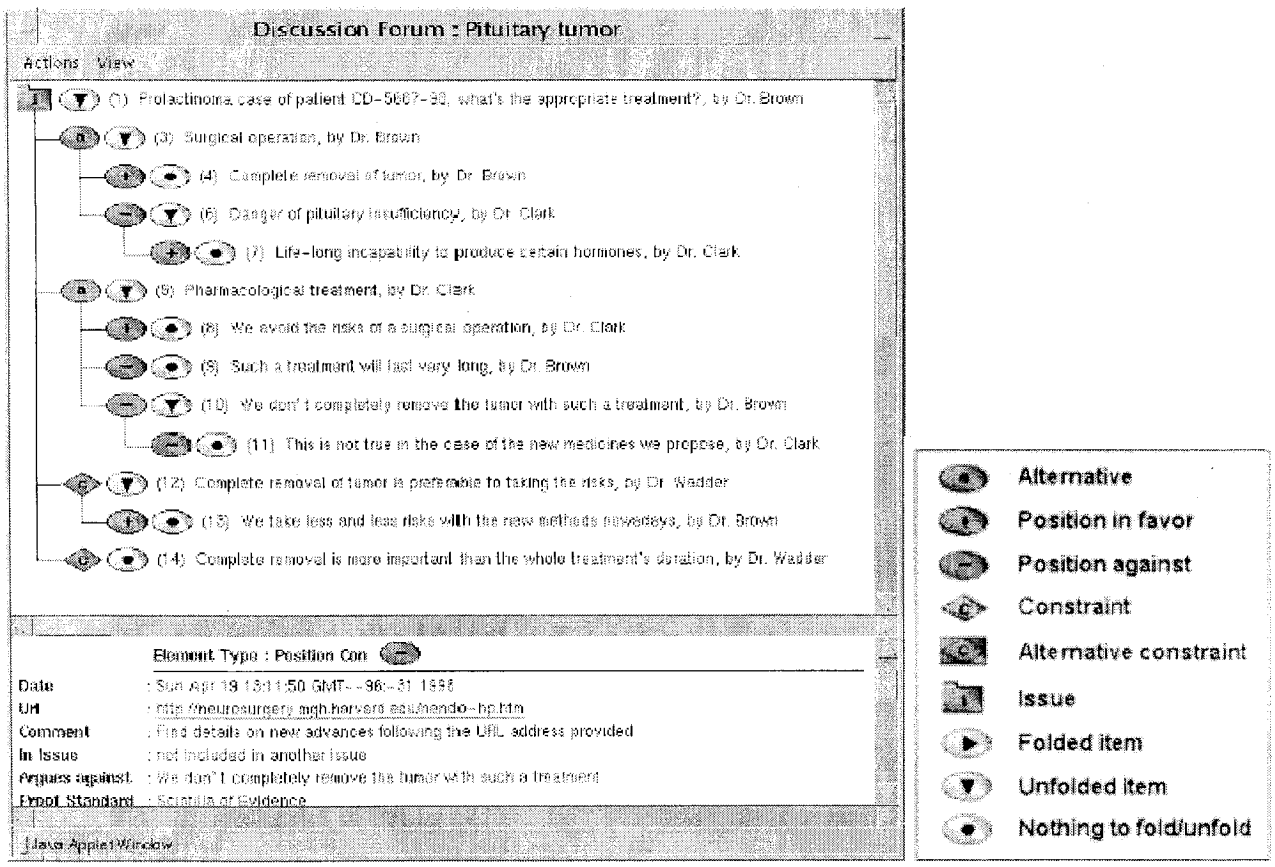

Figure 3-C HERMES Argumentative Discourse Screenshot Example

This interface is also web-based to facilitate communication between users at different computers. The evaluation for HERMES was conducted amongst different types of users, including high school and university students, experienced computer science researchers, medical doctors, and engineers. The feedback was positive regarding usability of the system, and very positive regarding the proposed CDM

environment. The majority of the users were convinced that the appropriate integration of web-based tools in a collaborative decision-making environment has a high capacity to enhance its effectiveness.

3.2.3 Patient Centered CDSS

The Ottawa Personal Decision Guide [O'Connor, 2004] is an exemplary model of decision aid for patients. The tool can be found at https://decisionaid.ohri.ca/. A screenshot of the first step of nine step process is displayed in Figure 3-D. The application leads the user through a serious of screens that indicates the user's progress at all times. The Ottawa Personal Decision Guide is based on the Ottawa Decision Support Framework [O'Connor *et al.*, 2002].

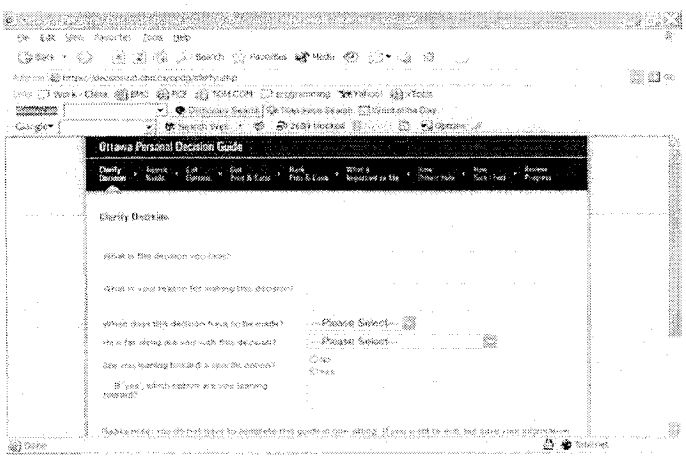

Figure 3-D: Screenshot of Ottawa Personal Decision Guide - Online version

3.2.4 AI-based CDSS

Ohlsson presents a sophisticated UI for the CDSS WeAidU, which performs automated interpretation of diagnostic heart images. This UI is, again, available over the Internet. The system is based on image processing techniques, ANN, and large high-quality medical databases. The UI (see Figure 3-E) presents results from ANN processing compared with two other classification methods on retrospective dataset containing a large number of images.

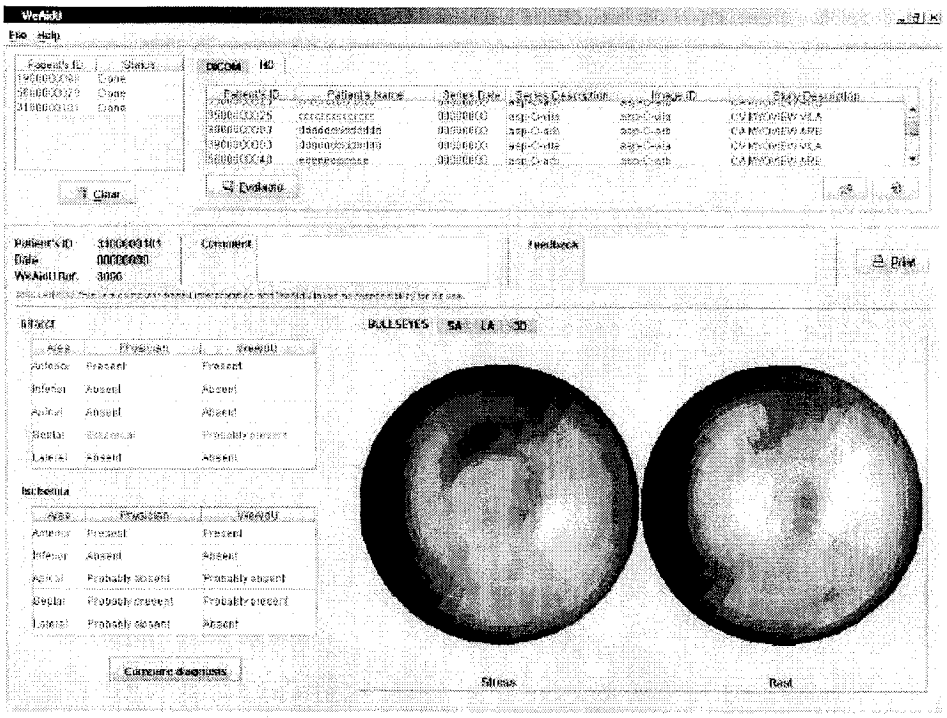

Figure 3-E: WeAidU Screenshot adapted from [Ohlsson, 2002]

The WeAidU interface is organized around patients and associated data, and client-server architecture from ANN services is evoked by the user at the client side. An important interfacing detail is that the system requires the physician interpretation to precede the ANN suggestion. The author's reason that since the system supports the physician, the physician is still the responsible person for the final diagnosis. This is an interested cognitive detail that constraints the UI design in CDSS. We note that this UI does not include any mechanism for identifying the user or protecting patient confidentiality.

3.3 Usability Evaluation of CDSS

While CDSS have consistently performed well in research studies, with effects such as improved patient safety, improved quality of care, and improved delivery of healthcare services [Coiera, 2003], CDSS remains absent from standard clinical practice. Thus, we wish to examine the methods used to evaluate CDSS, so that we may run a more useful evaluation.

3.3.1 Evaluation of CDSS

The evaluation of CDSS is not a straightforward task. While it is simple enough to demonstrate the prototype to clinical users, there is very little standard overseeing the evaluation of decision support frameworks. In similar works ([Warren, 2002], [Ohlsson, 2002]), the evaluation procedure consisted of pilot studies with potential users and qualitative observations. Ruland proposes a framework that contains eight components that are important to consider in the development, implementation, and evaluation of DSS in patient care [Ruland & Bakken, 2003]. These components are depicted in Figure 3-F.

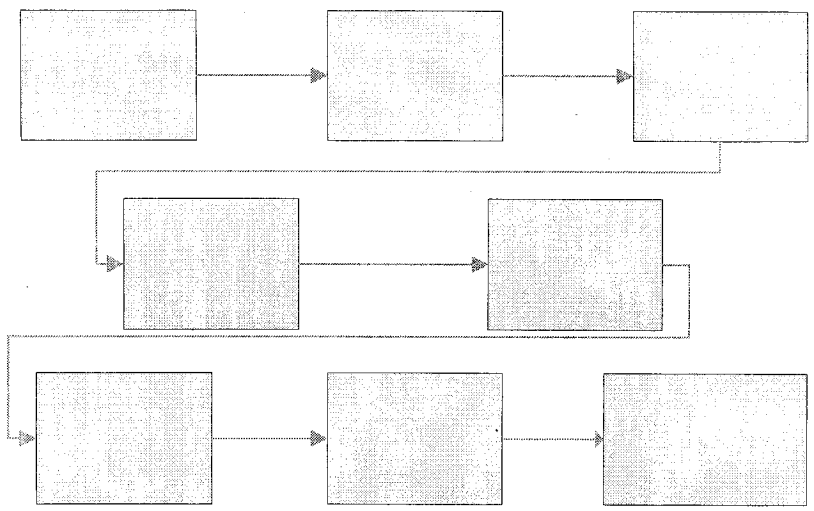

Figure 3-F: Key components for creating support systems for shared decision making and preference-based patient care – adapted from [Ruland & Bakken, 2003]

3.3.3 Motivation for Usability Evaluation

As an evaluation method, usability testing can provide certain benefits. First, it can built bridges with intended users by familiarizing the user with the tool even during the development process. Two, it allows users to have an input into the development by giving them a chance to examine a close-to-

finished model. Three, it forces the researcher to implement partial functionalities which reduces the time required for later development.

3.3.4 Usability Evaluation Methods

In most cases, usability evaluation involves presenting to the users prototypes that simulate some aspect of system functionality. Through visual inspection of the interface, most users gain an immediate impression of how they will react to the actual system in the future. Some of the formal usability study methods are heuristic evaluation, cognitive walkthrough, and videotaped evaluation. Many aspects of usability can be best studies by simply allowing the user to try it out and eliciting feedback. This is especially useful in cases where users are likely to not welcome new technology or regard it with possible anxieties. Since CDSS is highly dependent on user participation, the research team must exercise diligence in collecting and analyzing user feedback. For example, needs assessments should be first conducted to find out what is actually needed. Then, as the prototype evolves, users should be able the review the prototypes periodically to ensure the design is acceptable.

3.4 Summary

In this chapter we explored several decision support concepts, both in business application and clinical application. We examined the user interface for these tools and examined the various methods to perform usability evaluation. Through this review, we are now ready to merge the various concepts to our research study.

Chapter 4 PROBLEM STATEMENT

4.1 Problem Statement

Given the complexity of developing a CDSS, our problem at this point is how to demonstrate that our prototype of collaborative intelligence-based decision support system meets basic usability objectives and therefore has the potential to be accepted for use in a Neonatal Intensive Care Environment. We believe the decision problem that we are interested in requires the use of collaborative and shared decision-making, as well as the use of predictive tools to deal with uncertainty. We want to know whether a conceptual framework that integrates so many complementary components could actually be accepted in the clinical environment. We are also interested in whether the conceptual framework can provide a subset of functionality that will prove to be useful for parents. The engineering objective is to improve the quality of decision-making process, in cases where collaboration between parents and professionals is desirable to determine whether to continue with aggressive care or to switch to palliative care. However, if our conceptual framework cannot even be accepted into the clinical environment, then it will inevitably fail to make a positive impact in healthcare delivery.

4.2 Critical Analysis of Existing Initiatives

Our conceptual framework is unique in that no CDSS attempts to integrate four different aspects of decision support – reduce uncertainty, shared decision, improved collaboration, and adaptive interfacing – into one system. Therefore, we have yet to see a closely matching initiative to what we are attempting. Literatures on the evaluation of CDSS suggest that pilot testing is an adequate and accepted methodology for demonstrating the potential usability and acceptability of the system. User-centered testing also has the advantage of incorporating the user's cognitive process and underlying assumptions

into consideration. Therefore, the existing initiative is a good basis and worthy for us to repeat for our purpose. However, we wish to build more scientific rigor into our evaluation by defining measurable usability requirements that the prototype must meet in order for us to consider the prototype to have meet the basic usability objectives.

4.3 Problem Justification

By demonstrating our prototype meets basic usability requirements, we also attempt to show that a computer-based solution could potentially be accepted in NICU and that the functionalities we envision could be used to contribute to a better decision-making experience. Our goal is a proof of concept – that a collaborative intelligence-based system could be used in NICU to assist in difficult decision making. By demonstrating an initial reaction of acceptance and usability, our PADS has a better chance of reaching later stages of development.

In addition, we noticed that despite the strong evidence of CDSS's efficacy, their presence in clinical practice is practically non-existent. We believe that while research evaluation repeatedly reports positive results, the CDSSs system were not developed with integration in planning. That is to say, while the CDSSs work well in principle, without the necessary integration framework, the CDSSs has very little chance of surviving in the clinical environment. Therefore, we suggest some ways for the PADS to be merged into existing process. By developing methods of implementation along with the prototype, we hope PADS can avoid most of the common resistance and barriers as listed in Table 4-1.

Table 4-1 Potential obstacles to computerization of clinical information

1 Clinical professional sometimes feels threatened by invasion of technology [Smith, 2004]. To them, technology is not filling a missing gap, but taking away human interaction.
2 Technology is not welcomed because clinical users feel they will interfere with existing practice, adding more work, or exacerbate certain problems.
3 There is often a lacking of necessary infrastructure, in both hardware and human resources, to support these tools. Cost will be incurred and people needs to be retrained.
4 Traditions of practice, established over more than a century, may have to change. Such changes may require considerable compromise and possibly the sacrifice of elements of the "art" of medicine.
5 The constituency (doctors, nurses, other healthcare providers) do not sit behind desks but are mobile and provide a service at bedside or in a clinic environment

Medical decisions with ethical implications are difficult problems to try to solve. We believe a usability study will be a small step towards using personalized information, structure and guideline, consistent documentation, communication, and machine intelligence to improve the decision process. Some medical researchers have challenged the premises of this problem, questioning whether we should be attempting to solve such an emotive and humane decision with cold hard computing prowess. According to shared decision experts [Ruland, 2002], decision aids are appropriate when decisions are difficult, e.g., under conditions where more than one treatment alternative is available, when outcomes are uncertain, or there are major differences in outcomes or complications, when decisions require

making trade-offs between near and long-term outcomes, when a choice can result in a small chance of a grave outcome [Kassier, 1994] or the values for the benefits relative to the risks are more variable or unknown [Eddy, 1992]. Also, DAs are useful in situations where patients may be very risk averse or attach unusual importance to certain possible outcomes. Decisions that require time to ruminate and re-deliberate are good candidates for decision support tools [Panniers, 2002]. Epsteyn offers computers as a good assistant for tasks that rely on manipulation of data and knowledge.

Another justification for this work is the need to broaden the usage and increase the validation of existing software tools developed by MIRG. MIRG has been developing evidence-based intelligence tools in estimating patient outcomes such as mortality, length of stay (LOS), duration of ventilation (DOV), as well as predicating complications that are common to extremely premature infants such as Intraventricular hemorrhage (IVH), Periventricular Leukomalacia (PVL), Bronchopulmonary Disease, (BPD), necrotizing enterocolitis (NEC), and retinopathy of prematurity (ROP). The tools have been demonstrated to perform with acceptable sensitivity and specificity [Frize, 2001]. If our conceptual framework can be initially accepted, then there is reinforced motivation for us to continue with our research in prediction technologies.

Finally, we can justify our efforts as a contribution to engineering research, as we are addressing the emerging need to incorporate multi-disciplinary studies and art to the engineering approach in order to solve a mismatch of technology and clinical problems. Our challenge not only encompasses engineering, computer science, and medicine, but social and behavioral aspects as well. Through this work, we can gain insight on how to successfully apply available technology to complex social environment.

Chapter 5 Software Requirements

The primary objective of this chapter is to develop the functional and non-functional requirements, with a focus on usability constraints. These requirements are derived from two sources: past literature and local specification gathered from the NICU at the CHEO. Literature on the collaborative decision-making in NICU is used to extract use cases and constraints. Needs analysis conducted in summer of 2003 is another source for our requirements [Yang, 2003]. Requirements are rules that are set up so that we can assess whether our work is at least partially meeting the users expectations. It is important to consider that as the research progress, requirements will change, reflecting evolvement in both the prototype and the user. The section answers the following questions:

- Who will use the system? Will we support parallel access? Can parents access the system on their own with time and spatial separation from the medical team?
- In face of conflicting or uncertain information, how does the decision proceed? Can physicians override machine-intelligence? Outcomes can be ambivalent and riddled with uncertainty; clinical staff needs to access evidence-based patient-specific outcome and risk information, but outcomes based on factual data may contradict clinical judgment. In those cases, who is in error and who is right? Will presenting those data support consensus building or perpetuate an existing problem? Before using a prognostic decision aid, the user must be able to recognize when an error has occurred.
- Do parents need to see conflicting information and rely on their own judgment? In many cases, parents are in post-natal trauma and inflicted with considerable self-doubt, despair, and guilt. Some may appreciate an alternative opinion, while others may find it stressful. While we want

to share as much information as possible with the parents, it is crucial that only accurate information be provided.

- How do we incorporate values, preference, and belief into the decision? The decision is highly dependent on the parents' own religious values and belief. We must extract those factors and incorporate them in the early stages of the design.
- How do we present the information to the different user-groups? With varying educational background and task objectives, the adaptive user-interface must adjust to individualized usability needs so that physicians and healthcare givers can get more detailed information while parents can view selected information with plain language and parent design guidelines.
- How can we provide interactivity? The tool should allow physicians to view, for specific complex cases, current status and clinical history, outcome estimates (machine-based and specialist-based), and electronic discussion. Physicians should also be able to update estimates for certain time-variant outcomes such as mortality. The tool should allow parents to review meeting notes, progress notes, validated prognostication, parent decision guidelines, and past treatment orders.. Finally, parent to clinical dynamic should be supported through several communication mechanisms.

The following provide a comprehensive look at the software requirements for PADS. The first section will focus on the system environment and users. Next, we specify the non-functional usability requirements, since UI design is the core of this research work. Following, we gather all functional requirements through use-case definition. We specify additional non-functional requirements that are specific to the clinical environment. The section finishes by separating the requirements into three categories:

1. requirements that must be met
2. requirements that are highly desirable

3. requirements that are possible but not necessary

Functional requirements in category 1 will be used to guide the prototyping described in section 8.1.2.

5.1 System Environment

The NICU is an intensive, hospital environment. It does not exist in isolation. Patients are frequently transferred from other departments such as obstetric department or Perinatal department. Sometimes, patients are transferred from remote locations. Within NICU facilities, the number of beds ranges from 20 – 50. NICU are also equipped with many pieces of sophisticated equipment ranging from monitoring to life sustaining devices. The occupancy rate of NICU varies, but due to the limitation on current healthcare budget, there are occasions when the NICU must operate despite being under equipped and under staffed.

In the NICU environment, a family is considered as a patient unit, which includes the infant, as well as the parents. This is because since the parents are requiring NICU services as well, they are considered to be patients as well. The length of stay for patients can vary depending on their condition and recovery; in some cases, patients stay up to 7-8 weeks. Because graduates from NICU often suffer long-term illness or are at higher risk for developing certain diseases, NICU will maintain long-term relationships with its patients.

The software will be implemented in an environment where it must interact with other devices on a local and distributed level (since it may need to access data from external departments). It must be scaleable and can handle longitudinal patient management. In addition, it must provide security features such as authentication and authorization. Access control is paramount in protecting patient confidentiality as according to the Health Information Act [Canadian Medical Association, 1998].

5.2 Users and actors

In our problem domain, we are concerned with shared decision-making between parents and physicians, and collaboration amongst clinical staff. While working as a team, the individual users have disparate roles and require different services. For instance, Neonatologists and nurses might need to assimilate parents' thoughts and wishes and translate them into a plan or a course of action. The clinical roles are follows:

Neonatologists - pediatricians with special training in newborn intensive care. They are responsible for the overall plan or care, diagnosis, prognosis, and significant decisions.

Resident Physicians - junior physicians, practicing towards a specialization (neonatal fellows are those practicing towards a specialization in neonatology). They are in training and are less experienced with decision-making, but are granted partial deciding powers in emergency situations.

Clinical Nurse Specialists - senior nursing staff with strong experience in patient care and are additionally trained in neonatology care.

Bedside Nurses - nurses in charge of shifts and in direct day-to-day contact with the patient.

Social workers – practitioners providing the parents with emotional guidance and counseling

Additional support staff includes: ethicists, pharmacists, occupational therapists, and others. These practitioners also act as informants during decision making. While they may have varying degrees in training and medical background, each member of the clinical team contributes knowledge to the decision-making [Walker, 2004].

As users of PADS, the team members are categorized into clinical role and non-clinical role. Clinical users are further subcategorized into two groups: physicians, and healthcare support staff. In addition,

physicians and patient-parents are considered to be decision-makers, while the others are considered informants. Table 5-1 summarizes the user profiles.

Table 5-1 Users analysis – roles, education, social interactive norm, and computer literacy

	Role	Education	Social Interaction	Computer Literacy
Clinical (Care – Provider)	Physicians			
	Neonatologist	High	Well-established, inert	Medium – High
	Resident	High	Less rigid	High
	Specialists	High	Well-established	High
	Nurses			
	Clinical Nurse Specialist	High to medium high	Values face to face interactions, rigid	Medium
	Bedside Nurse	Medium	Values face to face interaction, rigid	Medium
	Social Workers	Medium	Flexible	Varies
Non-Clinical (Care Receiver)	Parents	Varies	Flexible	Varies

5.3 Usability Requirements

Usability is defined as the extent to which a computer system enables users to achieve specified goals effectively and efficiently while promoting user-satisfaction [Nielsen, 1993]. Nielsen and other proponents in the field of usability and human factoring have repeatedly demonstrated the cost-effectiveness and other beneficial effects of applying usability metrics to a variety of software systems [Nielsen, 1993]. While usability is important to any system or tools, computer or otherwise, some distinctive issues need to be addressed for medical applications. Usability can be measured in terms of learnability, effectiveness, error handling, and user satisfaction [Nielsen, 1993]. In our context, there is additional complexity factor that we define as user diversification; this means that the user demography can be subdivided into cohort bands with distinctive usability requirements. This section elaborates on

the usability dimensions, followed by the usability requirements that we need to meet in order to consider our prototype acceptable.

Learnability is the time taken and the ease with which to reach a skilled level of performance (Thomas, 1998). When a user first encounters a system, exploration is the main activity undertaken to gain proficiency. If exploration cannot lead to immediate satisfaction or demonstration of an increased productivity, the user will lose interest in further learning. Clearly, system acceptance is depended on the ease of learning.

Efficiency is the cost of achieving a goal with respect to time and space [Rosson & Carrol, 2002]. Typically we speak of efficiency in terms of task completion time. In the treatment-withdrawal decisions, we are concerned with efficiency in terms of specific task (i.e. tracking the shifts in opinion for a particular patient case) rather than the time for making a decision. As one can imagine, it would be unethical to impose time limits on parents.

Effectiveness is the degree to which a system satisfies the needs it was intended to meet [Rosson and Caroll, 2002]. It embodies the general ability of the system to allow users to achieve their goal. This concept is more consistent with the design of an ethical decision support system. Effectiveness is often mistaken for efficiency; however, shorter completion time does not necessarily mean higher effectiveness. For instance, if a clinical communication tool allows parents' instantaneous access to a physician's outcome estimations, but the inconsistencies between the estimation overwhelms and confuses the parents, then the system is ineffective in solving the problem.

Error handing is the action or series of actions the system takes to prevent users from committing a mistake or a slip, and allows users to recover from an erroneous path [Rossen and Carroll, 2002]. In the medical context, this concept is highly correlated with human factor engineering, which attempts to offset human errors with a robust design. In our situation, a significant error that could occur is the entering of inconsistent information that might inflict confusion or pain on the parents. The system must

be designed to ensure that all members of the clinical team confer on the information to be released to the parents before the parents actually are presented with the information.

User satisfaction is the aesthetic appeal that renders the human-CDSS interaction enjoyable and satisfying. When CDSS tools are attractively designed, users are more likely to enjoy interacting with tool, resulting in improvement to overall quality of care [Catley, 2003].

User diversity is a prevalent usability issue in our application. In contrast to other applications, an NICU decision support tool would require the consideration of several cohorts of users, namely physicians, parents, and other healthcare practitioners, with gaping different in characteristics and requirements. We must consider the variance in education background, medical expertise, and technical know-how, and experience with decision making. In addition, one role may place value on usability factor differently from anther role. For example, whereas patients may want to gain a better understanding of their illness, physicians may be concerned with maximizing patient throughput by minimizing consultation time [Carroll, 2002].

As we are conducting a usability study, some non-functional usability requirements are imposed on PADS-III. The following listing specifies the usability requirements that we will be evaluating:

1. Except in exceptional circumstances, all users should find the tool easy to learn. Since we are anticipating a great deal barrier to people using PADS (resistance from the staff, parents under distress), we want to make the user-interface blindingly obvious.
2. At least 70% of the users will find the system intuitive. Because the prototype will be implementing a subset of functionality, not every one of the clinical users will be able to immediately recognize the terminology and metaphors; we allow more leeway on this usability factor.

5.4 Functional Requirements

The functional requirements of PADS describe the features of the system and what the system can do in order to help the users reach their goals. We will use the use-case analysis method to specify our functional requirements.

5.4.1 List of Actors

From the system's perspective, users form an informal decision-task team (DTT) centered on a patient-child. In this team, different roles are played by different users. For our purpose, we only consider the roles that exist in this subset. That is to say, we ignore the administrators and the system coordinators; we concentrate on only the roles that actively participated in the decision task for a particular patient-child:

1. Patient Decision-Maker (PDM): patient-parent (or the person acting in the role of parent on behalf of the family) who will be working with the physician to make a shared decision. There is a maximum of two PDM per patient-child.
2. Clinical Decision-Maker (CDM): the neonatologist, attending physician, or any other doctor who has the authority to make a diagnosis, prognosis, or a doctor's order. There is no limit on the number of CDM per patient-child[1].
3. Informant (INFO): any user who, or device that, participates in the care of the patient-child, or participates in servicing the patient-parent, or family members who/that may contribute to the knowledge pool. Examples of INFO are nurses, social workers, pharmacist, specialists, perinatologists, ethicist, and spiritual guidance.
4. Inquirer (INQU): any user who, or device that, may need to access information on the patient, or other information that will aid in the care of patient.

[1] Although there probably should be one primary CDM, currently the responsibility is shared between all the physicians in NICU.

5.4.2 List of Use Cases

A. Patient Decision maker (PDM)

1. Access estimates on patient-child's outcomes
    a. Short-term prognosis (e.g. likelihood of survival)
    b. Medium-term prognosis (e.g. probability of complications, disease development, recovery period, duration of ventilation, length of hospitalization)
    c. Long-term prognosis (e.g. possibility of long-term disability, probability of permanent brain damage, quality of future life (family))
2. Assimilate information on patient-child
    a. Patient current condition
    b. Patient history (diagnosis)
    c. Recent changes or updates
    d. Treatment alternatives, benefits, harms, risks, chances
    e. Recommendations from INFO
3. Interact with decision support tool
    a. Instructions on how to proceed
    b. View decision progress
    c. Facilitate progress
    d. Disclose preference
4. Ask questions
    a. directed to CDM
    b. directed to INFO
5. Research in database and libraries (find additional resources)
    a. Find other case-based evidence

b. Find other possible alternative scenarios.

B. Clinical Decision Maker (CDM): in addition to all use cases as listed for PDM, CDM also has the following use cases.

1. Access estimates on patient-child outcomes
    a. Artificial Neural Network Estimate
    b. Case Based Reasoning results
    c. Other Classification and Prognostic Models
2. Enter Prognostications
    a. Short term + probability
    b. Medium term + probability
    c. Long term + probability
3. Enter update to patient-child's case files (e.g. diagnosis, progress notes, inference, alternatives, recommendations)
4. Enter communication to team members
5. Access Patient-Parent Information (e.g. religion, culture, information collected through interaction with DSS)
6. Control accessibility of communication between users (e.g. controls when a piece of information is released to non-clinical user) under guidance of HIA [Health Informatics Act, 2004]

C. Informants (INFO)

1. View questions on discussion board
2. Access questions directed to themselves
3. Enter answers and communications

D. Inquirer (INQU)

1. Post question on discussion board

2. Query database or users for patient information
3. Receive notification of response via alert

E. PADS System

1. Authenticate and authorize user
2. Document user activity (log)
3. Record user profile and preference
4. Automatically adapt user interface according to user-interface preference data

5.4.3 Use Case Analysis

Use cases analysis is a technique which informally describes the functionality that the system is supposed to perform or exhibit by modeling the dialog that a user, external system, or other entity will have with the system. Each use case describes a possible scenario of how the external entity interacts with the system. A review of UML use case syntax is provided in appendix I.

The following is a short description listing the steps the actor has to perform as well as the prerequisite.

5.4.3.1 Use cases: Patient Decision Maker (PDM)

A1: To access estimates on patient-child's outcome, the PDM must:

1. Log in into the system
2. Identify the Patient-Child
3. Select to view Patient Case Summary
4. Select to view Prognosis

Prerequisites: PDM has valid log in, has at least one patient child, and patient child is added into NICU database

A2: To access patient-child information, assuming the PDM is logged in, the PDM must:

1. Identify the patient-child

2. Select to view Patient Case Summary
3. Select to view desired information (diagnosis, history, vitals, etc)

Prerequisites: same as A1

A3: To interact with the Decision Support Tool, assuming the PDM is logged in, the PDM must:

1. Select the Patient-Child to work with
2. Start the decision support tool
3. Work through the step by step forms
4. May quite at anytime, because session will be recorded and session data will be stored

Prerequisite: same as A1

A4: To ask a question, the PDM:

1. Selections the discussion forum
2. Enter their question
3. System moderator directs the question to the appropriate INFO by alerting attending INFO [optional]

Prerequisite: PDM logs in successfully

A5: To search in libraries and external database, the PDM must:

1. click on the library tab
2. Enter query string
3. view results

Prerequisite: same as A4

5.4.3.2 Use case: Clinical Decision Maker (CDM)

B1: To use prognostics modelling on patient-child, CDM must

1. Log in

2. Select patient-child
3. Select the appropriate tool
4. Run the Update command

Prerequisite: the patient-child exists, the tool is available

B2: To enter prognostications, the CDM

1. select patient-child
2. select the communication tool
3. enters the prognosis, specifying the time frame

Prerequisite: CDM logged in properly, the Patient Child exists.

*Note: for use cases CDM is identical for PDM except the CDM must specify the patient. In addition, the CDM does not get access the Parent Decision Support guide.

5.4.3.3 Use cases: Informant (INFO)

C1: To view questions on discussion board, the INFO:

1. logs in
2. selects a patient-child
3. select the discussion board

Prerequisite: INFO logs in successfully, patient-child exist

C2: To access questions directed to oneself, INFO must:

1. log in
2. select the notification alerting the arrival of question
3. respond and sent

Prerequisite: INFO logs in successfully, a notification is received

C3: To enter answers and communication:

1. INFO logs in
2. Selects discussion board[2]
3. Use the answer command to answer inquiries

Prerequisite: Log in successful

5.3.3.4 Use cases: Inquirer (INQU)

D1: INQU post question on discussion board by:

1. Logging in
2. selecting a patient case
3. selecting discussion board
4. use the post command to post a new post

Prerequisite: Log in successful

D2: INQU query database for patient information by:

1. Logging in
2. Selecting search
3. entering query string
4. run search command

Prerequisite: Log in successful, INQU has appropriate authorization

D3: INQU receives a notification by

1. logging in

Prerequisite: log in successful, INQU's question has been answered.

5.5.4 Uses Case Diagram

The relationship among actors and use cases is shown in Figure 5-A.

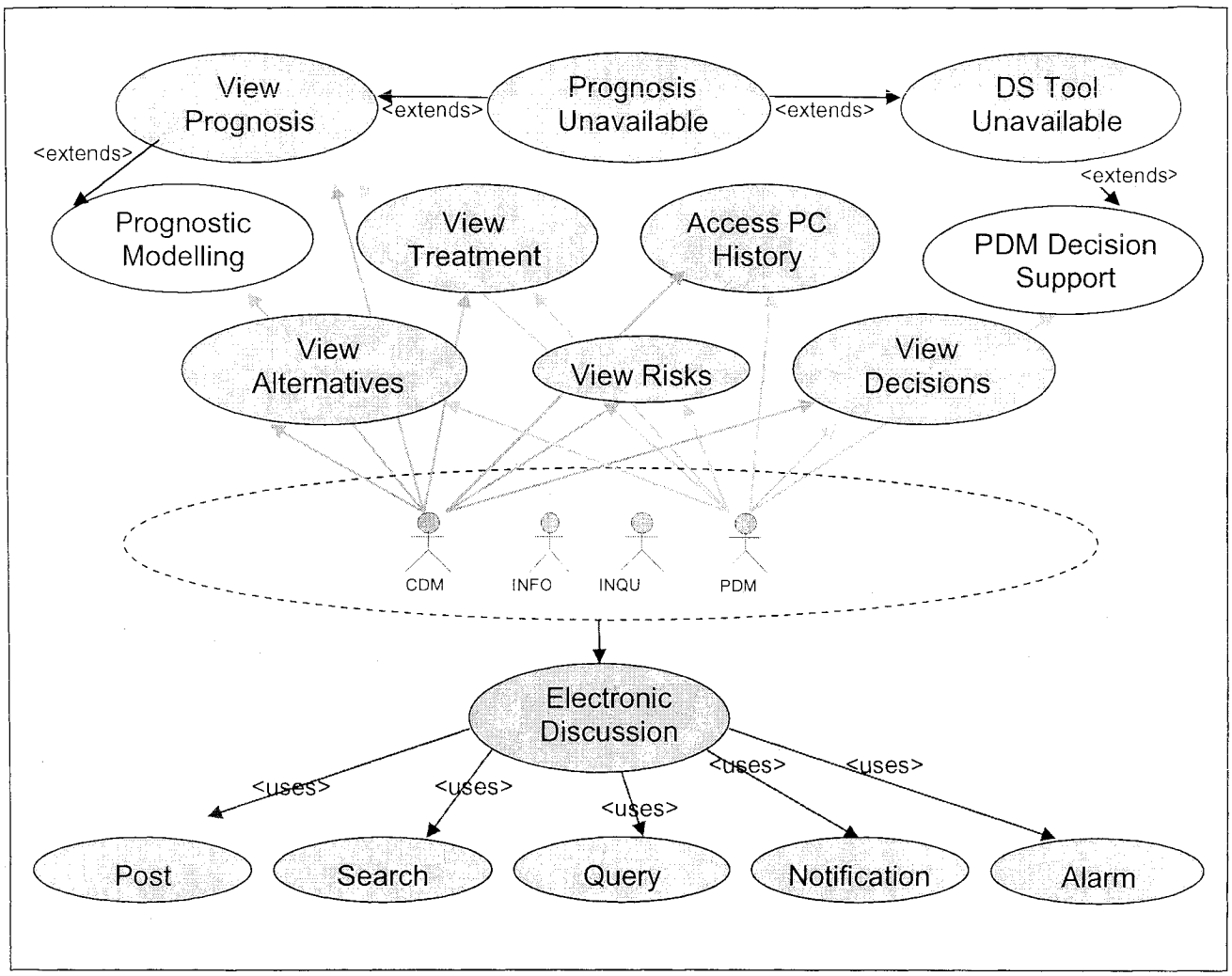

Figure 5-A: PADS Use Case Diagram

5.5 Clinical Constraints

Knowledge Management

1. Given the exponential expansion of medical knowledge, most clinicians cannot be expected to individually manage all relevant and current knowledge that bears on a clinical case. The system should minimize 'noise' information that interferes with decision making.

[2] Each patient is associated with a separate discussionboard. A CDM may possibly see a number of discussionboards at the same time.

2. Given the large number of available knowledge sources and disjointed nature of those sources, combined with the fact that most diseases come in complicated interrelated forms that manifest congruently, the task of knowledge integration and strategy selection becomes complex, weighed under constraints of uncertainty and conflicting goals. Therefore, scalability is a must.
3. Given need to chronically manage patients, the system should use a temporal model, providing real-time updates and error detection.
4. Tacit knowledge representation and presentation format dictates the ability of the user to use the tools. While automatically produced tables are popular due to their simplicity in implementation, they are less suited for certain untrained users such as the parents. Give the choice of different content and presentation according to individual user needs, thus achieving adaptive user interfacing.

Technophobia

5. Many healthcare professionals are suspicious of the accuracy, validity, and reliability of the data and the background processing that is being used to support the decision. The integrity of the data must be proven and made apparent for the clinical users.
6. Many clinical users erroneously assume that decision support systems will be replacing the 'human connection' that occurs between the practitioner and the patient. It is imperative that the users be made aware that this supportive system is just that - to supports human users. The tool leaves the final enforcement of decisions and action to the decision-makers involved. No users are ever coerced into participation.
7. There exist the potential for a communication system to provide inconsistent or excessive information to an uninformed decision-maker, such as the parent. In order to avoid causing unnecessary distress in parents due to conflicting evidence or advice, prognostics must be agreed

upon by the clinical team before verbal disclosure, and only after that disclosure has occurred would parents be able to view that information on that system[3].

Physician Pride

8. In situations where discrepancies between the neonatologist's estimation and the machine estimations occur, it will be the neonatologist's call on overriding the machine-based estimation. Although the machine estimation is based on solid facts, and should serves as a redundancy check for physicians, the neonatologist is the one legally responsible for the care of the infant. If parents need to review the machine estimates, including contradictory statements, then they should follow the hospital policy on patient information disclosure.

[3] In existing practice, a frequent occurrence during case analysis is that different specialists WILL have conflicting opinions, and rightly so, since so much uncertainty is involved. When this information is presented randomly, the parents may feel disoriented and distressed, adding stress onto an already disheartening state. Some clinical staffs fear that adding a tool will perpetuate or exacerbate the problem since communication is occurring faster. We feel that while there may be some potential negative side effects, with a well-defined work process, that pitfall can be avoided. For example, by allowing parents access to only information that has already been verbally disclosed, the system will only reinforce the trust between physician and parents.

Chapter 6 High level Architecture

The object of this chapter is to describe the high level architecture of how the system may be implemented in its context. We suggest a conceptual framework that integrates the functionalities described in chapter 5 and an implementation framework that suggest how the system may be deployed in the NICU environment.

6.1. Architectural Goals

Our architectural goals are defined and listed in Table 6-1.

Table 6-1 Architectural goals for PADS

Architectural Goals	
1.	To leverage the use of artificial intelligence and computational tools in selective non-treatment, including: (a) ANN (b) CBR (c) other classifier/computational methods
2.	To promote collaborative decision making between neonatologists/nurses/parents
3.	To encourage consistency and structure in decision making
4.	To facilitate open and constructive argumentative discourse
5.	To elicit parent preference and values and publish as medical data in web-enable repository structure that can be accessed by internal hospital staff
6.	To document the data and communication flow and store for ready retrieval by multiple users
7.	To adhere to an 'open' system solution
8	To accommodate real-time data transfer and processing of data received from the NICU's real-time data repository (and from other HIS data repositories as opportunities are presented).
9	To provide a high level of security to ensure medical data confidentiality and integrity, particularly for the above-described NICU processing. Security implications related to this medical information are referenced in this thesis
10	To clinically evaluate early prototypes to validate the approach and gain end-user feedback

Our collaborative systems approach may improve the overall ethical decision-making process by integrating the following advanced technologies: (1) artificial intelligence to facilitate outcome prediction (2) web-based informatics retrieval and communication; (3) user-friendly interfaces that adapts to multifarious needs of users; and (4) knowledge organization through systematic content management. On one hand, our objective is to help clinicians in their clinical decision support tasks; on the other hand, we wish to expand the role and involvement of parents.

6.2 System role in Clinical Practice

The decision process can be broken down into four major phases: acquisition, inference, discussion, and deliberation, as depicted in figure 5-B. The coaching and guidance process includes meetings (called "care conference") is illustrated in block (b) and block (c) in fig. 6. Using a central content management system allows timely clinical knowledge to be more equally distributed amongst the participants, resulting in an expansion in the role and involvement of the parents. The tool will help clinicians structure the process, regularly, objectively, and carefully documenting their concerns as prognoses and treatments changes. With this type of information readily and ubiquitously available, clinicians would be better equipped to act in the best interest of the family.

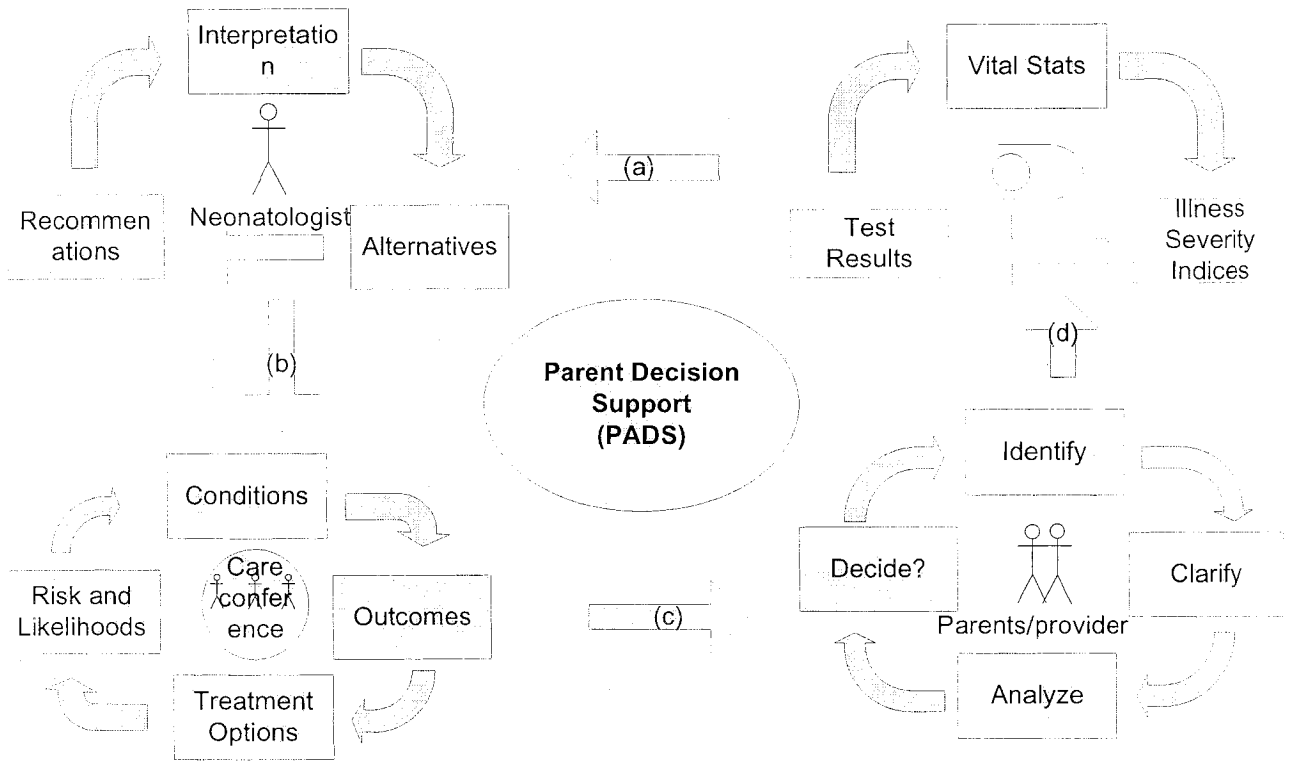

Table 6-2 PADS Functional Architecture

This clinical decision support model is unique because the clinical problem we are trying to solve has several distinctive characteristics. First, for the given patient cohort, the decision are complex involves a great deal of uncertain risks and outcomes with substantial impact. Secondly, the decision is subjected to ethical constraints, that is, the decision-maker (especially the neonatologist) has an obligation to discernibly use well-defined ethical theory in the decision. Third, the decision is also subjected to the needs and preference of the parents, which are defined according to culture, value, and religious beliefs. Fourth, the decision is convoluted by the medical complexities such as relationships between causes and effect of disease interventions. Fifth, rather than a discrete, single-occurrence event, the decision is a process that can change according to fluctuations in the patient's condition and vacillation in parents preference. Finally, the sharing of the decision leads to ramifications such as disparate perceptions and expectations leading to an argumentative discourse between the decision-participants.

6.3 System Process Integration

Based on preliminary research, we argue that the key to successful solution is smooth integration between system and environment; that is, the system must provide several functionalities to the needs of our users and the clinical practice and protocols. In particular, in the decision-making process, we want the consensus to be achieved through the process of collaboratively considering alternative understanding of the problem, conflicting interests, priorities, preferences, and constraints. We wish to expand the role and involvement of the parents, to educate them regarding the baby's conditions, and to objectively capture their concerns and translate that into choice that acts in the family's best interest. The key challenge is how to implement AI and DA technology in the clinical social context. How can we offer useful decision support? How do we codify the knowledge? How do we deliver customized user content? One of the cornerstones to the success of system design is the strategic management and delivery of knowledge. Highly granular diagnostic information from machine sources and rich descriptive medical data from human sources must be fused together into a flexible clinical process.

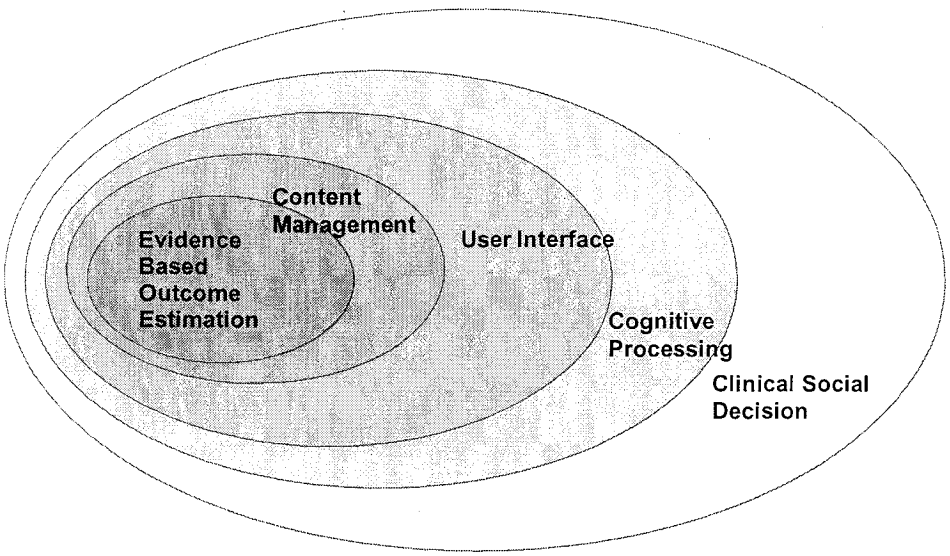

Figure 6-A: Logical Layering of Technological and Social-Behavioral Concepts

Our knowledge-transfer clinical decision support system is founded on the principle of integration of clinical data, artificial intelligence methods, knowledge management, and clinical social processes, conceptually depicted in figure 5-B. This diagram demonstrates how we conceptually organize the technology and social components of the proposed framework. The artificial intelligence is the core technology that provides the evidence-based estimations to the physician to support their prognostication. Content management encapsulates this function. It follows that the accuracy and validity of machine-based intelligence must be verified by professionals to identify errors or faults in machine prediction. Additionally, the data intelligence is fused with traditional clinical intelligence to provide multi-faceted evidence for forming a more complete notion regarding the patient's condition and outcome at any given time. Beyond this component, the information must be consumed by discerning users, including the decision makers for the value-laden decision. This requires an adaptive user interface that focuses on supporting the needs of the participants. Finally, any decision is made through

continuous interaction between the clinical team and the parents. As this is a continuous process rather than discrete events, the system must account for time variability in data and results.

6.4 PADS Architecture

IEEE defines architecture as the highest-level concept of a system in its environment [IEEE 1999]. Based on existing guidelines, we wish to define an architecture that supports the complex ethical decision-making process. An intelligent collaborative decision support system consists of four sub systems: (1) a communication component to handle private, protected, and public messages; (2) an artificial intelligence component capable of knowledge learning, processing, and derivation; (3) a knowledge repository that can aggregate information from multiple sources (professional opinion, ethical theory, parents religious values and culture, support argumentative discourse, and allow customized retrievals; (4) a multi-participant adaptive presentation component.

Building on existing work [Frize, 2001, 2004], and the cognitive decision support system design [Lee, 2000], we are not only incorporating advanced technologies for each sub-system mentioned above, but also *integrating* these sub-systems substantially to enhance collaborative interactions. Collectively, the framework is entitled **PArents Decision Support** (PADS) tool. Major components in this system, as depicted in Figure 6-B, are the following:

1) Evidence-based estimations block: provides intelligent outcome predictions based on an analysis of a set of diagnostic data inputs compared with past evidence of correlations between indicators and outcomes using an ANN and a K-Nearest Neighbour (KNN) algorithm;
2) Content management block: captures, manages, and retrieves all data objects for decision-making and data objects describing user context, including a local data repository for storing decision support data; retrieving information from external web content and syndication

3) Communication management: facilitating public, protected, and private message delivery via simple message protocols, controlled discussions facilitating argumentative discourse, and notifications

4) User-interface: includes content adaptation component, parent-oriented decision support tool, and context sensitive help

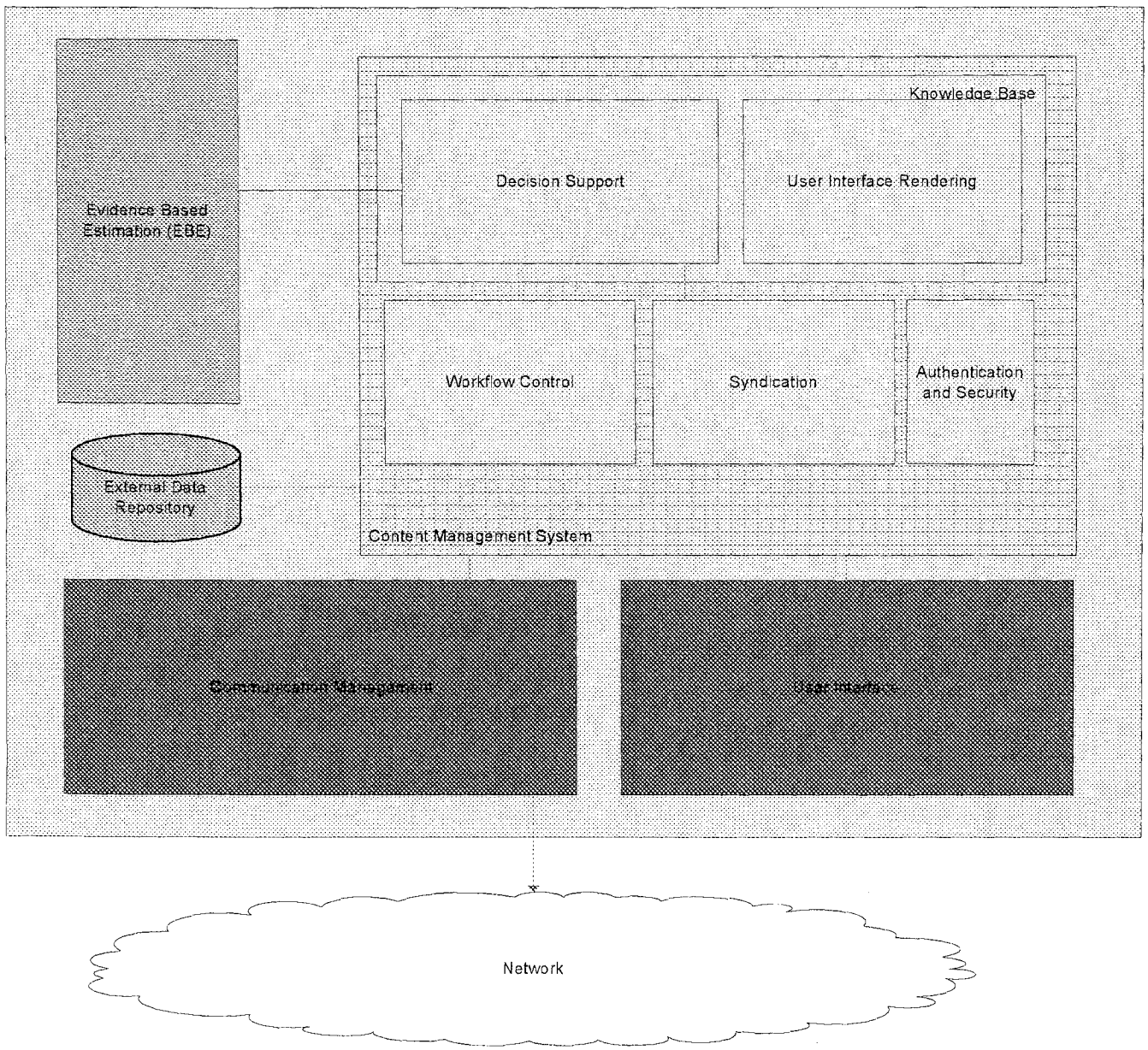

Figure 6-B PADS architectural components

These sub-systems will interact to provide services such as predictive analysis, information retrieval, and document repository, visualization of argumentative discourse, customized delivery, and adaptive interfaces. Each of the components will be described in sections 6.2 to 6.4.

6.5 Integrated Knowledge base repository

With the quantity, variety, and multiplicity of information comes the necessity to organize the knowledge in collections of objects entities. The fundamental component of any knowledge-based system is the underlying information data structures. Figure 6-C provides a logical view of the data construct that will be built into the system.

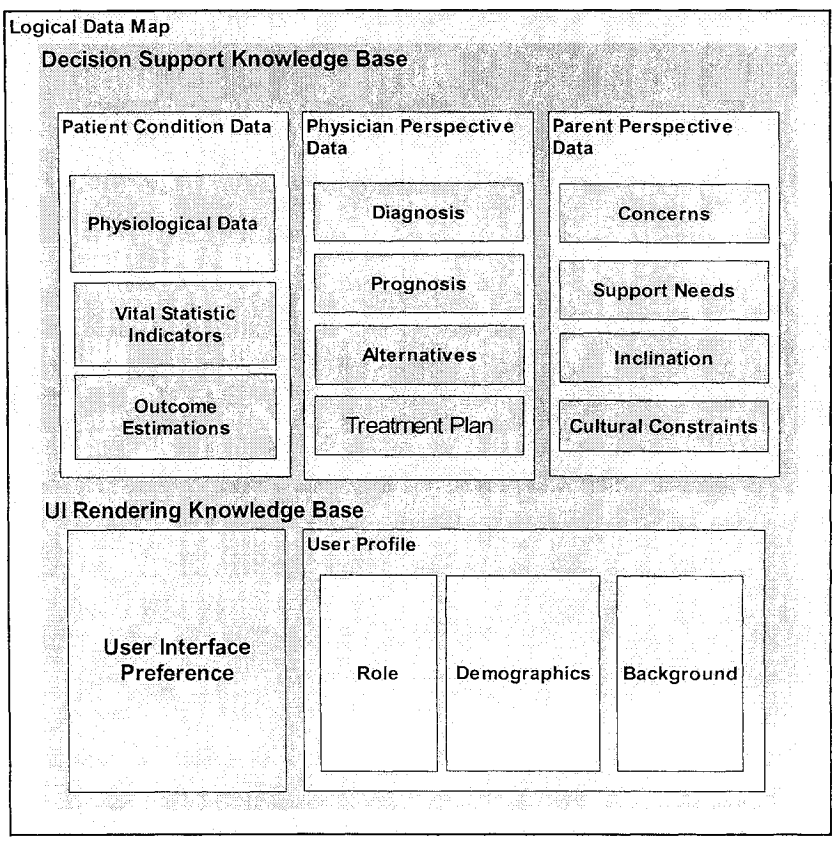

Figure 6-C PADS data components – logical view of knowledge repository

The data is hierarchically organized into *decision support knowledge base* (DSKB) and *user-interface rendering knowledge base* (UIRKB). The former is necessary to provide decision knowledge base. The latter describes user context, which enhances system capabilities to deliver custom content and user-interface features.

To complement the evidence-based results, data from the core decision-making experts, such as cognitive processing of medical team, are collected. These include medical interpretation of the physiological signs, conditions, outcomes, likelihood, treatments available, treatment recommended, notes regarding specific events or course of action, superseding the predicted estimates. These data are associated with an author and a time of entry, so that all facts and predications manually inserted can be tracked and accounted for. Authorship refers to who the originators and owners of the content are. In contrast, permission refers to which user has the right to access or manipulate a data. The contents are associated with different states and can change state according to the actions that an authorized user has performed at a certain time.

The other end of the shared-decision spectrum belongs to the parents. Shared decision making models recommend eliciting parents' preference in coherence to ethical principle of parent autonomy; they contribute by stating their perception, needs, inclination (what decision they are leaning towards), and constraints. It is also helpful to capture inhibiting factors that interfere with their decision-making capacity. Parents can base their decision on miniscule perceptive cues; the baby's display of vitality or frailty can become a crucial factor. Because of the deontological duties physicians have towards parents, their wishes must be respected as long as they are based on facts. Thus outcome estimates will be made known to the parents in a sensitive and caring way through physician-parent disclosure. In any case, parental demurring or concurring with clinical recommendations or suggestions must be explicitly

documented. In some cases, the parents' perspectives are indirectly entered into the knowledge base by nurses, who are trained to capture parents' attitude, responses, feedback, with acuity and minimal distortion.

UIRKN contains user data that is collected and maintained to support the users' interaction with the system. This knowledge is acquired and maintained to support the content adaptive function to enhance users' interaction with the system, improving system performance, and effectuating information retrieval. User context data include the users' profile and user-interface preference. The profile information describes the decisional and user-interface needs. For instance, parents' background information is collected: demographic, education, religion, computer literacy, experience with problem domain, and experiences with decision-making. These data are necessary to customize the user-interface for the family. These data are collected and entered by the clinical administrative staff.

6.3.3External medical knowledge and supporting data

Clinical decisions often need to be based on current medical knowledge. Despite the undisputable fact that the neonatologist may need to consult external resources in order to identify outcomes, alternatives, and latest therapeutic interventions, most systems developed were standalone applications that do not leverage the powers of interconnectivity and the wealth of knowledge available. Should the parents be uncertain about their preference and sustaining treatment needed to be administered, they are also more likely to seek out information. As most literature suggests, the most accessible, available and economic way of seeking and retrieving information is through the Internet. The system should easily interface with the network to allow accessing sources of knowledge. The knowledge that is offered by interconnectivity can be used to be used to support education, dissemination, and critical decisions. Certain knowledge elements will be cached locally within the data repository so that the neonatologist can use it as support for a diagnosis, prognosis, or treatment alternative. But the majority of this

knowledge will be offered as an external service that involves the activation of the communication component\

6.6 Workflow

The functionalities offered by CMS include workflow support, access control, syndication, email alert, search and update. Each organization has a workflow method for content that are transcribed from person to person in the task or process. The CMS maintains a workflow rule repository that guides the access control to contents in the repository. Access control maintains integrity to protect the privacy and confidentiality of the parent's decision while they seek external aids. The patient's information and disease information, as well as treatment plan must be protected from unauthorized access. Syndication is the automated distribution of content update to authorized subscribers in their preferred rendering system. When a change, an addition, or a deletion has been inserted into a patient case, inference has to be retracted and reasserted to reflect the update. Machine monitoring can also identify events undetected by humans. In those cases, email alerts can be generated and delivered to neonatologists on their mobile devices. Intelligent devices also need to offer search and update functionalities to accommodate to the needs of the user to find a specific post according to date of post, author, keywords, and other content parameters. The multiple-source content collection is merged into a single coherent index to facilitate information retrieval.

Chapter 7 User-interface Design

The interface between the device and the user is critical to successful integration into the system. As mention in section 2.1, earlier DSS often failed due to the poor interfaces between user and device. For decision support tools, the effectiveness of the devices is measured by perceived usefulness. In order to meet the multiplicity requirements, this system takes the adaptive user-interface approach, by incorporating the Multi-user Access User Interface (MUAI) proposed by Yang [Yang, 2003]. Figure 6-D illustrates the MUAI framework. As outlined during EMBS conference proceeding, Yang suggests the user-interface provides adapted content and user-specific functionalities. By using the MUAI framework, we focus on providing customized and personalized content delivery, adjusting the level of complexity and granularity according to the individual, role-dependent user needs.

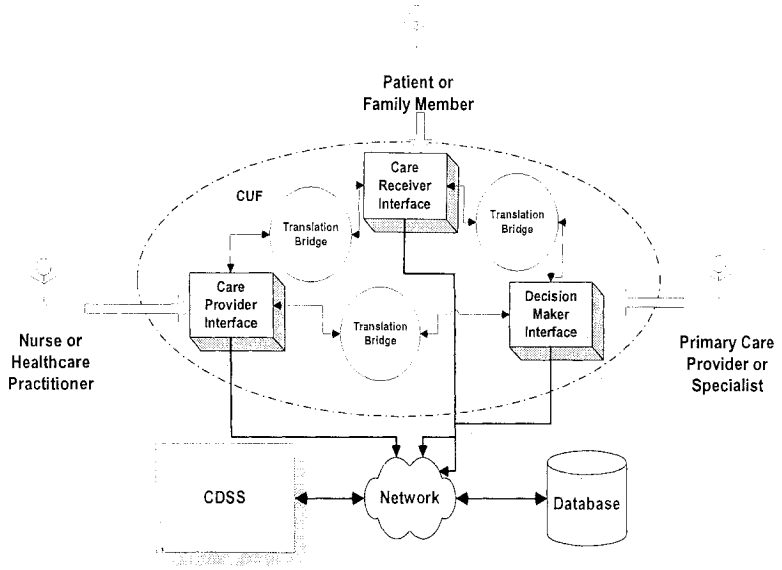

Figure 7-A Multiple User Access Interface framework

For clinical users, the UI should be consistent with clinical heuristic rules for software interface and clinical norms. For instance, clinicians are found to prefer numerical and tabular representation. Certain clinical roles require additional functions, such as providing a functionality to allow data insertion space

and automatic parsing to extract pertinent medical interpretation and instruction; for example, a course of action may be prescribed for certain medical events.

Parents, on the other hand, prefer more textual-based representations. Additionally, parent content must feature plain language and additional explanation for various medical concepts and terms. It is also necessary to provide some parent-specific features, such as step-by-step guideline for decision-making. Thus, each type of user will receive a set of user-interface feature components and version of content presentation, based on a filter created for each individual user. This is logically depicted in figure 6-E. The user interface component adapts content and determines functional set depending on the user profile. When the user logs into the portal, the personal user-interface implementation profile is fetched. Based on that information, aggregated content is filtered and customized according to pre-determined defaults or user-specified preferences. On the basis of a scoring scheme applied to different content versions, the adaptation engine executes an algorithm that computes the optimal version that could be rendered. "Version" for our purpose means a set of content objects that must be included for the client. Content objects include trend graphs, tables and controls, and menus. The adaptation then sends the results to the transcoder, which generates the content version on the fly. Then the server sends the adapted content to the users' client display for presentation [Lum, 2002].

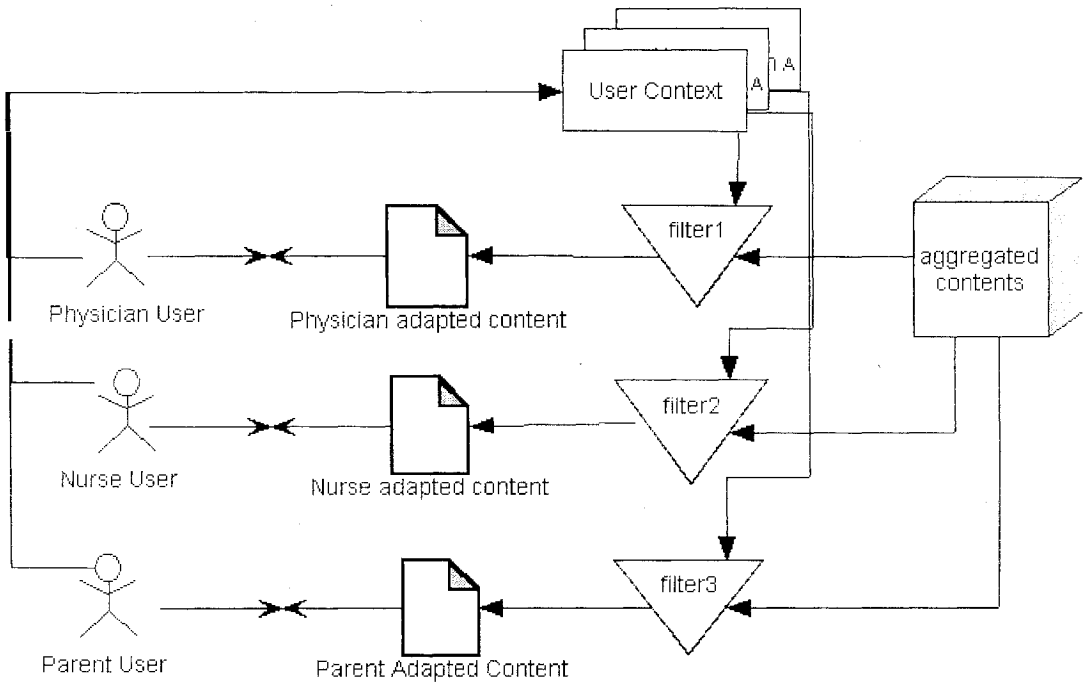

Figure 7-B Logical representation of adaptive user-interface delivery

7.1 Contextualization

This concept is derived from an emerging technique used in mobile computing to adapt content to device and user-specific preferences [Lee, 2003]. While the device does not change in our problem domain, specializations and activity sets are highly variable from user to user. A user's characteristics are part of the context of a client environment where decisional content rendering occurs. Context includes any information that can characterize a user's situation, such as task goal and computer literacy. A system uses context to provide relevant information or services to users, where relevancy depends on users' characteristics and tasks, that is, their context. In our system, adapting to user-specific preference presents certain challenges that could be addressed by applying a similar design concept. To design a customization and personalization service, we must understand the users' characteristics, environment, and task model. We can gain such an understanding through a contextualization framework that facilitates the expression and capturing of context information.

7.2 Qualitative user preference and quantitative content values

Content adaptation processes take into account that not all user preferences are easily expressed in terms of numerical values in a certain context, such as parents' perception of the readability of medical terminology. Ideally, the user specifies a preference without exact quantification. A preference relation such as ranking scale that connects different quality domains can describe the qualitative information. To reduce the user's cognitive workload, assigning a numeric score to a particular content is automated based on the user's actions. For instance, if a parent repeatedly requests more detailed prognosis information, the adaptation system saves this information and presents the parent with the possibility of switching to more detailed content display. In this method, content adaptation relies on a user's indication of preference in different interface domains.

This is a two-step process: pre-processing and on-demand processing. Pre-processing occurs before the user request arrives. The set of content attribute dimensions forms a description of depth and richness of the decisional content. The richness of a specific version of content can be viewed as a point in an n-dimensional space, where n is the number of different attributes [25]. For example, the quality of an instance of document object is related directly to the user's perceived level of difficulty in assimilating the information. Given this simple notion, we can define the quality of an interface as:

```
QoSinterface= F(readability, granularity, complexity) - perceived difficulty
Where:
Readability refers to the grade-level of language used.
Granularity refers to the depth of medical information given
Complexity refers to the number of primary interface controls on the interface
(i.e. no features)
```

Using quality axis, the system can quantitatively describe the user's preferences. For example, a user might have a strong educational background, but very low computer literacy. An aggregate score can be computed based on the weights entered for the three quality axes. Scoring information corresponding to specific users and version must be stored in organized fashion to facilitate efficient retrieval. For the

second step in the process, the on-demand processing, user login into the system and the adaptation processors access the user profile to retrieve preference specifications, thus building awareness of the user context. If the user has not specified any preference, the processor considers user demographics and background information to heuristically search for a compatible version. Through this technique, an individualized user-interface can be delivered and adapted as the users become more educated with the problem domain.

7.3 Design Concept

Our UI design was always centered on patient objects. Each patient would receive a work area, a case summary, a report on prognosis, and a discussion area. Additional functionalities were designed as additional tab spaces. The metaphor we used is the conventional medical file folder, with tab for the major sections and additional tabs for user specific tools such as decision aids.

In order to assess the basic content presentation concept, we utilize a rapid prototyping technique, an iterative development approach to quickly construct prototypes, modifying them as we develop them. The modifications are based on advices, feedback, and criticisms from expert panels. Prototype (1) is a set of user-interface screens using Visual Basic ® and Microsoft Access ®. These storyboards quickly elicited feedback on utility design and presentation. A complete sample of user-interface screens can be found in appendix III.

The screens were sorted into two groups: clinical users and parent users. Figure III-A to figure III-D are for clinical users and provides the functionality as targeted to physicians needs. For example, figure III-B shows the landing pad for neonatologists, providing them with lists of patients, urgent notifications, and emails. Figures III-E to III-K are designed for parent users. Figure III-E shows the information that

parents might receive automatically. Figure III-G to III-K shows the preliminary work of the parents' decision support, built using Visual Basic ®. This web application is created as an online informatics tool that provides step-by-step guidance to parents. This is a component that present the outcome estimation and prognostication to the parents. The content was adapted from O'Connor's Ottawa Patient Decision Support Tool [O'Connor, 1999].

O'Connor designed a decision tool to support patient decision-making process. Our framework is based on the concepts presented in this tool, which encourages parents to communicate their perceptions, concerns, values, and questions. It consists of four steps: 1) assessing the decisional needs, 2) providing decision support, 3) facilitating progress in stages of decision making, and 4) discussing implementation of choices.

Chapter 8 Usability Evaluation

8.1 Method

The evaluation of UI prototype for the clinical decision support system is a difficult task was conducted using standardized pilot testing method. UI prototypes were iteratively developed using usability engineering methods such as storyboarding, mock-ups, and finally semi-functional web applications. Earlier prototypes were reviewed by an expert panel consisting of a neonatologist, a clinical epidemiologist, and an engineer. In the PADS-III prototype, we created UI for requirements set represented in use cases A and B (see section 5.4.2); that is, the UI created for this prototype are for CDM functionalities and PDM functionalities. Since PADS-III demonstrates a limited set of functionality, we were able to pilot test the prototype with potential clinical users. In order to prepare for the pilot test, we developed a Usability Questionnaire [Appendix I] based on [Stacey, 2003], Testing Procedures [Appendix II], and an Informed Consent Form [Appendix III]. The evaluation sessions lasted approximately 30 minutes, including the time taken to fill out the associated questionnaires.

8.2 Data and Observation

Six clinical users participated in the pilot study, with 3 neonatologist, 1 critical care physician, and two social workers. The Usability and Acceptability Questionnaire consisted of seventeen usability questions to which respondent selected one of five multiple choices. The first seven questions uses five point scale which varies from 1 (very unsatisfied) to 5 (very satisfied). Question 8 is a qualitative question, while questions 9 to 17 required the respondent rate the agreement on a five point scare, ranging from 5 (likely) to 1 (unlikely).

Table 1 shows the overall rating for the UI prototype. A graphical representation of the results is provided in Figure X.

Table 8-1: Mean user rating with standard deviation in parenthesis

	Question	Rating
Q1	Your overall reaction to PADS-III is:	4.17 (0.41)
Q2	The organization of information in PADS-III is:	4.33 (0.51)
Q3	For you to recognize the meaning of the category label in PADS is:	4.17 (0.75)
Q4	The terminology related to tasks in PADS is:	4.17 (0.75)
Q5	Using PADS to perform tasks assigned is straightforward:	4.17 (0.41)
Q6	Remembering names and use of commands in PADS is	4.83 (0.41)
Q7	Do you think PADS is designed for all users?	4.17 (0.41)
Q9	I can see the tool being useful in my job in the future	4.67 (0.81)
Q10	Learning to operate the tool would be easy for me	4.83 (0.41)
Q11	I would find it easy to get the tool to do what I want it to do	4.5 (0.84)
Q12	My interaction with the tool would be clear and understandable	4.17 (0.41)
Q13	I would find the tool to be flexible to interact with	4.00 (0.63)
Q14	It would be easy for me to become skillful using the tool	4.83 (0.41)
	For parents interacting with PADS interface, PADS will	
Q15	Be useable with most of the parents making a preference-sensitive decision	3.67 (0.51)
Q16	PADS will enable me to see (observe) benefits to the parents	3.3 (0.53)
Q17	PADS will be easy to experiment with before deciding to adopt it in practice	4.0 (0.63)

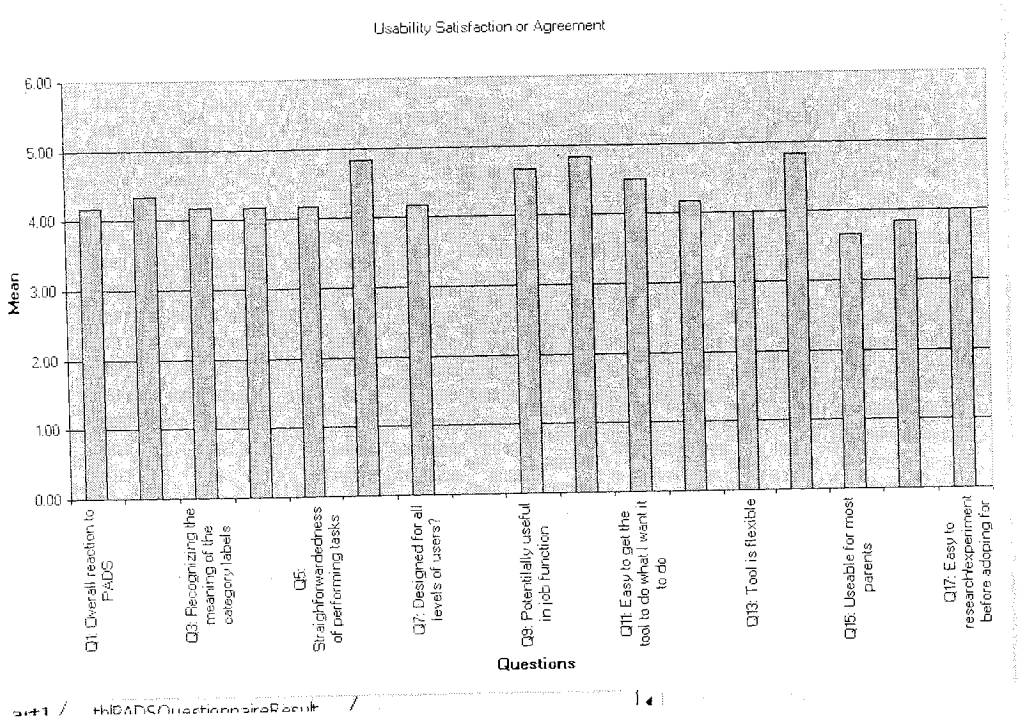

Figure 8-A: Plot of mean user ratings for the seventeen questions

8.3 Results

Our results indicate that 5 out of 6 users were overall satisfied with PADS-III; four of six users found the organization of PADS to be moderately clear. PADS really faired well in being easy to recall names of commands; 5 out of 6 participants ranked remembering names and use of commands very easy. There was only on person who had some difficulty recognizing the category labels of PADS, and this is attributed to the fact that this particular participant is not a member of the NICU department. From these data, no users found the tool difficult to learn. Our usability objective was: "Except in exceptional circumstances, all users should find the tool easy to learn". Therefore, we have met our first usability requirement. The second objective was that "at least 70% of the user will find the system intuitive." Except for the non-NICU physician, all the respondents recognized the meaning of category labels easily

or very easily, and all respondents found the terminology to be related mostly or always. Most or all of the time, all participants found using the prototype to perform tasks to be straightforward. From these findings, we believe the respondents found the UI reflecting concepts found in their normal practice. Therefore, it would be safe to conclude that that we have met the second usability objective.

8.4 Discussion

Graphical user interfaces are the direct interface between human users and the system. User-centric paradigm advocates have always praised the use of prototype interfaces for high-risk system. In this situation, a prototype evaluation is appropriate – to demonstrate key concepts, to elicit acceptability, and validate research direction. Previously members of our expert panel informally reviewed the graphical user-interfaces (GUI) and paper guideline prototype, and a functional web-based prototype. The GUI and paper prototypes were well received by the physician, the social worker, and the nurse specialist in our research study. Positive feedback was received:

"An excellent tool with immediate clinical application. [The tool] is exactly what we need".

Care providers commented that this tool could be applied to many unique situations such as:

"The case of a twin birth. One of the newborns is critically ill but not the other. The parents need to organize their decisions according to their specific needs. We could really use a generic tool like this in such a situation."

During the web-based prototype demonstration, both positive and negative feedback were received. One clinician commented that the tool has the potential to improve clinical decision-making. Other comments questioned the logistics of how to allow parents access to the tool at the hospital (i.e. kiosk?). Some of the concerns with the tool were whether the parents could actually be able to express their preference on the relative importance of the determinant. It was deemed that in such an ambivalent and

emotional decision, it was be difficult to rationalize the weights of the various decision factors. A frequently occurring misunderstanding was the false notion that the tool was trying to influence the final decision. We must repeatedly emphasize that the tools is merely supporting the prognostication, information gathering, and communication and documentation of the process.

Based on the most recent prototype evaluation, we are very encouraging about our conceptual framework. Almost all the participants felt the tool was very likely to be useful to their job in the future. Their verbal feedback also indicated an interest in seeing further research work to evaluate various aspects of the tool, such as interfacing with ANN components.

There are many hurdles to surpass before further investigation can proceed. Firstly, many of the technologies still require further validation. These technologies are still considered immature in the medical domain, and must undergo rigorous testing to assure their performance in terms of quality and reliability. In cases where patient lives are affected by medical decisions, any tools that the neonatologist may use must be proven to be beneficial and of clinical value. This is currently underway in MIRG, although it may involve a lengthy process. It was also very obvious there were still a lot of shortcomings of the UI and the concept itself. The concept of time duration is not clearly built into the prototype. In addition, some clinicians pointed out the logistics of operating a discussion board; that personnel resource would need to be devoted to direct questions to various places. Despite there limitations, most of the respondents were enthused by the prospects of this research.

Chapter 9 Conclusion

9.1 Concluding Remarks

Machivaelli [1532] has remarked centuries ago that "nothing is more difficult to take in hand, more perilous to conduct, or more uncertain in its success, than to take the lead in the introduction of a new order of things." Transition from traditional neonatal decision practices to a computer-support knowledge-based system is a complex and arduous process. The PADS framework could allow physicians to better predict certain outcomes in neonatal intensive care and use this information when they counsel families on prognosis and the desirability of initiating or withdrawing treatment. It is important to include parents in the decision loop and to take into consideration their values and manner and tempo in which the information should be provided to them. Our goal was to promote the involvement of parents and the interactivity between key informants in decision-making. Although other artificial intelligence techniques have been used to predict patient outcomes in various medical settings, the system described here appears to be the first effort at solving the difficult decisions that parents and clinicians face in NICU.

9.2 Thesis Contributions

The thesis contributions are as follows:

1. Described the software requirement of PADS through use case analysis
2. Proposed high level architecture on how to implement and integrate the DSS into clinical process.
3. Designed User Interface

4. Developed several versions of prototypes for evaluation purposes
5. Evaluated the UI prototype with a small group of clinicians to assess whether the prototype meets basic usability requirements.
6. Attempted to validate a small portion of the PADS framework through a questionnaire.

9.3 Future Directions

This thesis presented technology components that could be integrated to support collaborative ethical decision making in neonatal intensive care. Some of the constructs are evidence-based estimation, medical information retrieval and update, real-time physiological conditions update, argumentative discourse, ethical norms support, risk communication, parents preference elicitation, religious constraints, etc. While some of the proposed components are standalone, they need to be integrated and clinically validated to provide significant impact in decision making in the NICU. An important next step is to apply the proposed components in decision support system such as PADS and test their effect on parent-physician shared decision making processes, errors in these processes, rates of satisfaction, rates of undesired side-effects and patient outcomes. Also, the boundaries for the range of clinical decision situations and settings in which support systems with these components are applicable to solving medical ethical dilemmas need to be explored to broaden possible applications of this framework. Additional work is also needed to demonstrate the cost effectiveness of improving the efficacy of decision making.

Appendix I Unified Modeling Language Use Case Diagram Overview

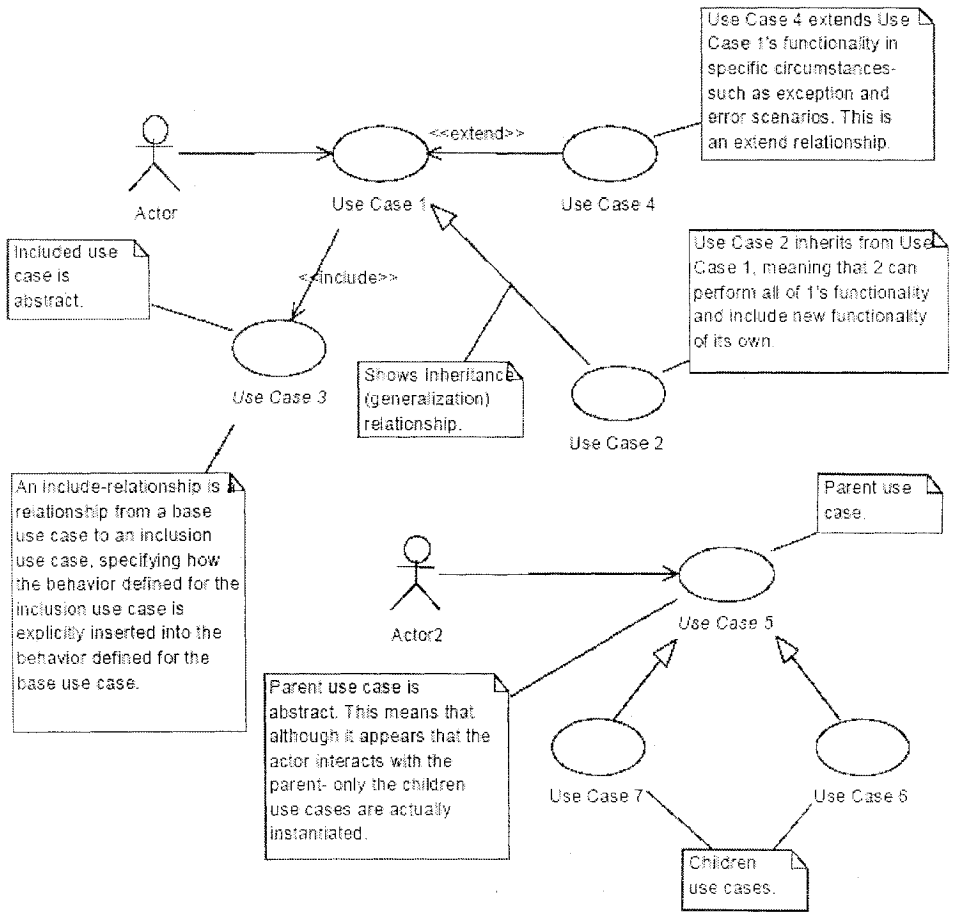

Figure I-9-A: Use Case Relationships

Note: In the <<include>> relationship between Use Case 1 and Use Case 3, Use Case 3 is an abstract use case (shown in italics) as it is never directly invoked by an actor, but invoke through another use case.

Appendix II Screenshots of PADS prototype version 1

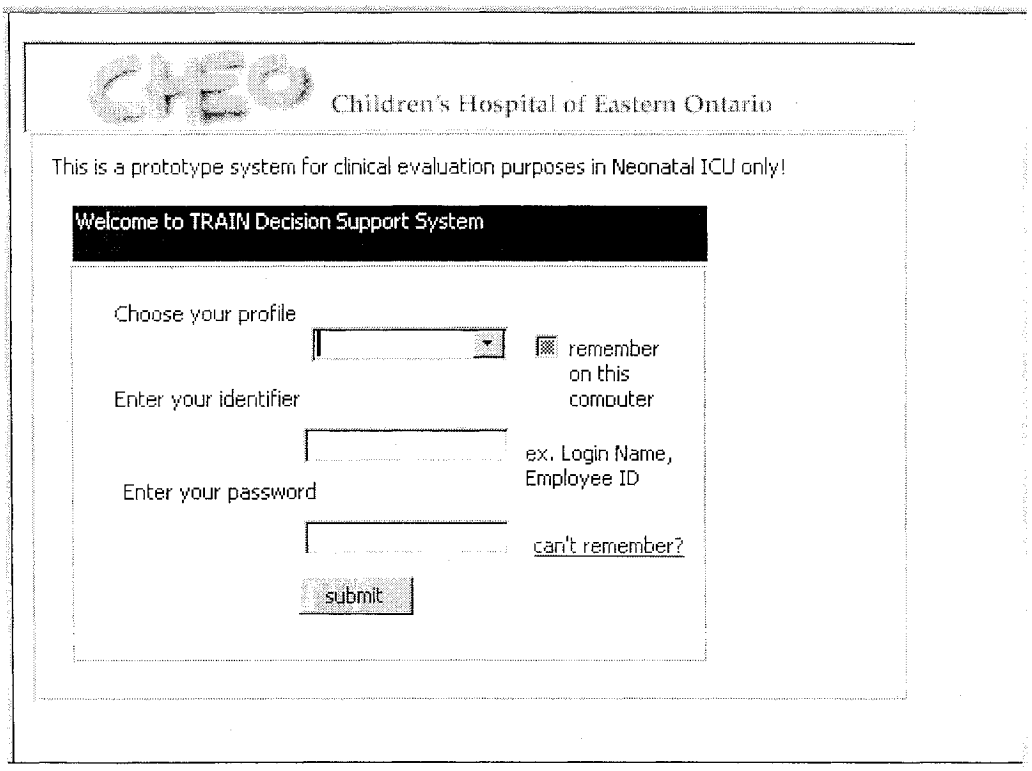

Figure III-9-B Prototype (1) Parent Decision Support - Login

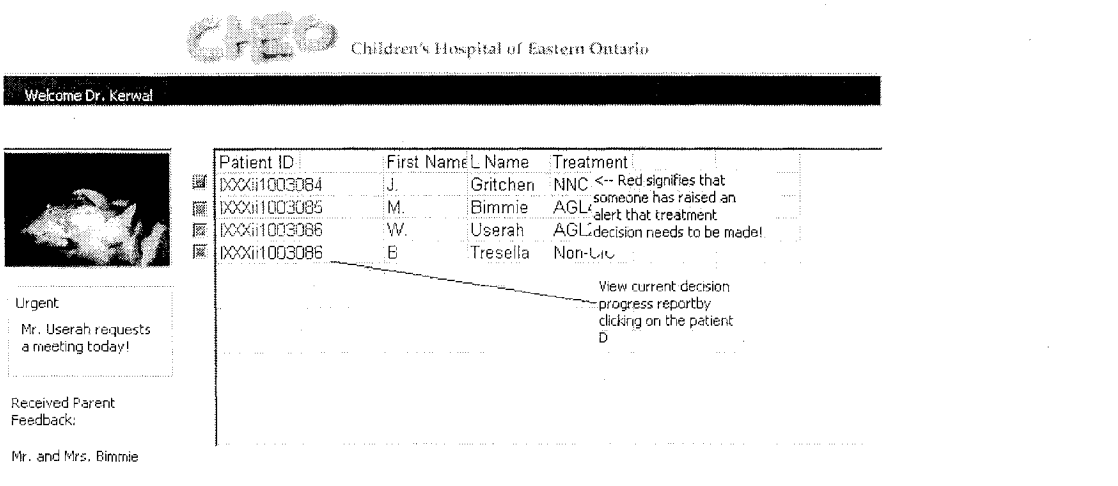

Figure III-9-C Prototype (1) Parent Decision Support – Clinical user welcome screen

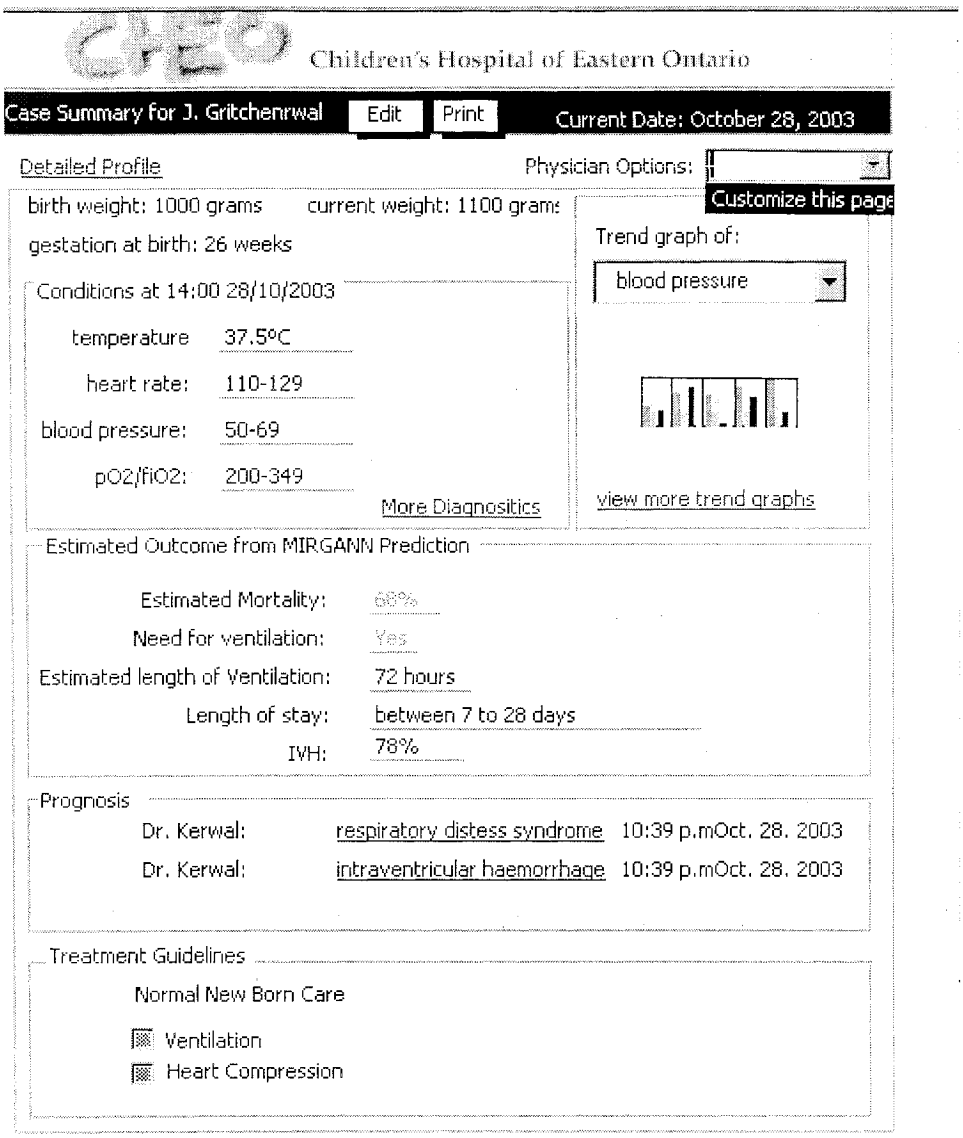

Figure III-9-D: Prototype (1) Summary of a Patients case

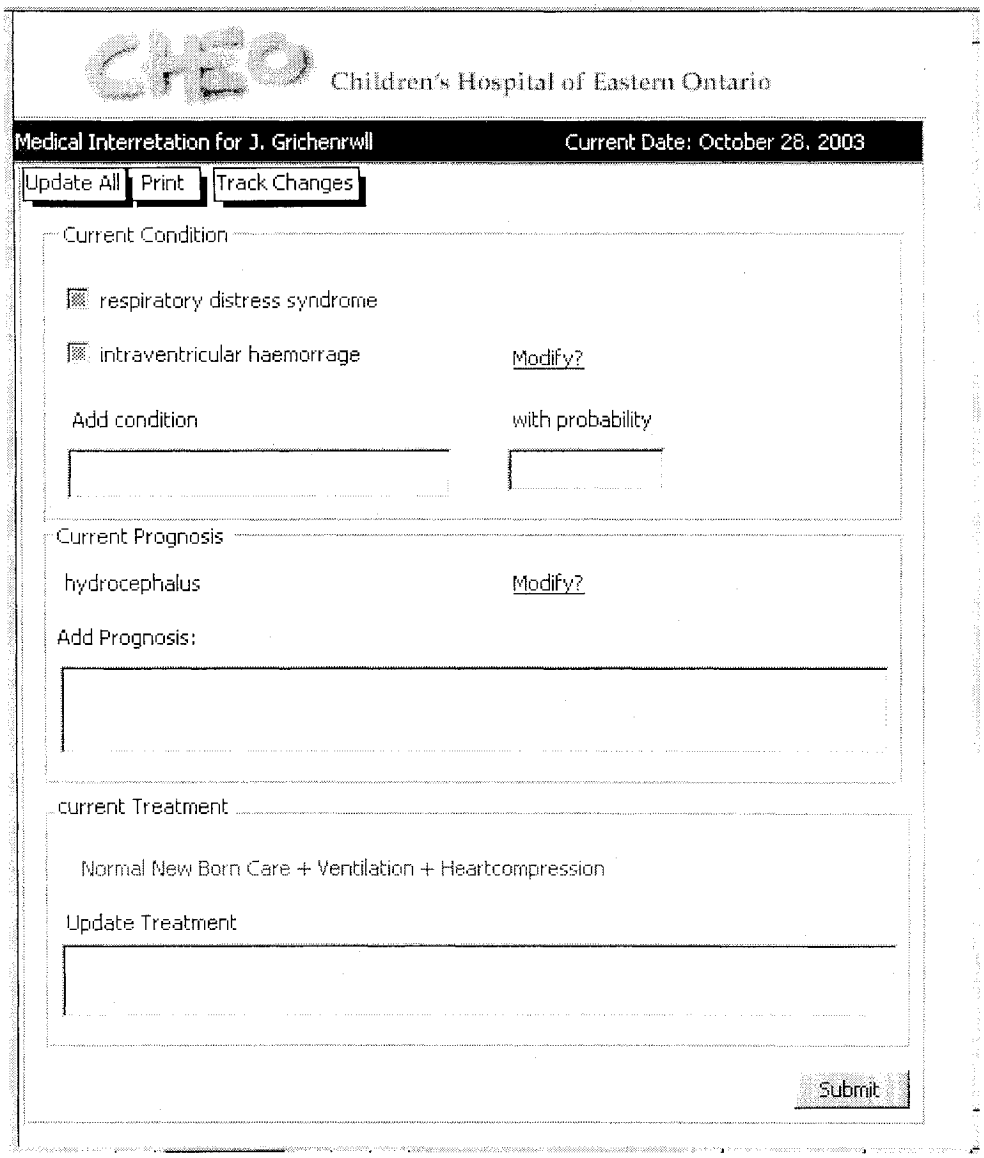

Figure III-9-E: Prototype (1) Parent Decision Support – Physician Input

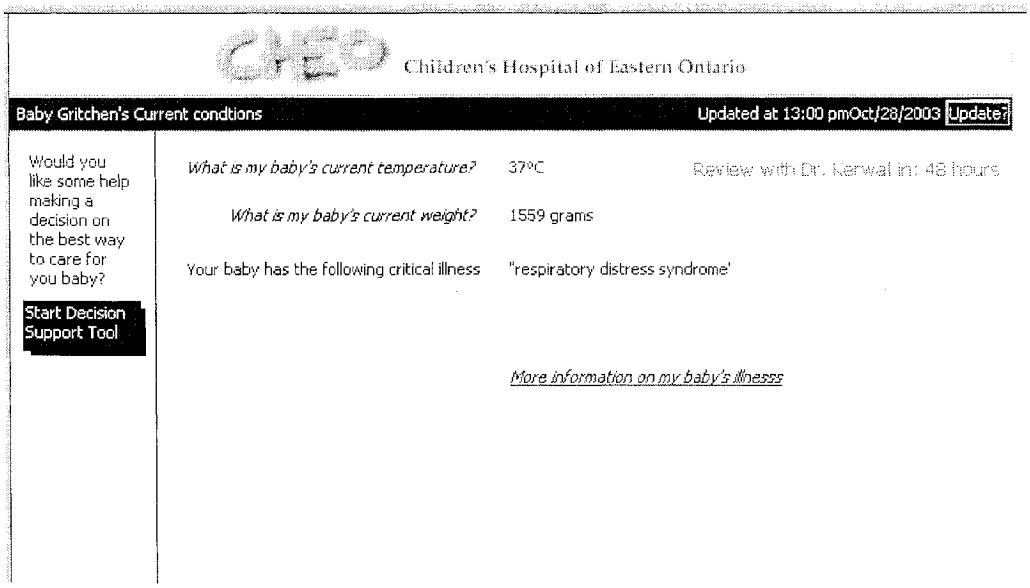

Figure III-9-F: Prototype 1 – Parent Decision Support Welcome page

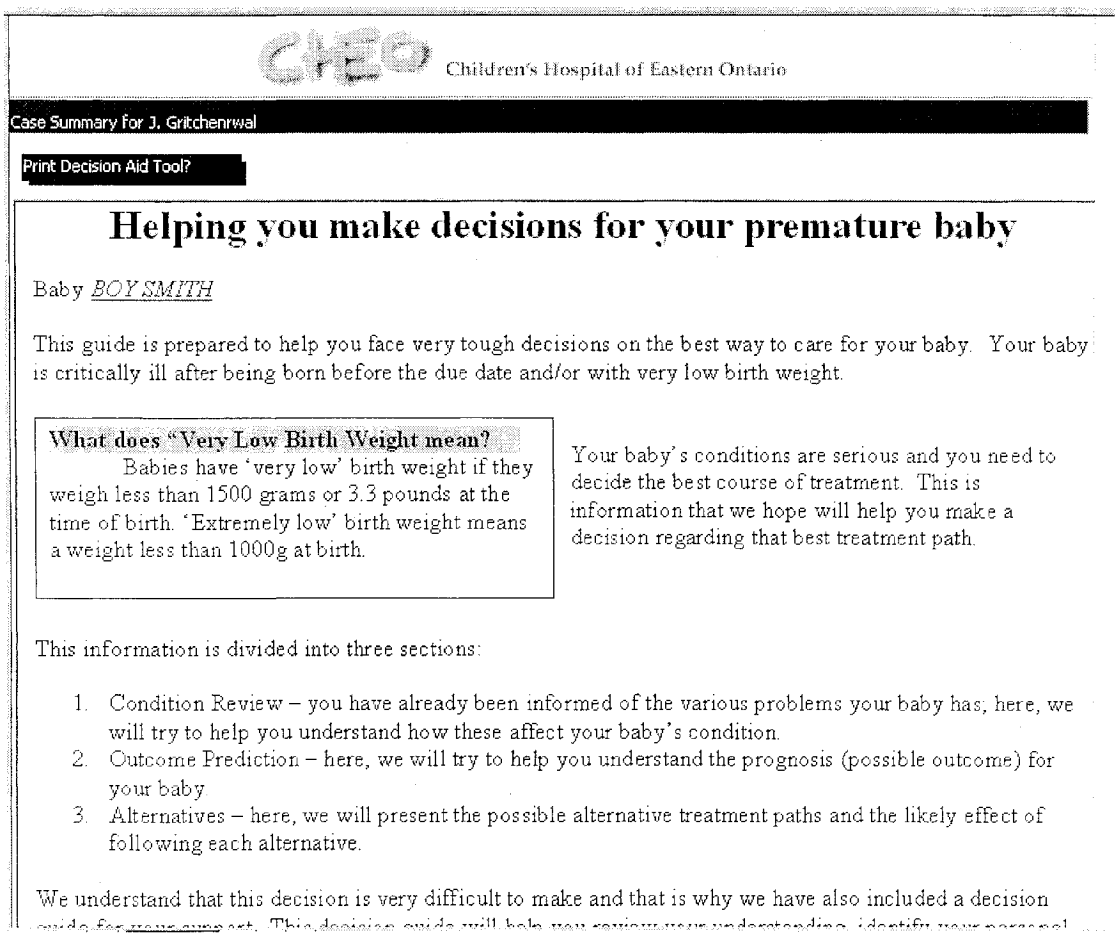

Figure III-9-G: Prototype (1) Parent Decision Support – Helping parents make decision

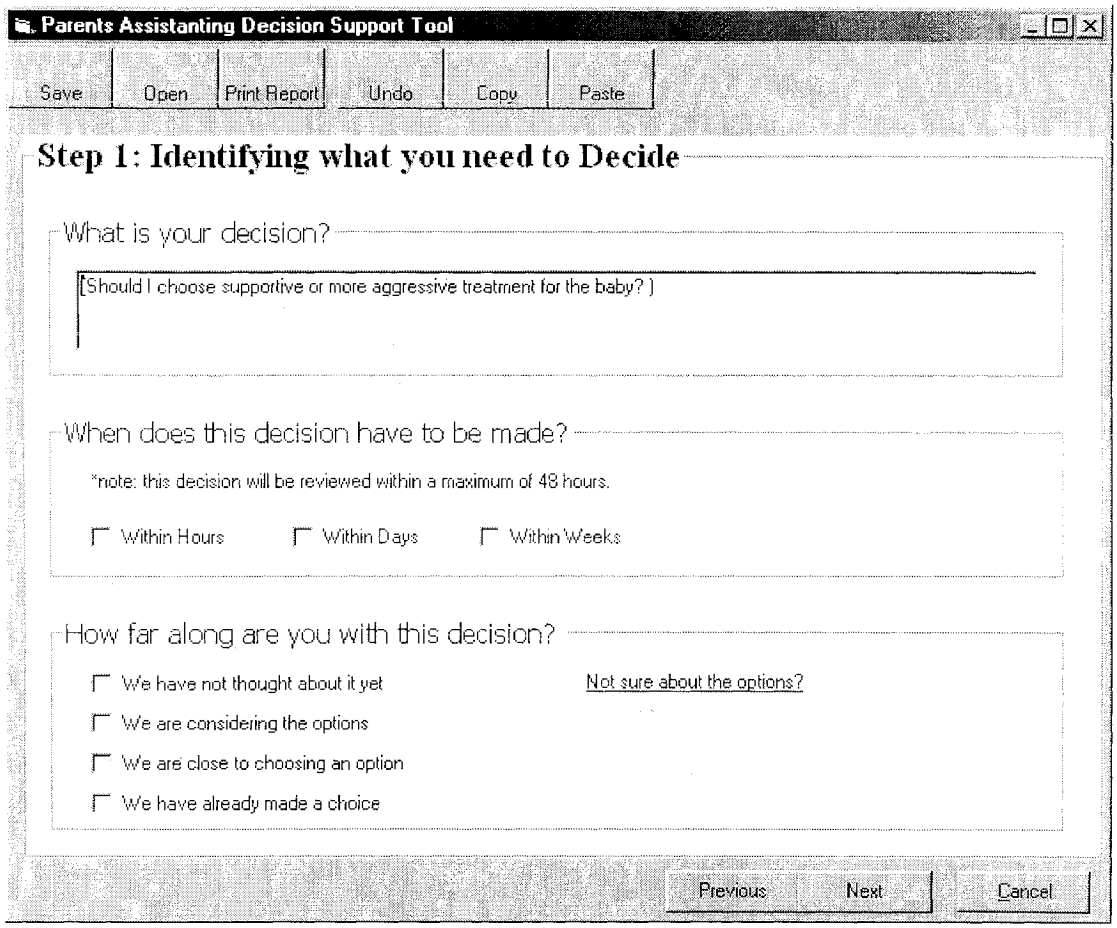

Figure III-9-H: Prototype (1) Parent Decision Support - Step 1

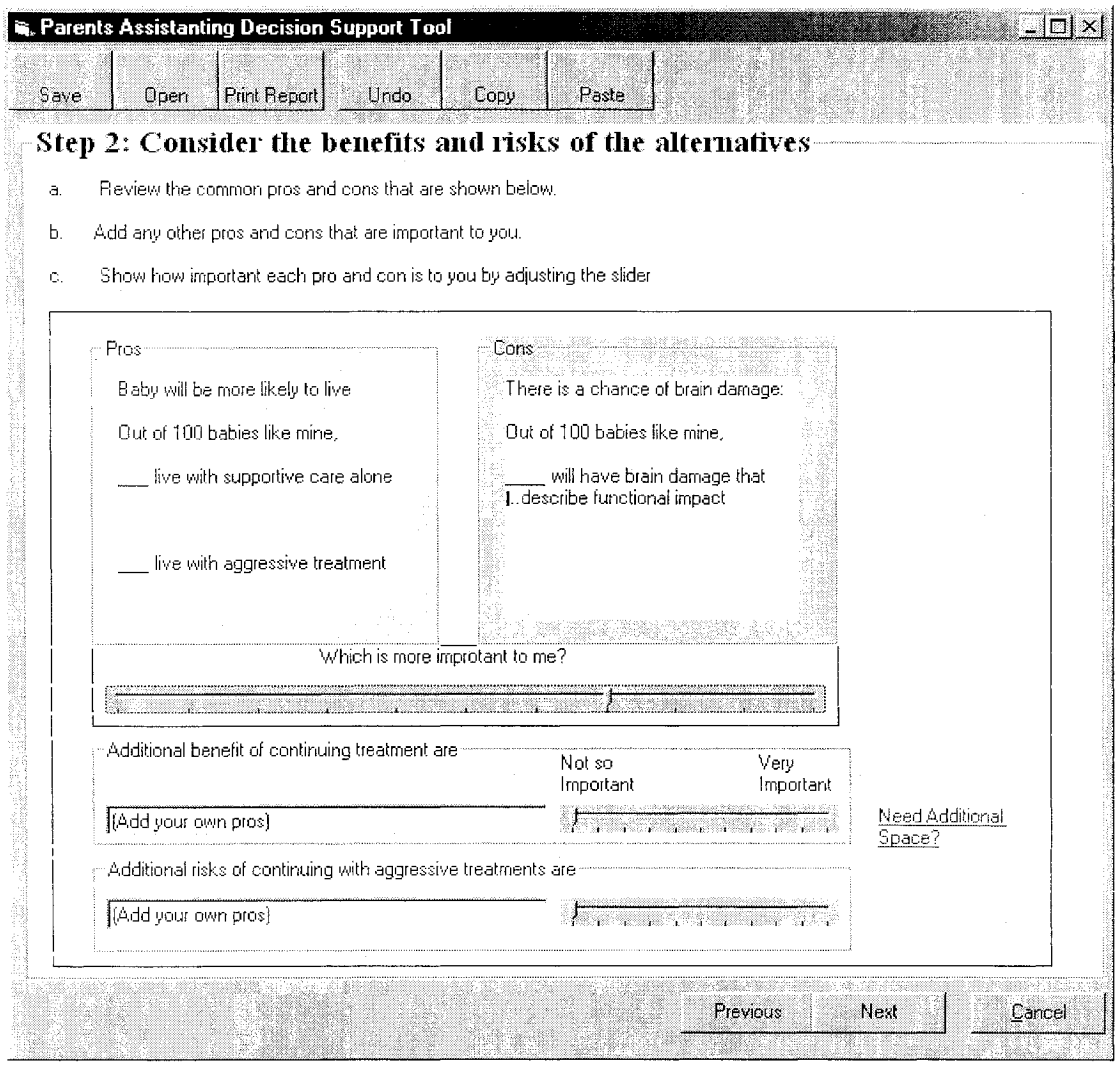

Figure III-9-I: Prototype (1) Parent Decision Support – Step 2a

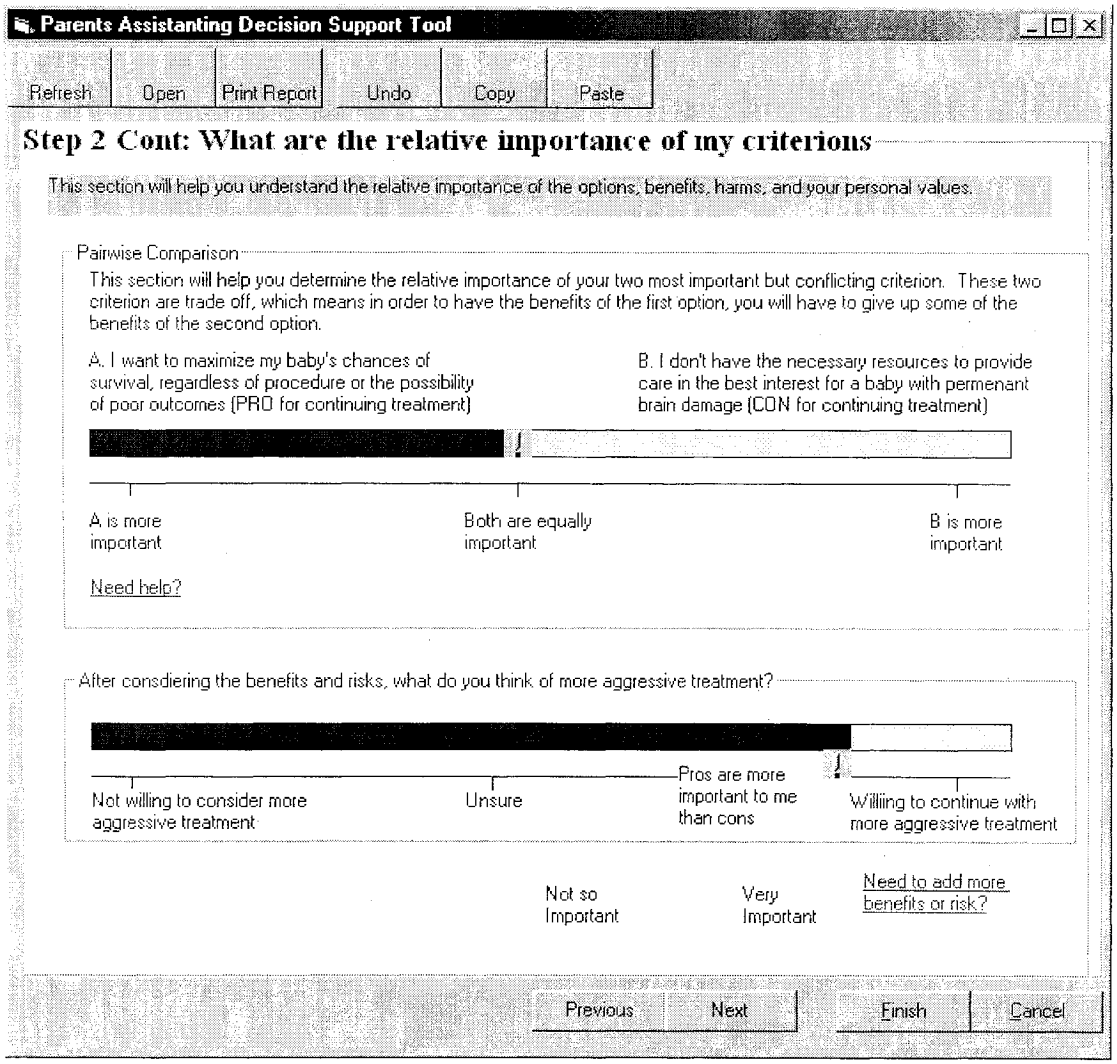

Figure III-9-J: Prototype (1) Parent Decision Support – Step 2b

This screen should help the parents consider the pros and cons of various treatment decisions for their baby. Indirectly, this step will collect information that help the physician understand the parents' assimilation of medical information, and what the parents deem to be important.

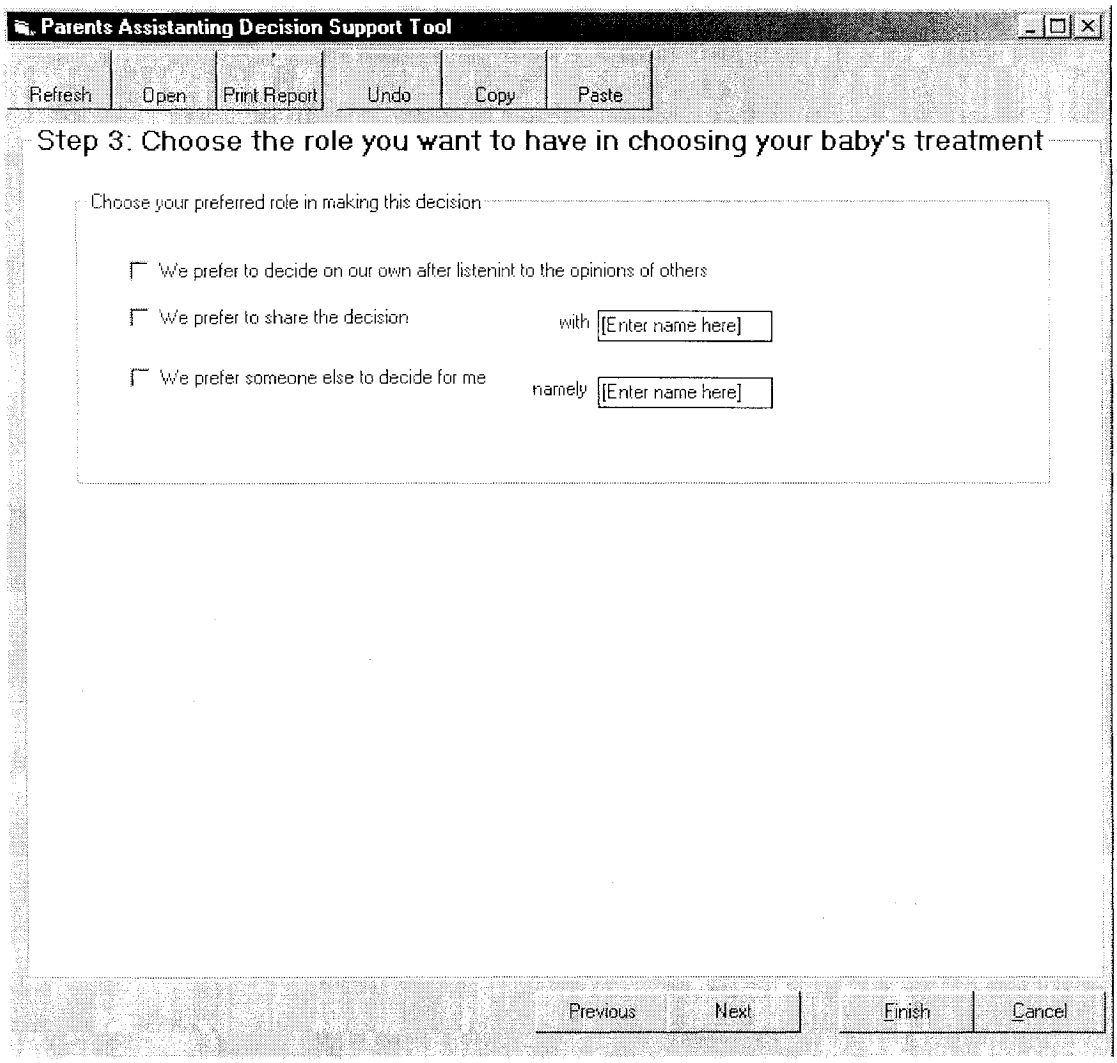

Figure III-9-K: Prototype (1): Parent Decision Support – Step 3

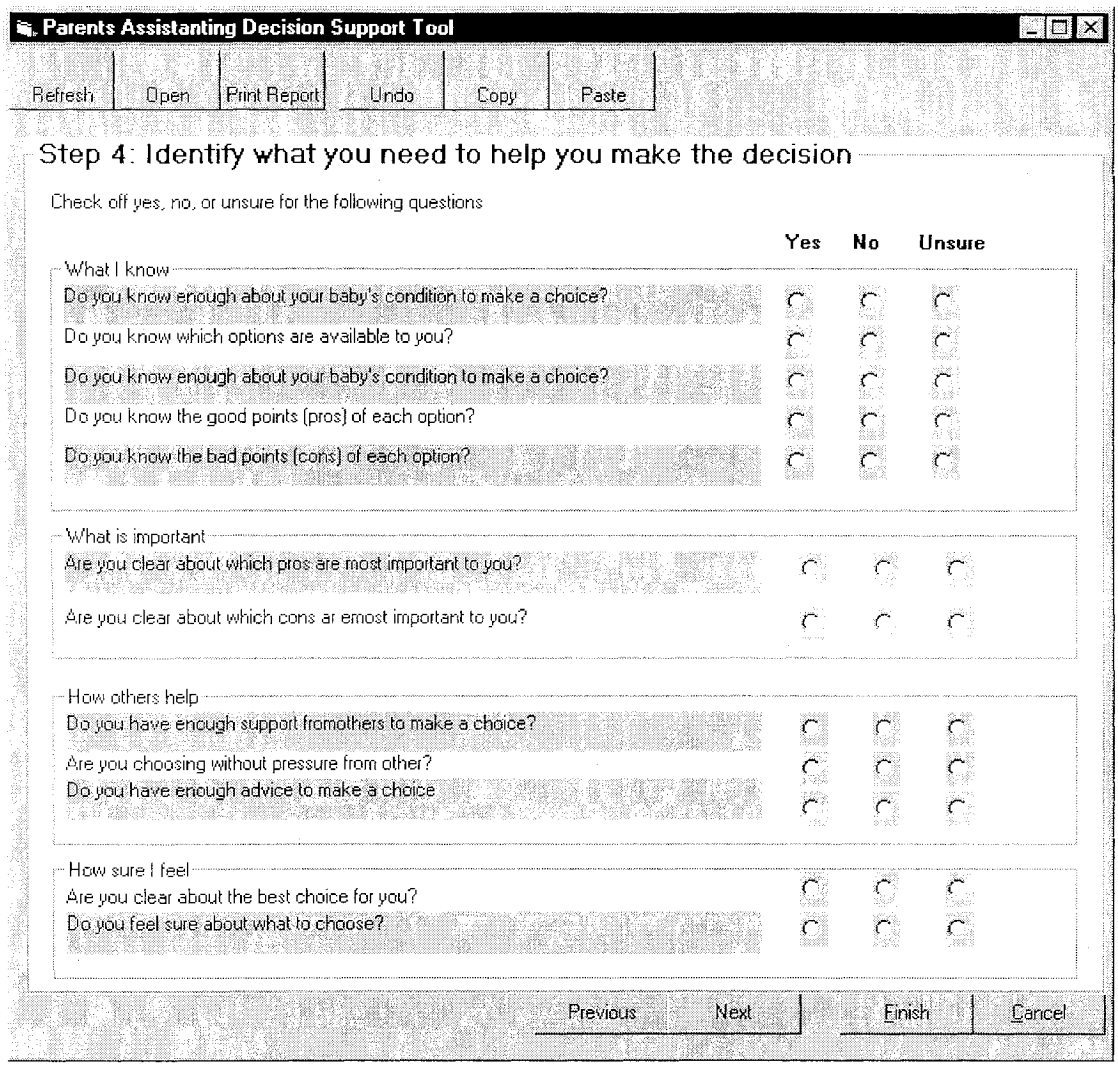

Figure III-9-L: Prototype (1) Parent Decision Support – Step 4

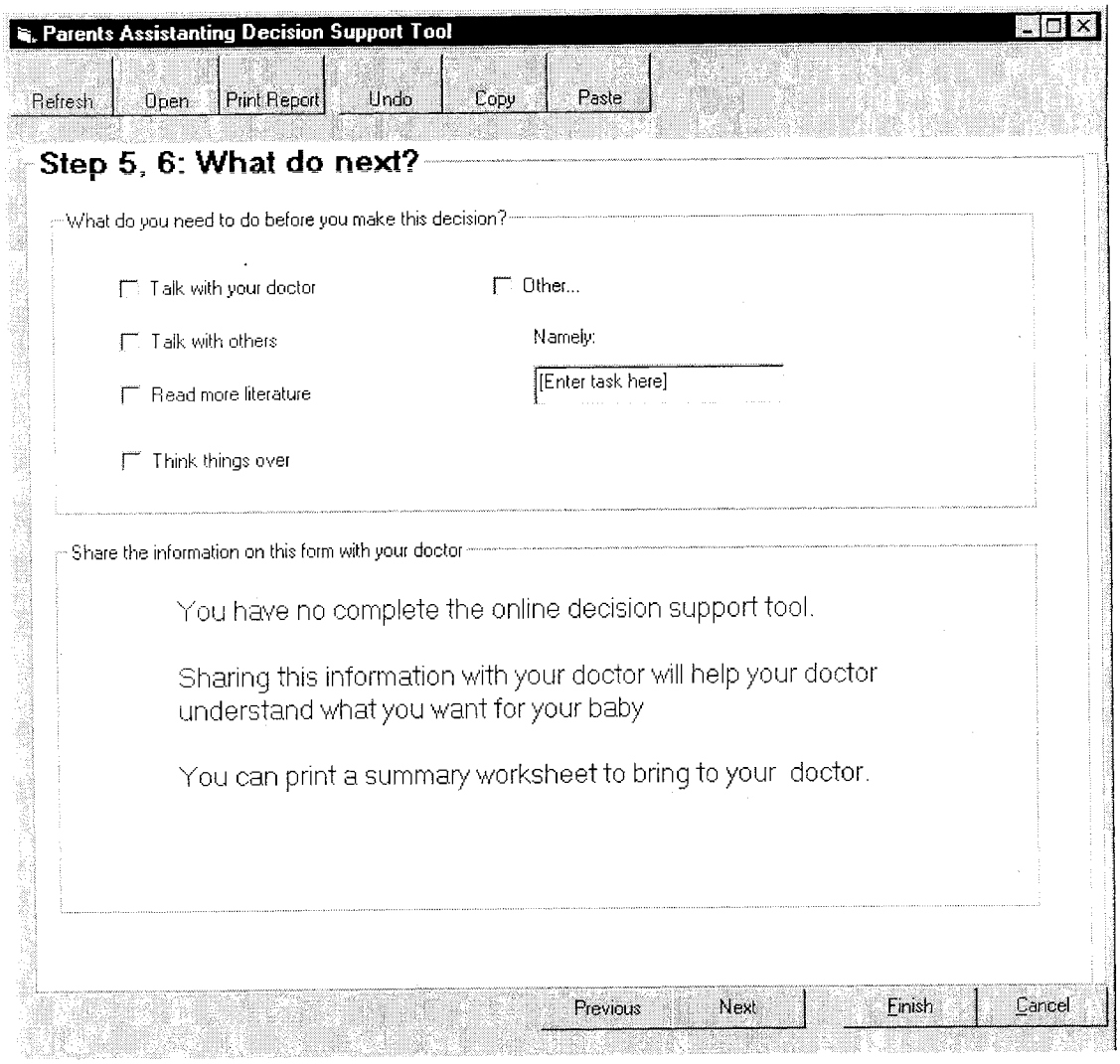

Figure III-9-M Prototype (1) Parent Decision Support – Step 5 and 6

Appendix III PADS Prototype Version 2

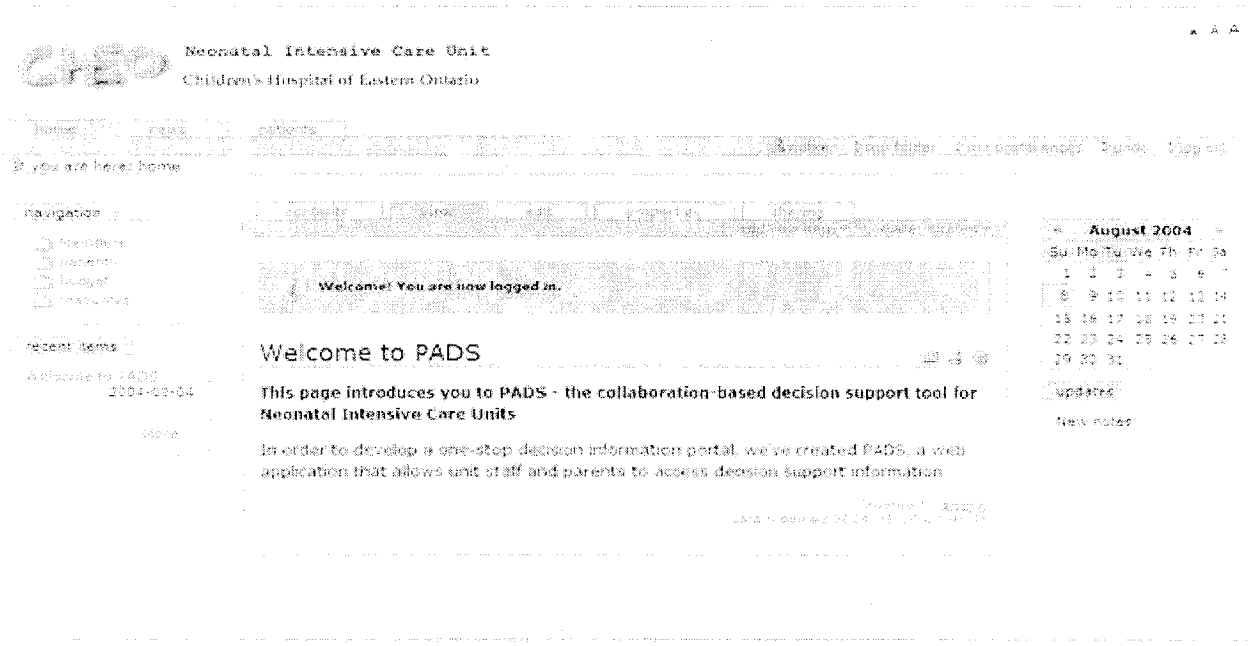

Figure IV-A: Prototype (2) PADS Welcome screen built using Plone ®

Appendix IV PADS Prototype Version 3

Figure V-9-N: PADS welcome screen built using ASP. NET

Figure V-9-O: Prototype (3): PADS note screen

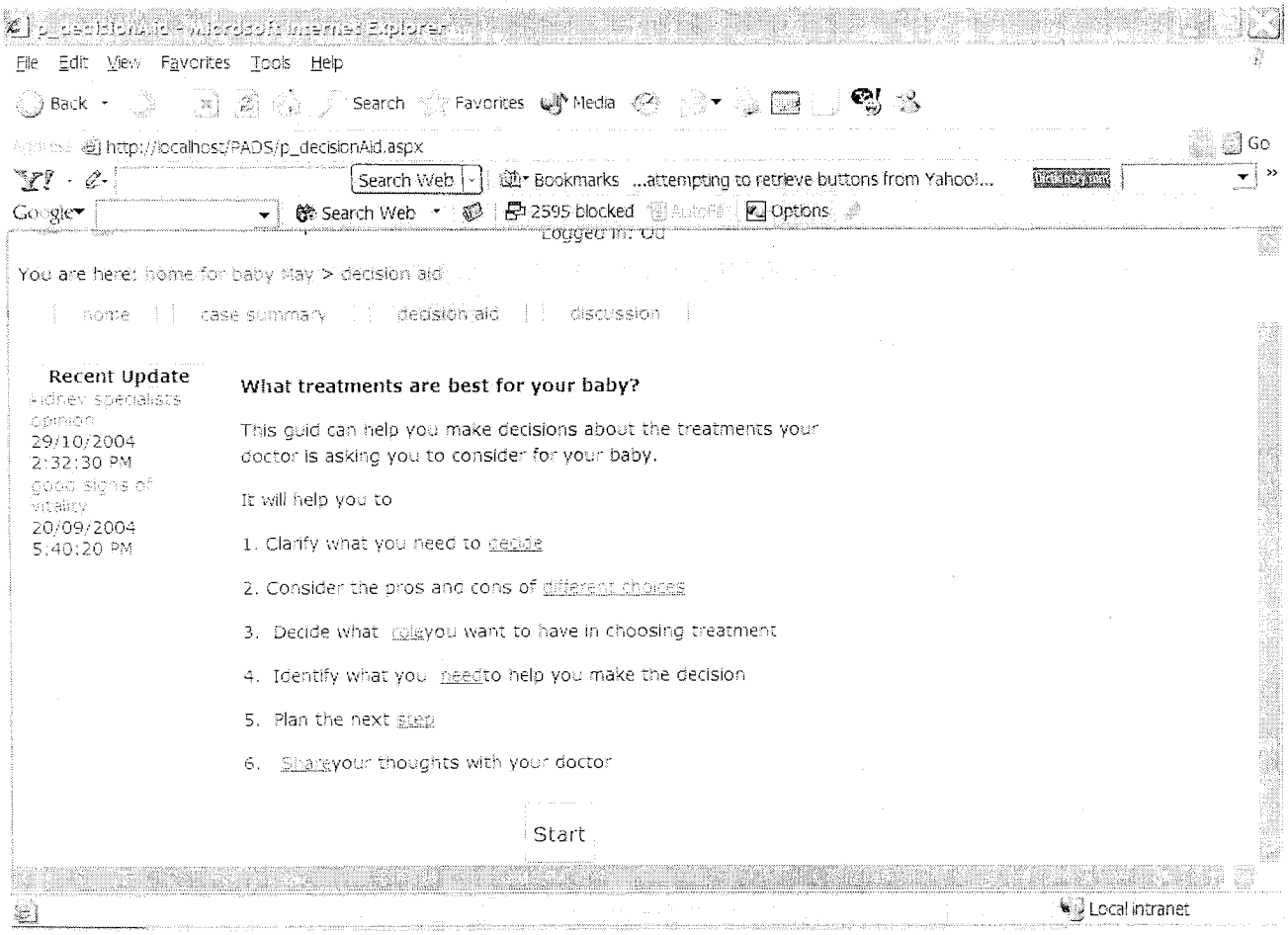

Figure 9-P: Prototype (3): PADS family decision support screen

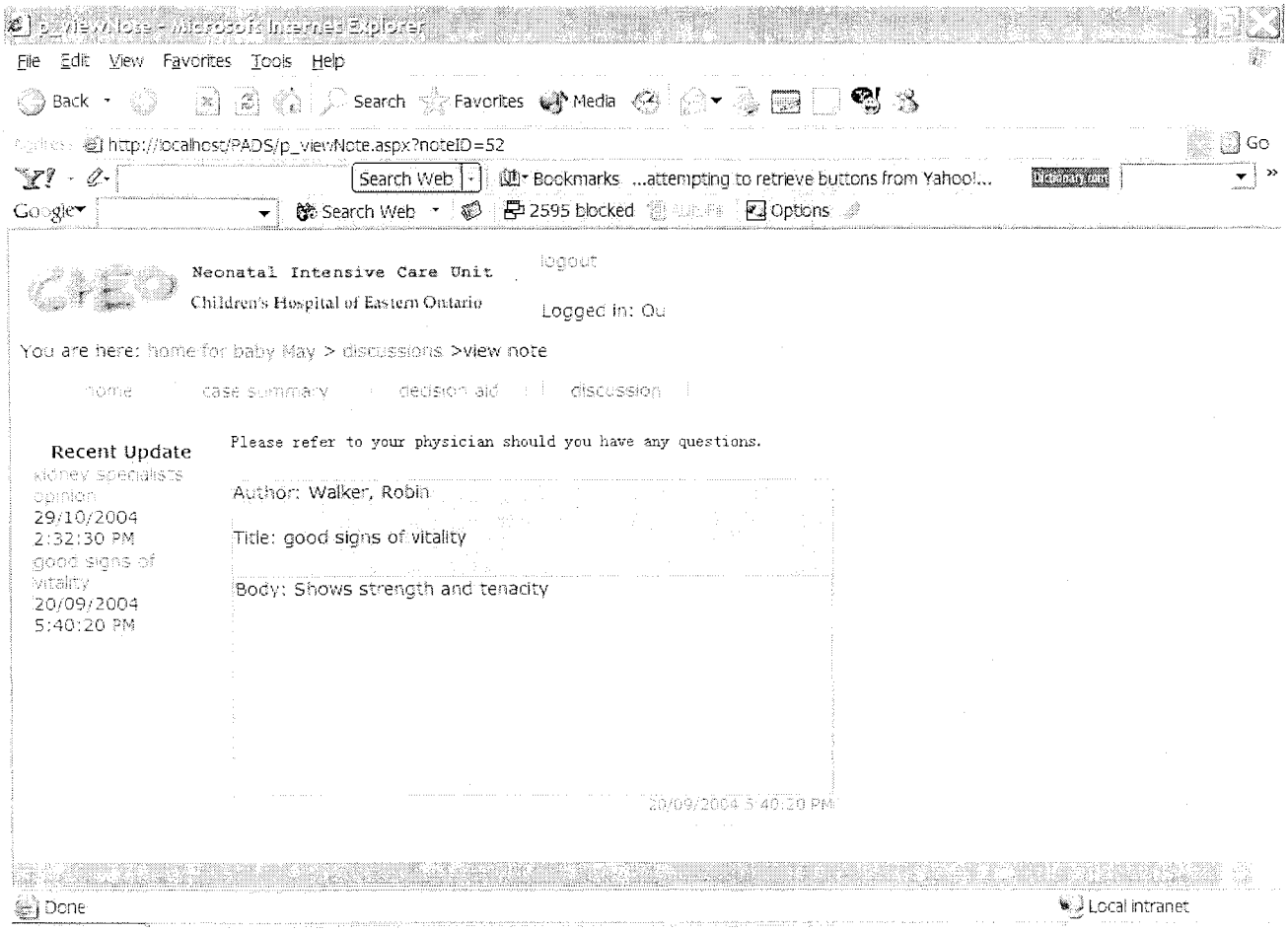

Figure 9-Q: Prototype (3): Team Communication

Appendix V Evaluation Questionnaire for PADS Prototype

Table VI-9-1 Evaluation questionnaire for assessing usability of PADS for knowledge transfer

Usability Questionnaire of the PADS

The purpose of this survey is to determine whether our computerized decision support prototype (PArents Decision Support [PADS]) meets basic usability objectives and therefore has the potential to be accepted in a neonatal intensive care environment. You are asked to fill out a multiple choice questionnaire and provide your perception of possible factors influencing its use. The survey contains two parts and will take about 20 to 25 minutes to complete. The first part (2 pages) is to elicit your opinion on the usability factors of the prototype interface. The second part (1 page) is to collect group demographics for statistical purposes. Please be aware that you are not under any obligation to complete this questionnaire.

Part 1: Usability of the User Interface

The following questions are to determine the usability of the *user interface* of the tool from the perspective of usefulness of the PADS in supporting the decision-making process.

1. Your overall reaction to the PADS is:
   - ☐ Exceptional
   - ☐ Satisfying
   - ☐ Neutral
   - ☐ Frustrating
   - ☐ Unacceptable

2. The organization of information in the PADS is:
   - ☐ Very clear
   - ☐ Moderately clear
   - ☐ Somewhat confusing
   - ☐ Very confusing

3. For you to recognize the meaning of the category label in the PADS is:
   - ☐ Very easy
   - ☐ Moderately easy
   - ☐ Somewhat difficult
   - ☐ Very difficult

4. The terminology related to tasks in the PADS is:
   - ☐ Always related
   - ☐ Mostly related
   - ☐ Sometimes related
   - ☐ Never related

5. Using the PADS to perform tasks assigned is straightforward:
   - ☐ Always

- ☐ Most of the time
- ☐ Sometimes
- ☐ Never

6. Remembering names and use of commands in the PADS is:
   - ☐ Very easy
   - ☐ Moderately easy
   - ☐ Somewhat difficult
   - ☐ Very difficult

7. Do you think the PADS is designed for all levels of users?
   - ☐ Always
   - ☐ Mostly
   - ☐ Sometimes
   - ☐ Never

8. Please list any other difficulties, such as any inconsistency, inflexibility, and limitations, you encountered with using the PADS.

_____

_____

_____

_____

Usability of the PADS User Interface Continued...

Please tell us how likely or unlikely you feel of the following statements:

For you using the PADS in supporting the decision-making process:	Likely		Neutral		Unlikely
1. I can see the tool being useful in my job in the future	☐	☐	☐	☐	☐
2. Learning to operate the tool would be easy for me	☐	☐	☐	☐	☐
3. I would find it easy to get the tool to do what I want it to do	☐	☐	☐	☐	☐
4. My interaction with the tool would be clear and understandable	☐	☐	☐	☐	☐
5. I would find the tool to be flexible to interact with	☐	☐	☐	☐	☐
6. It would be easy for me to become skillful using the tool	☐	☐	☐	☐	☐

Please tell us how much you agree or disagree with the following statements:

For parents interacting with the PADS interface, the PADS will:	Strongly agree		Neutral		Strongly disagree
7. Be usable with most of the parents making a preference-sensitive decision	☐	☐	☐	☐	☐
From my perspective, the PADS will:					
8. Enable me to see (observe) the benefits to the parents	☐	☐	☐	☐	☐
9. Be easy to experiment with before deciding to adopt it in practice	☐	☐	☐	☐	☐

Part 3: Please tell us a little about yourself

1. Your age range:
   - ☐ Under 29
   - ☐ 30 to 39
   - ☐ 40 to 49
   - ☐ 50 to 59
   - ☐ 60 and older

2. Your gender:
   - ☐ Female
   - ☐ Male

3. Your position status:
   - ☐ Neonatologist
   - ☐ Nurse
   - ☐ Social worker
   - ☐ Engineer
   - ☐ Ethicist
   - ☐ Others, specify _____

4. Your highest level of education completed:
   - ☐ Bachelor's degree
   - ☐ Master's degree
   - ☐ Doctoral degree
   - ☐ Others, specify _____

5. How well do you approach change in the workplace?
   - ☐ I am usually first in my group to find and try new ways of doing things.
   - ☐ Before I make a decision to change my approach, I like to have an opportunity to try it out first.
   - ☐ I prefer to wait until changes are pre-tested by others.
   - ☐ I usually wait until most of the "bugs" are worked out.
   - ☐ I don't really like making changes, unless I absolutely have to.

6. How long have you been working in your profession?
   - ☐ Less than 2 years
   - ☐ 2 to 5 years
   - ☐ 6 to 10 years
   - ☐ 11 to 15 years
   - ☐ 16 to 20 years
   - ☐ 21 to 25 years
   - ☐ 26 to 30 years
   - ☐ More than 30 years

Thank you for your participation. You may provide us with any additional comments on the lines below:

_____

_____

Appendix VI Palliative Treatment Plan and Consent

Patient Name: _____

Instructions: Date and Initial each appropriate box:

Treatments	Do	Try, If no Improvement, reassess	Do not do
1. Pain Medications – even if they dull consciousness and indirectly have an impact on breathing			
2. Simple Diagnostic Tests: e.g. Blood tests or x-rays			
3. Antibiotics: Drugs to fight infections			
4. Transfusions of blood or blood components			
5. Invasive Diagnostic Tests: e.g. Examining the stomach through a tube inserted down the throat			
6. Minor Surgery: e.g. Removing part of an infected toe			
7. Chemotherapy: Drugs to fight cancer			
8. Kidney Dialysis: Cleaning the blood by machine or by fluid passed through the abdomen			
9. Major Surgery: e.g. Removing the appendix or part of the intestine			
10. Help with Feeding: Giving liquid formulas intravenously (IV) or through a tube down the nose (nasogastric or NG tube) or through a hole in the stomach (gastrosnomy or Gtube) or into the intestines (jejunostomy or Jtube) to prevent malnutrition			
11. Help with Hydration: Providing salt, sugar and water solutions intravenously (IV) or through a tube down the nose (nasogastric or NGtube) or through a hole in the stomach (gastrostomy or Gtube) or into the intestines (jejunostomy or Jtube) to prevent dehydration			
12. Help with Secretions and			

Breathing: Providing oxygen (by tent, mask or nasal prongs), suctioning of the nose and throat, and positioning to ease the work of breathing			
13. Mechanical Ventilation or Respiration: breathing by machine, through a tube in the throat			
14. Cardiopulmonary Resuscitation (CPR): The use of pressure on the chest, drugs, electric shocks and artificial breathing to revive my child if his/her heart stops			
15. Other (medical resuscitation)			

PADS Acceptability and Usability Evaluation Procedure

Appendix VII Usability Evaluation Procedure

Thank you for taking the time to help us evaluate a prototype for PADS - a NICU collaborative decision support tool. This development is in an effort to improve the decision-making process for situations where there is a need to discuss with the parents the possibilities of limiting or withdrawing aggressive treatment. Please keep in mind that this research project is still at a conceptual level and the prototype you are evaluating is just a simulation of the actual tool. We merely want to demonstrate the look-and-feel for the tool, as well as to get some feedback on the usability of the prototype interface.

During the evaluation, we will ask you to visually inspect the prototype, and perform a few short simple tasks. We ask that you 'think-out loud' as you interact with the prototype. At anytime you feel like asking us a question, just go ahead. You may quite at any time should you wish to do so.

Clinician Tasks:

1. Log-in. To start using PADS, you will need to identify yourself to the tool. Your user ID and passwords is the first letter of your last name. The login screen is displayed. Enter the login and the password. Log-in with bad user name and password combination will show Error Log-in message.

2. Skim the home page. Notice that there are three areas: the top panel, the side bar, and the main content area.

3. Add New Patient. Locate the main table and find the last row. Click on the Add Patient. The addPatient page is loaded up. Click on a patient in the patient list and click on 'ok'. A confirmation page is displayed. Click on the patient workspace. The newly created patient workspace is displayed. Now click on 'home'. Now the home page is reloaded; notice the new patient added to the main table and the table in the left navigation bar.

4. View Patient Cases. Click on home. Click on the navigation panel in the left of the screen on a patient, e.g. 'ding'.

5. View patient workspace. Click on any patient (they are clickable if they are blue). Located the Team communication section and located the parent's communication section. In the Team Communication or Parents' communication sections, click on 'More'. Click on Add New to add orders or decisions.

6. View the ANN Estimates. Click on any patient. Click on the ANN. Notice the values for the ANN Estimates.

7. View case summary – Click on any patient. Click on the case summary tab. Notice the conditions and the outcomes table. Click on Add New to add new notes. View the current items.

8. View discussions – click on the discussions tab. On the discussions page, click on Add New to add clinical discussions. Notice that there's no delete command. View old discussion.

9. View most recent updates – locate the recent update table on the left panel, and click on any clickable link to the selected item display table.

10. Breadcrumb navigation – locate the navigation bar to locate the current display page and provide back links.

Parent's Tasks:
Log in as a Parent. User ID and Password is any of the following combination{ding/ding, doan/doan, ou/ou, yang/yang}

11. View the home page.
    a. User welcome page is displayed.
    b. Verify that only the baby belonging to the user is displayed.

12. View case summary. Click on the case summary tab.
    a. Patient's condition is displayed.
    b. Patient's outcome is displayed

13. View decision aid. Click on the decision aid tab.

14. View discussions. Click on the discussions tab. Add New function is available for new questions from the parents to the doctor.

Please fill out the questionnaire and provide any feedback you may have. Do you have any ethical concerns about using a system such as this in the NICU? Thank you for helping us with our evaluation.

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