Development and Usability Testing of a Neonatal Intensive Care Unit Physician-Parent Decision Support Tool (PPADS)

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Abstract

This thesis presents the development and evaluation of a computerized physician-parent decision support tool for a neonatal intensive care unit (NICU), known as Physician and Parent Decision Support (PPADS). The NICU is a specialized hospital unit that treats very-ill neonates. Many difficult care decisions are made daily for this vulnerable population. The PPADS tool aims to augment current NICU decision-making by helping parents and physicians make more informed decisions, improving physician-parent communication, increasing parent decision-making satisfaction, decreasing conflict, and increasing decision efficiency.

The development of the PPADS tool followed a five-step methodology: assessing the clinical environment, establishing the design criteria, developing the system design, implementing the system, and performing usability testing. Usability testing of the PPADS tool was performed on neonatologists and on parents of neonates who have graduated (survived) from a tertiary level NICU. The usability testing demonstrated the usefulness and ease of use of the tool.

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List of Acronyms

BPD: Bronchopulmonary Dysplasia

CDR: Clinical Data Repository

CDSS: Clinical Decision Support System

CHEO: Children’s Hospital of Eastern Ontario

CMNRP: Champlain Maternal Newborn Regional Program

DIC: Disseminated Intravascular Coagulation

DNR: Do Not Resuscitate

DSS: Decision Support System

ELBW: Extremely Low Birth Weight

EPTB: Extremely Preterm Birth

GQM: Goal-Question-Metric

IP: Interprofessional

IPDAS: International Patient Decision Aid Standards

ICU: Intensive Care Unit

IVH: Intraventricular Hemorrhage

LBW: Low Birth Weight

MeMeA: Medical Measurements and Applications

MDSS: Medical Decision Support System

MIRG: Medical Information-technology Research Group

NEC: Necrotizing Enterocolitis

NICU: Neonatal Intensive Care Unit

ODSF: Ottawa Decision Support Framework

OHRI: Ottawa Hospital Research Institute

PDA: Patent Ductus Arteriosus

PDSS: Patient Decision Support System

PPADS: Physician-Parent Decision Support

PTB: Preterm Birth

PVL: Periventricular Leukomalacia

SIRS: Sepsis / Systemic Inflammatory Response Syndrome

SQL: Structured Query Language

VLBW: Very Low Birth Weight

VPTB: Very Preterm Birth

Chapter 1: Background, Motivation and Problem Statement

This chapter provides an introduction to the thesis, including background information about the Neonatal Intensive Care Unit (NICU) environment and the motivation for this research to be conducted from the health care, engineering, human factors, and ethics perspectives. It also presents the problem statement of this thesis, the thesis objectives which are to be addressed by this work, and the resulting contributions to knowledge.

1.1 Background

The NICU is a specialized hospital unit that provides care to neonates (newborn infants). A brief introduction to the NICU environment is presented in this section, and a detailed description of the NICU environment is presented in Appendix A.

The NICU team consists of a highly specialized, multidisciplinary healthcare team headed by neonatologists. The number of births that result in the need for NICU care in Canada has been rising over the past few decades. In 2003-2004, 13.6% of newborns required NICU care, compared to 12.6% in 1994-1995 [1].

The types of neonates in the NICU are heterogeneous, including premature neonates, lower than normal birth weight neonates, and high risk neonates. Premature neonates are neonates born before 37 weeks of gestation (time in the womb) and make up approximately 75% of the population in the NICU [2],[3]. Lower than normal birth weight neonates are neonates who weigh less than 2500g. High risk neonates are neonates with congenital abnormalities, diseases, or other complications [4].

In 2002-2003, NICU care in Canada cost about 295 million dollars [1]. The cost of NICU care for one patient excluding physician fees and surgical treatments was about $1700 per day in 2002 [5]. The total cost of care including treatment costs and physician fees was just over $9700 per baby per day in 2002-2003 [1]. A study by Lim et al. was conducted on the average cost of live births in acute care facilities in Newfoundland and Labrador, Ontario, Manitoba, Saskatchewan, and British Columbia in 2005-2006. The total cost of care for neonates ranged from \$117,000 for newborns weighing less than 750g to \$1,000 for newborns weighing over 2500g.

1.1.1 NICU Outcomes

The NICU is a complex environment, usually containing several neonates with a wide range of medical conditions and undergoing various treatment therapies. The NICU team is faced with a wide range of medical conditions on a day-to-day basis. A few of the most common neonatal conditions include: intraventricular hemorrhage (IVH), seizures, apnea, brain death, periventricular leukomalacia (PVL), pneumothorax, bronchopulmonary dysplasia (BPD), patent ductus arteriosus (PDA), and necrotizing enterocolitis (NEC). A brief description of each of these medical conditions can be found in Table 28 of Appendix A. A few of the most common treatment therapies used in the NICU include: artificial nutrition, artificial ventilation, catheters, chest tube drainage, and transfusions. A brief description of each of these treatment therapies can be found in Table 29 of Appendix A.

There is a lot of uncertainty in the short-term and long-term outcomes of NICU neonates. The possible outcomes of neonates in the NICU include death, morbidity (survival with disability), and intact survival (minor or no disabilities) [6].

Researchers have shown general trends of decreasing birth weight and gestational age resulting in a lower probability of survival and a higher probability of short term and long term morbidity [7],[8]. Numerous researchers have shown negative long term effects of LBW and PTB. A long term study of extremely low birth weight (ELBW) children by Taylor et al. showed that families of children who weighed less than 750g at birth experienced greater stress than families of full term children [9]. Hack et al. compared 242 very low birth weight (VLBW) neonates with 233 normal birth weight neonates. The study showed that VLBW infants in the NICU had a lower graduation rate from high school with 74% graduating by age 20 compared to 83% of normal weight babies. The NICU survivors also had a lower mean IQ of 87 versus 92, and a lower academic average [10]. Saigal et al. found that ELBW teenagers continue to function significantly worse intellectually and on other achievement measures compared to higher birth weight babies. The study showed that achievement scores of teenagers who had a birth weight of less than 750g was less than half of the normal range [11].

1.2 Motivation

The motivation for the development of a NICU decision support tool comes from the areas of healthcare, engineering, human factors, and ethics.

1.2.1 Healthcare Perspective

Over the past few decades, there have been significant advances in the field of healthcare technologies and in the field of decision support systems (DSSs). However, the use of DSSs in the health care field has been limited. Although the development of medical decision support systems (MDSSs) has been limited, numerous studies have shown that they have the potential to significantly improve patient care [12],[13]. In order to realize the full potential of a health care system, there is a need for the development of MDSSs [14].

There has been a great increase in scientific knowledge in health care, with advances in pathophysiological understanding, data acquisition technologies, and development of therapeutics, medical devices, and medical instruments. As a result of these advances, patient care has significantly improved in many areas of health care [14].

The NICU is a fast paced, high-tech environment that has evolved from the development of many new technologies. There are infants being treated who are at the edge of viability and would not have had a chance of survival a few decades ago. With this new technology, the same trends in NICU care are still seen, where greater birth weight and gestational age result in a greater chance of survival, but the survival at any given gestational age and birth weight has increased [15],[16]. Unfortunately, as a result of increasingly aggressive care to reduce mortality, the incidence of morbidity and the length of hospital stay of infants who do not end up surviving have been increasing [14],[16],[15],[17],[18].

These trends of increasing survival, increasing severe complications, and increasing length of stay of non-survivors have resulted in new neonatal care issues. The main issues that have been brought about are the allocation of resources, the appropriateness of intervention, and the ethical dilemmas involved with treatment decisions.

The first issue is the allocation of resources. Critical neonates at the edge of vitality usually require extended hospital stays with a high risk of death and other complications. This is very costly and results in limited NICU space. With an increasing length of stay of non-survivors, overfilling of the NICU occurs, resulting in less individualized care for each infant and a shortage of NICU equipment. The second issue is the appropriateness of care. Extremely ill infants who previously would have had no chance of survival are being treated despite increasingly high risks of severe complications, including long-term neurological, cognitive and behavioural problems, as well as the chance that death will still occur after long, intense, and potentially painful treatment. What treatment is appropriate and warrants the risks is a difficult decision, which must nonetheless be made. The third issue is the ethical dilemmas involved with making difficult care decisions about very ill neonates. These ethical decisions must be made in the best interest of the neonate. However, the best decision is often not clear and depends on personal views, opinions, and beliefs [19],[5],[20],[21].

As healthcare is moving towards shared decision-making, patient empowerment, and family-centred care, parents of neonates in the NICU are more involved in making difficult care decisions. Participation in making these decisions can be overwhelming and confusing for parents. Studies have shown that parents feel physically and emotionally overwhelmed, confused and intimidated by the high-tech NICU environment and complexity of the infant's care, and often feel they do not have enough information to make an informed decision. As a result, many NICU parents are filled with guilt, regret, or uncertainty, leading to a general dissatisfaction with the decision-making processes. Numerous literature sources have established the need to aid physicians and parents in making difficult collaborative care decisions. Researchers have shown that currently parents turn to the Internet to augment information provided by hospital staff. A study by Brazy et al. showed that during the first week of their neonate's life, more than half of parents of premature infants spend at least 20 hours seeking information [22]. The development of a decision-aid can help guide parents and provide them with reliable information to aid in making difficult care decisions [14],[21].

From a health care perspective, the development of a MDSS for the NICU may increase the quality of care by aiding physicians and parents in collaborative decision-making. A NICU physician-parent decision-aid for making difficult care decisions may result in more ethical decisions, more informed decisions, better physician-parent communication, less decisional conflict, less parent guilt, less parent regret, less parent uncertainty, and higher parent satisfaction. Additionally, the development of a decision-aid may increase the efficiency of the decision-making process, which could in turn help with the better allocation of resources.

1.2.2 Engineering Perspective

There have been significant advances in engineering technology over the past few decades. In the medical field, engineers have been involved with the development of new medical instruments and devices that increase the quality of patient care. In the business field, engineers have developed many DSSs that aid in assembling raw data, business models and other knowledge. There is a wide variety of commercially available decision support tools ranging from tools that aid in making complex decisions about life-cycle cost analysis to tools that aid in deciding what type of paper a company should buy [23].

The development of MDSSs which consist of both clinician and patient decision support tools is still in its infancy. There is a vast amount of research and data available that can be used to make tools for both parents and physicians to aid in various aspects, from clinical diagnostics to care decisions. Engineers are able to take this data and express the information in an intelligent way.

Early clinical decisions support systems (CDSSs) have been designed to assist clinicians at the point of care and have been developed for various clinical environments since the early 1970s. More recently, DSSs, known as patient decision support systems (PDSSs), have also been developed for patients themselves [24]. However, the acceptance and deployment of these MDSSs has been limited. Numerous literature sources have attributed this lack of adoption to additional barriers that must be addressed by engineers before successful adoption can occur. Key concerns include patient privacy, confidentiality, and the ability of the MDSS to fit into the workflow of physicians and of other healthcare personnel [25].

From an engineering perspective, the development of a NICU DSS that can be successfully deployed in a clinical environment would contribute to knowledge in the field of engineering MDSSs, and aid in the development of future MDSSs.

1.2.3 Multidisciplinary Perspective

Motivation for the development of a MDSS for the NICU can also be found in the fields of human factors and ethics.

The field of human factors is concerned with applying knowledge about human capabilities to the design, development, and adoption of systems. From a human factors perspective the development of a tool that aids in the workflow and accomplishment of tasks in a non-strenuous manner would be a great contribution to knowledge. The knowledge gained from the usability of the PPADS tool can help human factor engineers better understand human capabilities during high stress decision-making.

NICU care decisions are filled with uncertainty and are made on behalf of a vulnerable population. These decisions depend on one's views and beliefs, so ethical decision-making is very important. From an ethical point of view, the development of a system to aid in making an ethical decision that aligns with one's beliefs and views is a motivation for the development of a MDSS for the NICU. The knowledge gained about the ability of the PPADS tool to aid in ethical decision-making may help in further understanding the ethical dilemmas that are present and may aid in future development of other ethical DSSs [26].

1.3 Problem Statement

The Medical Information-technology Research Group (MIRG) at the University of Ottawa and Carleton University has been involved with the development of MDSSs since the early 1990's. This thesis continues on work conducted by previous MIRG group members, including Lan Yang, Stuart Tozer, Daphné Townsend, and Jeff Gilchrist. Lan Yang previously worked on an early conceptual architecture of a NICU DSS. Lan Yang developed a simple semi-functional prototype using Visual Basic and Microsoft Access, which was evaluated by physicians at the Children’s Hospital of Eastern Ontario (CHEO) in a short usability study. The physicians expressed their interest in the further development and the need for a NICU decision support tool. Stuart Tozer was involved with the early system design of a NICU decision support tool. Daphné Townsend worked on the ability to predict NICU clinical outcomes, such as the risk of mortality and various diseases, using archived data. Jeff Gilchrist developed a clinical data repository which collects real time streaming data from neonates in the NICU at CHEO, and is currently working on developing real-time predictions for mortality and various other diseases using this data [27],[28],[29],[30],[31].

This thesis involves the development and evaluation of a fully functional computerized physician-parent decision support tool, known as PPADS, that aids in making difficult care decisions in the NICU. The PPADS system is comprised of a clinician tool and parent tool. The system aims to aid in making more ethical decisions, more informed decisions, improve physician-parent communication, decrease parent guilt, decrease parent regret, decrease parent uncertainty, increase parent satisfaction, decrease physician-parent conflict, and increase decision efficiency.

1.4 Thesis Objectives

The overall goal of this thesis is the development of a physician-parent decision support tool. The decision support tool should provide information about the neonate to both the physician and the parents. The tool aims to help parents to be more informed, better understand the complex NICU environment, better understand the current condition of their neonate, make ethical decisions and improve physician-parent communication.

There are three objectives that must be completed in order to achieve this overall goal. The first objective is to establish a need for the development of a NICU decision support tool, establish a framework for the development of the tool, and establish the design criteria, guidelines, system design and system architecture that will be used throughout the developmental life cycle of the tool.

The second objective is the development of a parent decision support instrument that aids parents in making the difficult care decision of whether to change the direction of care for their neonate. The decision support form should help parents understand the decision which must be made and the available options, feel more certain about their decision, understand how their values and beliefs affect the decision, and feel more satisfied about the decision.

The third objective of this thesis is the design and execution of a usability study to determine the usefulness and ease of use of the PPADS tool. The usability study was conducted on parents who have had a child who graduated (survived) from the NICU at CHEO within the last year, and on neonatologists currently working at CHEO. The data collected from this study was used to perform an initial evaluation of the PPADS tool's ability to aid parents in ethical decision-making, aid parents in feeling more informed, improve physician-parent communication, decrease decision uncertainty, and increase satisfaction.

1.5 Contributions to Knowledge

The first contribution to knowledge is the development of a physician-parent decision support tool that provide personalized information about the neonate to both the physician and parents, aids parents in feeling more informed, aids parents in understanding the complex NICU environment, aids parents in understanding the current condition of their neonate, and improves physician-parent communication. The results of the usability test show the usefulness, effectiveness, efficiency, acceptability, and satisfaction of the PPADS tool.

The second contribution to knowledge is the design and development of the change in direction of care decision support instrument, which aids parents in making the difficult care decision of whether to change the direction of care for their neonate. The results of the usability test show the usefulness and ease of use of the change in direction of care decision support instrument.

The third contribution to knowledge is the design of a five-step framework for developing the PPADS tool. This framework can be applied to the development of other decision-aids.

The fourth contribution to knowledge is the development of two sets of design criteria. The first set of design criteria aims to increase the likelihood of successful adoption of a MDSS. The second set of design criteria aims to ensure that the tool meets the decision-making needs of parents of neonates in the NICU.

The fifth contribution to knowledge is the design and execution of the usability study to determine the usefulness, efficiency, effectiveness, acceptability and satisfaction of the PPADS tool. The usability study provided a wealth of information about parent decision-making in the NICU and the PPADS tool.

Finally, this thesis work resulted in the publication of three papers. The first paper, entitled "Suggested Criteria for Successful Deployment of a Clinical Decision Support System", was presented and published at the IEEE International Symposium on Medical Measurements and Applications (MeMeA) on April 30th, 2010 [25]. The second paper, entitled "Combined Physician-Parent Decision Support Tool for the Neonatal Intensive Care Unit", was published at the IEEE International Symposium on Medical Measurements and Applications (MeMeA) on May 30th, 2011 [32]. The third paper, entitled "Development and Usability Testing of a Parent Decision Support Tool for the Neonatal Intensive Care Unit", will be presented and published at the 33rd Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC '11) on August 30th, 2011.

1.6 Thesis Outline

Chapter 2 provides a detailed literature review of NICU decision-making, ethics in the NICU, decision-making in health care, current MDSSs, DSS development frameworks, system architectures, and usability testing.

Chapter 3 details the five-step methodology used for the development of the PPADS tool. The first step is assessing the clinical environment; the second step is establishing the design criteria; the third step is developing the system design; the fourth step is implementation with expert input; and the final step is usability testing.

Chapter 4 presents a discussion of the results from the development and usability testing of the PPADS tool. The results are presented in two sections: implementation results, and usability testing results.

Chapter 5 presents the conclusions made as a result of this work, the contributions to knowledge, and future work.

Chapter 2: Literature Review

This chapter provides a review of the literature pertinent to this work. The literature review explores decision-making in the NICU, ethics in the NICU, shared decision-making in health care, parent decision-making in the NICU, decision-making conflicts, decision-aids in health care, current physician-parent NICU decision-aids, DSS frameworks, current patient decision support systems in medicine, architecture of computerized decision support systems, and usability testing.

2.1 Decision-Making in the NICU

There are numerous difficult decisions that must be made about the care of neonates in the NICU on a daily basis, including what medications to administer, how much medication to administer, and whether or not to perform surgery. One of the most ethically difficult and important decisions in the NICU is deciding if a change in the direction of care should be undertaken.

There are four main directions of care in the NICU: full active care, non-escalation of care, do not resuscitate (DNR) order, and withdrawal of life support. A brief description of each direction of care is provided in Table 1.

Table 1. NICU directions of care.

Direction of Care	Description
Full, active care	This involves continuing and adding all available and necessary invasive and non-invasive treatments in an attempt to cure the baby's medical conditions.
Non-escalation of care	This is a change in the focus of care for the infant. Instead of providing full, escalating treatment with the goal of curing a baby's medical conditions, it involves continuing all treatments that are currently in place, but not providing any escalation of care or any new treatment options. This care option is provided when the team is very likely to provide palliative care to the baby but is not withdrawing life support yet. It is often accompanied by a Do Not Resuscitate (DNR) order.

Do Not Resuscitate (DNR) Order	This is a plan that involves not providing a full resuscitation in the event of a severe cardiac (heart) or pulmonary (lung) deterioration. It involves not providing cardiopulmonary resuscitation (CPR) or chest compressions to the baby, not providing injections of medications to restart the heart, but instead keeping the baby comfortable while notifying the parents of the event and waiting for their arrival at the bedside.
Withdrawal of life support / palliative care	This is a change in the focus of care for the infant. Instead of providing full, invasive treatment with the goal of curing a baby's medical conditions, it involves the removal of invasive and often painful life support technology with the aim to keep the baby comfortable while accepting that the baby will likely die.

Numerous researchers have shown that a change in the direction of care in the NICU environment is not uncommon. Cook et al. conducted a study of 122 neonates who died at the University of Pittsburgh’s School of Medicine. The study showed that 80% of deaths in the NICU were the result of a decision to limit, withhold, or withdraw life support [33],[34]. A retrospective study conducted by Ryan et al. looked at the modes of death in the NICU at the University of Alberta Hospital between January 1st and December 31st of 1991. The mortality rate in the NICU was 75/1333, or 5.6%. Withdrawal of therapy was found to be the most common cause of death, accounting for 69% of deaths; death after no-CPR orders accounted for 17% of deaths; and failed cardiopulmonary resuscitation accounted for 13% of deaths. The study concludes that both withdrawals of therapy and no-CPR orders are an important part of the current clinical practice in the NICU, and are not uncommon [35].

2.1.1 Ethics in the NICU

All NICU decisions should be made in the best interest of the neonate. However, what is in the best interest of the neonate is not always obvious. There are many factors that must be taken into account, including the neonate’s chance of survival, the neonate’s pain and suffering, and the neonate’s short-term and long-term quality of life. Ethical decision-making in the NICU is centered on four main principles:

- Beneficence: The principal of beneficence is the duty to do good both individually and for all. This involves doing the most good possible for the baby.

- Nonmaleficence: The principle of nonmaleficence is the duty to cause no harm both individually and for all. This involves doing no harm, or causing minimal harm/suffering.
- Justice: The principle of justice is the duty to treat all fairly.
- Autonomy: The principle of autonomy is the duty to maximise an individual's right to make their own decision. Since the neonates cannot make their own decisions, autonomy is passed on to the principal decision maker (parents or legal guardian).

The decision maker is faced with the difficult task of deciding what is in the best interest of the neonate, by maximizing beneficence and minimizing nonmaleficence, while ensuring that the decision is not influenced by race, ethnicity, ability to pay, or other factors (justice).

The debate between the quality of life and the sanctity of life plays a major role in the difficult and not uncommon NICU decision of changing the direction of care [36]. This ethical dilemma depends on personal beliefs and opinions. Some believe that with current NICU trends towards higher risks of morbidity and longer NICU care of non-survivors, in many cases, the pain, suffering and poor future quality of life does not justify the use of aggressive treatment. They suggest that technology has taken control; and that in many cases, what can be done, rather than what should be done, is being looked at. Silverman suggests that we are being lured on to a "treatment train" which is hard to get off, even when the outcome is very likely to be futile, and therefore could result in unnecessary suffering. Others believe that survival of the infant should be the ultimate goal. They believe that if there is any chance of survival, all possible treatment methods should be used [37].

A very famous case which shows the difficulties in ethical decision-making on behalf of a neonate is the case of Baby Doe. Baby Doe was allowed to die due to the presence of a non-fatal condition that would cause mental retardation. Baby Doe was born with Down's syndrome, oesophageal astersia, and a gastrointestinal tract anomaly on April 9th, 1982. None of Baby Does' symptoms were fatal; however, without surgical correction of the esophageal astersia, he would die. The parents of Baby Doe decided to withdraw life support, but since the condition was not fatal, a national controversy ensued. As a result of this case, the Department of Health and Human Services issued guidelines preventing handicapped newborns from being deprived of life-saving therapies. These guidelines were later declared invalid. The Baby Doe case is still widely debated with some supporting the decision of withdrawing life support due to a low future quality of life, while others argue that it is discrimination against a disabled child and that the sanctity of life is most important [38],[39].

2.2 Collaborative Care and Shared Decision-Making in Medicine

There is a wide range of decision-making models in health care, ranging from a purely paternalistic approach, with the physician being the only decision maker, to a pure patient autonomy approach, where the physician presents the patient with options and odds but withholds their own opinions and recommendations to avoid influencing the patient [40],[41],[42],[43].

In recent years, decision-making in the field of health care has been moving away from the paternalistic approach, where solely the physician makes the decision, towards an approach that emphasizes the need for patient autonomy, or in the case of neonates who cannot express their own opinion, parent autonomy. Numerous research studies have been conducted on the importance of shared decision-making in medicine. In most medical decisions, the physician and patient (parent) are equipped with different knowledge. The physicians bring a vast amount of knowledge and understanding; however, they do not fully know the patient’s views, beliefs and opinions. The patient (parent) knows what is in their best interest, their views, beliefs and opinions, but they do not have the same level of understanding of the medical situation as the doctors. For this reason, most researchers agree that the best decision-making will occur when the knowledge of both the physician and parents is used. It is now widely accepted that shared decision-making is an important part of ethical health care [40],[41],[42],[43].

In a collaborative care approach, patients (parents) faced with making medical decisions are subject to being over- or under- influenced by physicians [42]. They are subject to not fully understanding the information supplied to them, not understanding how their values affect the decision at hand, and not fully understanding the risks and benefits [41]. For collaborative decision-making to be effective, it is very important that patients (parents) are well informed and understand their values and beliefs.

It is important to note that, even though one can consider the decision-making to involve only two parties, the patient (parents) and the physician, in many cases each of these parties does not represent a single person's opinion. The patients (parents) have friends, family, and coworkers influencing them with their opinions. The physicians have coworkers and consultants influencing their opinions. Additionally, there are outside factors influencing both parties' decisions, such as nurses, insurance companies, policies, and media [40].

2.3 Parent Decision-Making in the NICU

From a legal perspective, parents (or guardians) are usually considered the ultimate decision maker in the NICU environment. Parents know best the values of the family culture or environment in which the infant will be raised and have the responsibility of making difficult care decisions on behalf of their neonate. Parents are responsible for the final decision and for providing informed consent. In the case of emergency care, where there is no time to obtain consent, this right is waived. It is important to note that even though parents are considered the ultimate decision maker, there is a wide range in the amount of involvement that parents would like to have in the decision-making process. Some parents wish to be fully involved and would like to have full autonomy in making the final decision; some prefer to work in a collaborative manor with the physicians; while others prefer to agree to any decision the NICU staff make [21],[35],[43],[44].

2.3.1 Decision-Making Conflicts in the NICU

In most cases, parents and physicians are able to work collaboratively and agree on treatment decisions. However, in some cases, physician-parent conflicts arise. The most common types of conflicts arise when parents and physicians do not agree on the direction of care, or when parents have expressed their views on the direction of care, but in an emergency situation, doctors did not follow the parents' wishes. If parents and physicians do not agree on a decision that must be made, or if parents do not agree with a decision that was made by the physician, the court is involved [38].

Some of the more publicized NICU conflicts that required court decisions include the Miller case and the Baby K case. In the case of Miller versus the hospital, the Millers sued the hospital because their daughter was treated without their consent. Sidney Miller was born at 23 weeks gestation and 615g in 1990. Due to the low probability of the survival the parents decided they did not want the baby resuscitated at birth. However, despite their wishes, resuscitation was performed at delivery. Sidney grew up to be severely handicapped. At the trial court, the Millers were awarded a total of 60 million dollars. This verdict was later overturned by the appellate court, which ruled that the parents did not have the right to refuse consent for resuscitation in the emergency situation. The court stated that during the emergency situation, the physician did not need the consent of the parent to perform the resuscitation. The court also reiterated that during NICU care, parent consent is required and a court order must be obtained before treatment proceeds; however, this does not apply to emergency care situations [38].

In the case of Baby K, the doctors of Baby K did not agree with the mother's decision to continue intubation and mechanical ventilation. Baby K, was born on October 13th, 1992 with anencephaly, a neural tube defect that leads to brain development abnormalities. Due to the grim prognosis, doctors recommended that Baby K be moved to a palliative care model. Based on firm religious beliefs, the mother insisted the baby receive mechanical ventilation. The staff did not agree with this decision and the hospital tried to transfer the baby to another facility. However, this transfer was unsuccessful. The doctors felt they were providing ethically inappropriate care and sought judicial intervention to allow for a stop in treatment. In this case, the court sided with the mother, and the hospital was obliged to provide care to Baby K. Baby K spent many months in intensive care and ended up dying of cardiac arrest after vigorous resuscitation failed at the age of 2 years, 174 days [38].

Although most cases are not as high profile as the Miller and Baby K case, conflicts about a change in the direction of care between physicians and parents are not uncommon. A research study conducted by Kopelman found that most conflicts between parents and physicians resulted from inadequate communication between the medical team and the parents. The article stresses that the majority of conflicts could be resolved if the physicians were able to better understand the parents' values and beliefs, if the parents were given more information about their baby's current state and risk predictions, and if physicians understood why parents were not agreeing with their recommendations. The paper concluded that in most cases, parent and physician conflicts can be resolved by better communication and could be mitigated by the development of a NICU decision support system [34].

2.4 Decision-Aids in Health Care

CDSSs which aid clinicians in making decisions at the point of care have been developed since the early 1970s. There are many different types of CDSSs, differing by the timing (provide information before, during, or after a clinical decision has been made); they can be active (provide alerts) or passive (respond to physician input); the information can be general or specialty based; and the system can be knowledge or non-knowledge based [45]. There are four main types of CDSSs: alerting systems, critiquing systems, suggestion systems, and retrospective quality assurance systems. Alerting systems continuously look at clinical data and respond with an alert. Critiquing systems respond to recorded decisions and suggest alternative care if appropriate. Suggestion systems respond to a request by the decision maker by suggesting a set of diagnostic or therapeutic manoeuvres. Retrospective quality assurance systems abstract data from patient records and summary decisions and provide this information to the caregiver [46].

The development of patient decision-aids has only flourished in the last decade. In 1999, there were only 15 patient decision-aids available, but by 2006, there were more than 500 patient decision-aids available. There are many forms of patient decision-aids ranging from paper-based aids to computerized PDSSs [24],[43].

Patient decision-aids are designed to aid patients in making care decisions and should supplement, rather than replace, conventional patient-practitioner interactions. Patient decision-aids can provide patients with a better general knowledge about the options, benefits, risks, and probability of different outcomes. They can also make patients feel more certain about decisions, make patients feel clearer about their values and beliefs, provide information tailored to the patient's medical profile, and emphasize choice and shared decision-making [47],[43]. Numerous researchers have shown the effectiveness and feasibility of decision-aids. It has been shown that patient decision-aids provide patients with more knowledge and more realistic expectations, help to involve the patient in shared decision-making, aid in the agreement between values and choices, and decrease decisional conflict [43],[48],[49].

2.5 Current Physician-Parent NICU Decision-Aids

Currently, most NICUs provide parents with access to books, pamphlets and consultations to aid in making care decisions. Other novel suggestions of decision-aids for parents, which are being used in some NICUs, are soft cards, pre-delivery counselling and PDSSs.

Books and pamphlets can provide information about different conditions, the NICU environment, and treatment options. They have been shown to relieve parents' anxiety and provide an alternative access to information. One example is the use of a parental pamphlet developed by Whaley et al. entitled "A Sign of Hope", which introduces the parents to the NICU environment before their neonate arrives there [50]. Pamphlets have been shown to aid parents by providing written, pictorial and graphical descriptions; however, their use is limited, as the information provided is very general, they are not interactive, they are not adaptable to each individual case, and they can be cumbersome to use when looking for a specific piece of information.

NICU consultations provide parents with the bulk of their knowledge. Parents are provided a vast amount of information during daily consultations, including information about their baby's current conditions, current treatments, outcome probabilities, and decisions that must be made. Several limitations of consultations have been identified in literature – mainly parents feeling overwhelmed and finding it difficult to understand and absorb the information provided.

Soft cards are being used in some NICU environments. Soft cards help parents prioritize their perceived information needs. The cards help parents to identify points that are important to them, which they can discuss with nurses and doctors during their consultations. The benefit of using soft cards is limited since they only provide very general information [21].

Allen and Saunder et al. have suggested that parent decision-making may be augmented by pre-delivery counselling. This decision-making method attempts to reduce the impact of stress on the decision, by conducting the decision-making process before delivery. This method would be beneficial if preterm delivery and other complications could be predicted with a high degree of accuracy; however, numerous literature sources have shown that this is not currently possible. Therefore this method is currently not feasible and would add unnecessary stress to many pregnancies [21]. Ongoing work by the MIRG succeeded to predict preterm births using data collected prior to week 23 of gestation, with similar performance to invasive fibronectin testing: 66% sensitivity and 84% specificity [51]. There is hope that in the future, pre-delivery counselling can be added to aid in decision-making.

Computerized PDSSs are currently rarely seen in the NICU environment. However, they have the potential to significantly increase parent knowledge and aid parents in making difficult care decisions. Computerized DSSs have the ability to provide personalised information to the parent on the current conditions, current treatments, and outcome predictions for their neonate. Additionally, they can aid parents in decision-making, they can help parents take into account their own beliefs and priorities, and they are adaptable to each individual case [6],[21]. PDSSs have the potential of providing information in written and pictorial representations, which may be easier for parents to understand and absorb. The only parent system for the NICU found in literature is a system developed by researchers at Harvard Medical School and the Beth Israel Deaconess Medical Center, known as Baby CareLink.

2.5.1 Baby CareLink

Baby CareLink is a commercially available Internet-based telemedicine system [14]. The Baby CareLink system aims to reduce the cost of care and provide enhanced medical information and emotional support to families of very low birth weight (VLBW) infants during and after their NICU stay. The Baby CareLink tool enhances interactions between families, staff, and community providers [52],[14].

The Baby CareLink system was created by a team of neonatologists, nurse practitioners, respiratory therapists, social workers, child life specialists, and software engineers. The system provides six major modules: daily clinical report, message center (allows the parent to compose a private message to the medical team), see your infant (allows the parent to view daily pictures taken by nurses), family room (contains answers to common questions and information about available resources), clinical information section, and a section focused on preparation for discharge. A videoconferencing module is also available and allows for virtual visits and distance learning while the neonate is in the NICU, and for virtual house calls and remote monitoring after discharge. The Baby CareLink system does not provide outcome predictions or decision support instrument to aid parents in decision-making [52].

Gray et al. evaluated the Baby CareLink tool in a randomized trial of VLBW neonates born between November 1997 and April 1999. It was found that the users of the CareLink group reported higher overall quality of care. Gray found that the visitations, telephone calls to the NICU and holding of the infant did not differ between parents who used the Baby CareLink tool and parents who did not. The duration of hospitalization also did not differ. However, from this study, it was concluded that the CareLink system improves family satisfaction with VLBW neonate care [52].

2.6 Development and Evaluation of Patient Decision Support Tools

Despite being in its infancy, there is much literature available on the conceptual design, development, implementation, and evaluation of PDSSs. There are several decision support frameworks available in literature. The two main frameworks that apply to the development of a parent NICU decision support tool are the Ottawa Decision Support Framework (ODSF) and Ruland and Baken's Framework.

2.6.1 Ottawa Decision Support Framework

The ODSF has been used to develop and evaluate more than 30 patient decision-aids designed to guide patients in making health or social decisions. It is based on general psychology, social psychology, decision analysis, decisional conflict, social support, and economic concepts of expectations and values [53].

The ODSF was designed by the Ottawa Hospital Research Institute (OHRI) and is shown in Figure 1. The ODSF details that the decisional needs, such as knowledge, values, support and uncertainty will affect aspects of the decision, such as quality, delay and regret. The framework also shows that decision support in the form of clinical consultation, decision tools and coaching can improve decision quality [53].

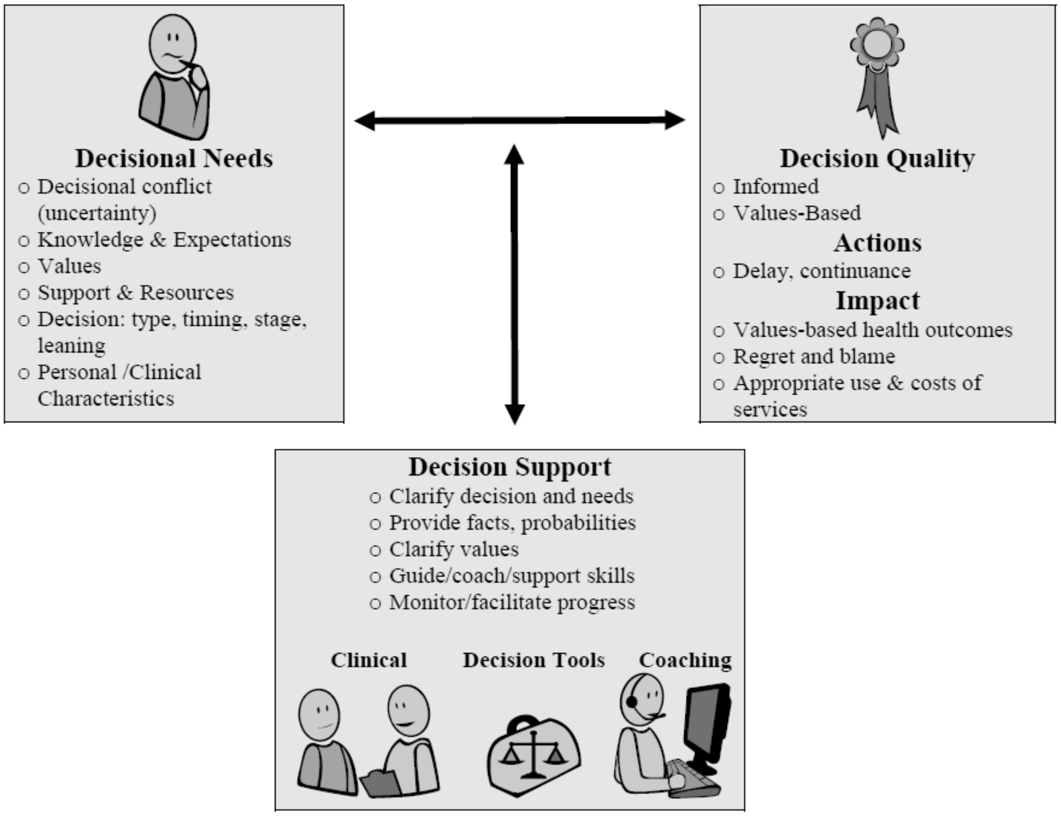


Figure 1. Ottawa Decision Support Framework [53].

The ODSF suggests using a three-step process for the development of PDSSs.

Step 1. Assessment of physician and patient decision support needs.
Step 2. Development of a system to provide decision support tailored to needs.
Step 3. Evaluate decision-making process and outcomes.

The ODSF outlines several evaluation criteria which can be used to evaluate patient decision-aids, including acceptability, decision regret scale, decision conflict scale, knowledge, decision/choice predisposition, realistic expectations, and stage of decision-making.

2.6.2 Ruland and Bakken's Patient Decision Support Framework

Another conceptual framework in literature is Ruland and Bakken's decision support framework, which is based on the need to integrate information from four areas: [54]

1) The clinical domain for understanding of the decision problem including the risks, treatment options, benefits, and harms.
2) The theoretical domain for understanding the techniques to elicit patient preferences.
3) The medical informatics domain to provide the technology to collect, process, structure, present, and integrate information.
4) The organizational knowledge domain to adapt the system into the work flow.

Ruland and Baken established an eight-step process to be followed when developing PDSSs.

Step 1. The first step is to clearly identify the clinical decision problem and confirm the need for a decision-aid for patient preferences.

Step 2. The second step is to clearly identify the system's purpose. This includes doing a literature review to ensure that a similar system does not already exist, and ensuring there is a need and a benefit of the system. Possible benefits include: better knowledge of options, more realistic expectations, better understanding of personal values, reduced decisional conflict, and increased satisfaction.

Step 3. The third step is to define the dimensions of the decision. The dimensions of the decision refer to what information is required to make the decision.

Step 4. The fourth step is selecting a measurement technique for eliciting patient preferences. From a cognitive perspective, there are many different theories of what occurs during decision-making. A common cognitive theory that can be applied to decision-making in the NICU is image theory. In image theory, the decision maker is viewed as a manager of knowledge. A decision maker's principles and goals are considered as three images: the value image, the trajectory image, and the strategic image. The value image contains the values, morals and principles and is used to guide decisions. The trajectory image describes what goal the decision maker wants to achieve. The strategic image uses a minimization strategy to align the trajectory image goals with the current situation, while not violating the values image. It has been shown that during decision-making, parents are likely to muddle together the different images and confuse their values, goals, and plans [21].

Helping patients understand how their views and values affect their decision is one of the most important aspects of a good DSS. Eliciting patient opinion can be done in many different ways, including decisional questions, standard gamble, the time trade-off, the probability trade-off, magnitude estimation, willingness to pay, and a rating scale. The most common methods used are rating scales and decisional questions, since they are easy to administer, and studies have shown they are as valid as any other method. Rating scale methods are based on psychometric approaches and use different types of rating scales or ranking scales, such as Likert-type scales, to aid in understanding how one's views affect the decision at hand. Asking decisional questions such as why one is doing something can be used to elicit the principles that motivate the behaviour; asking what one is doing can be used to elicit their goals; and asking how one is doing it can be used to elicit their plan [54].

Step 5. The fifth step is to validate the measurement technique, which refers to ensuring that the most up-to-date information is being used.

Step 6. The sixth step is to determine the application platform. This involves deciding on the computer application and algorithm used to create the DSS.

Step 7. The seventh step is to address practical implementation issues. This includes exploring the resource requirements, feasibility, acceptability and organizational issues of implementing the system.

Step 8. The eighth step is to identify the outcome measures and methods for outcome evaluation. Outcome measures include: ability to fit into the work flow, satisfaction, social support, physical functioning, and change in decisional conflict [54].

2.7 Current Patient Decision Support Systems in Medicine

There are over 500 patient decision instruments (decision-aids) currently available. Some of these decision support tools can be found online on the OHRI website (http://decisionaid.ohri.ca/AZlist.html). Two publically available patient decision support aids are of particular interest due to their similarities to the NICU decision of changing the direction of care. The first is a decision-aid entitled "Planning for critically ill patients in the Intensive Care Unit" and the second is a decision-aid entitled "Blocked tear ducts: should my baby have a probing procedure".

2.7.1 Planning for Critically Ill Patients in the Intensive Care Unit

The decision-aid entitled "Understanding the Options: Planning for critically ill patients in the Intensive Care Unit (ICU)" is a paper based tool that aids family members of adults in the ICU in making end of life decisions. Similarly to NICU change in direction of care decisions, this decision-aid deals with making end of life decisions on behalf of someone else. This decision support tool was developed by the Ottawa Patient Decision-aid Research Group in 2009. The decision support tool uses Likert rating scale questions to elicit the family's opinions and aid in understanding how these opinions influence the decisions at hand. Some limitations of this decision support tool are that it is not interactive, it highly depends on knowledge of the critically ill patient's opinion, it is not adaptive to individual cases, and it does not provide any patient specific medical information or predictions [55].

2.7.2 Blocked Tear Ducts: Should My Baby Have a Probing Procedure

The decision-aid entitled “Blocked tear ducts: should my baby have a probing procedure” is an online interactive decision tool that aids parents in deciding whether or not to probe their baby’s tear ducts. Similarly to NICU change in direction of care decisions, this decision-aid is for parents making decisions on behalf of their baby. This interactive tool allows users to navigate through step-by-step pages that provide the parents with information on the options, benefits, risks, how their views influence the decision, a quiz to check their knowledge, and a printable summary page. A major limitation of this decision-aid is that it does not take into account personal health care information and is not adaptive to individual cases [56].

2.8 Architectures of Computerized Decision Support Systems

A computer based DSS can be created using a downloadable tool or a web-based tool. The advantages of developing a web-based tool is that only a web browser is required to use the tool, and no additional software needs to be installed. Web-based systems can either run on the World Wide Web or on an internal network. The World Wide Web allows easy access from anywhere around the world; however, it is not as secure as an internal network. In both cases, the tool can be accessed on any web browser using a specific Uniform Resource Locator (URL) [57],[58].

Most web-based systems that store data use a three-layer architecture, consisting of the database tier, the middle tier, and the client tier [58].

The base layer is known as the database tier and consists of the database and database management system. This layer contains all the data that users of the system create, delete, modify and query (call). The database tier is responsible for managing the data, which includes the storage and retrieval of data, allowing simultaneous access to information, providing security, ensuring integrity of the data, and providing backups. Database management can be complex; however, the use of a database management system hides many of these complexities. A database management system is a set of components that organize, construct, store, manage, retrieve, and manipulate data in a database. Database management systems allow one to use languages, such as structured query language (SQL), to get information and manipulate the database. There are several different database management systems available. MySQL is one of the most popular database management systems because it is free and open source. It is used in many high-profile products, including Wikipedia, Google, and Facebook [58],[57].

The middle layer, or middle tier, contains most of the application logic and communicates between the other two tiers. The middle tier consists of the web server, the web scripting language, and the scripting language engine. The web server processes HTTP requests and formulates responses. The web server's basic function is to listen for HTTP requests, receive the request, serve the request, and return the HTTP response. The most common web server is Apache. Apache HTTP server is an open source web server used by more than 60% of Internet connected computers. PHP is a widely used, general-purpose scripting language that was originally designed for web development. PHP is an open source project of the Apache Foundation and is the most popular Apache HTTP server add-on, with about 40% of Apache HTTP servers having PHP capabilities [58],[57].

The top layer is known as the client tier, which consists of the web browser or interface. The web provides the protocols and network that connect the client tier (web browser) and the middle tier (web server). Hypertext Transfer Protocol (HTTP) allows resources to be communicated and shared over the web.

The middle and client tiers can be managed using a content management system. A content management system can be compared to an operating system (ex. Windows or LINUX), but for websites. One of the most common content management systems is Drupal. Durpal is a free, open source tool that is written in Hypertext pre-processor (PHP) platform, and can be used with Apache web server and MySQL databases.

2.9 Usability Testing

Usability testing on participants who are indicative of the population that will be using the tool is very important throughout the development of a computerized DSS. Usability testing aims to determine the usefulness (degree that the tool helps the users, and the degree with which the users desire to use the tool), efficiency (how fast users can accomplish their goals with accuracy), effectiveness (ease with which the users can do what they intend), acceptability (the comprehensibility and length of the tool), and satisfaction (users' perceptions and opinions of the tool) of the tool [59],[60],[61],[62].

One of the most common methods of usability testing is using the think-aloud protocol. In this method, the end users of the system are asked to verbalize their thoughts while performing a set of tasks. An observer records notes and encourages the participants to keep talking. By asking users to think aloud, insight into the user's mental process and opinions can be obtained. The best practice for usability testing involves videotaping the session for analysis; however, in some cases, due to the nature of the study, obtaining ethics approval to record participants is not always possible [59],[60],[61],[62].

There are several steps required to perform usability testing, including: understanding who will use the tool and choosing a representative set of users for testing; understanding the tasks users will perform and choosing a representative set of tasks for testing; and deciding on the measurements to be collected. One method for determining what measurements should be collected is the Goal-Question-Metric (GQM) approach. The GQM approach was developed in the 1980s by Dr. Basili and uses a hierarchal approach to developing measurements. The GQM approach has been employed by a wide variety of large companies to perform usability testing, including Philips, Siemens, and NASA [63]. The first step of the GQM approach is to define goals on a conceptual level. The second step of the GQM approach is to determine the questions that allow the goals to be traced to data that can be collected on an operational level. The final step of the GQM approach is to define a metric associated with every question that provides a quantitative answer. A schematic illustration of the hierarchical structure of the GQM approach is shown in Figure 2 [64],[65].

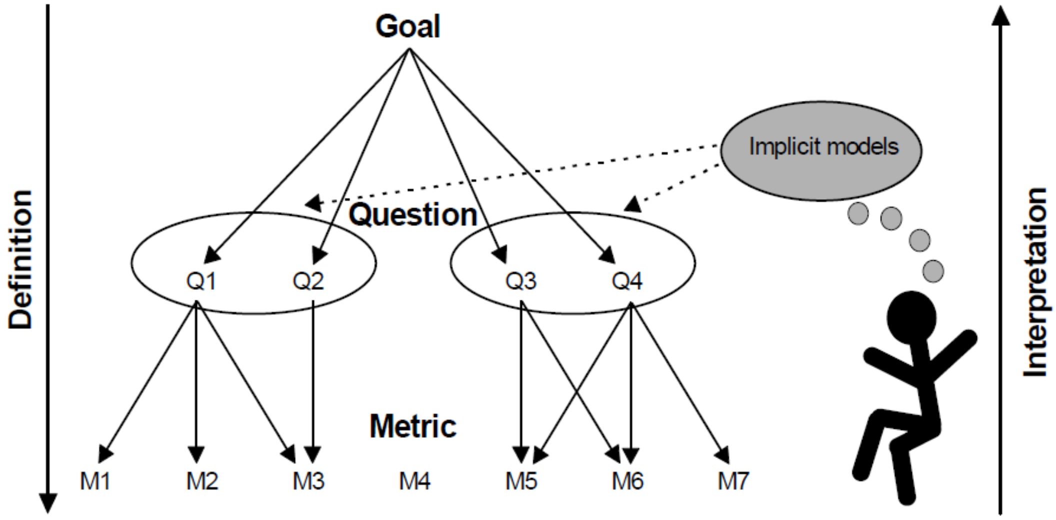


Figure 2. The Goal-Question-Metric approach to usability testing [66].

There are many usability measurements in literature that can be used for usability testing. Not all measurements apply to all types of usability testing. Some examples of measurements which can be used include: task completion rate, error rate, and various subjective measures. It is important that measurements such as completion time are only applied to applicable tasks. For example, the completion time for a user to read and digest what they have read does not depend on the usability of the tool and should not be analyzed. In contrast, completion time for navigation does depend on the usability of the tool and should be analyzed. Data collection is usually done through answers to surveys, observations, and recording of participant statements [64],[67].

The number of usability participants required for usability testing is widely debated among researchers. Some researchers believe that four participants are sufficient for a usability study, while other researchers believe that between five to eight participants are required for a good in-depth usability study. Most researchers agree that no more than 12 usability users should be used, since very little or no further benefit will come from any additional users at this point [59],[61],[62],[68],[60].

2.10 Literature Review Conclusion

The literature review in this chapter has explored the NICU environment, MDSSs, system architecture, and usability testing of computerized decision support tools. The current trends in NICU care have placed an emphasis on the need for aiding physicians and parents in making difficult care decisions. There is a need for physicians and parents to work collaboratively and for parent decision-making needs to be met. Currently, there are no NICU computerized decision tools to aid physicians and parents in making care decisions. This thesis aims to fill this void by developing and evaluating a neonatal parent-physician support tool, known as Physician-Parent Decision Support, or PPADS, which will aid physicians and parents in making ethical decisions. The methodology used in the development and evaluation of the PPADS tool is described in the next chapter.

Chapter 3: Methodology

The main goal of this thesis is the development of a physician-parent decision support tool (PPADS) to aid in making difficult care decisions in the NICU. In particular, this thesis focuses on aiding parents in making the difficult care decision of whether a change in direction of care should be undertaken. This chapter presents the methodology that was used to achieve this goal.

The methodology used for the development and evaluation of the PPADS tool followed a five-step process. The process was based on several decision support frameworks found in literature. It is most closely based on the Ottawa Decision Support Framework and Ruland and Bakken's framework, discussed in sections 2.6.1 and 2.6.2 of this thesis, respectively. A schematic representation of the five-step methodology that was used is shown in Figure 3.

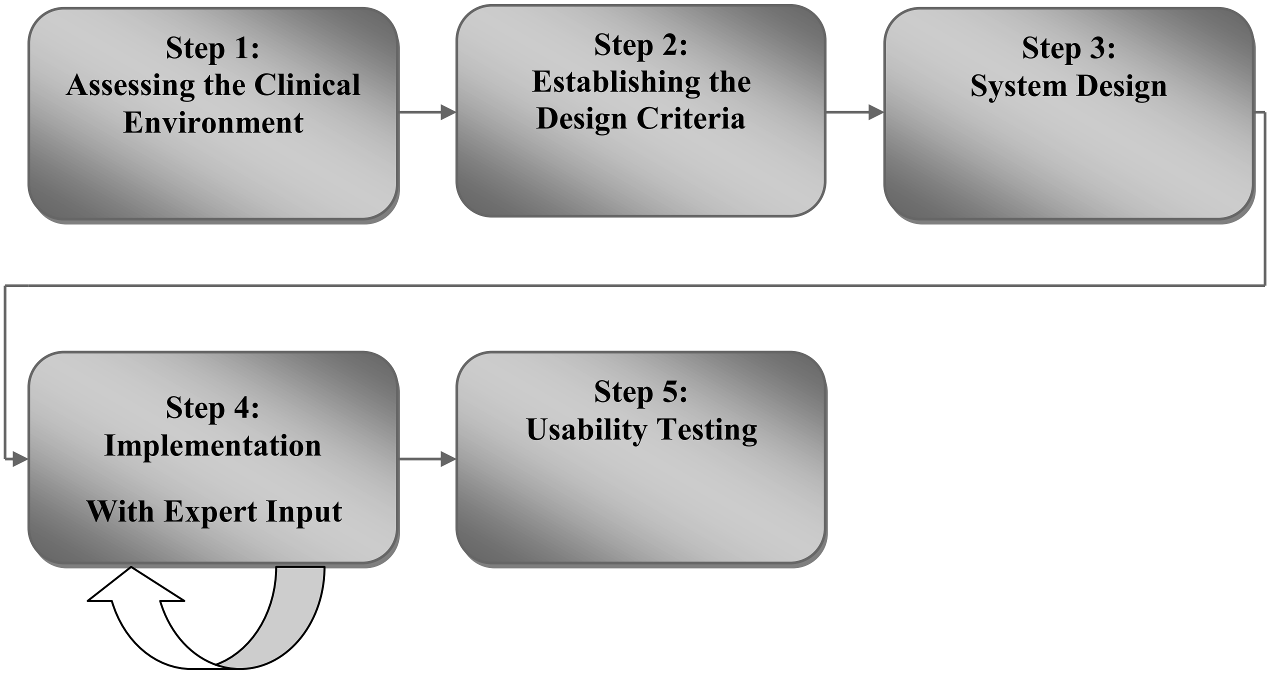


Figure 3. Schematic representation of the methodology used for the development and evaluation of the PPADS tool.

A brief description of each of the five steps is shown in Table 2. A detailed description of each of the five steps follows in sections 3.1-3.5.

Table 2. Methodology for the development and evaluation of the PPADS tool.

Step	Description
1. Assessing the Clinical Environment	This step involved increasing our understanding of the NICU environment, clarifying the process used for decision-making in the NICU, exploring the current state of the art for aiding with NICU decisions, and establishing the need for the development of a tool that aids parents in making difficult care decisions.
2. Establishing the Design Criteria	This step involved establishing two sets of design criteria that should be used throughout the development of the PPADS tool. The first set of design criteria aimed to aid in the successful adoption of the tool and the second set aimed to ensure that the tool meets the decision-making needs of NICU parents.
3. System Design	This step involved designing the system architecture, components, and interface. This involves choosing a database management system, a content management system, a web server, and various aspects of the user-interface.
4. Implementation with Expert Input	This step involved the implementation of the design criteria and execution of the system design. Throughout the implementation process, input from clinical neonatal experts was incorporated.
5. Usability Testing	This step involved the evaluation of the tool through usability testing at CHEO. The usability testing was conducted on eight parents, who have previously had a child which graduated (survived) from the CHEO NICU, and on five neonatologists currently working at CHEO. The study aimed to determine the tool's usefulness, efficiency, effectiveness, acceptability, and satisfaction.

3.1 Step 1: Assessing the Clinical Environment

The first step in the development of the PPADS tool was assessing the NICU clinical environment through a detailed literature review and several useful meetings with our collaborating clinical neonatal care experts, Dr. Erika Bariciak, a neonatologist at CHEO, and Sandra Dunn, a decision support specialist with the Champlain Maternal Newborn Regional Program (CMNRP). The evaluation of the clinical environment involved increasing our understanding of the NICU environment. This included understanding the most common NICU conditions, the most common NICU treatments, the most common NICU decisions, the various NICU outcomes, and the current trends in NICU care. It also involved determining who is involved in caring for infants in the NICU, clarifying the process used for NICU decision-making, exploring the current state of the art for aiding with NICU decisions and establishing the need for the development of a tool that aids parents in making difficult care decisions.

Chapters 1, 2 and Appendix A of this thesis describe the NICU environment. The research findings showed the need for the development of a decision support tool to aid physicians and parents in making efficient, collaborative, and ethical NICU care decisions.

3.2 Step 2: Establishing the Design Criteria

The second step in the development of the PPADS tool was establishing the design criteria. Two sets of design criteria for the development of the PPADS tool were established: general design criteria for successful adoption of a MDSS; and specific design criteria for aiding NICU parents in making difficult care decisions.

3.2.1 General Design Criteria for Successful Adoption of MDSSs

The first set of design criteria consisted of general criteria aimed to aid in the successful adoption of MDSSs. Despite the potential of MDSSs to significantly improve patient care and patient safety, their successful deployment has been limited, and in some cases, has resulted in conflict between physicians and hospital administrators. One example was the deployment of an online system for communications and records, named OSCAR, at the Foothills Hospital in Calgary. Physician and hospital administrator had a lengthy war of words after OSCAR was deployed since the physicians felt that OSCAR added a major source of stress and changed the way work was done [69].

The general design criteria developed as part of this research work were based on literature searches, conducted on both successful and unsuccessful deployments, as well as consultations with our clinical neonatal care experts.

Numerous factors that affect the successful adoption of clinical decision support systems were found in literature. Many researchers, including Dambro and Williams, cite that requiring too much manual data entry is the leading cause of failed MDSSs [70],[69]. In order for a MDSS to be successfully deployed, it is important that the tool minimize the time physicians spend entering data manually, as this will lead to greater usage and satisfaction with the system, and will help to ensure that time is not being taken from the provision of patient care [45].

Wetter and Bates et al. have found that speed is of utmost importance. They concluded that in order for a MDSS to be successfully deployed, it should require the least amount of time possible to complete a task. This includes time to logon to the system and time to acquire the desired information [71],[72],[45].

Researchers have also shown that in order for a MDSS to be successfully deployed, it is important that the tool be up to date. Since patient management is constantly changing, the MDSS can easily become obsolete. MDSSs are often created with soft funding and when the funding runs out, keeping the system up to date becomes a major challenge [45],[73].

Several other criteria have also been found to contribute to successful adoption. It is important for the MDSS to be easily accessible to those who want to use it and that the sensitive patient information is secure [45]. The MDSS must also be user-friendly, intuitive, and provide easy access to information. Bates et al. concluded that a MDSS interface works best using a single screen format, providing brief, concise questions and information [71]. Finally, in order for the system to be successfully deployed, there must be a need for the output of the MDSS. It is important that the output adds value, improves the quality of care, and/or decreases the costs of health care delivery [71],[45].

A checklist of the design criteria for aiding in the successful adoption of a MDSS was established, and is shown in Table 3. The general design criteria are divided into three main areas: input to the MDSS; human-computer interaction; and output of the MDSS [25].

Table 3. Checklist of design criteria to increase the likelihood of successful adoption.

MDSS General Design Criteria		***Answer***
Input to MDSS		
1	The tool should minimize manual data entry.	
2	It should be easy to update and perform maintenance on the tool.	

Human-computer interaction		
3	The tool should be easily accessible.	
4	The tool should have secure access.	
5	The tool should have a backup.	
6	The human-computer interaction should be speedy. The tool should respond to user requests in less than 2 seconds when pre-defined information is being displayed.	
7	The tool should allow multiple user access at the same time.	
8	The tool should be user-friendly and intuitive to use.	
Output of the MDSS		
9	The tool's output should add value to the physician and to parents.	
10	The tool should fit into the hospital workflow.	
11	The tool should be developed with expert input.	

3.2.2 Specific NICU design criteria

The second set of design criteria consisted of specific criteria aimed to meet the decision-making needs of NICU parents. The NICU is a high-tech environment that is foreign and confusing to most parents [52]. Admission of a newborn infant to the NICU is very emotionally distressing for families. From an ethical perspective, parents are owed the respect for autonomy in making decisions on behalf of the neonate and should be provided with the tools needed to make an informed decision [36]. In order for parents to make an informed decision, it is important that their decision-making needs are met. The specific NICU design criteria were established through literature reviews of NICU decision-making needs, decision-making theories, patient decision-aids in literature, and consultations with our clinical neonatal care experts.

Many factors were found in the literature that are important in facilitating parents' full involvement in decision-making. Several researchers, including Yee, Philips, and Harrison have stressed the importance of open and honest communication between parents and physicians in the NICU. It is important that parents feel as comfortable as possible in the foreign and high-tech NICU environment. Parents must be considered as part of the NICU team and need to be able to work collaboratively with nursing staff, medical staff, social services, ethicists, and the hospital’s legal counsel in making care decisions. The process should consist of two-way listening, sharing of information, answering of questions, and discussion of practical concerns [6],[21],[74].

King found that in some cases, physicians were waiting until they had reached near certainty to share the meaning of data with parents. The professional teams generally shared data on the infant’s condition with parents. However, they did not share the meaning of the data because they were waiting until certainty. When a decision was reached, the reasoning was not transparent to parents and the ability to work collaboratively was lost. Researchers suggest that the longer the professional team takes to share the meaning of the technological and perceptual data, the longer the parents spend gathering their own data from nurses, the Internet and other sources, and the wider the discrepancy between the professionals and the parents in the types of data being used to reach conclusions. Many parents become sophisticated in understanding the nature of the technological data; however, if the sharing of information is not done throughout the decision-making process, this may not be helpful [75]. Researchers have shown that currently, parents turn to the Internet to augment information provided by hospital staff. A study by Brazy et al. showed that after 4 weeks of hospitalization, more than one-third of parents perform the equivalent of a half-time job seeking information about their child. The survey was conducted on 19 parents and concluded that parents want more information about their infant’s NICU care [22].

It is important to focus on ensuring that parents are equipped with the clinical information needed to make a fully informed decision. As much information as possible should be provided to parents in the controlled clinical setting in order to minimize the amount of stressful and possibly misleading Internet research that is conducted [21],[74]. Parents need to be given information about their neonate’s condition, treatment therapies, and outcome predictions [36]. It is important that the information provided is presented to parents in an easy to understand, non-prescriptive manner. Having an infant in the NICU is a stressful and overwhelming experience for parents that can lead to isolation. The physical and technical complexities of the setting, the infant’s condition and the stress experienced by parents necessitate that information be provided to the parents in a clear and supportive way and without bias of the person conveying the information [36],[21],[75]. It is also important that parents' ability to cognitively and emotionally assess different treatments is increased by ensuring that there are no inconsistencies in the information provided, and that parents are given the opportunity to review the information [21]. Additionally, information should be provided in more than one form in order to facilitate understanding. When providing information to parents, it is important to consider that different parents have different needs due to language barriers, socioeconomic status, educational background, cultural differences, and beliefs. It is important that parents are provided with clinical information in a way they can comprehend. Different methods for communicating important information to parents include written, verbal, and graphical representations [37].

It is also important that parents are aided in understanding how their values and beliefs influence the decision at hand. In many cases, parents understand their morals and beliefs; however, they do not understand how they apply to the decision with which they are faced [54],[53]. Finally, it is important that the decision aid adheres to International Patient Decision Aid Standards which are further discussed in section 3.2.2.1.

A checklist of the design criteria for meeting the decision-making needs of parents in the NICU was established, and is shown in Table 4.

Table 4. Checklist of design criteria for development of PPADS tool.

NICU Specific Design Criteria		***Answer***
1	The parent tool should be informative, but not prescriptive.	
2	The tool should aid parents in making more informed decisions, in understanding the decision options, in feeling more certain about their decision, and in feeling clearer about their values.	
3	The tool should provide parents with information regarding the condition of their neonate.	
4	The tool should provide parents with information regarding the treatment therapies of their neonate.	
5	The tool should provide parents with information regarding the risk predictions of their neonate.	
6	The tool should provide parents with the meaning of medical terms and medical jargon.	
7	The tool should provide parents with reasoning as to why a decision must be made.	
8	The tool should provide parents with the positive and negative features of each	

	of the decision options.	
9	The tool should provide parents with a way to understand how their values and beliefs influence the decision.	
10	The tool should not provide conflicting information.	
11	The tool should be easy to understand (medical euphemism and jargon are avoided or explained).	
12	The tool should provide information in more than one form, to facilitate understanding.	
13	The parent tool should have a readability level of grade 8 or less.	
14	The tool should maximize coherence with international patient decision aid standards (IPDAS).	

3.2.2.1 International Patient Decision Aids Standards (IPDAS)

In order to monitor the quality of decision-aids, International Patient Decision Aids Standards (IPDAS) were established at the second International Shared Decision-making Conference in Swansea in 2003. The international quality based framework was established using a two stage web-based Delphi consensus by four stakeholder groups (researchers, practitioners, patients, and policy makers) from 14 countries, using online rating. In the first round, the participants reviewed summaries online and rated the importance of 80 criteria in 12 quality domains on a scale of 1 to 9. In the second round, participants received feedback from the first round and repeated the assessment of the 80 criteria along with three new ones. The aggregate ratings for each criterion were calculated using medians weighted to compensate for the different number of group members. All criteria rated between 7 and 9 were used. It should be noted that the IPDAS checklist contains a substantial number of criteria pertaining to many types of decision aids, and is intended to represent an ideal decision-aid. For any given decision aid, only a subset of the criteria will be applicable [43]. The IPDAS checklist is shown in Table 5.

Table 5. IPDAS checklist [53]**.**

	Content	Answer
1.	The decision aid describes the condition (health or other) related to the decision.	
2.	The decision aid describes the decision that needs to be considered (the index decision).	

3.	The decision aid lists the options (health care or other).	
4.	The decision aid describes what happens in the natural course of the condition (health or other) if no action is taken.	
5.	The decision aid has information about the procedures involved (e.g. what is done before, during, and after the health care option).	
6.	The decision aid has information about the positive features of the options (e.g. benefits, advantages).	
7.	The decision aid has information about negative features of the options (e.g. harms, side effects, disadvantages).	
8.	The information about outcomes of options (positive and negative) includes the chances they may happen.	
9.	The decision aid has information about what the test is designed to measure.	
10.	The decision aid describes possible next steps based on the test results.	
11.	The decision aid has information about the chances of disease being found with and without screening.	
12.	The decision aid has information about detection and treatment of disease that would never have caused problems if screening had not been done.	
13.	The decision aid presents probabilities using event rates in a defined group of people for a specified time.	
14.	The decision aid compares probabilities (e.g. chance of a disease, benefit, harm, or side effect) of options using the same denominator.	
15.	The decision aid compares probabilities of options over the same period of time.	
16.	The decision aid uses the same scales in diagrams comparing options.	
17.	The decision aid asks people to think about which positive and negative features of the options matter most to them.	
18.	The decision aid makes it possible to compare the positive and negative features of the available options.	
19.	The decision aid shows the negative and positive features of the options with equal detail.	
Development Process		**Answer**
20.	Users (people who previously faced the decision) were asked what they need to prepare them to discuss a specific decision.	
21.	The decision aid was reviewed by people who previously faced the decision who were not involved in its development and field testing.	

22.	People who were facing the decision field tested the decision aid.	
23.	Field testing showed that the decision aid was acceptable to users (the general public & practitioners).	
24.	Field testing showed that people who were undecided felt that the information was presented in a balanced way.	
25.	The decision aid provides references to scientific evidence used.	
26.	The decision aid reports the date when it was last updated.	
27.	The decision aid reports whether authors of the decision aid or their affiliations stand to gain or lose by choices people make after using the decision aid.	
28.	The decision aid (or available technical document) reports readability levels.	
	Effectiveness	**Answer**
29.	There is evidence that the decision aid (or one based on the same template) helps people know about the available options and their features.	
30.	There is evidence that the decision aid (or one based on the same template) improves the match between the features that matter most to the informed person and the option that is chosen.	

The coherence of the PPADS tool to the general design criteria, specific design criteria, and IPDAS criteria is presented in section 4.1.3 of the results chapter.

3.3 Step 3: System Design

The third step in the development of the PPADS tool was the system design. In this step, a formal description of the structure and components of the tool was developed. The system design was developed in accordance with the various design criteria established in section 3.2. The system design of the PPADS tool involved deciding on the architecture, identifying the various components, and designing the user-interface.

The architecture of the PPADS system was designed based on the three-tier architecture of web systems, described in section 2.8 in the literature review of this thesis. A schematic illustration of the system design is shown in Figure 4.

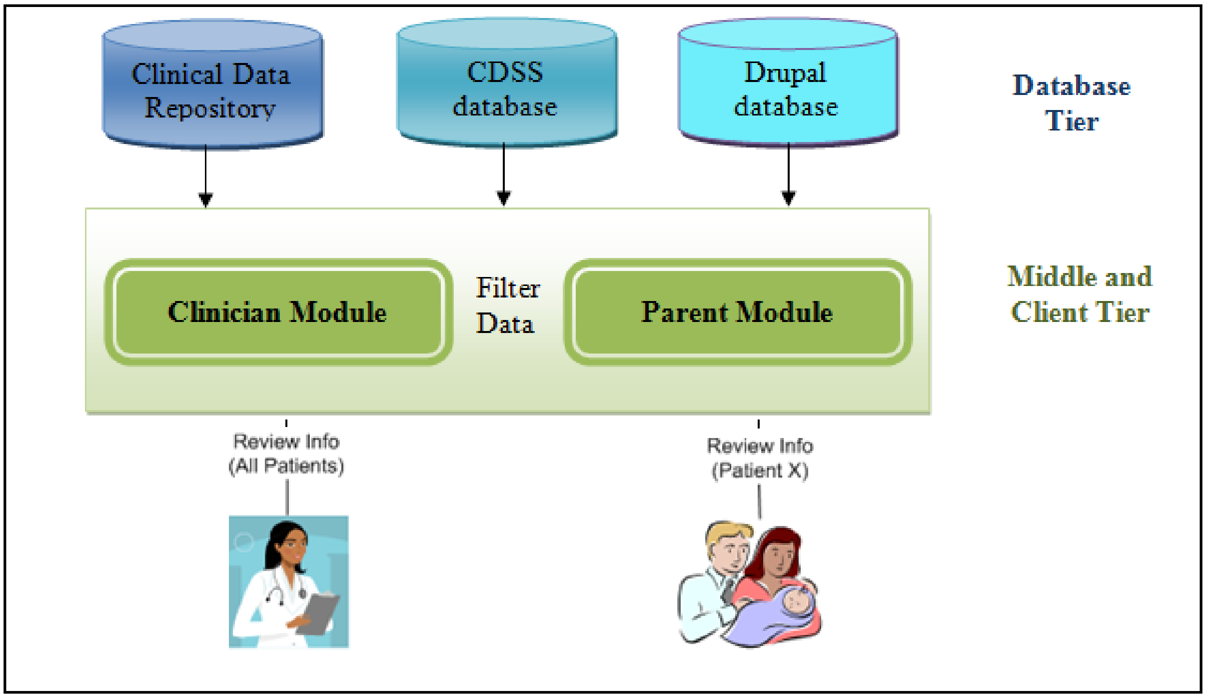


Figure 4. Schematic illustration of the PPADS system design.

3.3.1 Database Tier

The DSS developed is a web-based system and requires databases to store the content management data, the medical data, and the patient information [58]. The PPADS tool uses three MySQL databases: the Clinical Data Repository (CDR), the CDSS database, and the Drupal database, as shown in Figure 4. MySQL is a very common database management system and was chosen because it is open source, it can manage large amounts of data, and it has a great reputation for speed and performance.

The CDR was developed by previous MIRG members. The CDR collects real time data from patients at the CHEO NICU. It is linked to the hospital network and relies on continuous data received from the admissions, discharge, and transfer system, laboratory results, and patient monitors. It samples at a rate of once per minute [31]. The PPADS tool will access patient data stored in the CDR by sending data requests for specified patient information using SQL. The data from the CDR is used to display patients currently admitted to the NICU, medical outcome predictions, and trend data.

The Drupal database stores all of the user account information and content management data. The Drupal database contains 94 tables, including actions, blocks, users, and permission tables. The permission tables store the data that controls what information clinicians and parents can access and what information they can modify. The Drupal database is created and populated by the Drupal software.

The CDSS database was developed by MIRG group members. The CDSS database contains 14 tables, including: the completed decision support forms, the admitted patient data, the discharged patient data, the outcome predictions, the current conditions, the current direction of care, the current treatment therapies, the reason for a change in the direction of care being suggested, and the usage log. All of the CDSS tables were designed with future expansion and usability in mind. As a result, new therapies and conditions can be easily added to the tables without having to redesign the database.

3.3.2 Middle and Client Tier

The middle and client tier of the PPADS tool were developed using a content management system. Drupal was chosen for the content management system because it is a free, open source tool with sophisticated content management and numerous online modules.

Drupal has a sophisticated programming interface for developers, but no programming skills are required for basic website installations and administration. This feature allows nurses and doctors to easily update the tool. The web server software used with Drupal is Apache and PHP.

All connections to the PPADS tool are made through the secure CHEO internal network, either wired (desktop computers) or wirelessly (laptops and handheld devices) using the TCP/IP and HTTP protocols.

3.4 Step 4: Implementation

The fourth step in the development of the PPADS tool was the implementation of the tool, following the established design criteria and system design.

The implementation process was conducted with the close involvement of our clinical neonatal care experts, Dr. Erika Bariciak and Sandra Dunn. Several prototypes were developed and presented to the clinical neonatal care experts for their input. After consultation, changes were incorporated to improve the tool. Once a new prototype was developed it was once again presented to the neonatal care experts for further input. This process was repeated several times until a final prototype had been developed.

3.5 Step 5: Usability Testing

The PPADS tool was evaluated through two usability studies at CHEO. The usability studies were conducted at CHEO on parents of NICU graduates (neonates who survived) and on neonatologists currently working in the NICU at CHEO.

Ethics approval for the usability testing of the PPADS tool at CHEO was obtained from the CHEO Research Ethics Review Board, the University of Ottawa Research Ethics and Integrity Board, and the Carleton University Research Ethics Board. The ethics approval forms are included in Appendix C.

3.5.1 Parent Usability Testing

The parent usability study aimed to determine the usefulness, efficiency, effectiveness, acceptability and satisfaction of the tool. The study aims to answer the research question, "Does the PPADS tool meet usability criteria?" In particular, the study aims to answer the following questions [59],[60],[61],[62]:

- **Usefulness:** Does the tool help parents feel more informed, have a better understanding of their neonate's current condition, treatments, and risk prediction, have a better understanding of the different directions of care that they must choose between, feel more certain about their decision, and feel clearer about their values?
- **Efficiency and Effectiveness:** Is the tool easy to learn, easy to use, easy to navigate, and can it be navigated quickly?

- **Acceptability:** Is the tool applicable to all levels of users; does the tool use acceptable terminology; and does the tool contain an acceptable amount of information?
- **Satisfaction:** Is the tool generally satisfactory?

3.5.1.1 Data Collection

In the usability study with parents, we recruited eight participants who have had infants who graduated (survived) from the NICU in the past year. The number of participants chosen for this work is based on previous research findings, which concluded that five to ten participants of the representative population are required for a good in-depth usability study [59],[76],[60],[61],[62],[68].

Several inclusion criteria were used in selecting participants for the usability study: the parent must have had a neonate who graduated (survived) from the NICU within the last year; their infant must not have died after discharge; the parent must currently not have any infants in the NICU; and for reasons of consent, all participants must be 18 years of age or older. The participants were identified by Dr. Erika Bariciak, a neonatologist at CHEO, from discharge records kept in the NICU. Dr. Bariciak identified 24 families that met the inclusion criteria stated above. Once identified, each baby's electronic medical record was screened to ensure that the baby had not passed away since discharge from the NICU. A second round of recruitment of another 25 families was required to get a suitable number of participants.

The Chief of the Department, Dr. Thierry Lacaze, then sent each identified family a recruitment letter, which is included in Appendix D. The recruitment letter asked if either or both parents would be interested in participating in the research study. Each parent would participate separately, but for convenience, the two sessions could be scheduled in consecutive time slots. If parents chose to participate, they were given the option to contact or be contacted by Sabine Weyand via phone or email, to get more information. The parents were then provided with a copy of the consent form describing the study in more detail, and were asked to make an appointment to complete the study. The study was conducted in the

NICU conference room at CHEO, over a span of three months. Appointments were available on selected Saturdays and Sundays, from 8AM to 8 PM, and weeknights, from 6 PM to 8 PM.

Each participant study consisted of one testing session in the NICU conference room, which lasted approximately 45 minutes. A schematic illustration and a photograph of the usability room set up are shown in Figure 5 and Figure 6, respectively. The set up was designed so that the examiner (Sabine Weyand) and the participant could easily talk face to face and the examiner was able to observe what the participant's actions were when completing the tasks, and also see what was on the computer screen while the tasks were being completed; all this was done without disturbing the participant. It should be noted that even though it is considered best practice to record usability testing sessions, due to the sensitive nature of this project, it was not advisable to video tape the sessions.

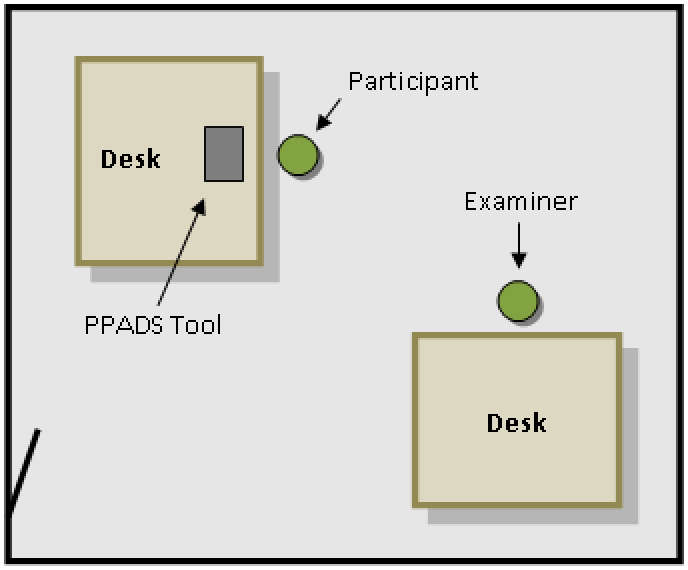


Figure 5. Schematic representation of usability testing room set up.

Figure 6. Photograph of usability testing set up at the Children's Hospital of Eastern Ontario.

Upon arrival in the study room, the examiner read the first part of the participant speech, which can be found in Appendix E. The script was read to each participant verbatim. This standardisation for each participant is important, since people are easily influenced by past events. For example, if the previous participants had a negative experience, the researcher's speech may be filled with discouragement and frustration, which could negatively affect the next participant. By reading a speech verbatim, one is forced to use the same language and expressions, which in turn controls one's mannerisms and voice modulation [59],[62]. Next, the participants were provided with a copy of the consent form shown in Appendix F. The usability study was conducted in English; however, consent could be provided in either English or French. Upon signing the consent form, participants were asked to complete the background information questionnaire shown in Appendix G.

Next, the participants were provided with the tasks sheet shown in Appendix H, and a laptop computer with the PPADS tool opened. The task sheet given to each person contained three tasks. The experiment was set up as a within-subject design with a counterbalance approach. This means that the first two tasks were switched randomly for each participant, and the third task, which just allows the parent to spend time browsing the tool, was always last. The reason that the first two tasks were switched randomly is that they could be done in any order in a real scenario. Therefore, in order to eliminate potential learning bias, the task orders were randomly chosen using Microsoft Excel's random number generator [59]. Participants were asked to think aloud and observations of the participants' comments and actions during their interaction with the tool were documented. The following pieces of information were recorded by Sabine:

- Number of wrong mouse clicks made
- Number of tasks completed correctly with and without questions
- Number of tasks not completed
- Number of negative verbal comments
- Number of positive verbal comments
- Start time of performing the tasks
- End time of performing the tasks
- Positive comments
- Negative comments
- Suggestions for improvements

Once the participants completed the tasks, they were asked to complete the evaluation questionnaire, which is shown in Appendix I. Upon completion of the study, participants were escorted to the exit by Sabine and their parking passes were paid.

3.5.1.2 Data Analysis

Each participant was given a unique participant ID number which was randomly generated using Excel's random number generator. The participant ID number was located on every form and questionnaire. This was done to ensure that the participants' forms did not get mixed up, as well as to ensure the anonymity of the participants during data processing, analysis, and publication. Once the data was entered into the computer, only the participant's ID number was used to track the information. The only aspect of the study that contained identifying information about the participant was the consent form, which contained the participant's name and signature. The identifying consent forms were kept in the locked office of Dr. Erika Bariciak at CHEO.

After collection, all de-identified data was analyzed. The data was summarized and the average, standard deviation, frequencies, and percentages for each of the questions were determined. Based on the research questions, the usability of the tool was then measured by its ability to meet the needs of 75% of the parents. A 75% agreement threshold was chosen for subjective measures based on the clinical relevance and usability thresholds used in literature. A 100% agreement threshold was chosen for performance measures, such as the ability to complete all tasks [59],[76],[62]. The goals, criteria, and measurements used for usability testing are shown in Table 6. The source of the information for each criterion is shown in the "Measurements" column, referring to the question number and sub question number if applicable, of the evaluation questionnaire or to general observations written down by Sabine.

Table 6. Criteria, usability thresholds, and measurements used for parent usability testing.

Criterion	Usability threshold	Measurements
Usefulness		
The current medical condition list is useful	75% of participants should agree or strongly agree	Q10-1
The current therapies list is useful	75% of participants should agree or strongly agree	Q10-3
The risk predictions are useful	75% of participants should agree or strongly agree	Q10-5
The reason a change in direction of care is suggested is useful	75% of participants should agree or strongly agree	Q10-7
The decision support form is useful	75% of participants should agree or strongly agree	Q10-9
The different directions of care options are presented in a balanced way	75% of participants should agree or strongly agree	Q10-11
The glossary definitions are useful	75% of participants should agree or strongly agree	Q10-12
After using the PPADS tool, users would feel more informed	75% of participants should agree or strongly agree	Q10-14
After using the PPADS tool, users would have a better understanding of their decisional options	75% of participants should agree or strongly agree	Q10-15
After using the PPADS tool, users would feel more certain about their decision	75% of participants should agree or strongly agree	Q10-16

After using the PPADS tool, users would feel clearer about how their values affect their decision	75% of participants should agree or strongly agree	Q10-17
If given the opportunity, participants would use the tool	75% of participants should agree or strongly agree	Q10-18
Efficiency and effectiveness		
The information is clearly organized	75% of participants should find the organization of information very clear or moderately clear	Q2
Navigation is easy	75% of participants should find the navigation of the tool very easy or moderately easy	Q3
Meaning of pages and buttons are easy to understand	75% of participants should find the meaning of the pages and buttons very easy or moderately easy to understand	Q4
Performing the tasks is easy	75% of participants should find performing the assigned tasks always easy or mostly easy	Q5
The tool is easy to learn	75% of participants should agree or strongly agree	Q9-1
Using the tool would not add stress	75% of participants should agree or strongly agree	Q9-2
It is easy for users to find the information they are looking for	75% of participants should agree or strongly agree	Q9-3
The tool can be navigated quickly	75% of participants should agree or strongly agree	Q9-4
Acceptability		
The amount of information displayed in PPADS is appropriate	75% of participants should find the amount of information in PPADS just right	Q6
The length of the decision support form is good	75% of participants should find the length of the decision support form just right	Q7
Terminology used is easy to understand	75% of participants should find the terminology used always easily understood or mostly easily understood	Q8
The decision support form is easy to understand	75% of participants should agree or strongly agree	Q10-10

The list of the current medical conditions is easy to understand	75% of participants should agree or strongly agree	Q10-2
The list of the current therapies is easy to understand	75% of participants should agree or strongly agree	Q10-4
The risk predictions are easy to understand	75% of participants should agree or strongly agree	Q10-6
The reason a change in direction of care is suggested is easy to understand	75% of participants should agree or strongly agree	Q10-8
The glossary definitions are easy to understand	75% of participants should agree or strongly agree	Q10-13
Users can successfully log in and complete the tasks without any questions and with less than 5 miss-clicks	All participants should be able to log in and complete the tasks without any questions and with less than 5 miss-clicks	miss-clicks questions
Users can complete all tasks	All participants should be able to complete all tasks	task completion
Satisfaction		
The PPADS tool is satisfying to use	75% of participants should find the PPADS tool satisfying or exceptional	Q1
Users have more positive than negative comments	75% of participants should have more positive than negative comments	positive and negative comments

3.5.2 Physician Usability Testing

The physician usability study aimed to determine if neonatologists find the PPADS tool useful, efficient, effective, acceptable, and satisfying. In particular, the study aimed to determine if neonatologists find that the tool would be useful for parents, easy for parents to use, useful for physicians, and easy for physicians to use.

3.5.2.1 Data Collection

The inclusion criterion for the usability study was that participants must currently be neonatologists working in the NICU at CHEO. The Chief of the Department, Dr. Thierry Lacaze, sent out recruitment letters to all 11 neonatologists (other than Dr. Erika Bariciak since she was involved in the development of the PPADS tool) working at CHEO. The recruitment letter is shown in Appendix J. The study aimed to recruit five neonatologists to perform usability testing of the PPADS tool.

The usability testing was conducted during NICU research rounds and meetings at CHEO. The study sessions included a demonstration of the PPADS tool followed by questions, comments, and completion of the consent form and the evaluation questionnaire. It should be noted that the physicians were not presented with the information from the parent usability study. The demonstration script, evaluation questionnaire, and consent form are shown in Appendix K, Appendix L, and Appendix M, respectively. The demonstration script was read verbatim. This standardization was important to control the examiner's speech, the examiner's mannerisms, and the examiner's voice modulation for all testing sessions. Each study session took about 30 minutes.

3.5.2.2 Data Analysis

Similarly to the parent usability study, each participant was given a unique participant ID number to ensure anonymity and that the participants' forms did not get mixed up. Once the data was entered into the computer, only the participant's ID number was used to track the information. The only aspect of the study that contained identifying information about the participant was the consent form, which contained the participant's name and signature. The identifying consent forms were kept in the locked office of Dr. Erika Bariciak at CHEO.

After collection, all de-identified data was analyzed. The data was summarized and the average, standard deviation, frequencies, and percentages for each of the questions were determined. Based on the research questions, the usability of the tool was then measured by its ability to meet the needs of 75% of the neonatologists. A 75% agreement threshold was chosen based on the clinical relevance and usability thresholds used in literature [59],[76],[62]. In order to meet usability criteria, 75% of neonatologists who participated must agree or strongly agree with the usability criterion. The criteria and measurements used for usability testing are shown in Table 7. The source of the information for each criterion is shown in the "Measurement" column, referring to the question number of the evaluation questionnaire.

Table 7. Criteria and measurements used for physician usability testing.

Criterion	Measurement
Usefulness	
The tool would be helpful to parents	Q9
The tool would help parents feel more informed	Q11
The tool would help parents understand their neonate's conditions	Q12
The tool would help with physician-parent communication	Q14
The decision support instrument would help parents come to a decision about change of care needs	Q15
The decision support instrument would help physicians understand the parents' views on their decision	Q16
The decision support instrument would help guide physician-parent consultation	Q17
The tool would be useful in my role as physician in the future	Q19
Efficiency and effectiveness	
It would be easy to integrate the tool into the current delivery of care	Q6
It is easy to learn to use the tool	Q7
The tool is easy for parents to use	Q13
Acceptability	
The organization of information in PPADS is clear	Q8
The tool provides the right amount of information to parents	Q10
Satisfaction	
Overall view of the PPADS tool is positive	Q5
If given the opportunity, I would offer parents of neonates in the NICU to use the PPADS tool	Q18

3.6 Methodology Summary

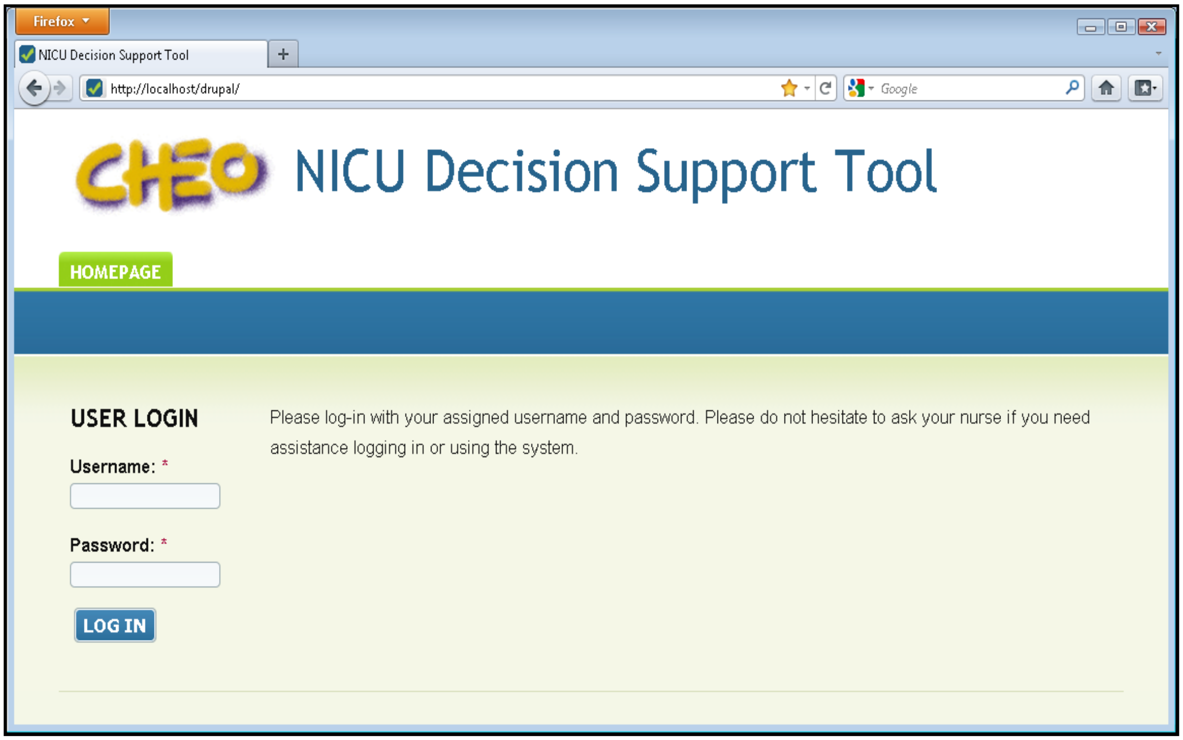
The methodology described in this chapter provides the technique used in the development and evaluation of the PPADS tool. The methodology followed a five-step process based on decision support frameworks in literature. The first step was assessing the clinical environment; the second step was establishing the design criteria; the third step was the system design; the fourth step was implementation with expert input; and the final step was usability testing. The next chapter presents the results and corresponding discussions.

Chapter 4: Results and Discussion

This chapter outlines the results of this thesis. The results are presented in two sections: implementation results and usability testing results.

4.1 Implementation Results

The PPADS tool consists of two distinct user-interfaces: a clinician interface and a parent interface. Both tools are accessed through the same Uniform Resource Locator (URL), based on the user account login information. The login screen for the PPADS tool is shown in Figure 7.

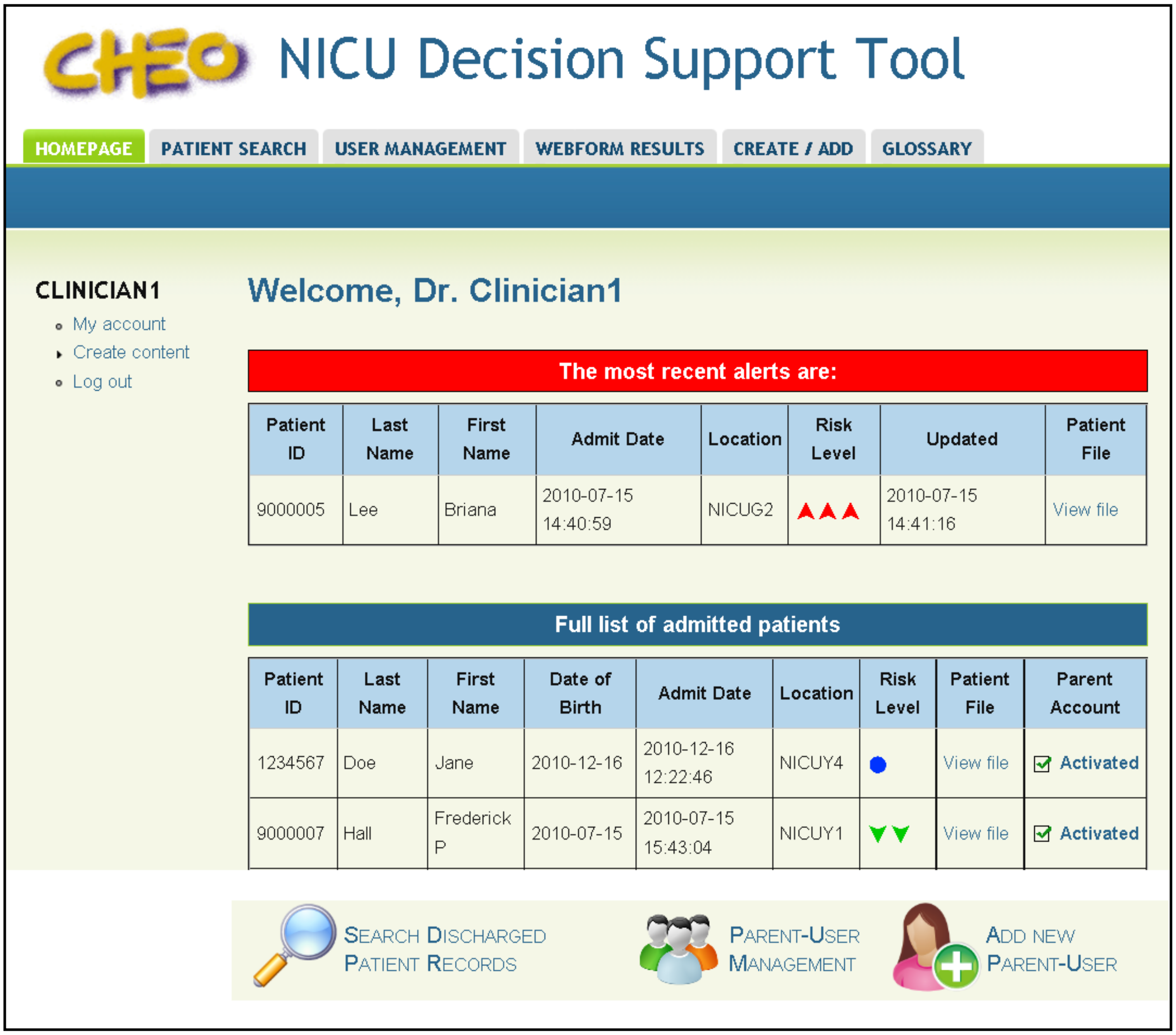


Please log-in with your assigned username and password. Please do not hesitate to ask your nurse if you need assistance logging in or using the system.

Figure 7. PPADS login screen.

4.1.1 Clinician Tool

The Clinician tool homepage shows a summary of important information for all patients currently admitted to the NICU. A screen shot of the clinician tool homepage is shown in Figure 8. From the homepage, the clinician can access each individual neonate's patient file, activate parent accounts, search for past patients, create and add content, and edit the glossary.



Welcome, Dr. Clinician1

The most recent alerts are:

Patient ID	Last Name	First Name	Admit Date	Location	Risk Level	Updated	Patient File
9000005	Lee	Briana	2010-07-15 14:40:59	NICUG2	▲▲▲	2010-07-15 14:41:16	View file

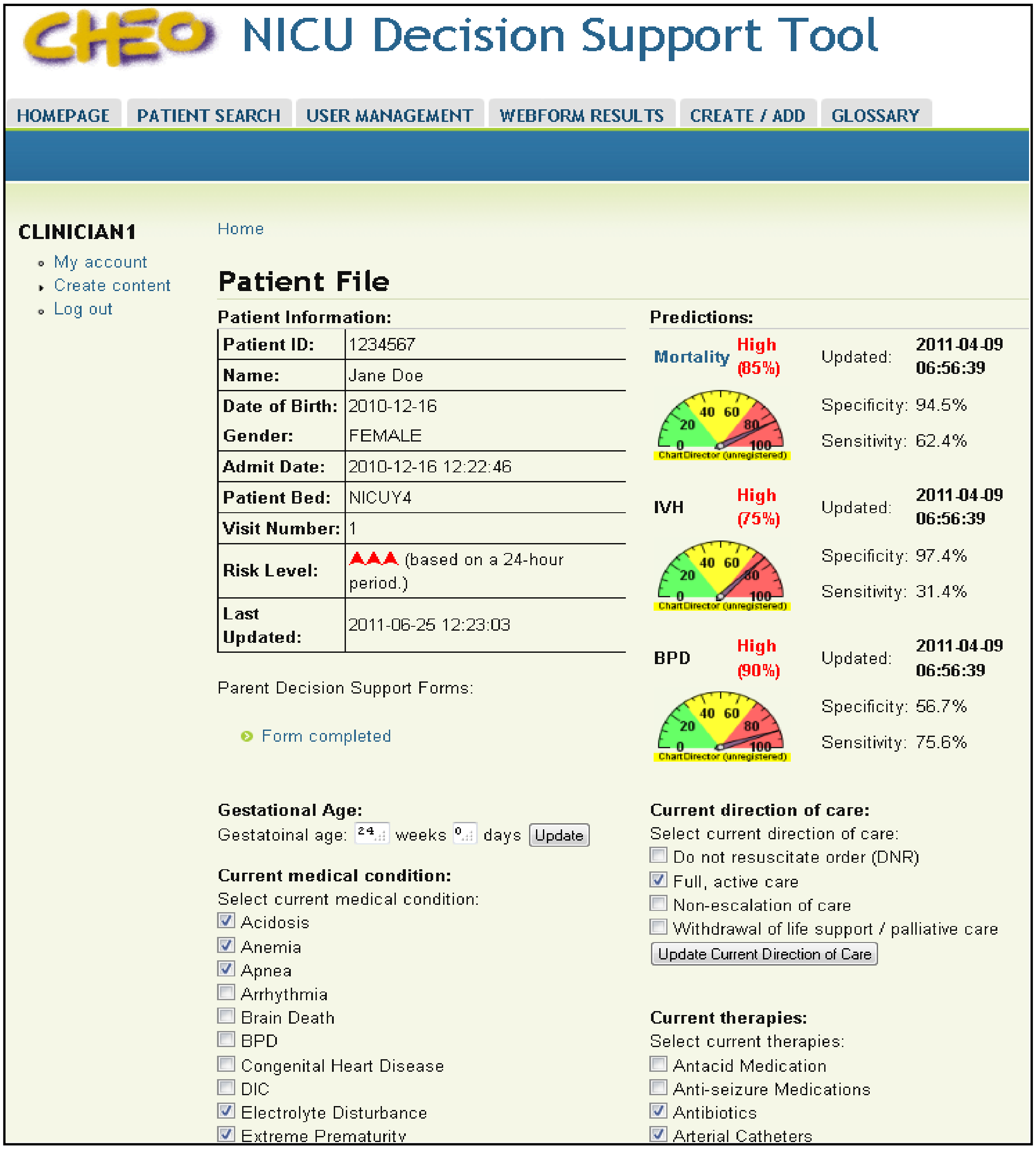
Full list of admitted patients

Patient ID	Last Name	First Name	Date of Birth	Admit Date	Location	Risk Level	Patient File	Parent Account
1234567	Doe	Jane	2010-12-16	2010-12-16 12:22:46	NICUY4	●	View file	☑ Activated
9000007	Hall	Frederick P	2010-07-15	2010-07-15 15:43:04	NICUY1	▼▼	View file	☑ Activated

Figure 8. PPADS clinician homepage.

Each patient file contains the neonate's patient ID, name, date of birth, gestational age, gender, NICU bed location, admission date, risk estimations for important outcomes, including mortality, severe intestinal infection (necrotizing enterocolitis or NEC), severe brain hemorrhage (intraventricular hemorrhage or IVH), and chronic lung disease (bronchopulmonary dysplasia or BPD), and any completed parent decision support forms.

Each patient file also contains a checkbox list of current conditions, current treatment options, current direction of care, reasons for suggesting a change in the direction of care, and gestational age. The clinician is able to quickly select the information pertaining to the neonate. This information is stored in the DSS database and can be accessed by both the parent and the clinician. The patient file also contains a free-form clinician's note section. This section allows clinicians to write a notation that is specific to a given neonate. A screen shot of the patient file page is shown in Figure 9 and Figure 10.



Patient File

Patient Information:

Patient ID:	1234567
Name:	Jane Doe
Date of Birth:	2010-12-16
Gender:	FEMALE
Admit Date:	2010-12-16 12:22:46
Patient Bed:	NICUY4
Visit Number:	1
Risk Level:	▲▲▲ (based on a 24-hour period.)
Last Updated:	2011-06-25 12:23:03

Parent Decision Support Forms:

- Form completed

Predictions:

Mortality	**High (85%)**	Updated:	**2011-04-09 06:56:39**
		Specificity:	94.5%
		Sensitivity:	62.4%
IVH	**High (75%)**	Updated:	**2011-04-09 06:56:39**
		Specificity:	97.4%
		Sensitivity:	31.4%
BPD	**High (90%)**	Updated:	**2011-04-09 06:56:39**
		Specificity:	56.7%
		Sensitivity:	75.6%

Gestational Age:

Gestatoinal age: 24 weeks 0 days [Update]

Current medical condition:

Select current medical condition:

☑ Acidosis
☑ Anemia
☑ Apnea
☐ Arrhythmia
☐ Brain Death
☐ BPD
☐ Congenital Heart Disease
☐ DIC
☑ Electrolyte Disturbance
☑ Extreme Prematurity

Current direction of care:

Select current direction of care:

☐ Do not resuscitate order (DNR)
☑ Full, active care
☐ Non-escalation of care
☐ Withdrawal of life support / palliative care

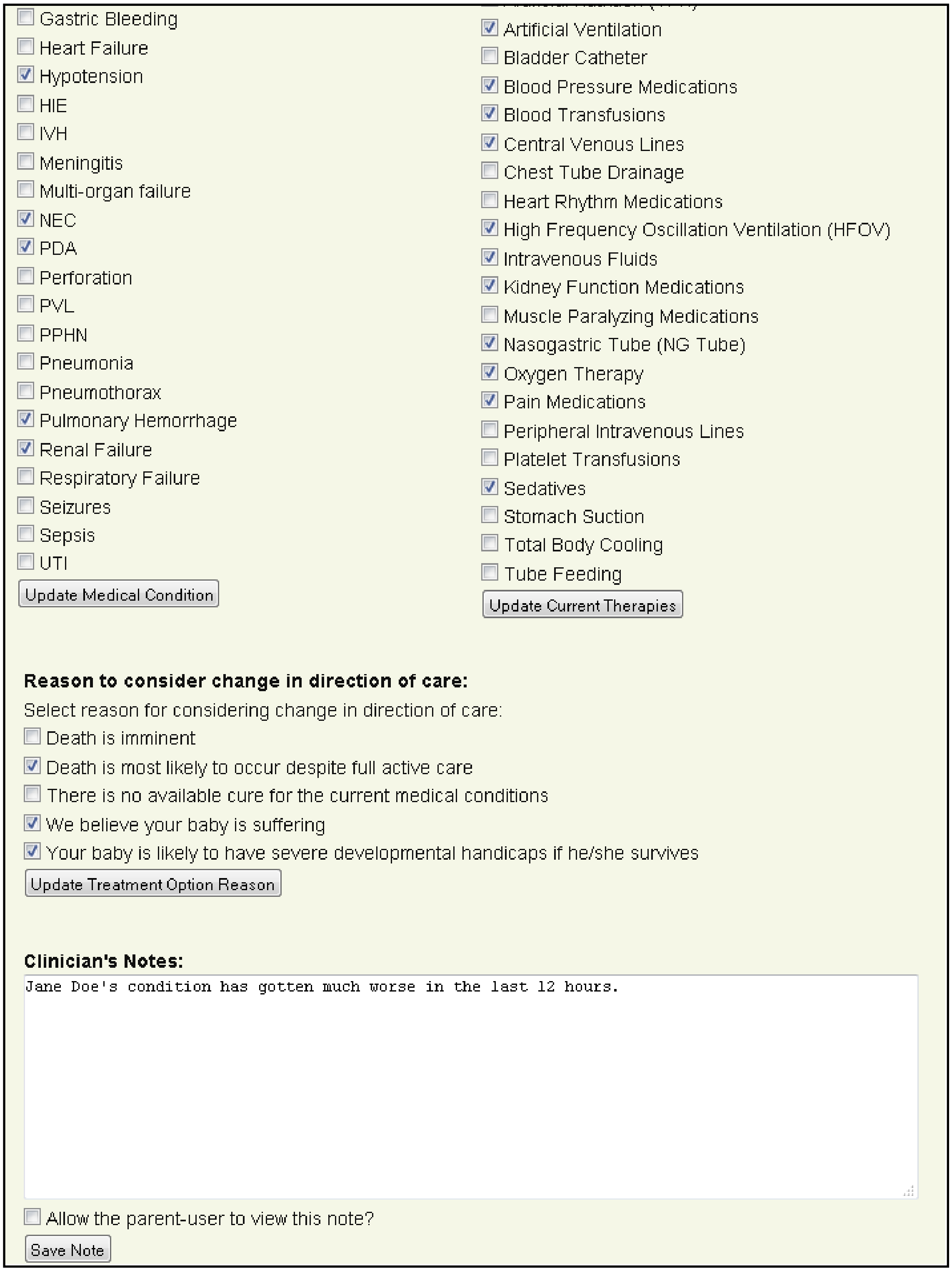
[Update Current Direction of Care]

Current therapies:

Select current therapies:

☐ Antacid Medication
☐ Anti-seizure Medications
☑ Antibiotics
☑ Arterial Catheters

Figure 9. PPADS patient file page, part 1.



☐ Gastric Bleeding
☐ Heart Failure
☑ Hypotension
☐ HIE
☐ IVH
☐ Meningitis
☐ Multi-organ failure
☑ NEC
☑ PDA
☐ Perforation
☐ PVL
☐ PPHN
☐ Pneumonia
☐ Pneumothorax
☑ Pulmonary Hemorrhage
☑ Renal Failure
☐ Respiratory Failure
☐ Seizures
☐ Sepsis
☐ UTI

☑ Artificial Ventilation
☐ Bladder Catheter
☑ Blood Pressure Medications
☑ Blood Transfusions
☑ Central Venous Lines
☐ Chest Tube Drainage
☐ Heart Rhythm Medications
☑ High Frequency Oscillation Ventilation (HFOV)
☑ Intravenous Fluids
☑ Kidney Function Medications
☐ Muscle Paralyzing Medications
☑ Nasogastric Tube (NG Tube)
☑ Oxygen Therapy
☑ Pain Medications
☐ Peripheral Intravenous Lines
☐ Platelet Transfusions
☑ Sedatives
☐ Stomach Suction
☐ Total Body Cooling
☐ Tube Feeding

Reason to consider change in direction of care:

Select reason for considering change in direction of care:

☐ Death is imminent
☑ Death is most likely to occur despite full active care
☐ There is no available cure for the current medical conditions
☑ We believe your baby is suffering
☑ Your baby is likely to have severe developmental handicaps if he/she survives

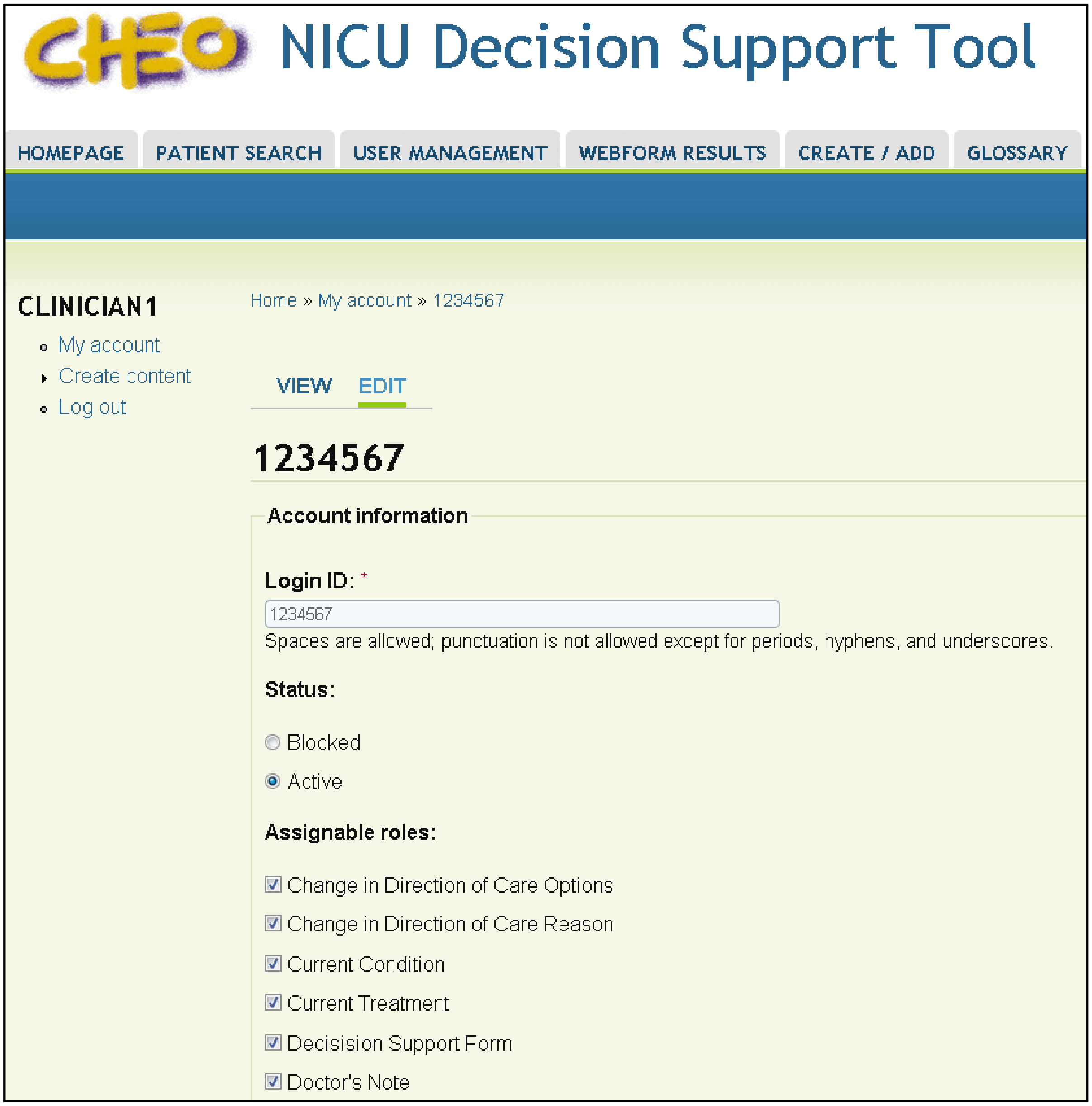
Clinician's Notes:

Jane Doe's condition has gotten much worse in the last 12 hours.

☐ Allow the parent-user to view this note?

Figure 10. PPADS patient file page, part 2.

The parent account activation module allows clinicians to activate a parent account for each neonate, and choose what information the parents will have access to. This is done using a checklist of available modules, including current conditions, current treatments, decision support forms, doctor's notes, and risk predictions. A screen shot of the parent account activation page is shown in Figure 11.



1234567

Account information

Login ID: *

1234567

Spaces are allowed; punctuation is not allowed except for periods, hyphens, and underscores.

Status:

○ Blocked

● Active

Assignable roles:

☑ Change in Direction of Care Options

☑ Change in Direction of Care Reason

☑ Current Condition

☑ Current Treatment

☑ Decisision Support Form

☑ Doctor's Note

Figure 11. PPADS parent account activation page.

To further aid in making care decisions, the patient search module provides clinicians access to past patient information contained within the system. Clinicians may search for past cases using the patient name, hospital number, or by date. A screen shot of the patient search page is shown in Figure 12.

Patient Search

First name:

Last name:

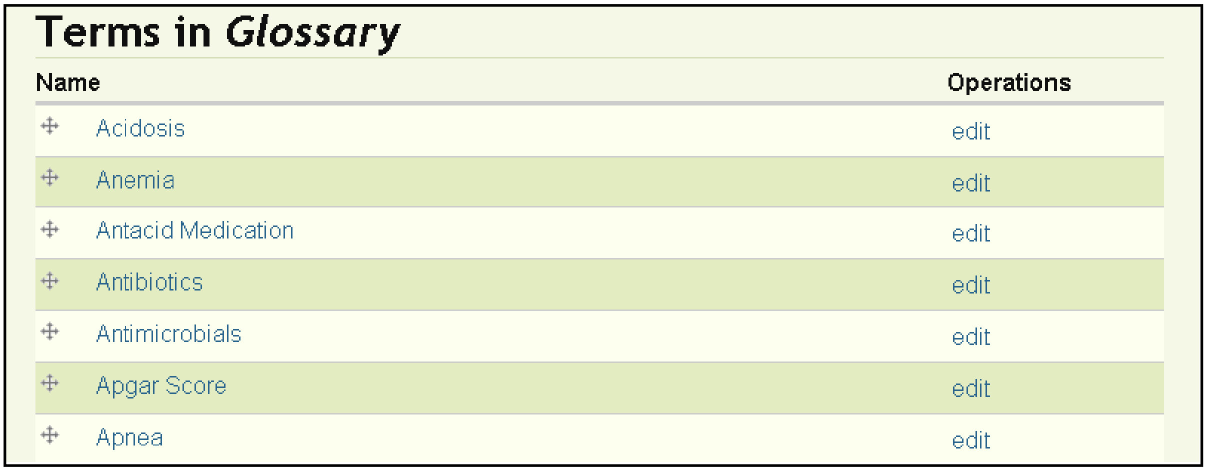
Patient ID:

Admitted between: YYYY-MM-DD

and: YYYY-MM-DD

Figure 12. PPADS patient search page.

The glossary module contains definitions for many medical terms, which are made available to parents. Clinicians are able to edit the existing definitions, and can add new glossary terms as needed. A screen shot of the glossary add and edit terms page is shown in Figure 13.



Terms in *Glossary*

Name	Operations
Acidosis	edit
Anemia	edit
Antacid Medication	edit
Antibiotics	edit
Antimicrobials	edit
Apgar Score	edit
Apnea	edit

Figure 13. PPADS glossary add and edit terms page.

The clinician has the ability to create and add content to keep the tool up to date. The clinician can add medical conditions, add a new reason for suggesting a treatment option, add a parent user account, or add a new decision support form for a different decision to be made. A screen shot of the create and add content page is shown in Figure 14.

Create/Add

Create/Add Content:

Click the following pages to create or add content:

1. Add a condition
2. Add a reason treatment option was suggested
3. Add a parent user account
4. Add a new webform

Figure 14. PPADS create and add content page.

4.1.2 Parent Tool

The parent homepage contains a welcoming statement and easy navigation to five sections: current condition, current treatment, outcome prediction, decision support, and the glossary. Each parent account will only be able to navigate to the pages that have been activated by the physician. A screen shot of the parent homepage is shown in Figure 15.

NICU Decision Support Tool

1234567

- My account
- Log out

SEARCH GLOSSARY

Welcome!

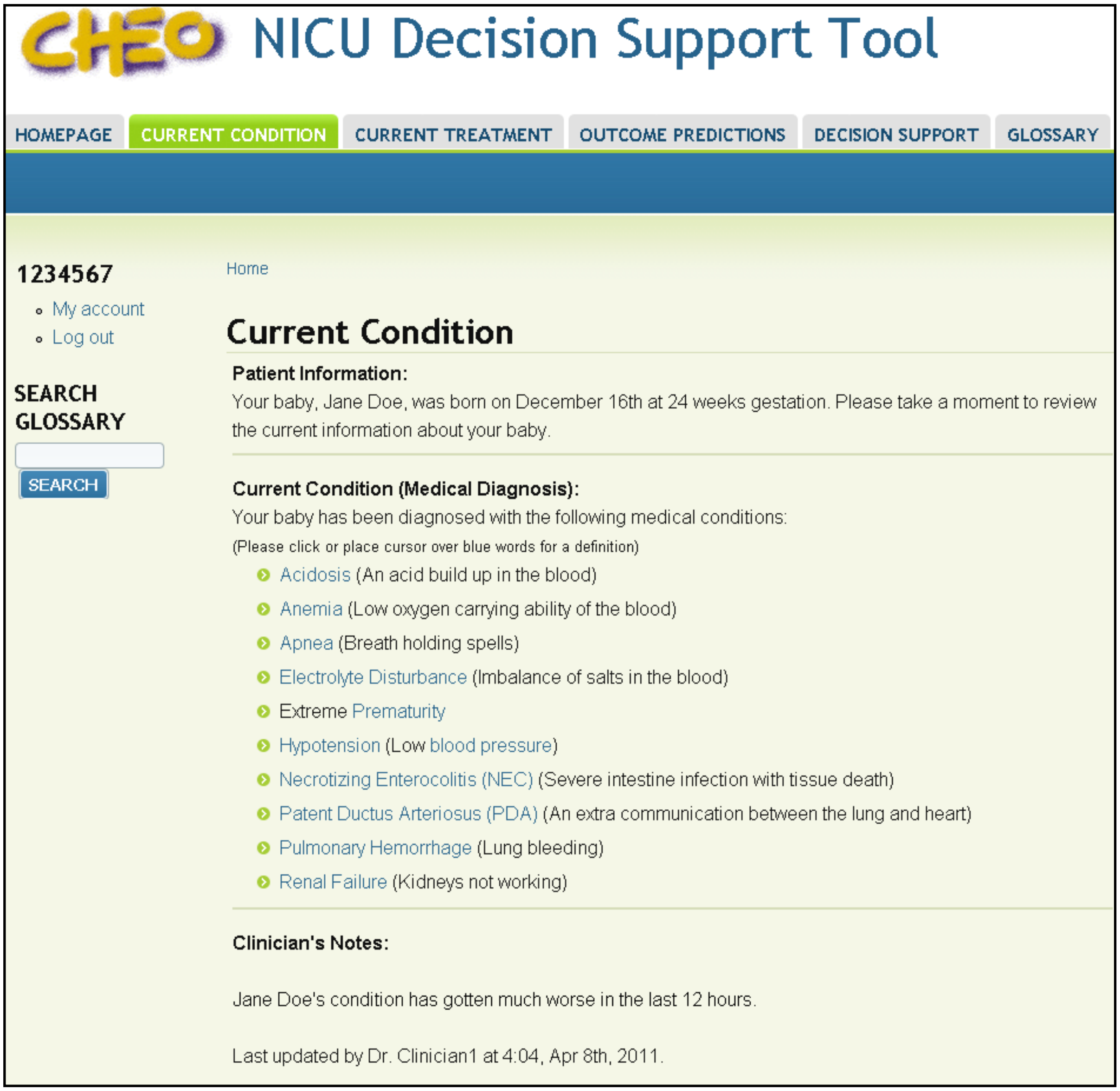
The purpose of this guide is to assist you in participating with the interprofessional team when making decisions about the best way to care for your sick baby.

This information is provided in five sections:

1. Your baby's current condition
2. Your baby's current treatment
3. Your baby's outcome predictions (possible outcomes)
4. Decision support
5. Glossary

Figure 15. PPADS parent homepage.

The current condition module displays the neonate's gestational age, a list of the neonate's current conditions, and a note from the doctor. Each of the neonate's current conditions is an active link to a glossary definition explaining the condition. Hovering or clicking on the active link displays the definition. A screen shot of the current condition page is shown in Figure 16.



Current Condition

Patient Information:

Your baby, Jane Doe, was born on December 16th at 24 weeks gestation. Please take a moment to review the current information about your baby.

Current Condition (Medical Diagnosis):

Your baby has been diagnosed with the following medical conditions:

(Please click or place cursor over blue words for a definition)

- Acidosis (An acid build up in the blood)
- Anemia (Low oxygen carrying ability of the blood)
- Apnea (Breath holding spells)
- Electrolyte Disturbance (Imbalance of salts in the blood)
- Extreme Prematurity
- Hypotension (Low blood pressure)
- Necrotizing Enterocolitis (NEC) (Severe intestine infection with tissue death)
- Patent Ductus Arteriosus (PDA) (An extra communication between the lung and heart)
- Pulmonary Hemorrhage (Lung bleeding)
- Renal Failure (Kidneys not working)

Clinician's Notes:

Jane Doe's condition has gotten much worse in the last 12 hours.

Last updated by Dr. Clinician1 at 4:04, Apr 8th, 2011.

Figure 16. PPADS current condition page.

The current treatment module displays the neonate’s current therapies. Each of the therapies is once again linked to a glossary definition which provides more details. A screen shot of the current therapies page is shown in Figure 17.

Current Treatment

Current direction of care:

The current direction of care is:

- Full, active care

Current therapies:

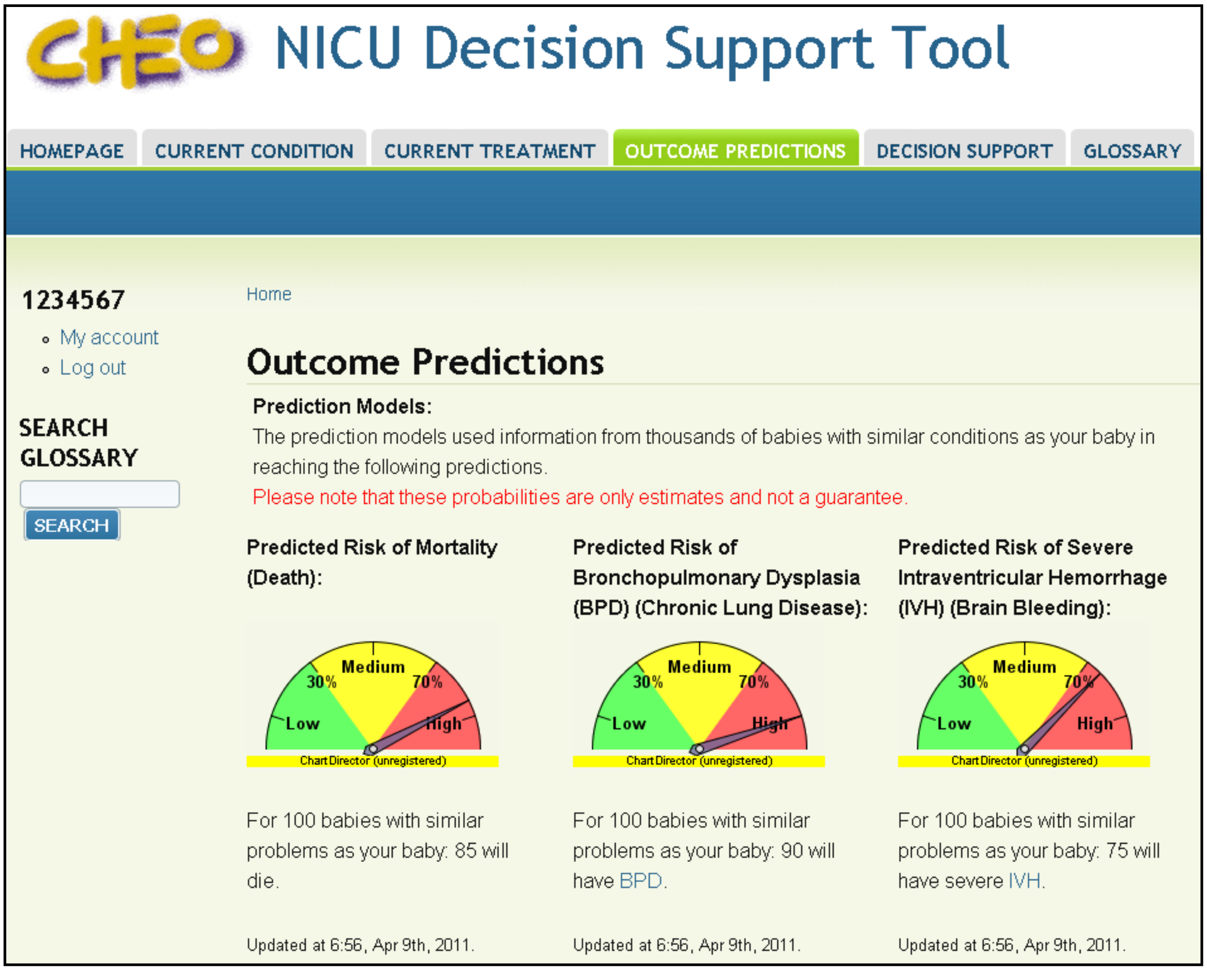
The current therapies being used are:

(Please click or place cursor over blue words for a definition)

- Antibiotics
- Arterial Catheters
- Artificial Nutrition (TPN)
- Artificial Ventilation
- Blood Pressure Medications
- Blood Transfusions
- Central Venous Lines
- High Frequency Oscillation Ventilation (HFOV)
- Intravenous Fluids
- Kidney Function Medications
- Nasogastric Tube (NG Tube)
- Oxygen Therapy
- Pain Medications
- Sedatives

Figure 17. PPADS current treatments page.

The outcome predictions module provides parents with risk predictions for mortality and other conditions. The risk predictions are displayed in a graphical “speedometer” format and written out in sentence form to facilitate parent understanding. The risk predictions used for the usability study were hypothetical predictions. MIRG members are still working on producing accurate predictions from the real-time CDR data. Once predictions with a high degree of sensitivity and specificity have been achieved, these predictions will be used. A screen shot of the outcome predictions page is shown in Figure 18.



Outcome Predictions

Prediction Models:

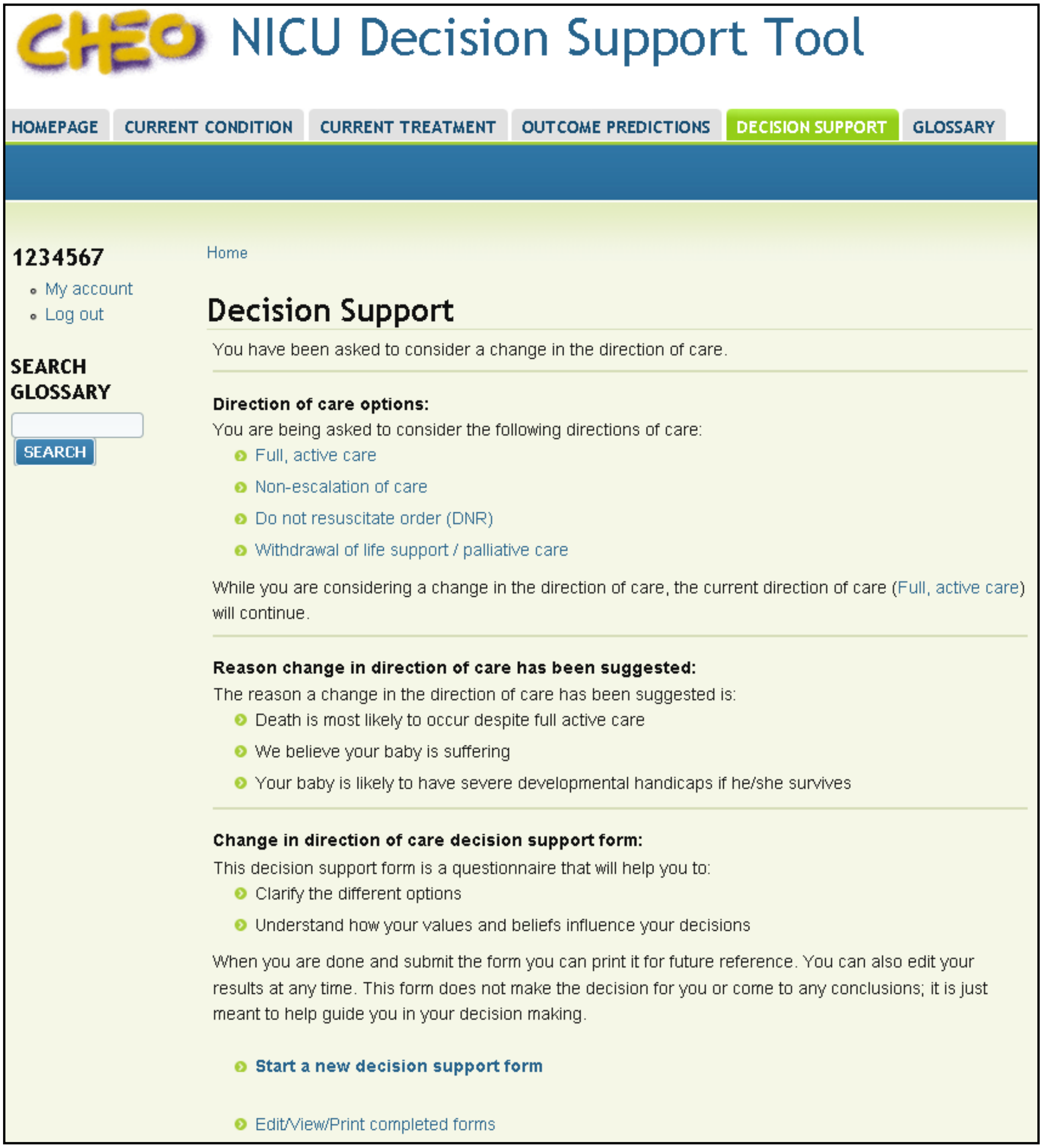
The prediction models used information from thousands of babies with similar conditions as your baby in reaching the following predictions.

Please note that these probabilities are only estimates and not a guarantee.

Predicted Risk of Mortality (Death):	Predicted Risk of Bronchopulmonary Dysplasia (BPD) (Chronic Lung Disease):	Predicted Risk of Severe Intraventricular Hemorrhage (IVH) (Brain Bleeding):
For 100 babies with similar problems as your baby: 85 will die.	For 100 babies with similar problems as your baby: 90 will have BPD.	For 100 babies with similar problems as your baby: 75 will have severe IVH.
Updated at 6:56, Apr 9th, 2011.	Updated at 6:56, Apr 9th, 2011.	Updated at 6:56, Apr 9th, 2011.

Figure 18. PPADS outcome predictions page.

The decision support module outlines any care decision which must be made, and provides decision support to assist parents in participating in decision-making. A screen shot of the decision support page is shown in Figure 19. There are numerous potential decisions to be made about the care of neonates in the NICU. One of the most difficult decisions is deciding on a change in the direction of care. A decision support instrument, to facilitate decision-making about a change in the direction of care, was developed as part of this work. The instrument consists of six steps, which address different aspects of the decision that must be made. The decision support instrument provides information about the different options, the positives and negatives of each option, and questions that aid in determining how one's views and beliefs affect the decision at hand. It is important to note that the decision support instrument does not make the decision for the parent or come to any conclusions; it is used to inform parents, help guide the decision-making process and aid in physician-parent communication. The decision support instrument also aids in organizing decisional information, in determining what information is required for decision-making, and in identifying what additional information is required before a decision can be made. Screen shots of the decision support instrument are shown in Figure 20 – Figure 27.



Decision Support

You have been asked to consider a change in the direction of care.

Direction of care options:

You are being asked to consider the following directions of care:

- Full, active care
- Non-escalation of care
- Do not resuscitate order (DNR)
- Withdrawal of life support / palliative care

While you are considering a change in the direction of care, the current direction of care (Full, active care) will continue.

Reason change in direction of care has been suggested:

The reason a change in the direction of care has been suggested is:

- Death is most likely to occur despite full active care
- We believe your baby is suffering
- Your baby is likely to have severe developmental handicaps if he/she survives

Change in direction of care decision support form:

This decision support form is a questionnaire that will help you to:

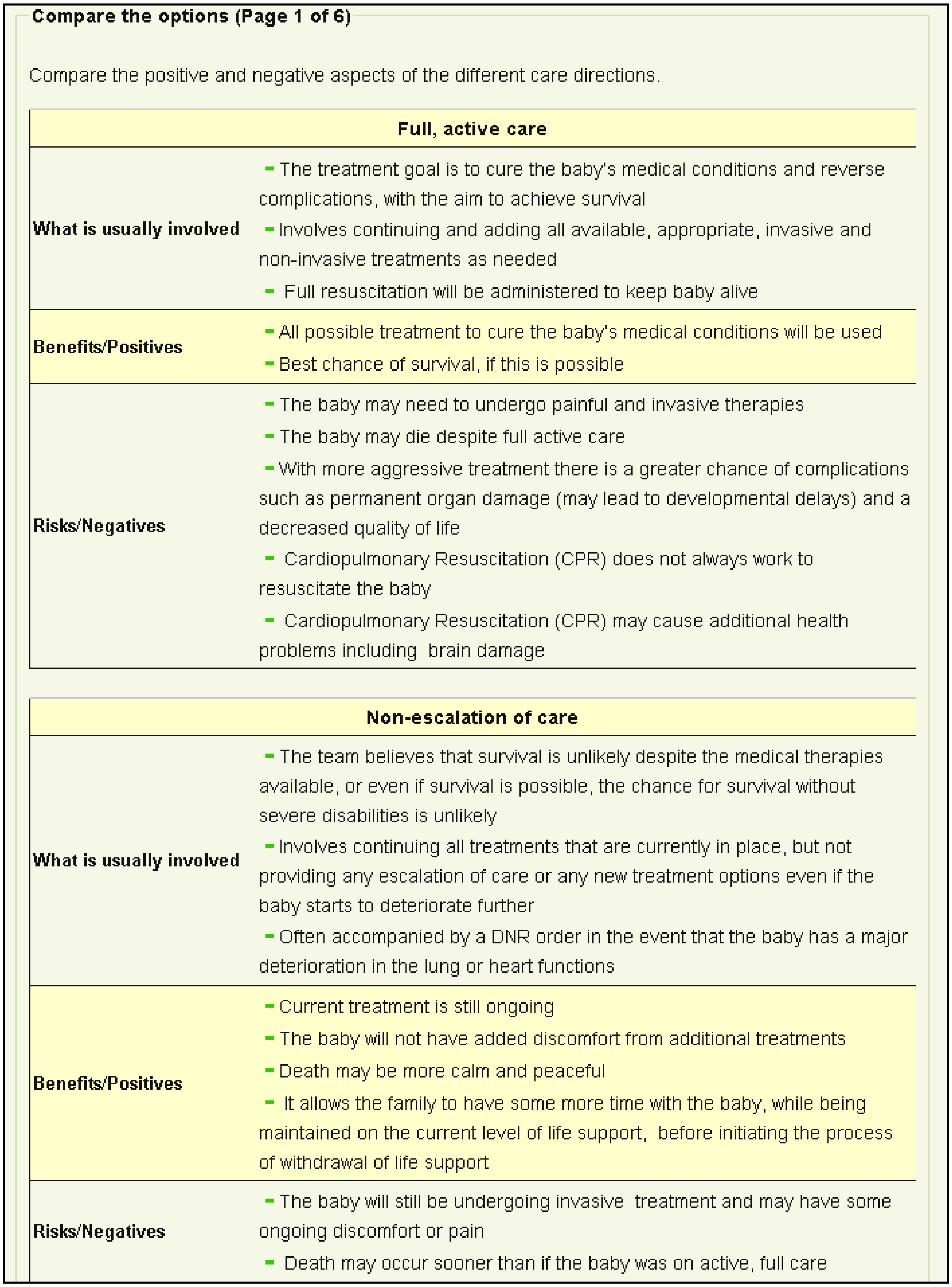
- Clarify the different options
- Understand how your values and beliefs influence your decisions

When you are done and submit the form you can print it for future reference. You can also edit your results at any time. This form does not make the decision for you or come to any conclusions; it is just meant to help guide you in your decision making.

- **Start a new decision support form**

- Edit/View/Print completed forms

Figure 19. PPADS decision support page.



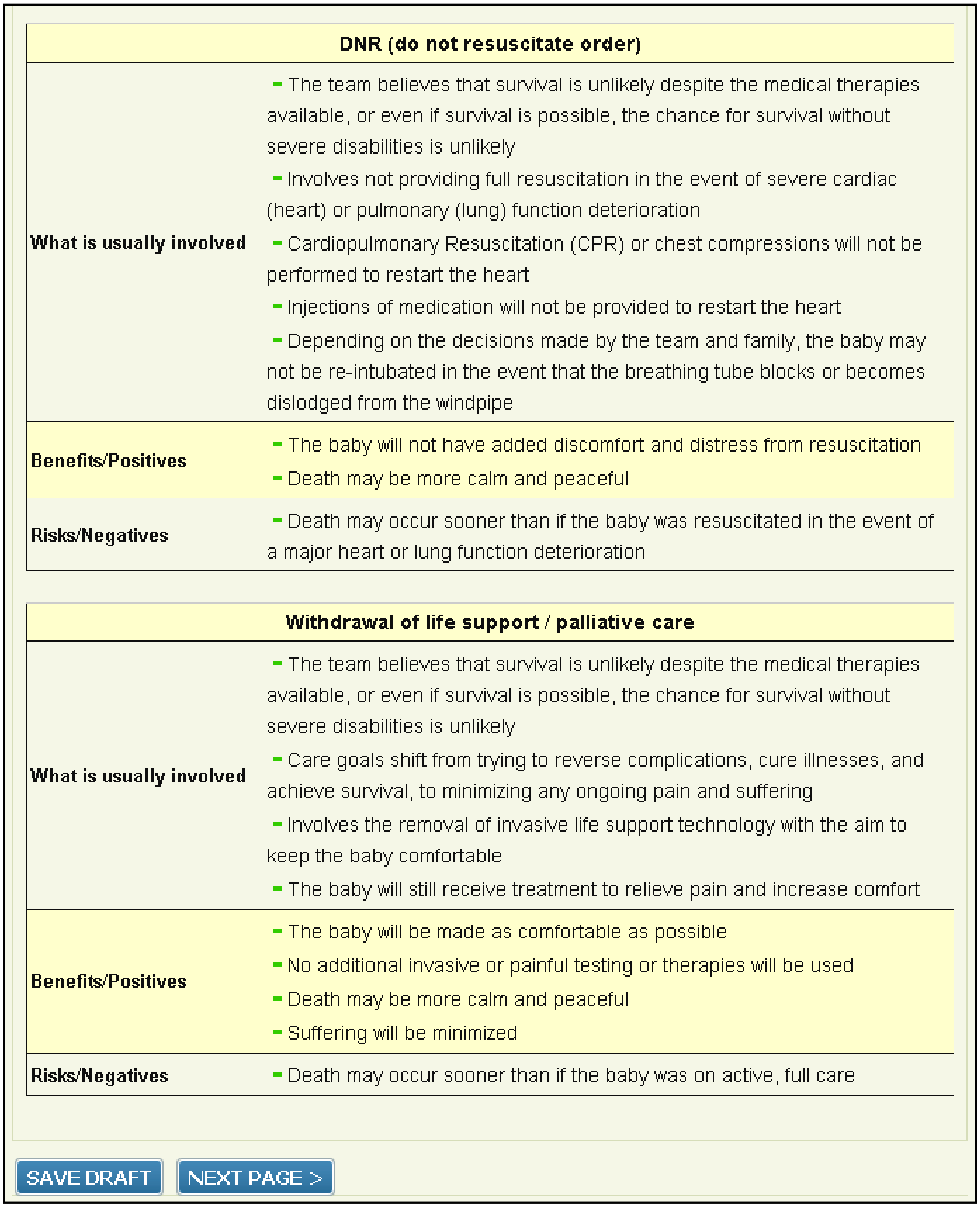
Compare the options (Page 1 of 6)

Compare the positive and negative aspects of the different care directions.

Full, active care	
What is usually involved	- The treatment goal is to cure the baby's medical conditions and reverse complications, with the aim to achieve survival - Involves continuing and adding all available, appropriate, invasive and non-invasive treatments as needed - Full resuscitation will be administered to keep baby alive
Benefits/Positives	- All possible treatment to cure the baby's medical conditions will be used - Best chance of survival, if this is possible
Risks/Negatives	- The baby may need to undergo painful and invasive therapies - The baby may die despite full active care - With more aggressive treatment there is a greater chance of complications such as permanent organ damage (may lead to developmental delays) and a decreased quality of life - Cardiopulmonary Resuscitation (CPR) does not always work to resuscitate the baby - Cardiopulmonary Resuscitation (CPR) may cause additional health problems including brain damage

Non-escalation of care	
What is usually involved	- The team believes that survival is unlikely despite the medical therapies available, or even if survival is possible, the chance for survival without severe disabilities is unlikely - Involves continuing all treatments that are currently in place, but not providing any escalation of care or any new treatment options even if the baby starts to deteriorate further - Often accompanied by a DNR order in the event that the baby has a major deterioration in the lung or heart functions
Benefits/Positives	- Current treatment is still ongoing - The baby will not have added discomfort from additional treatments - Death may be more calm and peaceful - It allows the family to have some more time with the baby, while being maintained on the current level of life support, before initiating the process of withdrawal of life support
Risks/Negatives	- The baby will still be undergoing invasive treatment and may have some ongoing discomfort or pain - Death may occur sooner than if the baby was on active, full care

Figure 20. PPADS decision-support instrument page 1, part 1.



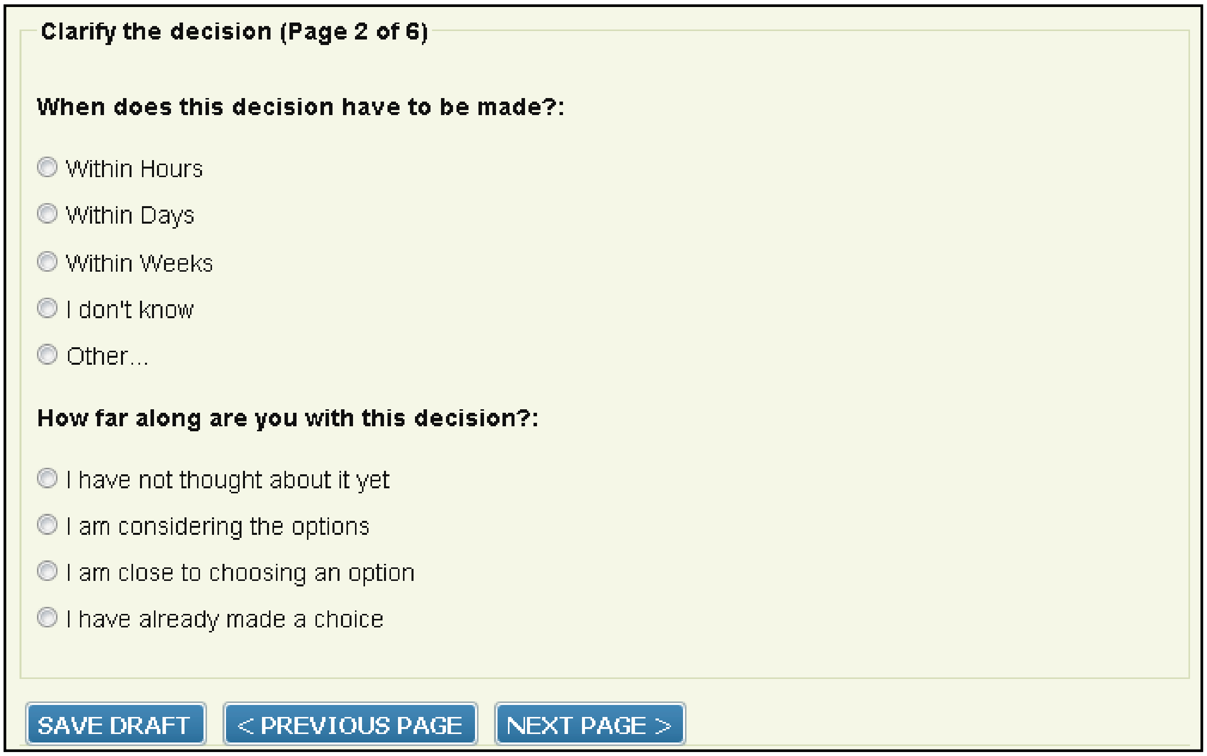
DNR (do not resuscitate order)

What is usually involved	- The team believes that survival is unlikely despite the medical therapies available, or even if survival is possible, the chance for survival without severe disabilities is unlikely - Involves not providing full resuscitation in the event of severe cardiac (heart) or pulmonary (lung) function deterioration - Cardiopulmonary Resuscitation (CPR) or chest compressions will not be performed to restart the heart - Injections of medication will not be provided to restart the heart - Depending on the decisions made by the team and family, the baby may not be re-intubated in the event that the breathing tube blocks or becomes dislodged from the windpipe
Benefits/Positives	- The baby will not have added discomfort and distress from resuscitation - Death may be more calm and peaceful
Risks/Negatives	- Death may occur sooner than if the baby was resuscitated in the event of a major heart or lung function deterioration

Withdrawal of life support / palliative care

What is usually involved	- The team believes that survival is unlikely despite the medical therapies available, or even if survival is possible, the chance for survival without severe disabilities is unlikely - Care goals shift from trying to reverse complications, cure illnesses, and achieve survival, to minimizing any ongoing pain and suffering - Involves the removal of invasive life support technology with the aim to keep the baby comfortable - The baby will still receive treatment to relieve pain and increase comfort
Benefits/Positives	- The baby will be made as comfortable as possible - No additional invasive or painful testing or therapies will be used - Death may be more calm and peaceful - Suffering will be minimized
Risks/Negatives	- Death may occur sooner than if the baby was on active, full care

Figure 21. PPADS decision-support instrument page 1, part 2.


Clarify the decision (Page 2 of 6)

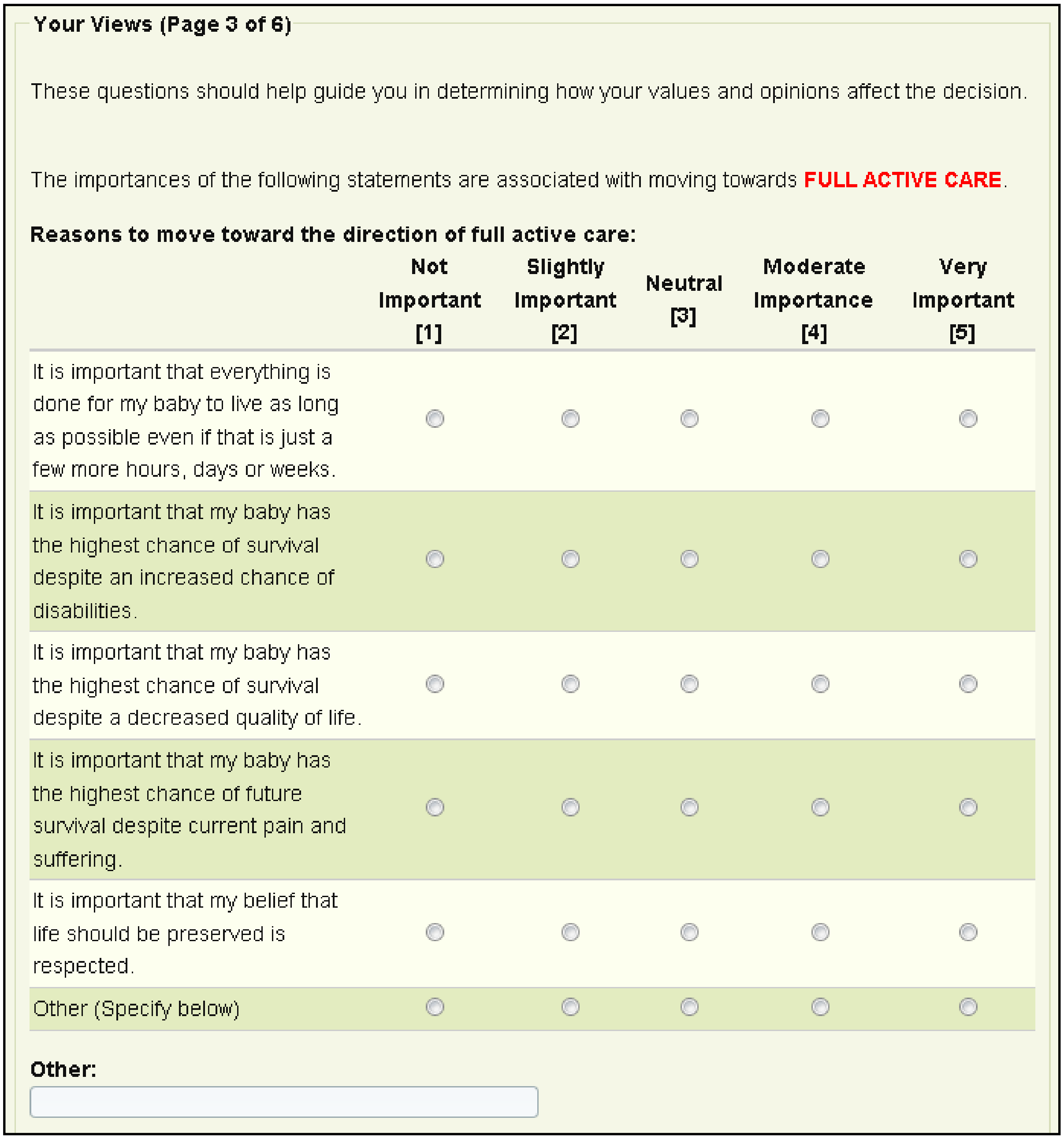
When does this decision have to be made?:

○ Within Hours
○ Within Days
○ Within Weeks
○ I don't know
○ Other...

How far along are you with this decision?:

○ I have not thought about it yet
○ I am considering the options
○ I am close to choosing an option
○ I have already made a choice

Figure 22. PPADS decision-support instrument page 2.



Your Views (Page 3 of 6)

These questions should help guide you in determining how your values and opinions affect the decision.

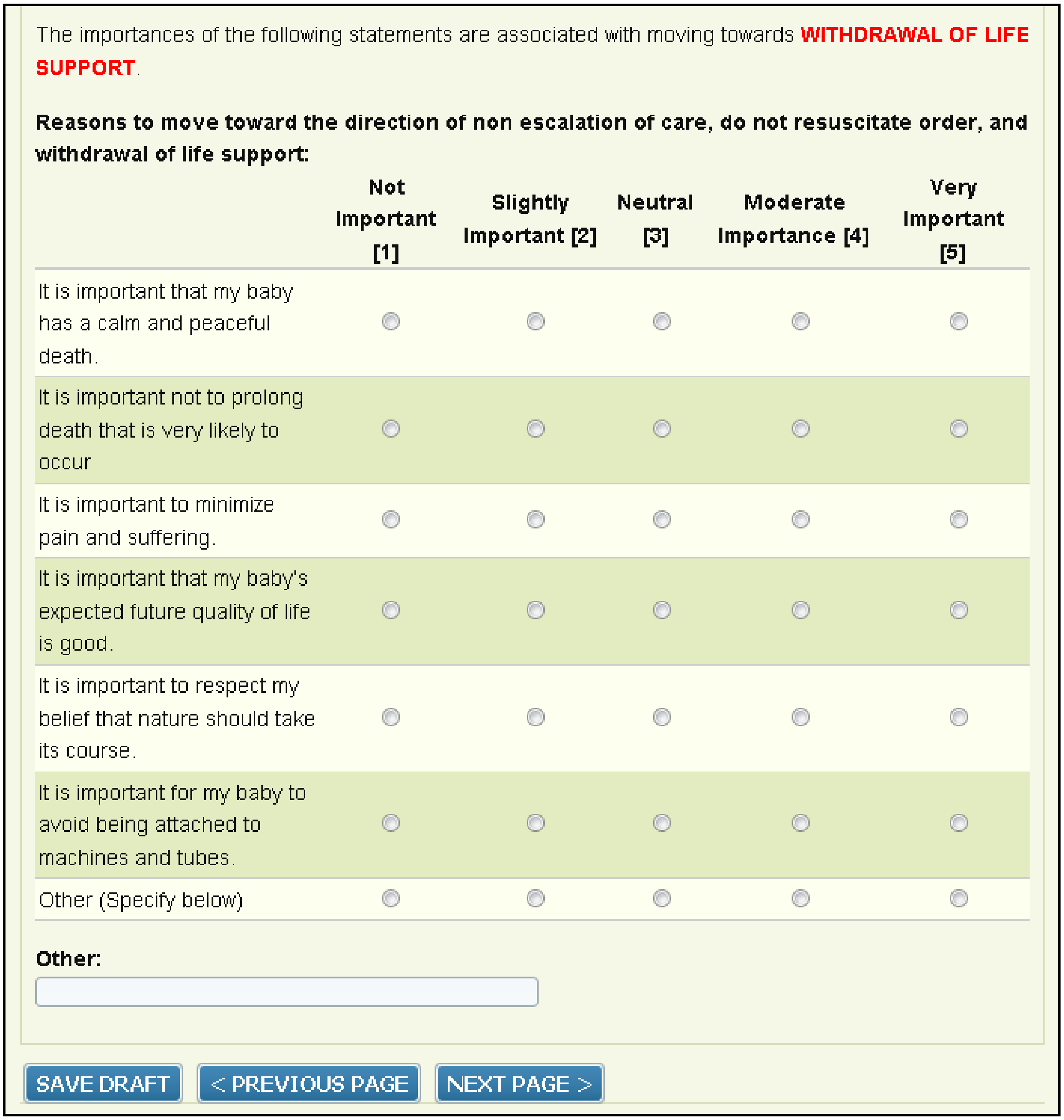
The importances of the following statements are associated with moving towards **FULL ACTIVE CARE**.

Reasons to move toward the direction of full active care:

	Not Important [1]	Slightly Important [2]	Neutral [3]	Moderate Importance [4]	Very Important [5]
It is important that everything is done for my baby to live as long as possible even if that is just a few more hours, days or weeks.	○	○	○	○	○
It is important that my baby has the highest chance of survival despite an increased chance of disabilities.	○	○	○	○	○
It is important that my baby has the highest chance of survival despite a decreased quality of life.	○	○	○	○	○
It is important that my baby has the highest chance of future survival despite current pain and suffering.	○	○	○	○	○
It is important that my belief that life should be preserved is respected.	○	○	○	○	○
Other (Specify below)	○	○	○	○	○

Other:

Figure 23. PPADS decision-support instrument page 3, part 1.



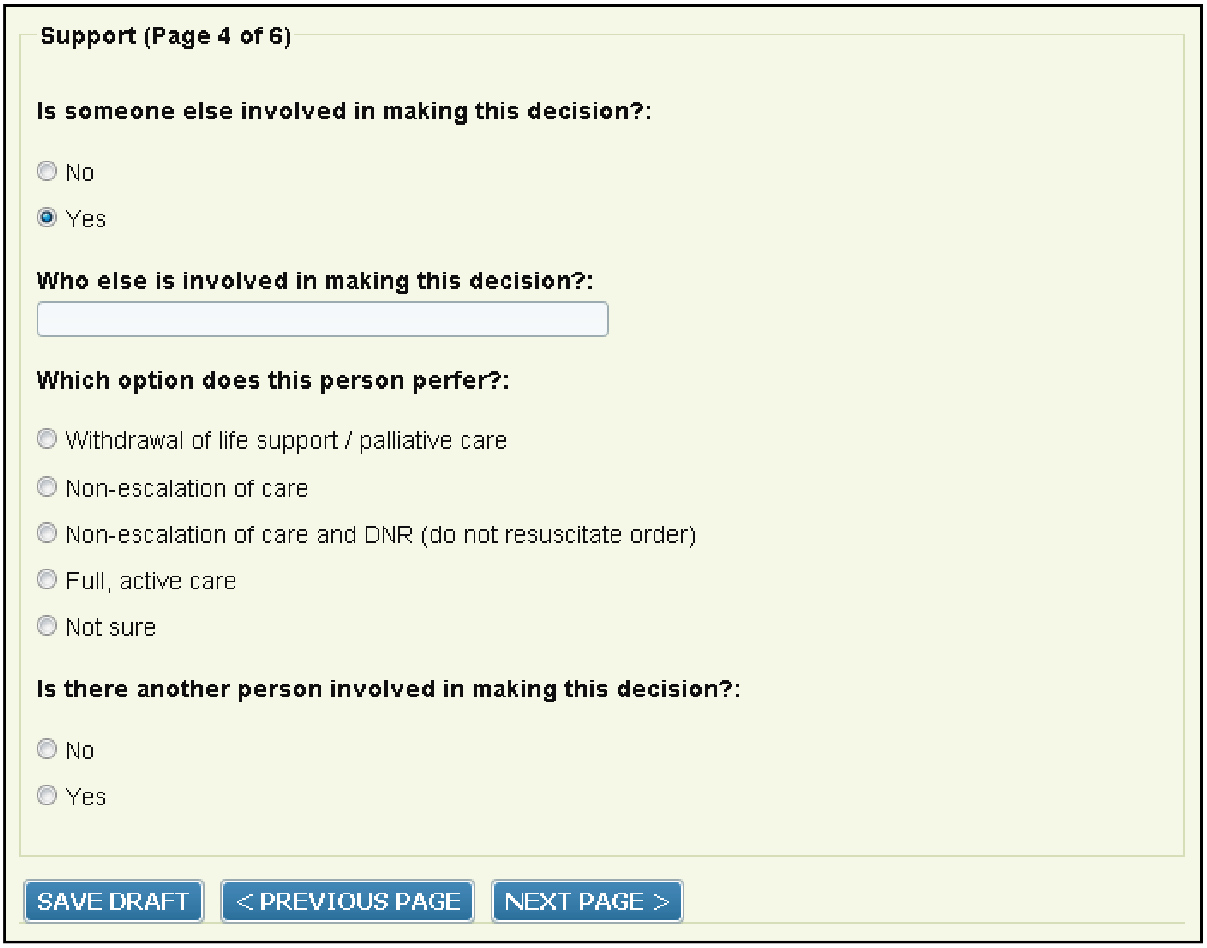
The importances of the following statements are associated with moving towards **WITHDRAWAL OF LIFE SUPPORT**.

Reasons to move toward the direction of non escalation of care, do not resuscitate order, and withdrawal of life support:

	Not Important [1]	Slightly Important [2]	Neutral [3]	Moderate Importance [4]	Very Important [5]
It is important that my baby has a calm and peaceful death.	○	○	○	○	○
It is important not to prolong death that is very likely to occur	○	○	○	○	○
It is important to minimize pain and suffering.	○	○	○	○	○
It is important that my baby's expected future quality of life is good.	○	○	○	○	○
It is important to respect my belief that nature should take its course.	○	○	○	○	○
It is important for my baby to avoid being attached to machines and tubes.	○	○	○	○	○
Other (Specify below)	○	○	○	○	○

Other:

Figure 24. PPADS decision-support instrument page 3, part 2.



Support (Page 4 of 6)

Is someone else involved in making this decision?:

○ No

● Yes

Who else is involved in making this decision?:

Which option does this person perfer?:

○ Withdrawal of life support / palliative care

○ Non-escalation of care

○ Non-escalation of care and DNR (do not resuscitate order)

○ Full, active care

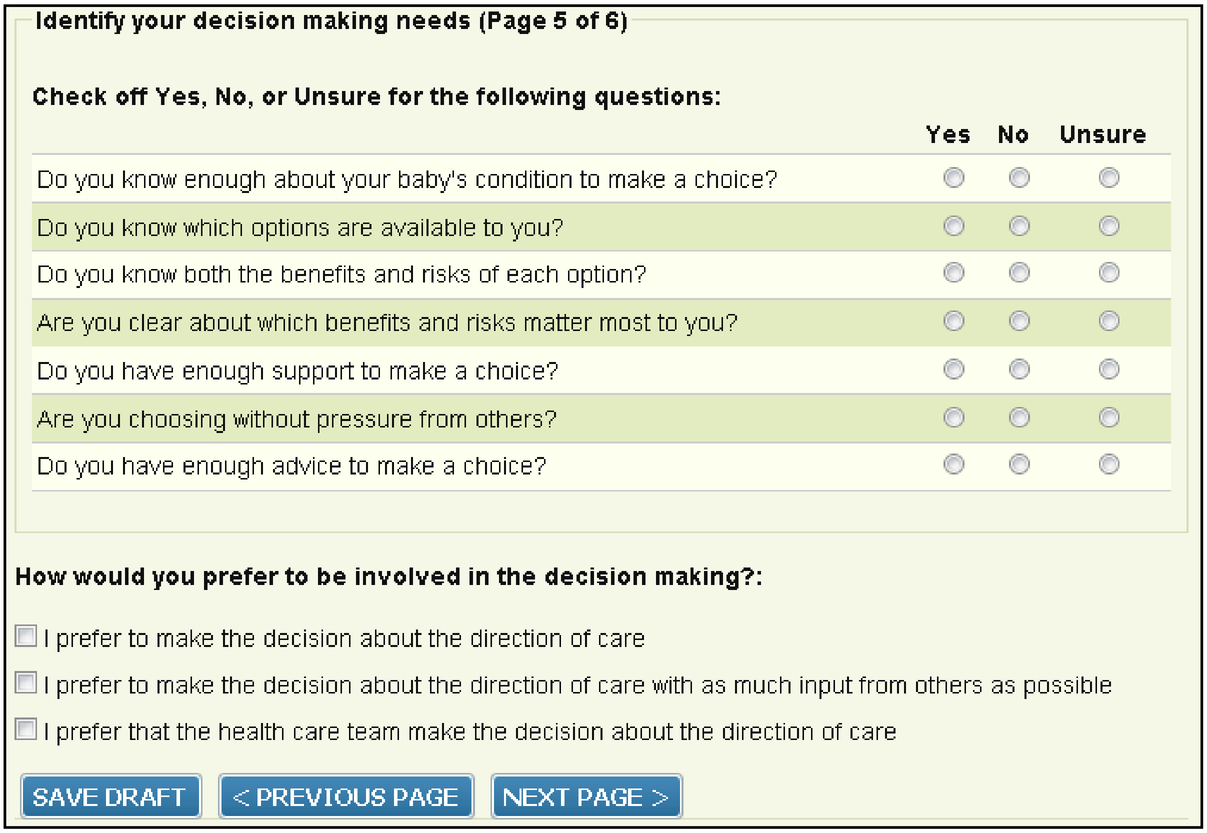
○ Not sure

Is there another person involved in making this decision?:

○ No

○ Yes

Figure 25. PPADS decision-support instrument page 4.



Identify your decision making needs (Page 5 of 6)

Check off Yes, No, or Unsure for the following questions:

	Yes	No	Unsure
Do you know enough about your baby's condition to make a choice?	○	○	○
Do you know which options are available to you?	○	○	○
Do you know both the benefits and risks of each option?	○	○	○
Are you clear about which benefits and risks matter most to you?	○	○	○
Do you have enough support to make a choice?	○	○	○
Are you choosing without pressure from others?	○	○	○
Do you have enough advice to make a choice?	○	○	○

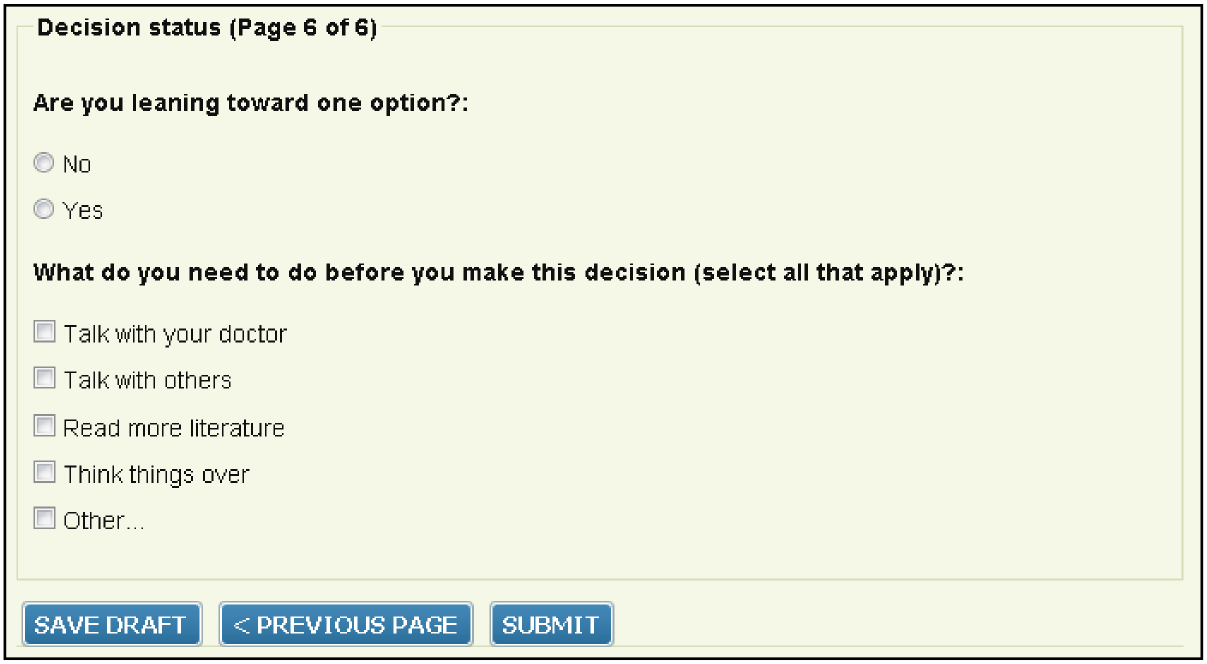
How would you prefer to be involved in the decision making?:

☐ I prefer to make the decision about the direction of care

☐ I prefer to make the decision about the direction of care with as much input from others as possible

☐ I prefer that the health care team make the decision about the direction of care

Figure 26. PPADS decision-support instrument page 5.



Decision status (Page 6 of 6)

Are you leaning toward one option?:

○ No

○ Yes

What do you need to do before you make this decision (select all that apply)?:

☐ Talk with your doctor

☐ Talk with others

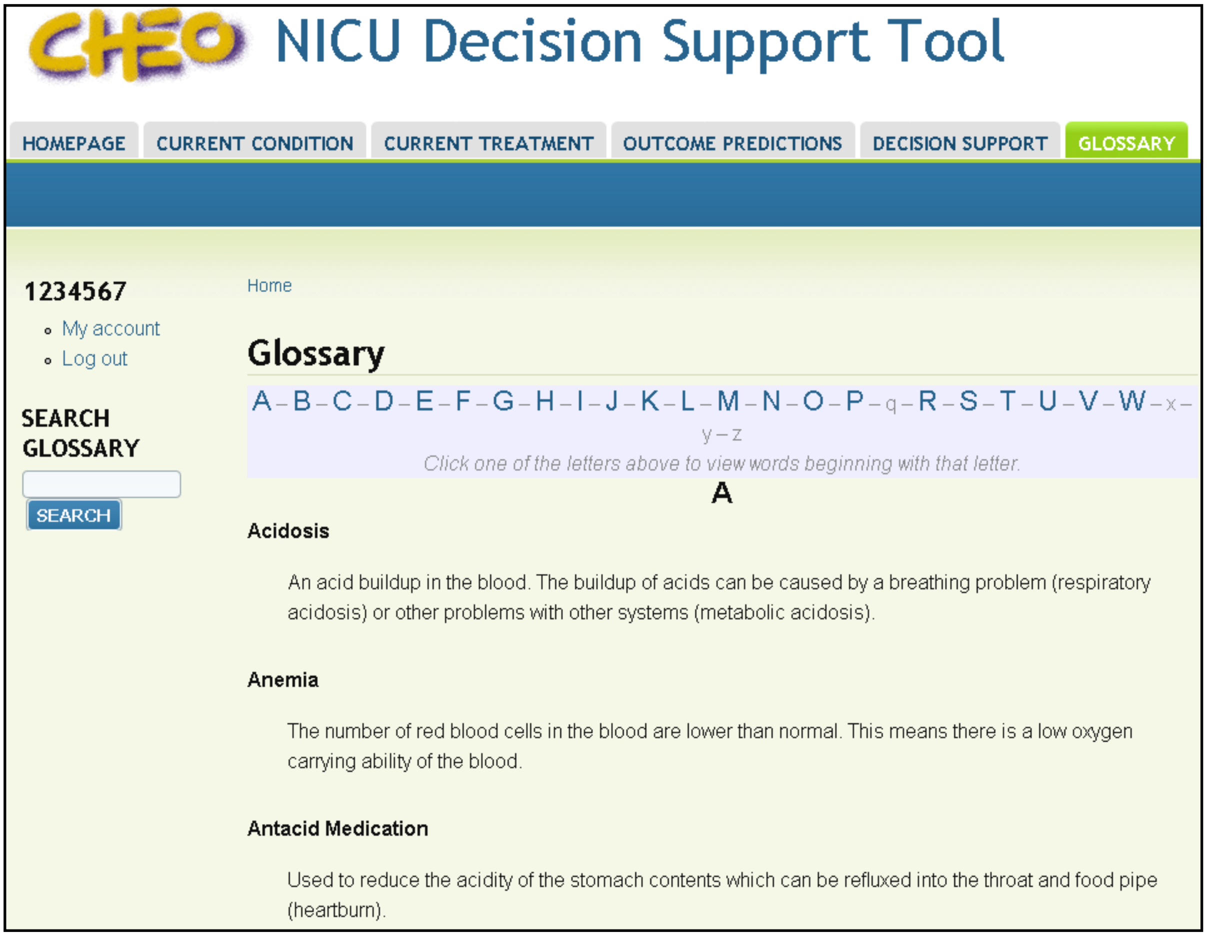
☐ Read more literature

☐ Think things over

☐ Other...

Figure 27. PPADS decision-support instrument page 6.

The glossary contains definitions of the different medical terms. A screen shot of the glossary is shown in Figure 28. The glossary definitions are based on several literature sources as well as input from our clinical neonatal care experts [77],[78],[79],[80]. A complete list of the current glossary definitions is shown in Appendix B.



Glossary

Click one of the letters above to view words beginning with that letter.

A

Acidosis

An acid buildup in the blood. The buildup of acids can be caused by a breathing problem (respiratory acidosis) or other problems with other systems (metabolic acidosis).

Anemia

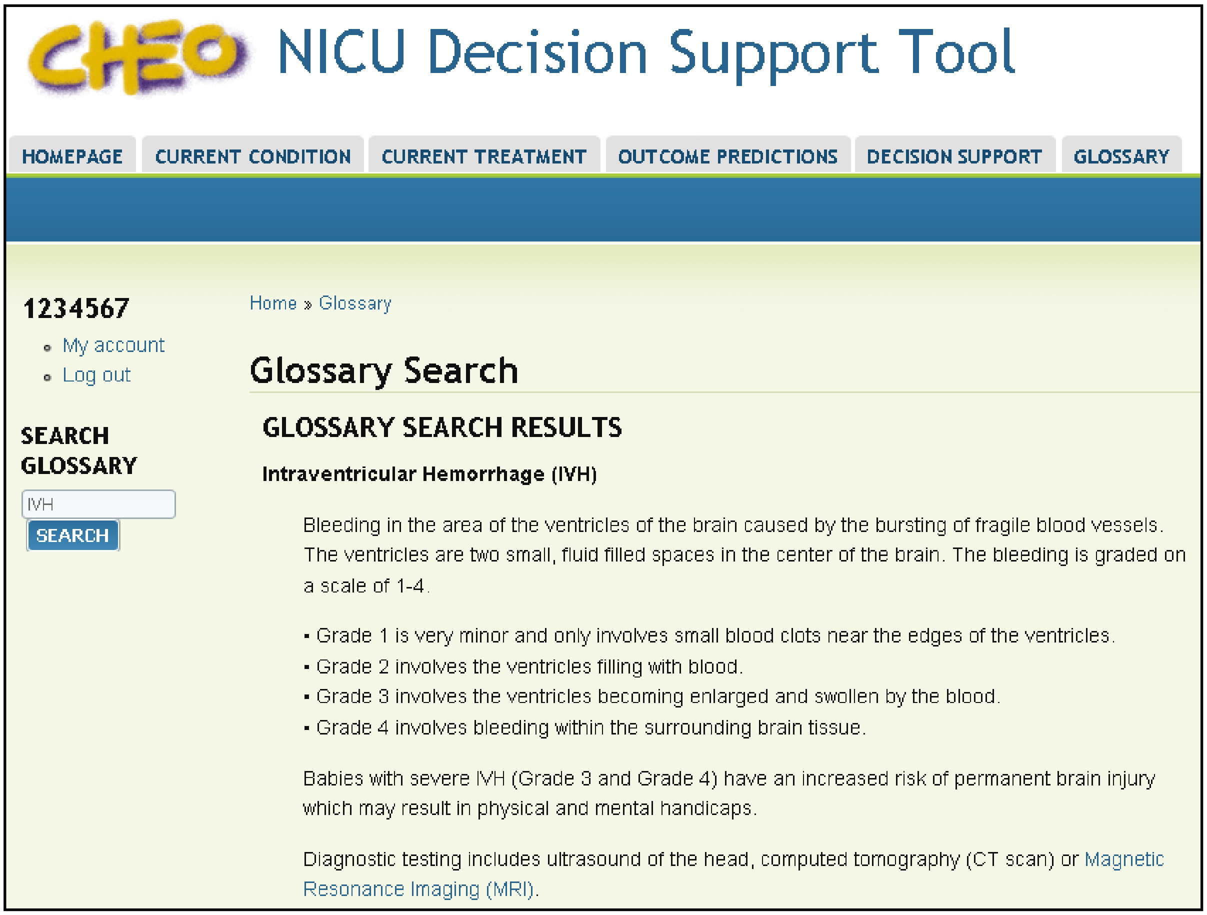
The number of red blood cells in the blood are lower than normal. This means there is a low oxygen carrying ability of the blood.

Antacid Medication

Used to reduce the acidity of the stomach contents which can be refluxed into the throat and food pipe (heartburn).

Figure 28. PPADS glossary page.

Parents can also search glossary terms by typing in the term in the search glossary box, located in the left hand column of every page. A screen shot of the glossary search result of the term IVH is shown in Figure 29 as an example.



Glossary Search

GLOSSARY SEARCH RESULTS

Intraventricular Hemorrhage (IVH)

Bleeding in the area of the ventricles of the brain caused by the bursting of fragile blood vessels. The ventricles are two small, fluid filled spaces in the center of the brain. The bleeding is graded on a scale of 1-4.

- Grade 1 is very minor and only involves small blood clots near the edges of the ventricles.
- Grade 2 involves the ventricles filling with blood.
- Grade 3 involves the ventricles becoming enlarged and swollen by the blood.
- Grade 4 involves bleeding within the surrounding brain tissue.

Babies with severe IVH (Grade 3 and Grade 4) have an increased risk of permanent brain injury which may result in physical and mental handicaps.

Diagnostic testing includes ultrasound of the head, computed tomography (CT scan) or Magnetic Resonance Imaging (MRI).

Figure 29. PPADS IVH glossary search.

The PPADS tool also contains an about page which can be accessed by both clinicians and parents. The about page provides information about the decision-aid, including the date when the tool was last updated, the readability level, and the scientific evidence that was used for developing the tool. A screen shot of the about page is shown in Figure 30.

About

About Decision Aid:

This decision aid was made by the Medical Information-technology Research Group in collaboration with the Children's Hospital of Eastern Ontario in 2011. The authors of the decision aid do not stand to gain or lose by choices people make after using the decision aid.

The tool was last updated in February 2011.

The readability level of this decision aid is at a grade 8 level or less.

This decision aid was developed using the following scientific evidence:

- Elwyn, G., OConnor, A., Stacey, D., Volk, R., Edwards, A., Coulter, A., Thomson, R., Barratt, A., Barry, M., Bernstein, S., Butow, P., Clarke, A., Entwistle, V., Feldman-Stewart, D., Holmes-Rovner, M., Llewellyn-Thomas, H., Moumjid, N., Mulley, A., Ruland, C., Sepucha, K., Sykes, A. & Whelan, T. 2006, "Developing a quality criteria framework for patient decision aids: online international Delphi consensus process.", BMJ.British medical journal, vol. 333, no. 7565, pp. 417-417.
- Kryworuchko, J. 2009, Understanding the Options: Planning for critically ill patients in the Intensive Care Unit (ICU). Available: http://decisionaid.ohri.ca.proxy.bib.uottawa.ca/docs/das /Critically_Ill_Decision_Support.pdf [2011, January 5].
- OConnor, A.M. & Jacobsen, M.J. 2003, Workbook on Developing and Evaluating Patient Decision Aids, www.ohri.ca/decisionaid.

Figure 30. PPADS about page.

4.1.3 Implementation of Design Criteria

The PPADS tool was designed to meet as many of the established design criteria as possible. Table 8 describes how the implementation of the PPADS tool met the general design criteria aimed to increase the likelihood of successful adoption, established in section 3.2.

Table 8. Implementation of PPADS general design criteria.

	MDSS General Design Criteria	***Answer***
	Input to MDSS	
1	Criterion: The tool should minimize manual data entry. Manual data entry was minimized by linking the tool to the hospital network. Some information must currently still be entered manually (ex. current condition), but this manual data entry has been made as easy as possible and was designed with the aid of our clinician partners. For example, the clinician is able to enter the neonates` current condition using a check box list of the most common neonatal conditions as shown in Figure 9 and Figure 10 on pages 55 and 56. If the condition is not listed, the clinician can manually enter the condition.	Yes
2	Criterion: It should be easy to update and perform maintenance on the tool. The PPADS tool allows for easy updating and maintenance of the tool without any programming knowledge. Figure 13 on page 58 shows how the physician can easily update and add new glossary definitions. Figure 14 on page 59 shows how the clinician can easily update the tools’ conditions list, reason a change in direction of care was suggested list, add parent user accounts, and add additional decision support forms.	Yes
	Human-computer interaction	
3	Criterion: The tool should be easily accessible. The PPADS tool can be accessed 24/7 through any web browser on any operating system, including desktop computers, laptops, and mobile devices within the hospital network.	Yes
4	Criterion: The tool should have secure access. The PPADS tool can only be accessed from inside the hospital’s secure network. Each of the parents and clinician accounts have their own username and password. Parents will only have access to information which they have been given permission from the clinician to view.	Yes
5	Criterion: The tool should have a backup. The PPADS databases are all backed up once a day.	Yes
6	Criterion: The human-computer interaction should be speedy. The tool should respond to user requests in less than 2 seconds when pre-defined information is being displayed. Testing has shown that the tool responds to user requests in less than 2 seconds when pre-defined information is being displayed.	Yes
7	Criterion: The tool should allow multiple user access at the same time. The system was designed to support simultaneous multi-user access. Testing	Yes

	has verified that at least four users can access the tool at the same time.	
8	Criterion: The tool should be user-friendly and intuitive to use. Usability testing on parents has shown that the tool is user-friendly and intuitive to use. The results of the usability study are presented in detail in section 4.2.	Yes
	Output of the MDSS	
9	Criterion: The tool's output should add value to the physician and to parents. Usability testing on parents and physicians has shown that the tool adds value. The results of the usability study are presented in section 4.2.	Yes
10	Criterion: The tool should fit into the hospital workflow. The tool has been developed with clinical neonatal care experts to fit into hospital workflow and consultations.	Yes
11	Criterion: The tool should be developed with expert input. Expert input from Dr. Erika Bariciak, a neonatologist at CHEO, and Sandra Dunn, a decision support specialist with the CMNRP has been incorporated throughout the development process. Several prototypes were developed and physician feedback was incorporated after each prototype.	Yes

Table 9 describes how the implementation of the PPADS tool met the specific design criteria aimed to meet the decision-making needs of parents established in section 3.2.

Table 9. Implementation of PPADS specific design criteria.

	NICU Specific Design Criteria	***Answer***
1	Criterion: The parent tool should be informative, but not prescriptive. Usability testing has shown that the tool is informative, but not prescriptive. As part of the usability study, each participant used the PPADS tool on the same hypothetical case study. After using the tool, three participants were leaning towards non-escalation of care, two participants were leaning towards withdrawal of care, two participants were leaning towards full active care, and one remained neutral. The differing directions of care show that the tool is informative, but not prescriptive. The results of the usability study are presented in section 4.2.	Yes
2	Criterion: The tool should aid parents in making more informed decisions, in understanding the decision options, in feeling more certain about their decision, and in feeling clearer about their values. Usability testing has shown that the tool aids parents in making more informed decisions, understanding the decision options, in feeling more certain about their decision, and in feeling clearer about their values. The results of the usability study are further discussed in section 4.2.	Yes

3	Criterion: The tool should provide parents with information regarding the condition of their neonate. The PPADS tool’s current condition page provides parents with a list of the current conditions their neonate has been diagnosed with. Each of the conditions is an active link, which leads to a glossary definition of the condition. The current condition page is shown in Figure 16 on page 61of this thesis.	Yes
4	Criterion: The tool should provide parents with information regarding the treatment therapies of their neonate. The PPADS tool’s treatment page provides parents with a list of their neonate’s current treatment therapies. Each of the therapies is an active link, which leads to a glossary definition of the therapy. The treatment page is shown in Figure 17 on page 62 of this thesis.	Yes
5	Criterion: The tool should provide parents with information regarding the risk predictions of their neonate. The PPADS tool’s outcome predictions page provides parents with risk predictions for their neonate. Currently, the risk of mortality, BPD, IVH and NEC are displayed. The risk predictions used for the usability study were hypothetical predictions. MIRG members are still working on producing accurate predictions from the real-time CDR data. The outcome predictions page is shown in Figure 18 on page 63 of this thesis.	Yes, In Progress
6	Criterion: The tool should provide parents with the meaning of medical terms and medical jargon. The PPADS tool’s glossary page provides parents with a large glossary of terms, which explains many medical conditions, treatment therapies, and medical jargon. The glossary page is shown in Figure 28 on page 72 of this thesis.	Yes
7	Criterion: The tool should provide parents with reasoning as to why a decision must be made. The PPADS tool’s decision support page provides parents with the reason why the clinician has suggested a decision must be made. The decision support page is shown in Figure 19 on page 64 of this thesis.	Yes
8	Criterion: The tool should provide parents with the positive and negative features of each of the decision options. The first page of the decision support form provides a table outlining the positive and negative features of each decision option. The first page of the decision support form is shown in Figure 20 and Figure 21 on pages 65 and 66 of this thesis.	Yes
9	Criterion: The tool should provide parents with a way to understand how their values and beliefs influence the decision. The third page of the decision support form provides a Likert scale questionnaire that helps parents understand how their values and beliefs influence the decision. The third page of the decision support form is shown	Yes

	in Figure 23 and Figure 24 on pages 68 and 69 of this thesis.	
10	Criterion: The tool should not provide conflicting information. The PPADS tool does not provide conflicting information.	Yes
11	Criterion: The tool should be easy to understand (medical euphemism and jargon are avoided or explained). Usability testing has shown that the PPADS tool is easy to understand. The results of the usability study are presented in section 4.2.	Yes
12	Criterion: The tool should provide information in more than one form, to facilitate understanding. The PPADS tool has been designed to provide information in more than one way to facilitate understanding. One example is the way risk predictions are presented to the user. Instead of displaying the risk level for mortality of the neonate to be 85%, a graphical representation showing a high risk and a written description is used, as shown in Figure 18 on page 63 of this thesis.	Yes
13	Criterion: The parent tool should have a readability level of grade 8 or less. The PPADS tool readability is at a grade 8 level or less. The PPADS tool has been screened using the Flesch-Kincaid grade level tool. The readability of each of the parent pages is shown in Table 10.	Yes
14	Criterion: The tool should maximize coherence with IPDAS criteria. The tool has been developed to maximize coherence with the IPDAS standards. The PPADS tool currently meets 21 out of 22 applicable IPDAS requirements, as shown in Table 11.	Yes

The PPADS tool has been designed to have a grade 8 Flesch-Kincaid readability level or less for all parent pages. Table 10 shows the Flesch-Kincaid readability grade level for each of the PPADS parent pages.

Table 10. Flesch-Kincaid readability grade level for PPADS parent pages.

Page	Grade level
Homepage	7.5
Glossary	8.0
Current Condition Page	6.1
Current Treatment Page	4.4
Outcome Predictions Page	7.9
Decision Support Main Page	7.3
Decision Support Instrument Page 1	8.0
Decision Support Instrument Page 2	3.0
Decision Support Instrument Page 3	7.9
Decision Support Instrument Page 4	5.0
Decision Support Instrument Page 5	4.6
Decision Support Instrument Page 6	2.8

The PPADS tool has been designed to maximize coherence with the IPDAS requirements. The PPADS tool currently meets 21 out of 22 applicable IPDAS requirements. A list of the IPDAS requirements, the applicability of the IPDAS criteria, and how the tool conforms or does not conform is shown in Table 11.

Table 11. Implementation of IPDAS standards.

	IPDAS Criterion	**Answer**
1	Criterion: The decision aid describes the condition (health or other) related to the decision. The current condition page, shown in Figure 16 on page 61 of this thesis, describes the current conditions related to the decision. The current treatment page, shown in Figure 17 on page 62 of this thesis, describes the current therapies related to the decision.	Yes
2	Criterion: The decision aid describes the decision that needs to be considered (the index decision). The decision support page, shown in Figure 19 on page 64 of this thesis, describes the decision to be made.	Yes
3	Criterion: The decision aid lists the options (health care or other). The decision support page, shown in Figure 19 on page 64 of this thesis, lists the decision options.	Yes
4	Criterion: The decision aid describes what happens in the natural course of the condition (health or other) if no action is taken. The decision support page, shown in Figure 19 on page 64 of this thesis, states that if no action is taken the current direction of care is continued.	Yes
5	Criterion: The decision aid has information about the procedures involved (e.g. what is done before, during, and after the health care option). The first page of the decision support instrument, shown in Figure 20 and Figure 21 on pages 65 and 66 of this thesis, provides information about the procedures involved.	Yes
6	Criterion: The decision aid has information about the positive features of the options (e.g. benefits, advantages). The first page of the decision support instrument, shown in Figure 20 and Figure 21 on pages 65 and 66 of this thesis, provides information about the positive features of each option.	Yes

7	Criterion: The decision aid has information about negative features of the options (e.g. harms, side effects, disadvantages). The first page of the decision support instrument, shown in Figure 20 and Figure 21 on pages 65 and 66 of this thesis, provides information about the negative features of each option.	Yes
8	Criterion: The information about outcomes of options (positive and negative) includes the chances they may happen. Not applicable. The chance that the positive and negative features of each of the four directions of care options will occur is not applicable. However, the neonate's current predictions of mortality and various diseases are displayed. The prediction algorithm for mortality and various diseases is currently still being developed by MIRG group members. For usability testing hypothetical predictions were used.	N/A
9	Criterion: The decision aid has information about what the test is designed to measure. Not applicable. (No test)	N/A
10	Criterion: The decision aid describes possible next steps based on the test results. Not applicable. (No test)	N/A
11	Criterion: The decision aid has information about the chances of disease being found with and without screening. Not applicable. (No test)	N/A
12	Criterion: The decision aid has information about detection and treatment of disease that would never have caused problems if screening had not been done. Not applicable. (No test)	N/A
13	Criterion: The decision aid presents probabilities using event rates in a defined group of people for a specified time. The predictions of mortality and various diseases are calculated using data collected by the CDR from neonates at CHEO since 2010. The prediction algorithm for mortality and various diseases is currently still being developed by MIRG group members. For usability testing hypothetical predictions were used.	Yes, In Progress
14	Criterion: The decision aid compares probabilities (e.g. chance of a disease, benefit, harm, or side effect) of options using the same denominator. Not applicable. The probabilities of the different options are not applicable.	N/A
15	Criterion: The decision aid compares probabilities of options over the same period of time. Not applicable. The probabilities of the different options are not applicable.	N/A

16	Criterion: The decision aid uses the same scales in diagrams comparing options. Not applicable. There are no diagrams comparing the options.	N/A
17	Criterion: The decision aid asks people to think about which positive and negative features of the options matter most to them. The third page of the decision support instrument, shown in Figure 23 and Figure 24 on pages 68 and 69, asks people to think about which positive and negative features of the options matter most to them.	Yes
18	Criterion: The decision aid makes it possible to compare the positive and negative features of the available options. The first page of the decision support instrument, shown in Figure 20 and Figure 21 on pages 65 and 66 of this thesis, compares the positive and negative features of the available options.	Yes
19	Criterion: The decision aid shows the negative and positive features of the options with equal detail. The first page of the decision support instrument, shown in Figure 20 and Figure 21 on pages 65 and 66 of this thesis, displays the positive and negative features of each option with equal detail.	Yes
	Development Process	**Answer**
20	Criterion: Users (people who previously faced the decision) were asked what they need to prepare them to discuss a specific decision. Past and current usability testing asked users what information they need to make NICU decisions. The results of the usability study are presented in section 4.2.	Yes
21	Criterion: The decision aid was reviewed by people who previously faced the decision who were not involved in its development and field testing. Usability testing was performed on parents who had a neonate who graduated from the NICU within the last year and on neonatologists currently working at the CHEO NICU. The results of the usability study are presented in section 4.2. Future usability testing will be performed on parents who had a neonate who did not survive to be followed by parents who currently have a neonate in the NICU.	Yes
22	Criterion: People who were facing the decision field tested the decision aid. Usability testing was performed on parents who had a neonate who graduate from the NICU within the last year and on neonatologists currently working at the CHEO NICU. The results of the usability study are presented in section 4.2. Future usability testing will be performed on parents who had a neonate who did not survive to be followed by parents who currently have a neonate in the NICU.	Yes

23	Criterion: Field testing showed that the decision aid was acceptable to users (the general public & practitioners). Usability study results indicated that the PPADS tool was acceptable to users. The results of the usability study are presented in section 4.2.	Yes
24	Criterion: Field testing showed that people who were undecided felt that the information was presented in a balanced way. Usability study results showed that users found the information presented in a balanced way. The results of the usability study are further discussed in section 4.2.	Yes
25	Criterion: The decision aid provides references to scientific evidence used. The 'About' page, shown in Figure 30 on page 74 of this thesis, provides references to scientific evidence used.	Yes
26	Criterion: The decision aid reports the date when it was last updated. The 'About' page, shown in Figure 30 on page 74 of this thesis, provides the date when the decision aid was last updated.	Yes
27	Criterion: The decision aid reports whether authors of the decision aid or their affiliations stand to gain or lose by choices people make after using the decision aid. The 'About' page, shown in Figure 30 on page 74 of this thesis, states the authors do not stand to gain or lose by choices people make after using the decision aid.	Yes
28	Criterion: The decision aid (or available technical document) reports readability levels. The 'About' page, shown in Figure 30 on page 74 of this thesis, reports the readability level.	Yes
Effectiveness		**Answer**
29	Criterion: There is evidence that the decision aid (or one based on the same template) helps people know about the available options and their features. Usability testing has shown that the PPADS tool helps users know the options available to them. All parent participants agreed or strongly agreed that they would have a better understanding of decisional options after using the PPADS tool. The results of the usability study are further discussed in section 4.2.	Yes

30	Criterion: There is evidence that the decision aid (or one based on the same template) improves the match between the features that matter most to the informed person and the option that is chosen. Usability testing showed that participants were leaning towards a direction of care that aligned with their indicated views and beliefs. Further usability testing must be performed in order to confirm that the PPADS tool improves the match between features that matter most to the parent and the option that is chosen. Future usability testing will involve a prospective study to assess the tool in the NICU environment, and a randomized multi-centre clinical trial.	No

4.2 Usability Testing Results

Usability testing was performed on eight parents who had a neonate who graduated (survived) from a tertiary level NICU within the last year and on five neonatologists currently working at CHEO. The usability results have confirmed the usefulness, efficiency, effectiveness, acceptability, and satisfaction of the tool.

4.2.1 Parent Usability Testing Results

Data analysis of the parent usability results was performed as detailed in section 3.5.1.2 of the methodology. All questions, unless otherwise indicated, were evaluated on a four point Likert scale, with 4 being the highest score and 1 being the lowest score. Unless otherwise indicated, the usability threshold was that 75% or more of parent participants must agree (3) or strongly agree (4) to the usability criterion.

4.2.1.1 Parent Usefulness Results

The usability results showed the usefulness of the PPADS tool. The PPADS tool made participants feel more informed, have a better understanding of the neonate's current condition, treatments, and risk prediction, have a better understanding of the different directions of care options, feel more certain about their decision, and feel clearer about their values. All usefulness criteria were met with an agreement of 75% or more. All eight participants indicated that they would use the tool if given the opportunity.

All participants agreed or strongly agreed that the current medical condition list, the reason a change in direction of care was suggested, and the decision support form are useful.

Seven of eight, or 88%, of participants agreed or strongly agreed that the current therapies list and risk predictions are useful. Participant 624126 indicated that the list of therapies would be useful if more information was given. Participant 601267 indicated that the outcome predictions would not be useful to them. They would personally not want to see the risk predictions as this would make it too real and they would prefer to only be told the risk prediction verbally by the clinician. This issue is already addressed in the PPADS tool as the clinician can choose not to activate risk predictions if the parent does not want to see them.

Seven of eight, or 88%, of participants agreed or strongly agreed that after using the PPADS tool they would feel more informed, and that the glossary definitions are useful. Participant 750199 indicated that the glossary definitions are useful, but would be even more useful if more information was given.

All participants agreed or strongly agreed that they would have a better understanding of decisional options, and they would feel clearer about how their values affect the decision after using the PPADS tool.

All participants agreed or strongly agreed that the decision support form was presented in a balanced way.

75% of participants indicated that after using the PPADS tool, they would feel more certain about their decision. Participant 750199 indicated that the PPADS tool would help them feel more certain about their decision, but they would never be completely certain about such a difficult decision.

The tool's usefulness was also displayed in the direction participants were leaning towards after completing the decision support form. For the same hypothetical case, after using the tool, three participants were leaning towards non-escalation of care, two participants were leaning towards withdrawal of care, two participants were leaning towards full active care, and one was not leaning in either direction. The different directions show that the tool was presented in a balanced way; additionally the reasoning as to why each person was leaning towards a specific direction was evident and was supported by their values and views. This shows that the decision support instrument helps organise one's decisional thoughts, aids in aligning one's beliefs with one's decision, and aids in communicating one's views.

Detailed usability results of the usefulness of the PPADS tool are shown in Table 12, including the number of participants selecting each response (participant frequencies), and whether the 75% usability threshold was met. The score associated with each Likert option is displayed in parenthesis on the left of the option. This value is used to compute the average score and standard deviation for each question.

Table 12. Parent usefulness results.

Criterion	Usability Results				Meets Criteria
	Likert option	Participant Frequency	Avg.	Standard Deviation	
The current medical condition list is useful	(4) Strongly Agree	4	3.5	0.5	Yes 100%
	(3) Agree	4			
	(2) Disagree	0			
	(1) Strongly Disagree	0			
The current therapies list is useful	(4) Strongly Agree	4	3.4	0.7	Yes 88%
	(3) Agree	3			
	(2) Disagree	1			
	(1) Strongly Disagree	0			
The risk predictions are useful	(4) Strongly Agree	1	2.9	0.8	Yes 88%
	(3) Agree	6			
	(2) Disagree	0			
	(1) Strongly Disagree	1			
The reason a change in direction of care was suggested is useful	(4) Strongly Agree	4	3.5	0.5	Yes 100%
	(3) Agree	4			
	(2) Disagree	0			
	(1) Strongly Disagree	0			
The decision support form is useful	(4) Strongly Agree	5	3.6	0.5	Yes 100%
	(3) Agree	3			
	(2) Disagree	0			
	(1) Strongly Disagree	0			
The directions of care options are presented in a	(4) Strongly Agree	5	3.6	0.5	Yes 100%
	(3) Agree	3			
	(2) Disagree	0			

balanced way	(1) Strongly Disagree	0			
The glossary definitions are useful	(4) Strongly Agree	6	3.4	0.7	Yes 88%
	(3) Agree	1			
	(2) Disagree	1			
	(1) Strongly Disagree	0			
After using PPADS would feel more informed	(4) Strongly Agree	4	3.4	0.7	Yes 88%
	(3) Agree	3			
	(2) Disagree	1			
	(1) Strongly Disagree	0			
After using PPADS better understanding of decisional options	(4) Strongly Agree	4	3.5	0.5	Yes 100%
	(3) Agree	4			
	(2) Disagree	0			
	(1) Strongly Disagree	0			
After using PPADS would feel more certain about decision	(4) Strongly Agree	2	3	0.8	Yes 75%
	(3) Agree	4			
	(2) Disagree	2			
	(1) Strongly Disagree	0			
After using PPADS clearer about how values affect decision	(4) Strongly Agree	2	3.3	0.5	Yes 100%
	(3) Agree	6			
	(2) Disagree	0			
	(1) Strongly Disagree	0			
If given opportunity participants would use the tool	(4) Strongly Agree	5	3.6	0.5	Yes 100%
	(3) Agree	3			
	(2) Disagree	0			
	(1) Strongly Disagree	0			

4.2.1.2 Parent Efficiency and Effectiveness Results

The usability results showed that the PPADS tool is easy to learn, easy to navigate, and can be navigated quickly. All efficiency and effectiveness criteria were met.

All participants agreed or strongly agreed that the information is clearly organized, that the meaning of pages and buttons are easy to understand, that performing the tasks is easy, that the tool is easy to learn, that it is easy for users to find the information they are looking for, and that the tool can be navigated quickly. All participants indicated that navigating the tool is very easy.

Six of eight, or 75%, of the participants indicated that the tool would not add stress. Several participants indicated that this question was difficult to answer since the whole situation would be stressful.

All users were observed to easily and quickly navigate the tool.

Detailed usability results of the efficiency and effectiveness of the PPADS tool are shown in Table 13.

Table 13. Parent efficiency and effectiveness results.

Criterion	Usability Results				Meets Criteria
	Likert option	Participant Frequency	Avg.	Standard Deviation	
The information is clearly organized	(4) Very Clear	7	3.9	0.4	Yes 100%
	(3) Moderately Clear	1			
	(2) Some Confusing	0			
	(1) Very Confusing	0			
Navigation is easy	(4) Very Easy	8	4.0	0	Yes 100%
	(3) Moderately Easy	0			
	(2) Some Difficult	0			
	(1) Very Difficult	0			
Meaning of pages and buttons are easy to understand	(4) Very Easy	7	3.9	0.4	Yes 100%
	(3) Moderately Easy	1			
	(2) Some Difficult	0			
	(1) Very Difficult	0			
Performing the tasks is easy	(4) Always Easy	5	3.6	0.5	Yes 100%
	(3) Mostly Easy	3			
	(2) Sometimes Easy	0			
	(1) Never Easy	0			
The tool is easy to learn	(4) Strongly Agree	7	3.9	0.4	Yes 100%
	(3) Agree	1			
	(2) Disagree	0			
	(1) Strongly Disagree	0			
Using the tool would not add stress	(4) Strongly Agree	0	2.8	0.5	Yes 75%
	(3) Agree	6			
	(2) Disagree	2			
	(1) Strongly Disagree	0			

It is easy for users to find the information they are looking for	(4) Strongly Agree	4	3.5	0.5	Yes 100%
	(3) Agree	4			
	(2) Disagree	0			
	(1) Strongly Disagree	0			
The tool can be navigated quickly	(4) Strongly Agree	7	3.9	0.4	Yes 100%
	(3) Agree	1			
	(2) Disagree	0			
	(1) Strongly Disagree	0			

4.2.1.3 Parent Acceptability Results

The usability results demonstrated the acceptability of the PPADS tool. All acceptability criteria, except for the amount of information displayed, met the 75% usability criteria.

Usability testing verified that the PPADS tool is applicable to all levels of users. All eight participants agreed or strongly agreed that the decision support form, current medical conditions, current treatments, risk predictions, glossary definitions, and the terminology used were easy to understand.

All eight participants agreed or strongly agreed that the reason a change in direction of care was suggested was easy to understand and that the decision support form was the right length.

Five of eight, or 63%, of participants indicated that the amount of information displayed in the PPADS tool is just right, while 3 of 8 participants found that the PPADS tool had too little information. Participants provided numerous suggestions about what additional information would be useful for parent decision-making. The most common suggestion was to provide more information in the glossary definitions and in the treatment therapies list. A complete list of participant suggestions is included in section 4.2.1.6.

All eight participants successfully logged in and completed all tasks without any miss-clicks, in an efficient manner. Task completion times ranged from 22 minutes to 36 minutes. The difference in task completion time was attributed to the amount of time participants spent reading and absorbing the information. The ease and speed of navigation was fast for all users.

Detailed usability results of the acceptability of the PPADS tool are shown in Table 14. The first two criteria, “amount of information in PPADS is good” and “the length of the decision support form is good”, are evaluated on a three point Likert scale. For these two questions, the acceptability criteria requires 75% of participants to choose the second Likert option “Just right”.

Table 14. Parent acceptability results.

Criterion	Usability Results				Meets Criteria
	Likert option	Participant Frequency	Avg.	Standard Deviation	
Amount of information in PPADS is good	(3) Too much	0	1.6	0.5	No 63%
	(2) Just right	5			
	(1) Too little	3			
The length of the decision support form is good	(3) Too much	0	2.0	0	Yes 100%
	(2) Just right	8			
	(1) Too little	0			
Terminology used is easy to understand	(4) Always	3	3.4	0.5	Yes 100%
	(3) Mostly	5			
	(2) Sometimes	0			
	(1) Never	0			
The decision support form is easy to understand	(4) Strong Agree	6	3.8	0.5	Yes 100%
	(3) Agree	2			
	(2) Disagree	0			
	(1) Strong Disagree	0			
The list of the current medical conditions is easy to understand	(4) Strong Agree	6	3.8	0.5	Yes 100%
	(3) Agree	2			
	(2) Disagree	0			
	(1) Strong Disagree	0			
The list of the current treatments is easy to understand	(4) Strong Agree	4	3.5	0.5	Yes 100%
	(3) Agree	4			
	(2) Disagree	0			
	(1) Strong Disagree	0			
The risk predictions are easy to understand	(4) Strong Agree	4	3.5	0.5	Yes 100%
	(3) Agree	4			
	(2) Disagree	0			
	(1) Strong Disagree	0			
The reason a change in direction of care	(4) Strong Agree	5	3.6	0.5	Yes 100%
	(3) Agree	3			

was suggested is easy to understand	(2) Disagree	0			
	(1) Strong Disagree	0			
The glossary definitions are easy to understand	(4) Strong Agree	5	3.6	0.5	Yes 100%
	(3) Agree	3			
	(2) Disagree	0			
	(1) Strong Disagree	0			
Users can successfully login and complete the tasks without any questions and with less than 5 miss-clicks	All participants successfully logged in and completed all tasks without any miss-clicks.				Yes
Users can complete all tasks	All participants successfully completed all three tasks.				Yes

4.2.1.4 Parent Satisfaction Results

Usability results showed that the PPADS tool meets satisfaction criteria. All satisfaction results met usability criteria.

All eight participants found the tool satisfying or exceptional to use. Additionally, all eight participants had more positive than negative comments. Usability testing resulted in a total of 56 positive comments and one negative comment about the tool.

Detailed usability results of the satisfaction of the PPADS tool are shown in Table 15.

Table 15. Parent satisfaction results.

Criterion	Usability Results				Meets Criteria
	Likert option	Participant Frequency	Avg.	Standard Deviation	
The PPADS tool is satisfying to use	(4) Exceptional	3	3.4	0.5	Yes 100%
	(3) Satisfying	5			
	(2) Frustrating	0			
	(1) Unacceptable	0			

Users have more positive than negative comments	All participants had more positive than negative comments or did not have any comments. The number of positive and negative comments of each participant is presented in Table 16 of section 4.2.1.5.	Yes

4.2.1.5 Parent Quotes

Usability testing resulted in a total of 56 positive comments and one negative comment about the tool. The number of positive and negative comments of each participant is presented in Table 16.

Table 16. Parent usability study results: number of positive and negative comments of each participant.

Participant ID	Negative comments	Positive comments
750199	0	1
317363	0	15
863557	0	4
104499	0	4
601267	1	3
591877	0	0
624126	0	21
717258	0	8

Participants provided positive comments on the usefulness, efficiency, effectiveness, acceptability and satisfaction of the tool. The only negative comment was from participant 601267 who indicated that they would personally rather not see the outcome predictions. Table 17 and Table 18 show the observed positive and negative comments, respectively.

Table 17. Parent usability study results: positive quotes.

Participant ID	Positive Quote
750199	Very good.
317363	Really good hover. It is very helpful.
317363	Very clear.
317363	Tool helps one know exactly what doctors are doing.
317363	Really easy to go from one section to the next with tabs.
317363	Graphs are very handy show you clearly what the risks are.
317363	Links to abbreviations are really good.
317363	Updated date is really important and good to know.

317363	Good to know what happens while you make a decision.
317363	Good organization of information seems to follow what doctors talk about on rounds.
317363	Very good.
317363	Very helpful.
317363	A lot of information that would definitely help. The first thing they tell you in the NICU is don't surf the Internet. This is hard because you want more information. This tool really helps provide more information.
317363	I really like the tool.
317363	I find the information the tool provides very helpful.
863557	Good.
863557	Clear.
863557	User-friendly.
863557	I find it easy to use the tool.
104499	Easy to Navigate.
104499	Nice Layout.
104499	Nice to have multiple ways to navigate with the tabs, back button, and homepage links.
104499	I like it.
104499	This tool would be really helpful for when switching between NICUs.
601267	I like it.
601267	It is a very nice program.
601267	Abbreviations used in NICU environment are very useful.
624126	Great tool.
624126	I would use it.
624126	Great visual representation of outcome predictions.
624126	Good glossary definitions.
624126	Would be really useful.
624126	Definitions are very clear.
624126	Text is clear and user-friendly.
624126	The tool would make sure you wouldn't miss anything.
624126	Doctors have a tendency to speak in doctor speak this tool is very clear.
624126	Makes understanding clearer.
624126	First page of decision support form is very clear.
624126	First page of decision support form aids in making more informed decisions.
624126	The form helps a lot in understanding what are the positives and negatives of each decision option.
624126	Very good that it gives you a lot of information.
624126	Perfect that you can view your completed forms.
624126	Overall tool is very good.
624126	As a parent the tool would give all information I wanted at a glance.
624126	Like the detailed glossary.

624126	Explanations of terms are very clear.
624126	Anybody could understand.
624126	Very good how the tool gives parents the opportunity to sit down and deal with the decision.
717258	Pop up definition is nice.
717258	Really nice treatment therapies page. Would have been really nice to have when we were in the NICU.
717258	Wording is very straightforward.
717258	Tables on page 1 of decision support form are very useful.
717258	Really like current condition and current treatment options pages.
717258	Good to have documentation.
717258	May be hard (emotionally) to read, but good.
717258	Very good glossary.

Table 18. Parent usability study results: negative quotes.

Participant ID	Negative Quote
601267	Would rather not see outcome predictions. Personally would rather just be told.

4.2.1.6 Parent Suggestions for Improvements

All participants provided rich comments on how to improve the tool. The most common suggestion for improvement amongst parent participants was the addition of more information. Numerous participants stated that the glossary definitions were very useful, but they would want even more information. The participants suggested the addition of glossary definitions which describe specific medications and the side effects of treatments. Additionally, participants suggested adding more details to the current treatments list. For example, participants suggest displaying the specific antibiotic that the neonate is receiving, instead of generally stating that the neonate is receiving antibiotics. The results for the usability testing suggestions are shown in Table 19.

Table 19. Parent usability study results: suggestions.

Participant ID	Suggestion
750199	Add more explanations for glossary terms.
750199	Add more medical jargon explanations.
317363	Add links to what happens long term to glossary definitions.
317363	Add more information for glossary definitions.
317363	Group conditions together that link together.

317363	Add side effects of therapies to glossary definitions.
317363	Add more information.
317363	Add blurb at end of form to say form will now be used during your next consultation.
104499	Add more detail on prescription medication.
104499	Add more personalized glossary definitions for case.
601267	Make French version with easy to switch option for bilingual.
601267	Add more abbreviations that are used in the NICU environment.
601267	List the type of antibiotics and information about specific antibiotics in the glossary definitions.
601267	List type of medication being used in current therapies.
624126	Add what specific medications in current treatments.
624126	Add more details in current treatments.
624126	Write how long baby has been in the NICU in current condition section.
624126	Add a navigation bar on side.
624126	Add patient's name at top of each page.
624126	May want to make less blunt example reason change in direction of care has been suggested.
624126	Add a section that allows parents to write notes.
717258	Perhaps when clicking a definition can pop up in separate window.
717258	Perhaps change wording of page 3 decision support to disagree and agree instead of not important and important.
717258	Add list of medications.
717258	Add list of medical acronyms.

4.2.2 Physician Usability Testing Results

Data analysis of the physician usability results was performed as detailed in section 3.5.2.2 of the methodology. Five physicians completed the usability evaluation questionnaire. One of the five physicians chose not to answer three of the evaluation questions, indicating that they were unsure how to answer. All questions were evaluated on a four point Likert scale, with four being the highest score and one being the lowest score. The usability success criteria was that 75% or more of physician participants must agree (3) or strongly agree (4) to the usability criterion.

4.2.2.1 Physician Usefulness Results

The physician usability results demonstrated the usefulness of the PPADS tool. Seven of the eight usefulness criteria met the 75% usability threshold.

All physicians agreed or strongly agreed that the tool would be helpful to parents. All physicians also agreed or strongly agreed that the decision support form would help guide physician-parent consultations. Four out of the five physicians indicated that the decision support form would help them better understand the parent's views, that the decision-aid would help parents come to a decision about a change in the direction of care, and that the tool would be useful in their role as a physician in the future.

Four physicians indicated that the tool would help parents feel more informed and three physicians indicated that the tool would help with parent-physician communication. One physician chose not to answer these two questions, indicating that they were unsure.

The only usefulness criterion which failed to meet the 75% usability threshold was the tool's ability to help parents understand their neonate's condition. Three of the five physicians indicated that they think the tool would help parents understand their neonate's conditions. The other two physicians indicated that it is difficult for them to know if the tool would help parents understand their neonate's condition. Recall that during parent usability testing, all parents indicated that the tool would help them understand their neonate's condition.

Detailed usability results of the usefulness of the PPADS tool are shown in Table 20.

Table 20. Physician usefulness results.

Criterion	Usability Results				Meets Criteria
	Likert option	Participant Frequency	Avg.	Standard Deviation	
The tool would be helpful to parents	(4) Strongly Agree	1	3.2	0.4	Yes 100%
	(3) Agree	4			
	(2) Disagree	0			
	(1) Strongly Disagree	0			
The tool would help parents feel more informed	(4) Strongly Agree	1	3.3	0.5	Yes 100%
	(3) Agree	3			
	(2) Disagree	0			
	(1) Strongly Disagree	0			
The tool would help parents understand their	(4) Strongly Agree	0	2.6	0.5	No 60%
	(3) Agree	3			
	(2) Disagree	2			

neonate's conditions	(1) Strongly Disagree	0			
The tool would help with physician-parent communication	(4) Strongly Agree	0	2.8	0.5	Yes 75%
	(3) Agree	3			
	(2) Disagree	1			
	(1) Strongly Disagree	0			
The decision support instrument would help parents come to a decision about change of care needs	(4) Strongly Agree	0	2.8	0.4	Yes 80%
	(3) Agree	4			
	(2) Disagree	1			
	(1) Strongly Disagree	0			
The decision support instrument would help physicians understand the parents' views on their decision	(4) Strongly Agree	0	2.8	0.4	Yes 80%
	(3) Agree	4			
	(2) Disagree	1			
	(1) Strongly Disagree	0			
The decision support instrument would help guide physician-parent consultation	(4) Strongly Agree	0	3.0	0.0	Yes 100%
	(3) Agree	5			
	(2) Disagree	0			
	(1) Strongly Disagree	0			
The tool would be useful in my role as physician in the future	(4) Strongly Agree	0	2.8	0.4	Yes 80%
	(3) Agree	4			
	(2) Disagree	1			
	(1) Strongly Disagree	0			

4.2.2.2 Physician Efficiency and Effectiveness Results

The usability results demonstrated the efficiency and effectiveness of the PPADS tool.

All physicians agreed or strongly agreed that they would find the tool easy to learn. All physicians also indicated that the tool would be easy for parents to use.

The only efficiency and effectiveness criterion which failed to meet the 75% usability threshold was the ease of integrating the tool into the delivery of care. Two of the five physicians indicated that they think it would be easy to integrate the tool into the current delivery of care, while three of the five physicians indicated that they think adding the tool to the delivery of care would not be easy. One physician commented that adding anything that takes physician time to the delivery of care is usually difficult. Work was done throughout the development of the tool to minimize the physician time required; however, a few minutes of physician time are still required to activate each parent account. It should also be noted that the tool may increase the efficiency of decision-making which could decrease physician time.

Detailed usability results of the efficiency and effectiveness of the PPADS tool are shown in Table 21.

Table 21. Physician efficiency and effectiveness results.

Criterion	Usability Results				Meets Criteria
	Likert option	Participant Frequency	Avg.	Standard Deviation	
It would be easy to integrate the tool into the current delivery of care	(4) Strongly Agree	0	2.4	0.5	No 40%
	(3) Agree	2			
	(2) Disagree	3			
	(1) Strongly Disagree	0			
It is easy to learn to use the tool	(4) Strongly Agree	3	3.6	0.5	Yes 100%
	(3) Agree	2			
	(2) Disagree	0			
	(1) Strongly Disagree	0			
The tool is easy for parents to use	(4) Strongly Agree	0	3.0	0.0	Yes 100%
	(3) Agree	5			
	(2) Disagree	0			
	(1) Strongly Disagree	0			

4.2.2.3 Physician Acceptability Results

The usability results demonstrated the acceptability of the PPADS tool. Four physicians agreed or strongly agreed that the organization of information in PPADS was clear. One physician chose not to answer this question, indicating that they are unsure.

The only acceptability criterion which failed to meet the 75% usability threshold was the question of whether the tool provided the right amount of information to parents. Three out of the five physicians thought that the tool provides the right amount of information to parents, while the other two indicated that they thought the tool provided too much medical information to parents. On the other hand, during parent usability testing, five of the eight participants found that the amount of information displayed in PPADS is just right, while three of the eight participants indicated that they wanted even more information.

Detailed usability results of the acceptability of the PPADS tool are shown in Table 22.

Table 22. Physician acceptability results.

Criterion	Usability Results				Meets Criteria
	Likert option	Participant Frequency	Avg.	Standard Deviation	
The organization of information in PPADS is clear	(4) Strongly Agree	2	3.5	0.6	Yes 100%
	(3) Agree	2			
	(2) Disagree	0			
	(1) Strongly Disagree	0			
The tool provides the right amount of information to parents	(4) Strongly Agree	1	2.8	0.8	No 60%
	(3) Agree	2			
	(2) Disagree	2			
	(1) Strongly Disagree	0			

4.2.2.4 Physician Satisfaction Results

The usability results showed the physician's general satisfaction with the PPADS tool. All satisfaction criteria met the 75% usability threshold.

All the physicians indicated that if given the opportunity, they would offer parents of neonates in the NICU the option of using the PPADS tool. Four out of the five physicians indicated that their overall view of the PAPDS tool was positive.

Detailed usability results of the satisfaction of the PPADS tool are shown in Table 23.

Table 23. Physician satisfaction results.

Criterion	Usability Results				Meets Criteria
	Likert option	Participant Frequency	Avg.	Standard Deviation	
Overall view of the	(4) Strongly Agree	1	3.0	0.7	Yes

PPADS tool is positive	(3) Agree	3			80%
	(2) Disagree	1			
	(1) Strongly Disagree	0			
If given the opportunity, I would offer parents of neonates in the NICU to use the PPADS tool	(4) Strongly Agree	1	3.2	0.4	Yes 100%
	(3) Agree	4			
	(2) Disagree	0			
	(1) Strongly Disagree	0			

4.2.2.5 Physician Comments

Physician usability testing resulted in a total of 10 positive comments and three negative comments about the tool. All participants had more positive than negative comments. The number of positive and negative comments of each participant is presented in Table 24.

Table 24. Physician usability study results: number of positive and negative comments of each participant.

Participant ID	Positive Comments	Negative Comments
960341	0	0
826229	2	0
372041	2	1
415796	3	1
804253	3	1

Table 25 and Table 26 show the positive and negative comments of the physicians, respectively.

Table 25. Physician usability study results: positive comments.

Participant ID	Positive Comment
826229	Helpful for parents.
826229	Makes parents more comfortable having the information written.
372041	Brings forward issues that may otherwise not be discussed.
372041	Provides information to parents.
415796	Could be used to help guide discussions.
415796	Excellent to help parents think of reasons why to choose certain options.
415796	Excellent for MD to understand where parent is coming from.
804253	Looks like a great tool to help in decision-making.
804253	Seems very user-friendly.

804253	Seems like a very useful tool.

Table 26. Physician usability study results: negative comments.

Participant ID	Negative Comment
372041	I think some parents would be confused when using the tool.
415796	There may be too much information for parents about medical stuff.
804253	May require too much physician time.

4.2.2.6 Physician Suggestions for Improvements

The physician participants provided several suggestions on how to improve the tool, which are shown in Table 27.

Table 27. Physician usability study results: suggestions.

Participant ID	Suggestions for Improvements
960341	Look into legal value of tool.
960341	Look into applicability to all babies in NICU.
372041	Make sure that it is clear that it is not meant to replace physician-parent interactions.
372041	Prior to use, ensure there would be clear instructions on how to use the tool and that it should not replace verbal communication.
372041	Make sure there is no bias in the decision support form.
372041	Ensure that it truly stresses the best interest of the neonate (their sanctity of life and future quality of life).
415796	Provide more information to physicians on where mortality and severe neuroimpairment predictions are coming from.
804253	Perform real time evaluation with real parents to determine if the tool would add stress.

4.3 Results and Discussion Summary

This chapter described the results of this thesis. The results of the implementation of the PPADS tool were presented, including a description of the PPADS tool, screen shots of the PPADS tool, and the ability of the PPADS tool to meet the established design criteria. The results of both the parent and physician usability studies were also presented. The usability studies showed the usefulness, effectiveness, efficiency, acceptability, and satisfaction of the PPADS tool. There were only a few negative results, which were analyzed in more detail, with an explanation of what has been or will be done in the future to address the concern. The next chapter presents the conclusions of this thesis.

Chapter 5: Conclusions, Contributions to Knowledge, and Future Work

This chapter presents the conclusions made as a result of this work, the resulting contributions to knowledge, and future work.

5.1 Concluding Remarks

This thesis accomplished the main goal of developing a physician-parent decision support tool and completed all three objectives set forth in section 1.4.

The development and evaluation of the PPADS tool followed the five-step methodology outlined. The need for the development of a NICU decision support tool, the framework for the development of the tool, the design criteria, and the system architecture that was used throughout the developmental life cycle of the tool were established.

The PPADS tool provides information about the neonate to both the physician and the parent, aids parents in feeling more informed, aids parents in understanding the complex NICU environment, aids parents in understanding the current condition of their neonate, and aids in physician-parent communication. The parent decision support instrument aids parents in making the difficult care decision of whether to change the direction of care of the neonate. The decision support instrument helps parents understand the decision which must be made and options that are available, helps parents feel more certain about their decision, increases parent decision satisfaction, and helps parents understand how their values and beliefs affect the decision. The PPADS tool has the potential to augment decision-making in the NICU, and to benefit future parents and physicians in making collaborative care decisions in the NICU.

The PPADS tool uses three MySQL databases, and was developed using Drupal, a content management system. The PPADS interface consists of a physician tool and a parent tool. Both tools are accessed through a given URL, using any common web browser on a desktop, laptop, or mobile device. The clinician interface contains a summary of important patient information, risk predictions, and the ability to search for past patients. The clinician interface also provides the ability to edit the medical information, and to activate a parent account for each neonate. During the parent account activation, a clinician is able to choose what modules parents will have access to, including current condition of the neonate, current treatment therapies of the neonate, outcome predictions, decision support, and the glossary.

Two usability studies were designed and executed to determine the usefulness and ease of use of the PPADS tool. Usability testing of the PPADS tool was performed on eight parents who had a neonate graduate (survive) from a tertiary level NICU within the last year, and on five neonatologists currently working at CHEO. The usability studies showed the usefulness, efficiency, effectiveness, acceptability, and satisfaction of the PPADS tool.

The data collected from the usability studies showed the PPADS tool's ability to aid parents in ethical decision-making, to aid parents in feeling more informed, to improve physician-parent communication, to decrease decision uncertainty, and to increase satisfaction.

Usability testing on parents showed that the decision support module helps parents understand why the clinician suggested a change in direction of care, and better understand how their values and views affect their own decisions. The completed decision support forms show why a participant is leaning towards a certain direction of care, which would aid physician-parent communication, aid in collaborative decision-making, and could help reduce parent-physician conflicts. 32 out of 33 parent usability criteria met the 75% requirement for usability. The only criterion which did not meet the requirement was the acceptability of the amount of information displayed in PPADS, where 37% of parents indicated that they wanted more information.

The physician usability study showed that neonatologists find the tool easy to use and that the tool would be useful for parents and physicians. Twelve of the fifteen physician usability criteria met the 75% requirement for usability, while three criteria did not. Only 60% of physicians thought that the tool would help parents understand their neonate's condition; however, parent usability testing showed that all parents found that the tool would help them understand their neonate's condition. Only 40% of physicians indicated that the tool would be easy to integrate into the current delivery of care. 60% of physicians found that the tool provides the right amount of information to parents, while 40% of physicians thought the tool provides too much information to parents. On the other hand, during parent usability testing, parents found that the tool did not provide enough information. This conflicting opinion may be resolved if a future study provides physicians with results of parents' views before obtaining theirs.

In order to increase the usability of the tool, criteria that did not meet the usability threshold, had lower Likert averages, or had high standard deviations, and other suggested improvements should be addressed in future work. One example is exploring how to decrease the possible added stress involved with using the PPADS tool and identify the average time physicians would need to spend to prepare the tool for parents.

The usability results provided a wealth of knowledge. The studies showed the relevance of the development of the tool and demonstrated parents' and physicians' interest in the tool. The participants of the studies provided useful suggestions on how to improve the tool and help meet physician and parent decision-making needs.

5.2 Contributions to Knowledge

The first contribution to knowledge is the development of a physician-parent decision support tool that provides personalized information and risk predictions about the neonate to both the physician and parents, aids parents in feeling more informed, aids parents in understanding the complex NICU environment, aids parents in understanding the current condition of their neonate, and improves physician-parent communication. The results of the usability test show the usefulness, effectiveness, efficiency, acceptability, and satisfaction of the PPADS tool.

The second contribution to knowledge is the design and development of the change in direction of care decision support instrument, which aids parents in making the difficult care decision of whether to change the direction of care for their neonate. This decision support instrument can be used in the development of future decision-aids for other difficult care decisions in the NICU, such as whether or not surgery should be performed, as well as for the development of decision support forms for other healthcare decisions. The results of the usability test show the usefulness and ease of use of the change in direction of care decision support instrument.

The third contribution to knowledge is the design of a five-step framework for developing the PPADS tool. The first step of the framework is to assess the clinical environment; the second step is to establish the design criteria; the third step is to develop the system design; the fourth step is to implement the system; and the fifth step is to perform usability testing. This framework can be applied to the development of other decision-aids.

The fourth contribution to knowledge is the development of two sets of design criteria. The first set of design criteria aims to increase the likelihood of the successful adoption of the MDSS. This set of design criteria can be applied in the design of any medical decision support system. The second set of design criteria aims to ensure that the tool meets the decision-making needs of parents of neonates in the NICU. This set of design criteria can be applied in the design of other NICU decision support tools.

The fifth contribution to knowledge is the design and execution of the usability study to determine the usefulness and ease of use of the PPADS tool. The usability study provided a wealth of information about parent decision-making in the NICU and about the PPADS tool. This usability study can be applied to future studies of the PPADS tool, as well as for evaluating other MDSSs.

Finally, this thesis work resulted in the publication of three papers. The first paper, entitled "Suggested Criteria for Successful Deployment of a Clinical Decision Support System", was presented and published at the IEEE International Symposium on Medical Measurements and Applications (MeMeA) on April 30th, 2010 [25]. The second paper, entitled "Combined Physician-Parent Decision Support Tool for the Neonatal Intensive Care Unit", was published at the IEEE International Symposium on Medical Measurements and Applications (MeMeA) on May 30th, 2011 [32]. The third paper, entitled "Development and Usability Testing of a Parent Decision Support Tool for the Neonatal Intensive Care Unit", will be presented and published at the 33rd Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC '11) on August 30th, 2011.

5.3 Future Work

Many suggestions for future work have resulted from this thesis research. The first suggestion for future work is to update the PPADS tool to incorporate the suggested improvements and address areas that received a low usability testing score.

It is also suggested to perform four more phases of usability testing. Even though there were no miss clicks or errors found in the first phase of usability testing, a formative evaluation focusing on finding errors should be conducted to ensure there are no errors in using the system. The second phase should continue to assess the clinical impact on the users of the PPADS tool by conducting a usability study on parents with neonates who did not survive, and a separate study on physician usability, which includes the presentation of parent results. The third phase should be a prospective study to assess the tool in the NICU environment. Finally, a randomized multi-centre clinical trial should be conducted.

Future work should also include incorporating real-time risk predictions of mortality and various diseases using data collected by the CDR, as well as up-to-date real-time information on each of the NICU patients for the physician module.

The final suggestion for future work is to develop additional decision support forms for other NICU decisions. The PPADS tool has been designed to be adaptable to many NICU decisional situations. Currently, the PPADS tool contains decision support to help parents decide if a change in direction of care should be undertaken. Many of the basic decision-making needs of parents would already be met by the PPADS tool's current condition, current treatment therapies, risk predictions and glossary modules. Adding support for a new NICU decision would only require an additional decision support instrument to be developed, which can be based on the existing change in direction of care decision support form.

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Appendix A: NICU Environment

This appendix provides a detailed description of the NICU environment, including the cost of NICU care, NICU outcomes, trends in NICU care, the NICU team, NICU medical conditions, and NICU treatment therapies.

Introduction to the NICU

The Neonatal Intensive Care Unit (NICU) is a specialized hospital unit that provides care to neonates (newborn infants). The types of neonates in the NICU include premature neonates, lower than normal birth weight neonates, and high risk neonates. Premature neonates are neonates born before 37 weeks of gestation (time in the womb) and make up approximately 75% of the population in the NICU. There are three classes of premature neonates: preterm birth neonates, very preterm birth neonates and extremely preterm birth neonates. Preterm birth (PTB) neonates are defined as neonates born between 35 weeks of gestation and 37 weeks of gestation; very preterm birth (VPTB) neonates are neonates born between 29 weeks of gestation and 35 weeks of gestation; and extremely preterm birth (EPTB) neonates are neonates born before 28 weeks of gestation [2],[3]. The incidence of premature births has increased in the past 20 years, reaching 7.7% in 2003. This is largely attributed to the rise of in-vitro fertilization, which often results in multiple births that have a higher risk of being premature. This rise in premature births has resulted in a rise in the number of neonates born at the edge of viability and requiring NICU care [4].

Lower than normal birth weight neonates are neonates who weigh less than 2500g. There are three classes of lower than normal birth weight neonates: low birth weight, very low birth weight, and extremely low birth weight. Low Birth Weight (LBW) neonates are defined as neonates born weighing between 1500g and 2500g; Very Low Birth Weight (VLBW) neonates are neonates born weighing between 1000g and 1500g; and Extremely Low Birth Weight (ELBW) neonates are neonates born weighing less than 1000g. Most premature neonates also fall under the category of low birth weight neonates [4].

High risk neonates are neonates with congenital abnormalities, diseases or other complications. High risk neonates include term neonates (born after 37 weeks in womb) and normal birth weight neonates (over 2500g) who require NICU care [4].

Cost of NICU Care

In 2002-2003, NICU care in Canada cost about 295 million dollars [1]. The cost of NICU care for one patient excluding physician fees and surgical treatments was about $1700 per day in 2002 [5]. The total cost of care including treatment costs and physician fees was just over $9700 per baby per day in 2002-2003 [1]. A study by Lim et al. was conducted on the average cost of live births in acute care facilities in Newfoundland and Labrador, Ontario, Manitoba, Saskatchewan, and British Columbia in 2005-2006. The total cost of care for neonates ranged from $117,000 for newborns weighing less than 750g and $1,000 for newborns weighing over 2500g. The results of this study are shown in Figure 31 [81].

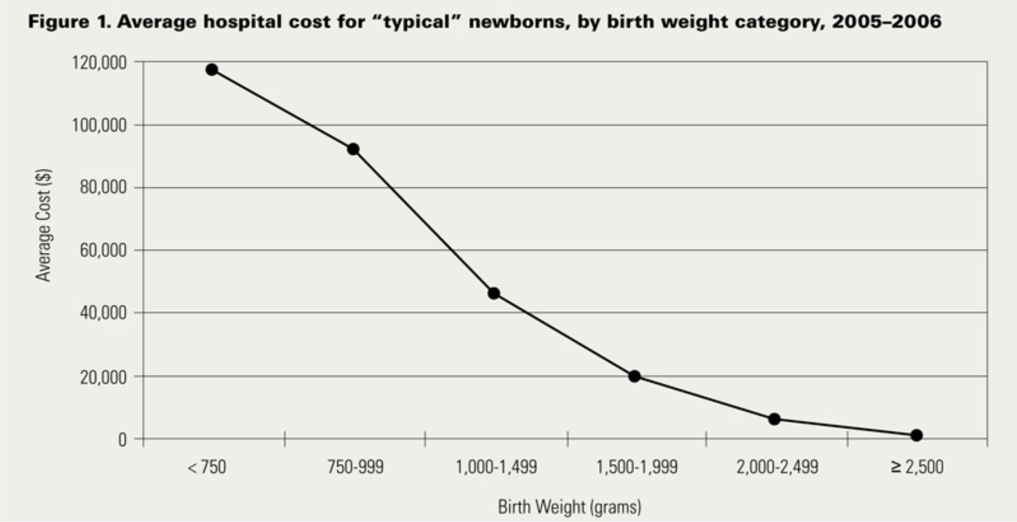


Figure 31. Average hospital cost for newborns by birth weight [81]**.**

NICU Outcomes

Researchers have shown general trends of decreasing birth weight and gestational age resulting in a lower probability of survival and a higher probability of short term and long term morbidity [7],[8].

Allen et al. conducted a study on 142 infants born at the Johns Hopkins Hospital in Baltimore between 1988 and 1991. The study showed that there is a decrease in survival rate with decreasing gestational age. A graphical representation of the survival rates of varying gestational ages with respect to time in the NICU is shown in Figure 32. The study also showed that amongst the neonates who survived, the probability of having a good outcome (survival with no abnormalities) versus survival with abnormalities decreases with lower gestational age. This trend is illustrated in Figure 33 [8].

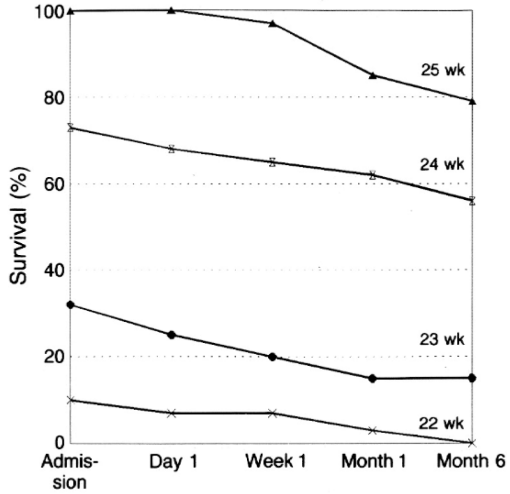


Figure 32. Variation in neonate survival with gestational age during first six months after admission [8].

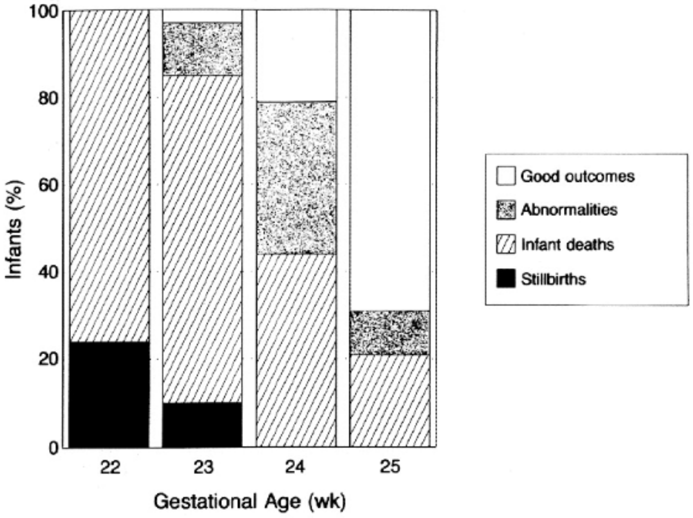
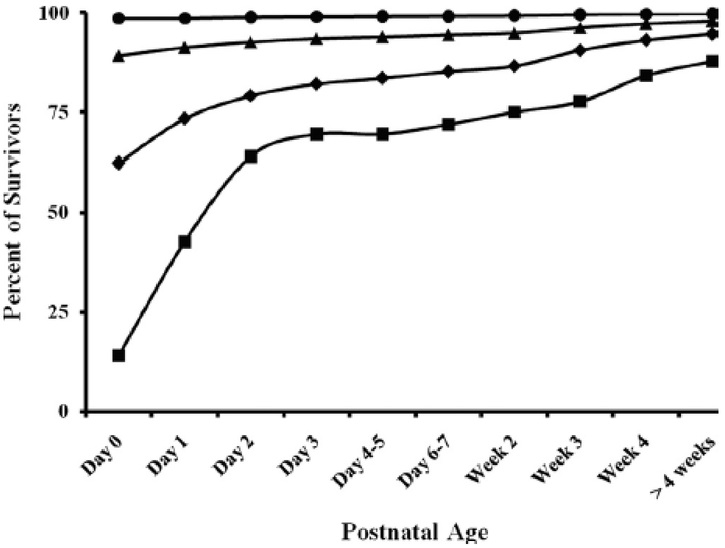


Figure 33. Variation of survival, morbidity and death with gestational ages [8].

Mohamed et al. conducted a study of the national inpatient database by the Agency for Healthcare Research and Quality between the years of 1997-2004. The data set contains data from about 1000 hospitals across the United States. The study found that the chance of survival decreases with decreasing birth weight [7]. A graphical representation of the percent of survivors with respect to time in the NICU, for different birth weights, is shown in Figure 34.



Percentage of survivals according to postnatal age in each birth weight category (*N* = 102 493). ■ indicates <500 g; ♦, 500 to 749 g; ▲, 750 to 999 g; ●, 1000 to 1499 g.

Figure 34. Variation of percent survival with birth weight [7]**.**

Trends in NICU care

Over the past few decades the NICU has evolved from the development of many new technologies. There are infants being treated who are at the edge of viability and would not have had a chance of survival a few decades ago. Examples of technology that has increased the quality of care include the development of incubators and surfactants. With this new technology, the same trends in NICU care are still seen, where greater birth weight and gestational age result in a greater chance of survival, but the survival at any given gestational age and birth weight has increased. A study conducted by Meadow et al. on 1142 ELBW infants admitted to the NICU at the University of Chicago Hospital between 1991 and 2001 found that the survival rate at various birth weights significantly increased between 1991 and

2001, as shown in Figure 35 [15]. Horbar et al. showed that the mortality rate of LBW infants decreased from 1991-1999 in a study conducted at 362 hospitals around the world. 325 of the hospitals were in the United States, six were in Canada, and the other 31 were from 17 other countries around the world. The decrease in mortality rate for LBW infants from 1991-1999 is shown in Figure 36 [16].

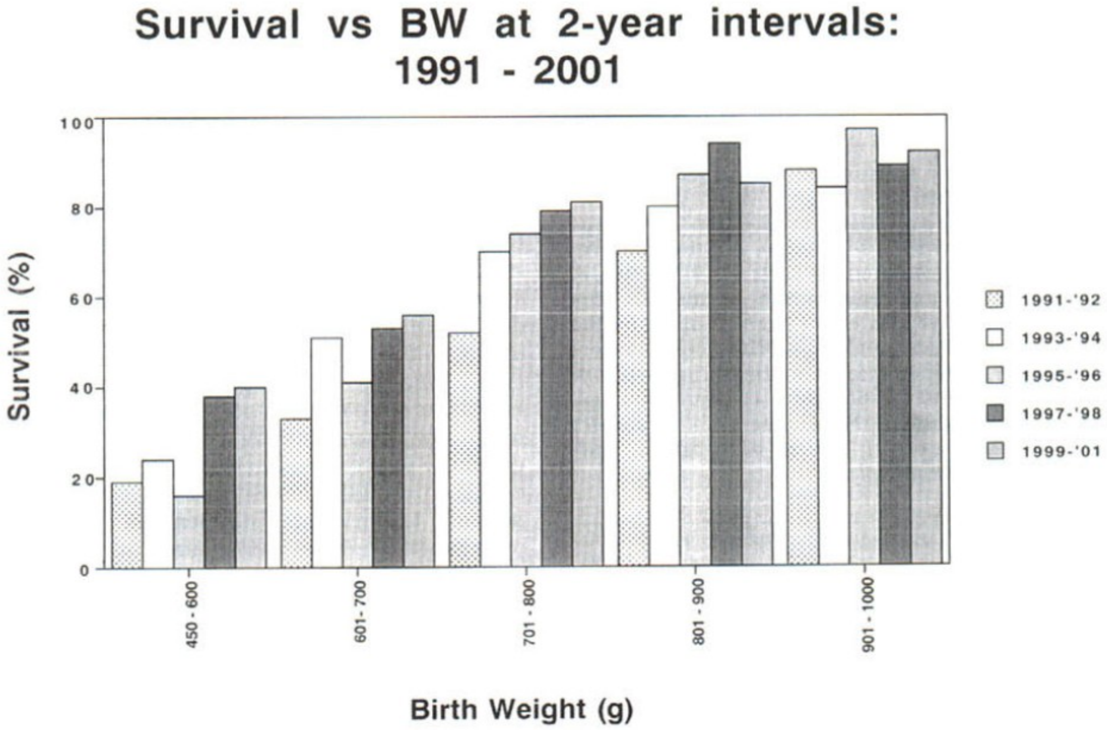


Figure 35. Variation of survival with birth weight from 1991-2001 [15].

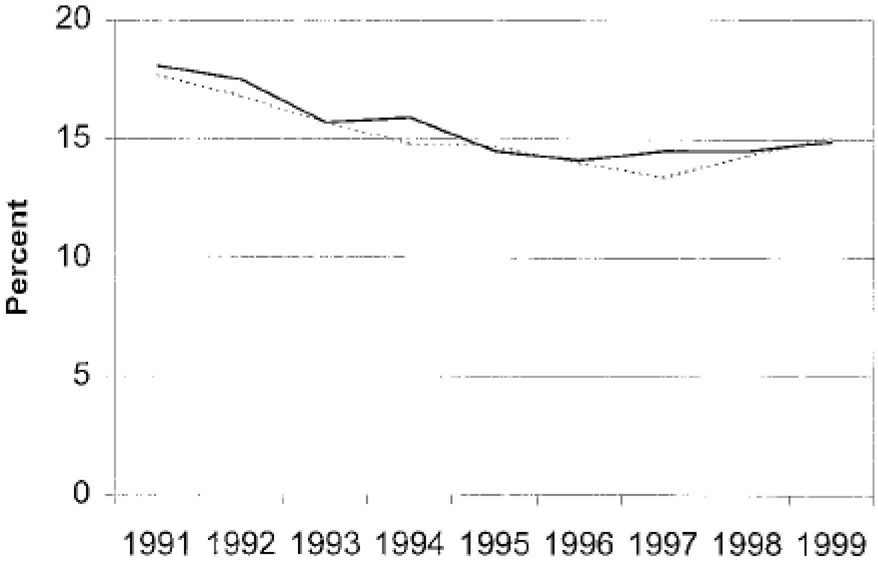


Figure 36. Variation of mortality of low birth weight neonates from 1991-1999 [16].

Unfortunately, as a result of increasingly aggressive care to reduce mortality, the incidence of morbidity (survival with disability) has been increasing [14],[16],[15],[17],[18]. Stoelhorst et al. conducted a study of two cohorts of very premature infants in the Dutch Health Region, one from 1983 (known as pops 83) and the other from 1996/1997 (known as ifupp 96-97). It was found that the mortality rate decreased from 30% in the 1983 cohort to 11% in the 1996/1997 cohort. However, the rate of morbidity (abnormal at discharge) increased from 14% of survivors in 1983 to 34% of survivors in 1996/1997. A few examples of the increase in morbidity include an increase in Bronchopulmonary Dysplasia (BPD) from 6% to 19%, an increase in Sepsis from 16% to 28%, an increase in Patent Ductus Arteriosus (PDA) from 5.4% to 9.2%, and an increase in Necrotizing Enterocolitis (NEC) from 4% to 9%. (Definitions for these and other medical terms can be found in Appendix B) The trend of decreasing mortality and increasing morbidity for gestational periods of less than and greater than 27 weeks is shown in Figure 37 [17]. Similarly, Wilson-Costello et al. conducted a study comparing 496 infants born between 1982 and 1989 (period 1) and 682 infants born between 1990 and 1998 (period 2) at the Mac-Donald Hospital for Women in Cleveland. The study found that there was an increase in survival and increase in morbidity (neurodevelopment impairment) in period 2 compared to period 1. The findings are shown in Figure 38 [18].

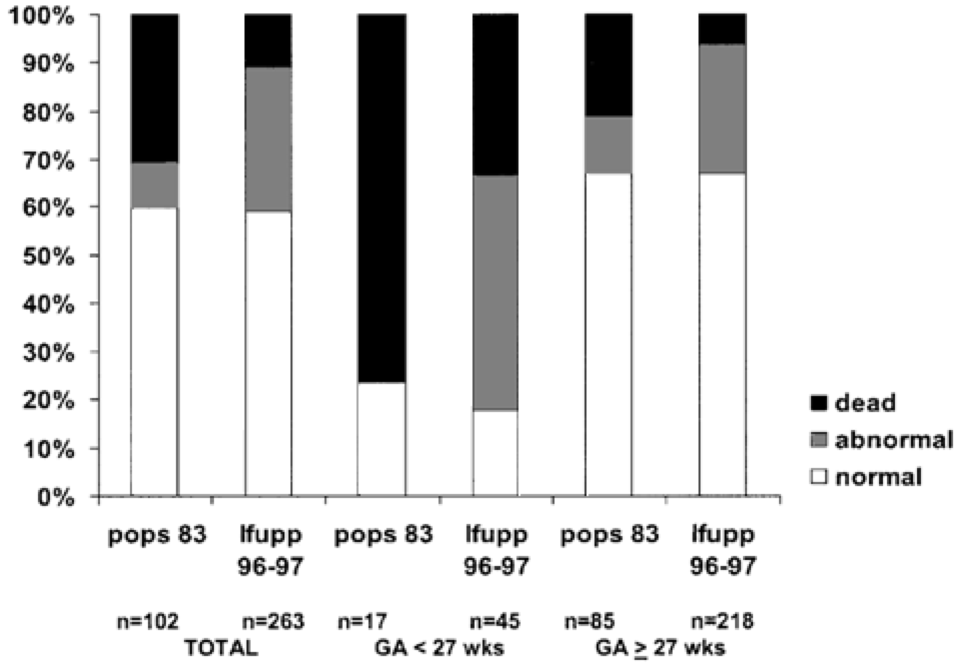


Figure 37. Variation of mortality and morbidity from 1983 to 1996/1997 [17].

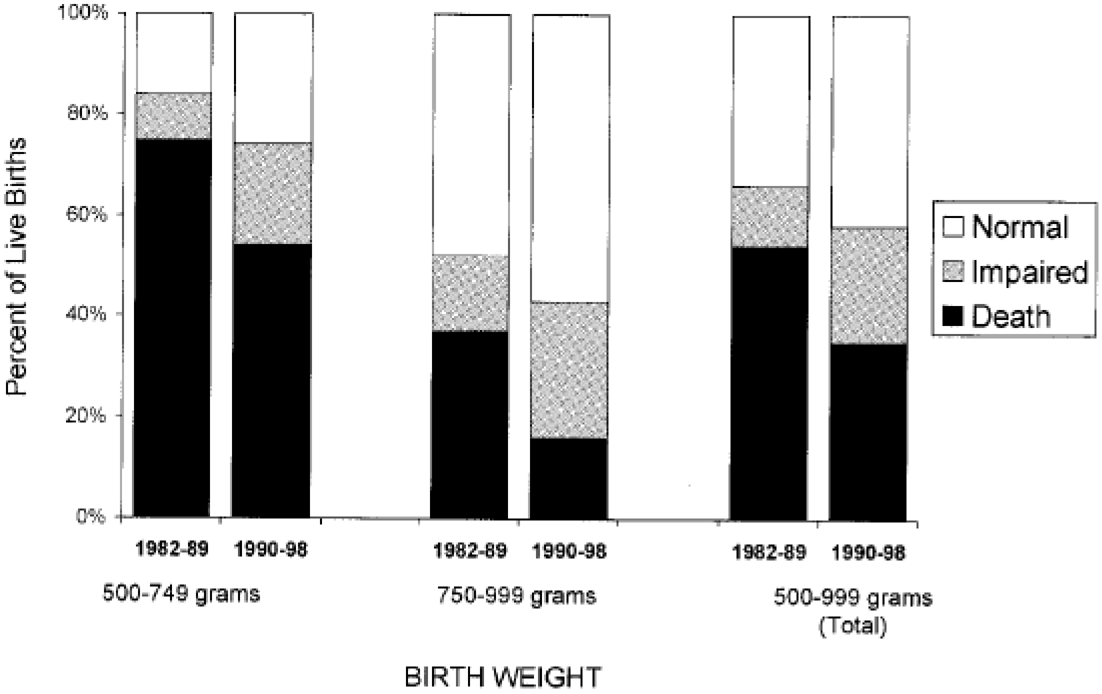


Figure 38. Variation of mortality and morbidity from 1982-1989 to 1990-1998 [18].

Researchers have also shown that technological advances have resulted in an increase in the length of hospital stay of infants who do not end up surviving. Stoelhorst et al. found that the mean NICU admission time of surviving infants stayed the same at around 44 days for both the 1983 cohort and the 1996/1997 cohort. However, the mean NICU length of stay of all NICU neonates increased from 27 days in 1983 to 41 days in the 1996/1997 cohort [17]. Similarly, Meadow et al. found that the median length of stay of non-survivors in the NICU increased from two days in 1991 to ten days in 2001, and the average length of stay of non-survivors increased from 5 days in 1991 to 17 days in 2001. These results are shown in Figure 39 [15].

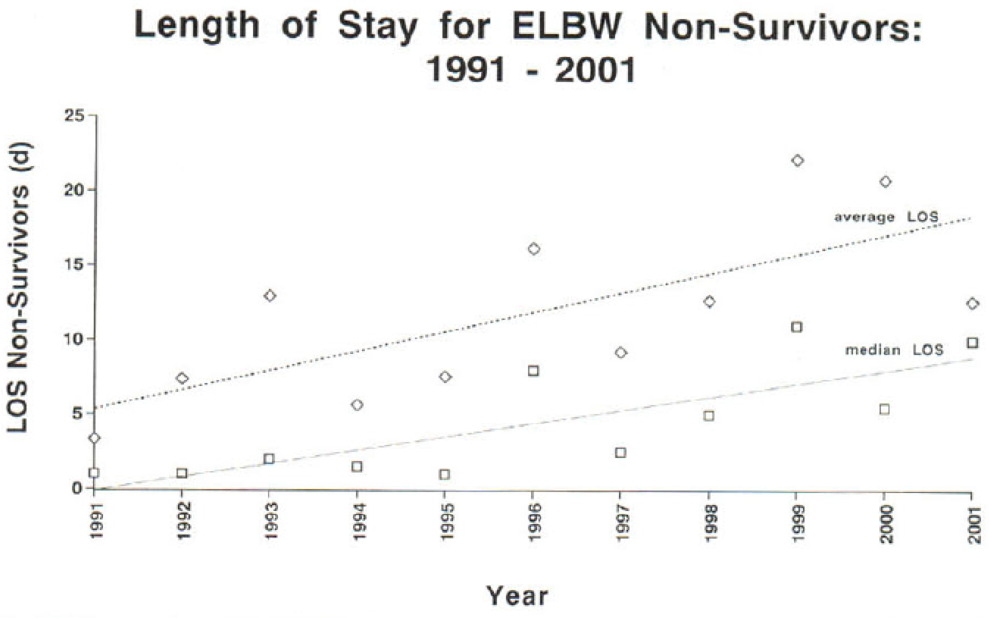


Figure 39. Length of stay for ELBW non-survivors from 1991 to 2001 [15]**.**

NICU Team

The NICU consists of a highly specialized, multidisciplinary healthcare team headed by neonatologists. Brief summaries of the various members of a typical NICU interprofessional (IP) team are given below [82].

- **Neonatologists** head the NICU team and are the primary doctors in charge of caring for the infant. Neonatologists are trained to handle the most complex and high-risk neonatal cases.
- **Fellows** in the NICU are doctors who are specializing in NICU care and work under the guidance of the neonatologists.

- **Residents** in the NICU are doctors who are training to become NICU specialists.
- **Medical students** in the NICU have limited responsibilities and are under the careful supervision of neonatologists, residents, and fellows.
- **Registered nurses** in the NICU are specialized in caring for critically ill newborns. They are essential in providing knowledge and skills and are in charge of performing and coordinating the neonate’s daily care.
- **Nurse practitioners** in the NICU are in charge of performing the neonate’s daily care.
- **Respiratory therapists** help manage the ventilators and oxygen therapy of the neonates.
- **Pharmacists** work in collaboration with the doctors to choose the best medication for the neonates and educate parents about the medication.
- **Ward clerks** perform clerical duties and accompany visitors to the neonate’s bedside.
- **Dieticians** work to provide the proper nutrition to the neonate in the early stages of life and establish nutritional goals.
- **Lactation consultants** assist mothers with breastfeeding.
- **Social workers** assist parents through the wide range of emotions they experience.
- **Spiritual care services** provide emotional and spiritual support to families.

NICU Medical Conditions and Treatment Therapies

The NICU is a complex environment usually containing several neonates with a wide range of medical conditions, and undergoing various treatment therapies.

The NICU team is faced with a wide range of medical conditions on a day-to-day basis. A few of the most common neonatal conditions are summarized in Table 28 [83],[78],[79],[84],[77],[80].

Table 28. Most common NICU medical conditions.

Medical Condition	Description
Intraventricular Hemorrhage (IVH)	Bleeding in the area of the ventricles of the brain caused by the bursting of fragile blood vessels. The ventricles are two small, fluid filled spaces in the center of the brain. The bleeding is graded on a scale of 1-4. • Grade 1 is very minor and only involves small blood clots near the edges of the ventricles. • Grade 2 involves the ventricles filling with blood. • Grade 3 involves the ventricles becoming enlarged and swollen by the blood. • Grade 4 involves bleeding within the surrounding brain tissue. Babies with severe IVH (Grade 3 and Grade 4) have an increased risk of permanent brain injury which may result in physical and mental handicaps. Diagnostic testing includes ultrasound of the head, computed tomography (CT scan) or Magnetic Resonance Imaging (MRI).
Seizure	A "short-circuiting" of electrical activity in the brain causing irregular muscle activity. Generalized seizures affect the whole body. Focal seizures affect only one part or side of the body.
Apnea	A pause in breathing lasting 20 seconds or longer. Infants usually start breathing on their own, but sometimes stimulation or medication is required. It is often accompanied by a slowing of the heart rate known as bradycardia and the baby turning blue.
Brain death	An absence of electrical impulses from the higher-function areas of the brain that are necessary for being awake and interacting with our environment.
Periventricular Leukomalacia (PVL)	Periventricular tissue is located around the two fluid filled ventricles in the brain. If there is not enough blood reaching the periventricular tissue the tissue may die and be replaced by cysts or fluid. The brain tissue that dies may affect muscle control in the limbs. PVL is associated with cerebral palsy and other developmental problems.
Pneumothorax	Involves air leaking from an injured lung into the space between the lung and the chest wall. Small leaks may cause no problems but large leaks may cause the lung to collapse and may require drainage through a tube.
Bronchopulmonary Dysplasia (BPD)	A chronic lung disease that is the result of injury to the lungs and leads to trouble breathing and the need for extra oxygen.

Patent Ductus Arteriosus (PDA)	An extra communication between the lung and heart. Before birth the ductus arteriosus allows the baby’s blood to bypass the lungs. The bypass should close shortly after birth, but if it does not it is known as PDA.
Necrotizing Enterocolitis (NEC)	Swelling of the intestine resulting in tissue death caused by an infection or decreased blood supply.

A few of the most common treatment therapies used in the NICU are listed and briefly described in Table 29 [83],[78],[79],[84],[77],[80].

Table 29. Most common NICU treatment therapies.

Treatment	Description
Artificial nutrition	Receiving nutrition through a tube instead of by eating. The types of artificial nutrition differ based on the type of nutrition being given and the location of the tube. • Total parenteral nutrition (TPN): the tube is placed in a vein and IV fluid nutrtition is given • Nasogastic tube (NG tube): the tube is inserted in the nose and delivers milk or formula to the stomach • Gastrostomy tube: the tube is surgically placed directly into the stomach (G tube) through the abdominal wall.
Artificial ventilation	Breathing is helped by a machine called a ventilator which supplies and regulates air flow and oxygen content. The air flows through a tube which is inserted through the nose or mouth, down the back of the throat and into the windpipe.
Catheter	A hollow flexible tube for insertion into a body cavity, duct, or vessel to allow passage of fluids into and out of the body.
Chest tube drainage	A small plastic tube placed through the chest wall into the space between the lung and the chest to remove air or fluid.
Transfusion	A treatment in which blood from a donor is administered intravenously to the baby’s blood.

Appendix B: Glossary Terms

This appendix provides a complete list of the glossary definitions provided in the PPADS tool.

Table 30. Glossary terms and descriptions

Glossary	
Acidosis (An acid build up in the blood)	An acid build up in the blood. The build up of acids can be caused by a breathing problem (respiratory acidosis) or other problems with other systems (metabolic acidosis).
Anemia (Low oxygen carrying ability of the blood)	The number of red blood cells in the blood are lower than normal. This means there is a low oxygen carrying ability of the blood.
Antacid medication	Used to reduce the acidity of the stomach contents which can be refluxed into the throat and food pipe (heartburn).
Antibiotics	Medication that destroys bacteria and is used to treat infections.
Antimicrobials	Medication that destroy bacteria or fungus and is used to treat infections.
Apgar Score	A score used to describe a newborn's condition at birth based on heart rate, breathing, muscle tone, reflex response, and colour at 1 minute and 5 minutes after birth. A maximum of 2 points is assigned to each category for a maximum total of 10. Additional measurements are made every 5 minutes if the score is less than 7, until a score of greater than 7 is achieved.
Apnea **(Breath holding spells)**	A pause in breathing lasting 20 seconds or longer. Infants usually start breathing on their own, but sometimes stimulation or medication is required. It is often accompanied by a slowing of the heart rate known as bradycardia and the baby turning blue.
Arrhythmia **(Abnormal heart rhythm)**	An abnormal heartbeat rhythm.
Arterial catheters	A thin, flexible tube placed through the skin into the baby's artery used to measure blood pressure and sample blood for blood testing.
Artery	A blood vessel delivering blood from the heart to the rest of the body.
Artificial nutrition	Receiving nutrition through a tube instead of by eating. The types of artificial nutrition differ based on the type of nutrition being given and the location of the tube. • Total parenteral nutrition (TPN): the tube is placed in a

	vein and IV fluid nutrtition is given • Nasogastic tube (NG tube): the tube is inserted in the nose and delivers milk or formula to the stomach • Gastrostomy tube: the tube is surgically placed directly into the stomach (G tube) through the abdominal wall.
Artificial ventilation	Breathing is helped by a machine called a ventilator which supplies and regulates air flow and oxygen content. The air flows through a tube which is inserted through the nose or mouth, down the back of the throat and into the windpipe.
Bladder catheter	A hollow flexible tube is inserted into the urethra to drain urine from the bladder.
Blood pressure	The pressure of the blood in the arteries with each beat of the heart.
Blood pressure medications	Medication used to either increase or decrease the blood pressure.
Blood transfusions	The IV administration of donor blood to correct a situation involving low red blood cell levels.
Bradycardia	A heart rate slower than normal for an infant.
Brain death **(Absence of electrical impulses from the brain)**	An absence of electrical impulses from the higher-function areas of the brain that are necessary for being awake and interacting with our environment.
Bronchopulmonary Dysplasia (BPD) **(Chronic lung disease)**	A chronic lung disease that is the result of injury to the lungs and leads to trouble breathing and the need for extra oxygen. Also known as Chronic Lung Disease (CLD).
Catheter	A hollow flexible tube for insertion into a body cavity, duct, or vessel to allow passage of fluids into and out of the body.
Central venous lines	A thin, flexible tube placed through the skin into the baby's vein and is used to give fluids and medications. The catheter is placed in a major, large vein of the body and can be inserted through the arm, leg, belly button, or neck.
Cerebral Palsy	A type of brain damage due to injury to the brain that occurred at one point in time and is not progressive. It affects body movement and muscle control and has varying levels of severity.
Chest tube drainage	A small plastic tube placed through the chest wall into the space between the lung and the chest to remove air or fluid.
Computed Tomography (CT)	Computerized x-rays used to show an image of the inside of the body.
Congenital heart disease	A problem with the heart's form or function present at birth.

(A problem with the heart’s form or function)	
Conventional Mechanical Ventilation	A mode of ventilation that involves the baby being intubated with a tube that is inserted in the nose or mouth and ends in the windpipe. The ventilator then controls how the baby breathes.
Disseminated intravascular coagulation (DIC) **(Bleeding disorder)**	Excessive bleeding due to a lack of platelets and clotting factors.
Diruetic Medication	Medication used to help the baby pass more urine.
Do Not Resuscitate Order (DNR)	This is a plan that involves not providing a full resuscitation in the event of a severe cardiac (heart) or pulmonary (lung) deterioration. It involves not providing CPR or chest compressions to the baby, not providing injections of medications to restart the heart, but instead keeping the baby comfortable while notifying the parents of the event and waiting for their arrival at the bedside.
Down Syndrome	A chromosomal abnormality characterized by physical malformations and mental problems. Caused by an extra chromosome 21.
Echocardiogram	An ultrasound of the heart.
Electrocardiogram (ECG) (EKG)	The electrical activity of the heart is recorded using electrodes placed on the chest. Used to detect the heart rhythm changes and changes in the heart function or form.
Electroencephalogram (EEG)	The electrical activity of the brain is recorded using electrodes attached to the scalp. Used to detect seizures and baseline functioning of the brain.
Electrolyte disturbance **(Imbalance of salts in the blood)**	Imbalance of salts in the blood.
Endotracheal Tube (ET Tube)	A tube that is placed through the nose or mouth and down the windpipe to deliver warm humidified air and oxygen to the infant’s lungs from a ventilator.
Extremely Low Birth Weight (ELBW)	A baby born weighing less than 2 pounds, 3 ounces or 1000 grams.
Feeding Intolerance	The baby is showing signs of not tolerating feeds which may be due to gut immaturity or a disease state.
Full, active care	This involves continuing and adding all available and necessary invasive and non-invasive treatments in an attempt to cure the baby's medical conditions.

Gastric Bleeding (GI bleed) **(bleeding from the stomach)**	Bleeding from the stomach which may be vomited up or may come up the NG or feeding tube.
Heart failure **(Heart is having trouble pumping enough blood to the rest of the body)**	The heart is having difficulty pumping enough blood to the rest of the body because of a circulatory imbalance.
Heart Murmur	A noise heard between beats of the heart. Can signal a problem with the flow through the heart, but may be heard in a normal heart as well.
Heart rhythm medications	Medication used to control the rhythmic beating of the heart.
High Frequency Oscillation Ventilation (HFOV)	The highest mode of ventilation used at CHEO for babies with very sick lungs. The ventilator inflates the lungs and then gently "shakes" them to keep the lungs open and allow oxygen and waste products to travel in and out.
Hypoxic-Ischemic Encephalopathy (HIE) **(Brain injury due to low oxygen delivery)**	Brain injury due to low oxygen delivery.
Hypotension **(Low blood pressure)**	Low blood pressure.
Intravenous Fluids	Fluids delivered through a catheter in a vein that provides hydration, nutrition, or medications.
Intraventricular Hemorrhage (IVH) **(Brain bleeding)**	Bleeding in the area of the ventricles of the brain caused by the bursting of fragile blood vessels. The ventricles are two small, fluid filled spaces in the center of the brain. The bleeding is graded on a scale of 1-4. • Grade 1 is very minor and only involves small blood clots near the edges of the ventricles. • Grade 2 involves the ventricles filling with blood. • Grade 3 involves the ventricles becoming enlarged and swollen by the blood. • Grade 4 involves bleeding within the surrounding brain tissue. Babies with severe IVH (Grade 3 and Grade 4) have an increased risk of permanent brain injury which may result in physical and mental handicaps. Diagnostic testing includes ultrasound of the head, computed

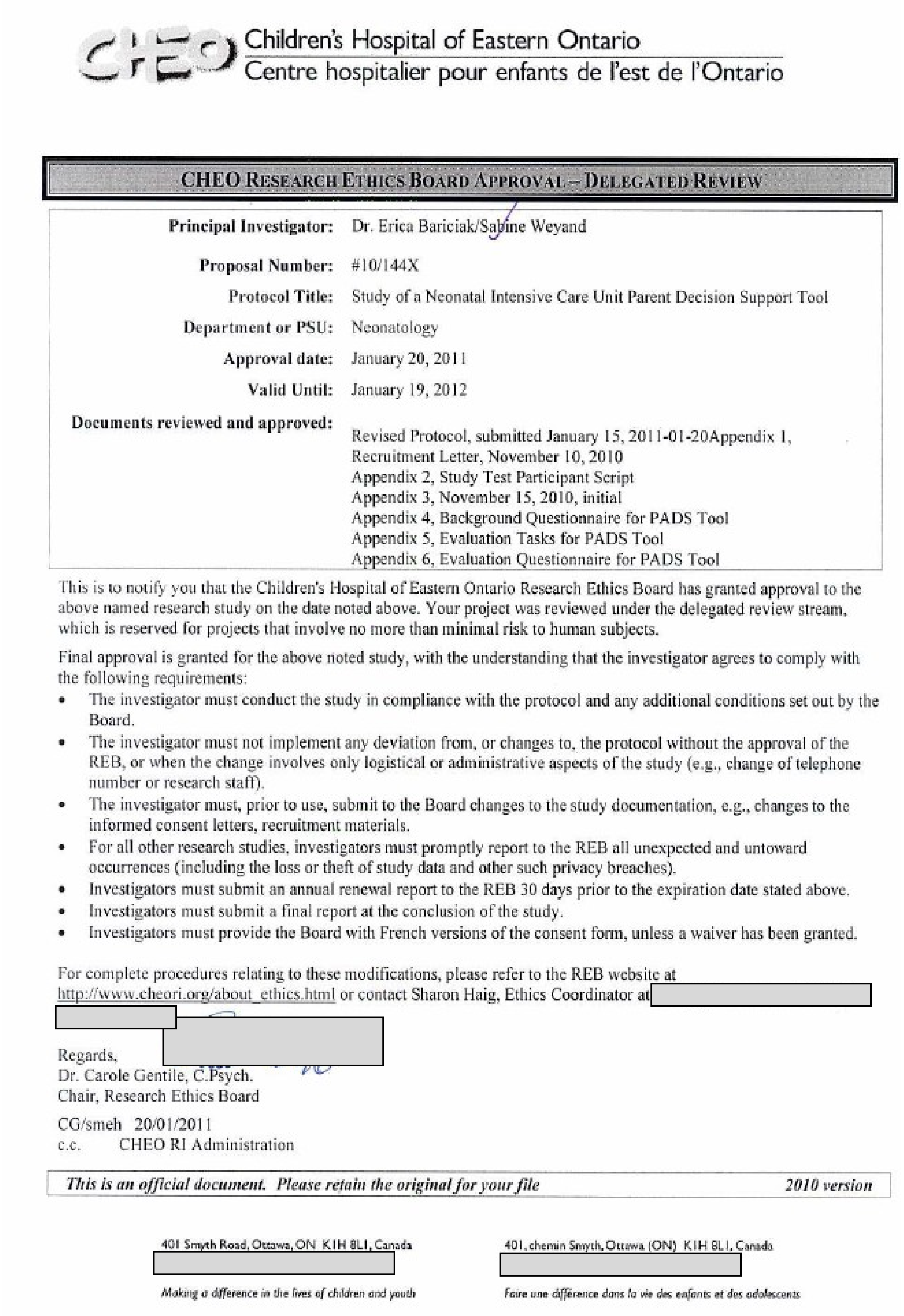
	tomography (CT scan) or Magnetic Resonance Imaging (MRI).
Intubation	The procedure involved in placing an endotracheal tube (ETT) or breathing tube through the nose or mouth and guiding it through the vocal cords to end up in the windpipe. This is done when a baby is being placed on a ventilator to control or support the breathing.
Jaundice (Hyperbilirubinemia)	A yellow coloration of the skin and eyes caused by increased amounts of bilirubin, a waste product of the normal break down of red blood cells and other tissues in the blood.
Kidney function medications	Medication used to treat kidney disease.
Low Birth Weight (LBW)	A baby born weighing less than 5 ½ pounds (2,500 grams) and more than 3 pounds, 5 ounces (1,500 grams).
Magnetic resonance imaging (MRI)	Computerized method of viewing the inside of the body using magnets instead of radiation.
Meningitis **(Infection of the fluid around the brain and spinal cord)**	Infection of the fluid that surrounds the brain and spinal cord.
Mortality	Death.
Multi-organ failure **(The failure of two or more organs)**	The failure of two or more organs.
Muscle paralyzing medications	Medication used to relax the muscles. The baby temporarily cannot move or breath on his or her own.
Nasogastric tube **(NG tube)**	A tube going from the nose to the stomach.
Necrotizing Enterocolitis (NEC) **(Severe intestine infection with tissue death)**	Swelling of the intestine resulting in tissue death caused by an infection or decreased blood supply.
Non-escalation of care	This is a change in the focus of care for the infant. Instead of providing full, escalating treatment with the goal of curing a baby's medical conditions, it involves continuing all treatments that are currently in place, but not providing any escalation of care or any new treatment options. This care option is provided

	when the team is very likely to provide palliative care to the baby but is not withdrawing life support yet. It is often accompanied by a Do Not Resuscitate (DNR) order.
Oxygen therapy	Giving extra oxygen to the tissues of the body through the lungs. Oxygen can be supplied through a breathing tube attached to a ventilator, a mask on the face, nasal prongs, or blow-by.
Pain medications	Medication used to relieve pain.
Patent Ductus Arteriosus (PDA) **(An extra communication between the lung and heart)**	An extra communication between the lung and heart. Before birth the ductus arteriosus allows the baby's blood to bypass the lungs. The bypass should close shortly after birth, but if it does not it is known as PDA.
Perforation **(Ruptured intestine)**	Ruptured intestine.
Peripheral intravenous lines	A thin, flexible tube placed in a small vein in the arm, hand, leg, foot, or scalp used to supply fluids such as nutrition and medication.
Periventricular Leukomalacia (PVL) **(Preterm brain injury)**	Periventricular tissue is located around the two fluid filled ventricles in the brain. If there is not enough blood reaching the periventricular tissue the tissue may die and be replaced by cysts or fluid. The brain tissue that dies may affect muscle control in the limbs. PVL is associated with cerebral palsy and other developmental problems.
Persistent Pulmonary Hypertension (PPHN) **(Lung blood vessel disease)**	Lung blood vessels are too tight resulting in difficulty getting blood to the lungs to then carry oxygen to the rest of the body. The heart may become strained and may start to fail as a result.
Platelet transfusions	The IV administration of platelets from a blood donor, which are small cells important for blood clotting.
Pneumonia **(An infection in the lungs)**	An infection in the lungs causing difficulty breathing. It is treated with antimicrobial medication.
Pneumothorax **(Air leaking from an**	Involves air leaking from an injured lung into the space between the lung and the chest wall. Small leaks may cause no problems but large leaks may cause the lung to collapse and

injured lung)	may require drainage through a tube.
Prematurity (Preterm birth) (PTB)	Babies are normally born between 37-42 weeks gestation (nine months). Infants born before 37 weeks are premature. • Preterm birth (PTB) is any birth between less than 37 weeks of gestation. • Very preterm birth (VPTB) is birth between 29 and 35 weeks of gestation. • Extremely preterm birth (EPTB) is birth before 28 weeks of gestation.
Pulmonary hemorrhage **(Lung bleeding)**	A condition in which there is bleeding into the lung.
Pulse Oximeter	A device worn on the finger or toe that measures the amount of oxygen in the blood.
Renal failure **(Kidneys not working)**	The inability of the kidney to maintain normal function. May be evident in the bloodwork or may be shown by little or no urine being produced.
Respirator (Ventilator)	A machine that helps breathing by supplying and regulating air flow and oxygen content. The air flows through a tube placed through the nose or mouth, down the back of the throat and into the windpipe.
Respiratory Distress Syndrome (RDS)	Respiratory problem due to absence of surfactant, which is a fluid produced in the mature lung that prevents the lung from becoming stiff and collapsing.
Respiratory failure **(Inability of lungs to supply enough oxygen to the body or rid the body of gas waste products)**	The inability of the lungs to maintain an adequate concentration of oxygen in the blood or rid the body of gas waste products.
Sedatives	Medication used to calm a baby or induce a deep sleep state.
Seizures **(Involuntary muscle activity)**	A "short-circuiting" of electrical activity in the brain causing irregular muscle activity. Generalized seizures affect the whole body. Focal seizures affect only one part or side of the body.
Sepsis **(Infection of the blood)**	Infection of the blood stream involving bacteria, fungus, or a virus which makes the baby very ill and affects multiple organ systems. This condition is treated with antibiotics or antimicrobials.
Systemic Inflammatory Response Syndrome	A very severe illness state which occurs when the body's normal reaction to inflammation or infection goes into

(SIRS)	overdrive and involves the malfunction of several organ systems.
Tachycardia	A faster than normal heart rate.
Tachypnea	A faster than normal breathing rate.
Total body cooling	A therapy involving cooling the body to induce hypothermia or a low body temperature. Total body cooling is usually used when the baby has been diagnosed with HIE and has had low oxygen delivery to the brain. The goal is to reduce brain damage.
Transfusion	A treatment in which blood from a donor is administered intravenously to the baby’s blood.
Tube feeding	A tube inserted through the mouth or nose and ending in the stomach is used to provide food to the baby.
Ultrasound (US)	A test using sound waves which shows an image of the inside of the body. The test is not harmful or painful to the baby and can be done at the bedside.
Urinary Tract Infection (UTI) **(Infection of the bladder or kidneys)**	An infection involving the bladder or kidneys that requires antimicrobials for treatment.
Vein	A blood vessel bringing blood back to the heart.
Venous Catheter	A catheter inserted into a vein to deliver fluid, nutrition, or medication.
Very Low Birth Weight (VLBW)	A baby born weighing less than 3 pounds, 5 ounces (1,500 grams) and more than 2 pounds, 3 ounces (1000 grams).
Withdrawal of life support / palliative care	This is a change in the focus of care for the infant. Instead of providing full, invasive treatment with the goal of curing a baby's medical conditions, it involves the removal of invasive and often painful life support technology with the aim to keep the baby comfortable while accepting that the baby will likely die.

Appendix C: Ethics Approval



Children's Hospital of Eastern Ontario
Centre hospitalier pour enfants de l'est de l'Ontario

CHEO RESEARCH ETHICS BOARD APPROVAL – DELEGATED REVIEW

Principal Investigator:	Dr. Erica Bariciak/Sabine Weyand
Proposal Number:	#10/144X
Protocol Title:	Study of a Neonatal Intensive Care Unit Parent Decision Support Tool
Department or PSU:	Neonatology
Approval date:	January 20, 2011
Valid Until:	January 19, 2012
Documents reviewed and approved:	Revised Protocol, submitted January 15, 2011-01-20Appendix 1, Recruitment Letter, November 10, 2010 Appendix 2, Study Test Participant Script Appendix 3, November 15, 2010, initial Appendix 4, Background Questionnaire for PADS Tool Appendix 5, Evaluation Tasks for PADS Tool Appendix 6, Evaluation Questionnaire for PADS Tool

This is to notify you that the Children's Hospital of Eastern Ontario Research Ethics Board has granted approval to the above named research study on the date noted above. Your project was reviewed under the delegated review stream, which is reserved for projects that involve no more than minimal risk to human subjects.

Final approval is granted for the above noted study, with the understanding that the investigator agrees to comply with the following requirements:

- The investigator must conduct the study in compliance with the protocol and any additional conditions set out by the Board.
- The investigator must not implement any deviation from, or changes to, the protocol without the approval of the REB, or when the change involves only logistical or administrative aspects of the study (e.g., change of telephone number or research staff).
- The investigator must, prior to use, submit to the Board changes to the study documentation, e.g., changes to the informed consent letters, recruitment materials.
- For all other research studies, investigators must promptly report to the REB all unexpected and untoward occurrences (including the loss or theft of study data and other such privacy breaches).
- Investigators must submit an annual renewal report to the REB 30 days prior to the expiration date stated above.
- Investigators must submit a final report at the conclusion of the study.
- Investigators must provide the Board with French versions of the consent form, unless a waiver has been granted.

For complete procedures relating to these modifications, please refer to the REB website at http://www.cheori.org/about_ethics.html or contact Sharon Haig, Ethics Coordinator at [redacted] [redacted]

[redacted]

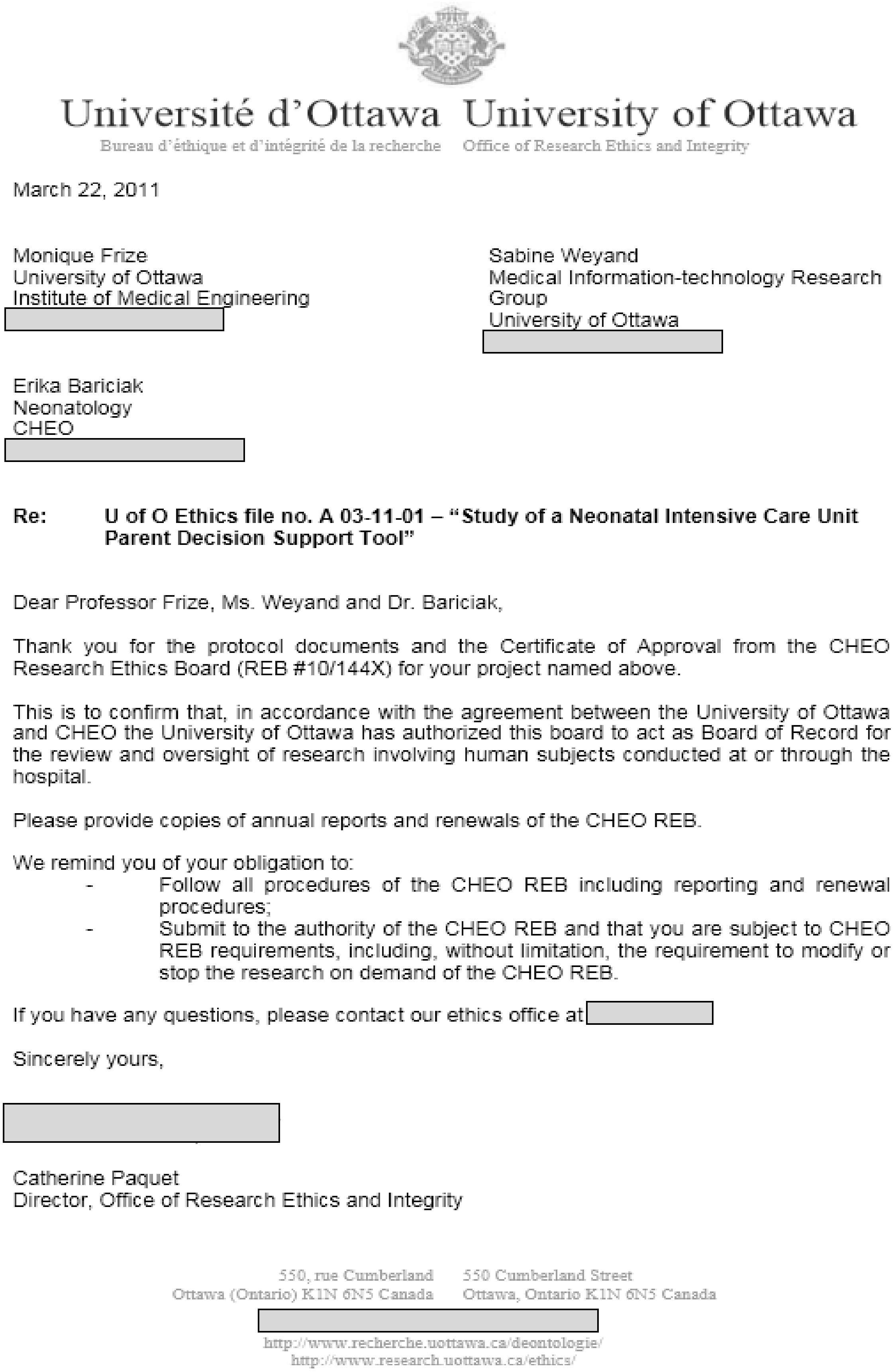
Regards,
Dr. Carole Gentile, C.Psych.
Chair, Research Ethics Board

CG/smeh 20/01/2011
c.c. CHEO RI Administration

This is an official document. Please retain the original for your file ***2010 version***

401 Smyth Road, Ottawa, ON K1H 8L1, Canada
[redacted]
Making a difference in the lives of children and youth

401, chemin Smyth, Ottawa (ON) K1H 8L1, Canada
[redacted]
Faire une différence dans la vie des enfants et des adolescents



Université d'Ottawa University of Ottawa
Bureau d'éthique et d'intégrité de la recherche Office of Research Ethics and Integrity

March 22, 2011

Monique Frize
University of Ottawa
Institute of Medical Engineering
[redacted]

Sabine Weyand
Medical Information-technology Research Group
University of Ottawa
[redacted]

Erika Bariciak
Neonatology
CHEO
[redacted]

Re: U of O Ethics file no. A 03-11-01 – "Study of a Neonatal Intensive Care Unit Parent Decision Support Tool"

Dear Professor Frize, Ms. Weyand and Dr. Bariciak,

Thank you for the protocol documents and the Certificate of Approval from the CHEO Research Ethics Board (REB #10/144X) for your project named above.

This is to confirm that, in accordance with the agreement between the University of Ottawa and CHEO the University of Ottawa has authorized this board to act as Board of Record for the review and oversight of research involving human subjects conducted at or through the hospital.

Please provide copies of annual reports and renewals of the CHEO REB.

We remind you of your obligation to:

- Follow all procedures of the CHEO REB including reporting and renewal procedures;
- Submit to the authority of the CHEO REB and that you are subject to CHEO REB requirements, including, without limitation, the requirement to modify or stop the research on demand of the CHEO REB.

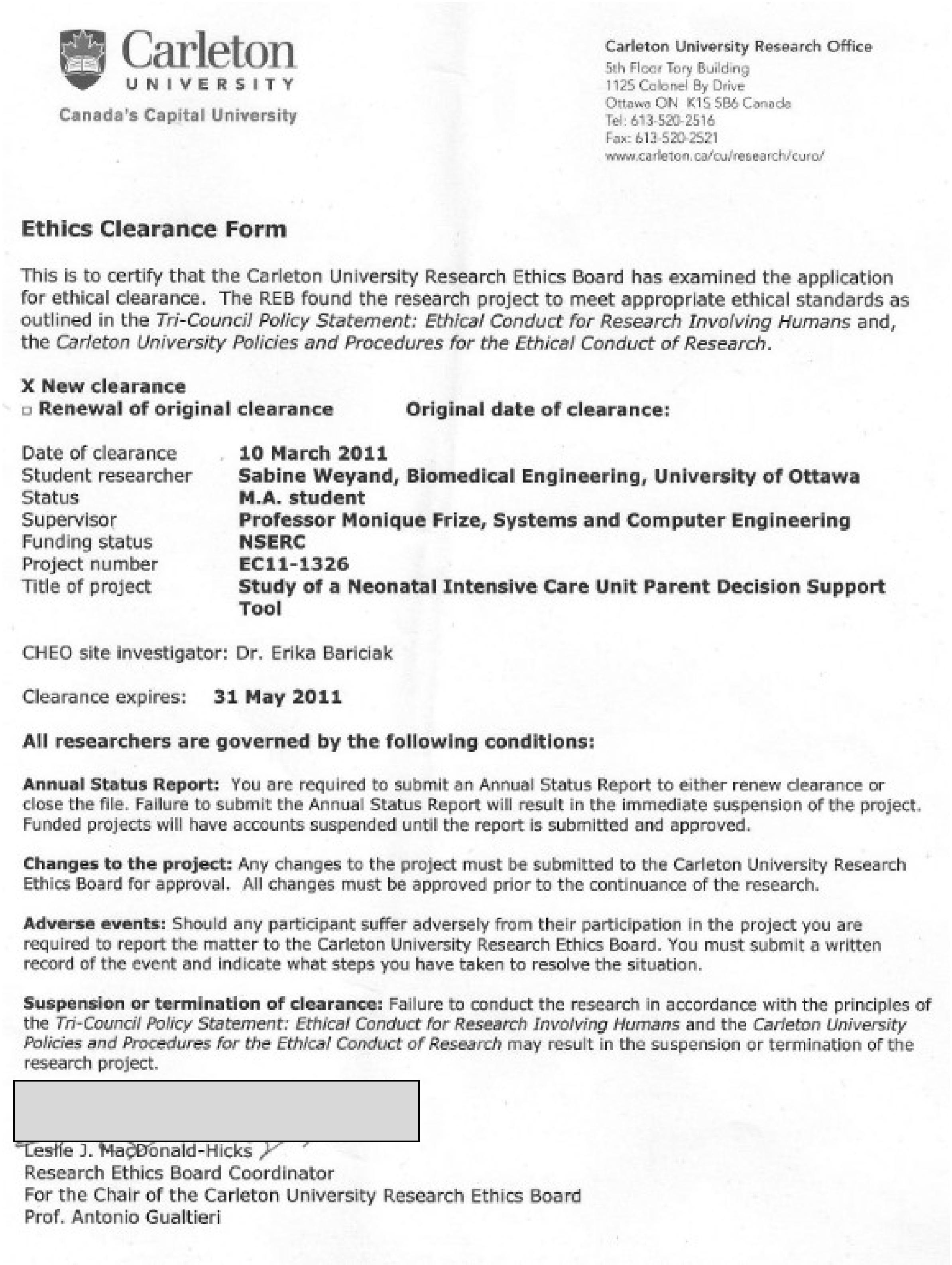
If you have any questions, please contact our ethics office at [redacted]

Sincerely yours,

[redacted]

Catherine Paquet
Director, Office of Research Ethics and Integrity

550, rue Cumberland 550 Cumberland Street
Ottawa (Ontario) K1N 6N5 Canada Ottawa, Ontario K1N 6N5 Canada
[redacted]
http://www.recherche.uottawa.ca/deontologie/
http://www.research.uottawa.ca/ethics/



Carleton
UNIVERSITY
Canada's Capital University

Carleton University Research Office
5th Floor Tory Building
1125 Colonel By Drive
Ottawa ON K1S 5B6 Canada
Tel: 613-520-2516
Fax: 613-520-2521
www.carleton.ca/cu/research/curo/

Ethics Clearance Form

This is to certify that the Carleton University Research Ethics Board has examined the application for ethical clearance. The REB found the research project to meet appropriate ethical standards as outlined in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* and, the *Carleton University Policies and Procedures for the Ethical Conduct of Research*.

X New clearance
☐ **Renewal of original clearance** **Original date of clearance:**

Date of clearance	**10 March 2011**
Student researcher	**Sabine Weyand, Biomedical Engineering, University of Ottawa**
Status	**M.A. student**
Supervisor	**Professor Monique Frize, Systems and Computer Engineering**
Funding status	**NSERC**
Project number	**EC11-1326**
Title of project	**Study of a Neonatal Intensive Care Unit Parent Decision Support Tool**

CHEO site investigator: Dr. Erika Bariciak

Clearance expires: **31 May 2011**

All researchers are governed by the following conditions:

Annual Status Report: You are required to submit an Annual Status Report to either renew clearance or close the file. Failure to submit the Annual Status Report will result in the immediate suspension of the project. Funded projects will have accounts suspended until the report is submitted and approved.

Changes to the project: Any changes to the project must be submitted to the Carleton University Research Ethics Board for approval. All changes must be approved prior to the continuance of the research.

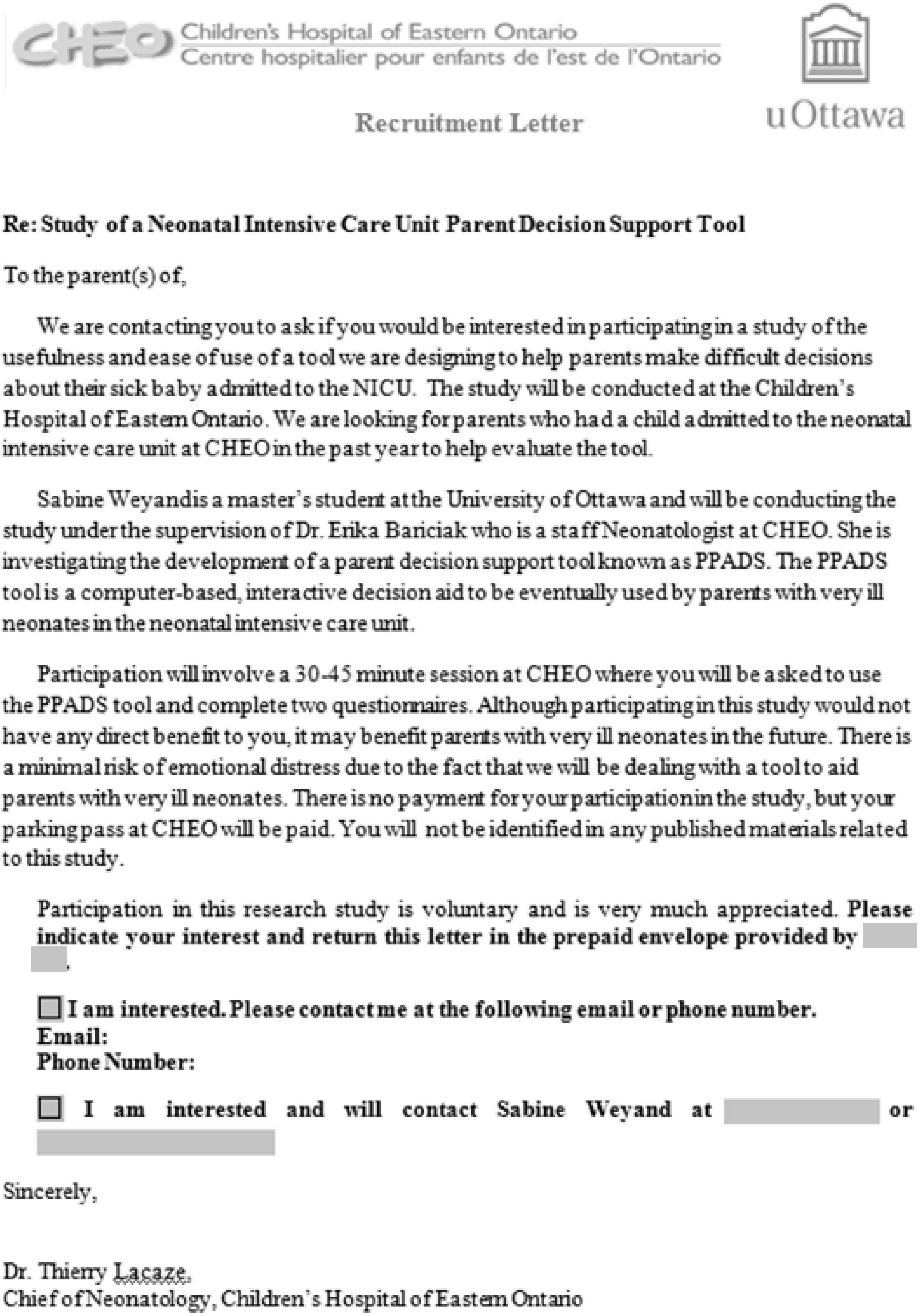
Adverse events: Should any participant suffer adversely from their participation in the project you are required to report the matter to the Carleton University Research Ethics Board. You must submit a written record of the event and indicate what steps you have taken to resolve the situation.

Suspension or termination of clearance: Failure to conduct the research in accordance with the principles of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* and the *Carleton University Policies and Procedures for the Ethical Conduct of Research* may result in the suspension or termination of the research project.

[redacted]

Leslie J. MacDonald-Hicks
Research Ethics Board Coordinator
For the Chair of the Carleton University Research Ethics Board
Prof. Antonio Gualtieri

Appendix D: Parent Recruitment Letter



CHEO Children's Hospital of Eastern Ontario
Centre hospitalier pour enfants de l'est de l'Ontario

uOttawa

Recruitment Letter

Re: Study of a Neonatal Intensive Care Unit Parent Decision Support Tool

To the parent(s) of,

We are contacting you to ask if you would be interested in participating in a study of the usefulness and ease of use of a tool we are designing to help parents make difficult decisions about their sick baby admitted to the NICU. The study will be conducted at the Children's Hospital of Eastern Ontario. We are looking for parents who had a child admitted to the neonatal intensive care unit at CHEO in the past year to help evaluate the tool.

Sabine Weyand is a master's student at the University of Ottawa and will be conducting the study under the supervision of Dr. Erika Bariciak who is a staff Neonatologist at CHEO. She is investigating the development of a parent decision support tool known as PPADS. The PPADS tool is a computer-based, interactive decision aid to be eventually used by parents with very ill neonates in the neonatal intensive care unit.

Participation will involve a 30-45 minute session at CHEO where you will be asked to use the PPADS tool and complete two questionnaires. Although participating in this study would not have any direct benefit to you, it may benefit parents with very ill neonates in the future. There is a minimal risk of emotional distress due to the fact that we will be dealing with a tool to aid parents with very ill neonates. There is no payment for your participation in the study, but your parking pass at CHEO will be paid. You will not be identified in any published materials related to this study.

Participation in this research study is voluntary and is very much appreciated. **Please indicate your interest and return this letter in the prepaid envelope provided by** [redacted].

☐ **I am interested. Please contact me at the following email or phone number.**
Email:
Phone Number:

☐ **I am interested and will contact Sabine Weyand at** [redacted] **or** [redacted]

Sincerely,

Dr. Thierry Lacaze,
Chief of Neonatology, Children's Hospital of Eastern Ontario

Appendix E: Parent Participant Script

Study Test Participant Script

Title of research project: **Study of a Neonatal Intensive Care Unit Parent Decision Support Tool**

Participant ID: ___________________

"Thank you for agreeing to take part in our research study. My name is Sabine Weyand and I am a research student from the University of Ottawa.

During the rest of the session, I'll be working from a script to ensure that my instructions are the same for everyone participating in this study.

My master's research explores the development, usefulness and ease of use of a decision support tool, which we have named "PPADS". The tool is for parents who have a very ill neonate in the neonatal intensive care unit. This study is designed to determine the usefulness of the tool, how easy it is to use, and the effectiveness of our decision support form.

During the session, I will ask you to use our current design of the decision support tool to do a variety of tasks and I will observe you while you do them. As you complete the tasks, please try to do whatever you would normally do. Please try to think and read out loud while you're working, as this will provide more information about the usability of the tool. Please know that we're not evaluating you, and there is no such thing as a wrong answer. Please do not hesitate to ask questions at any time. You will also be asked to complete a background questionnaire and an evaluation questionnaire. All questionnaires and notes will be tracked by a random number which has been assigned to you. You will not be identified in any data analysis or publication. The whole session will take about 30 – 45 minutes.

Some of the information contained in the decision support tool involves information about a sick baby in the NICU. For some people who have had the experience of having a sick baby of their own in the NICU, this might be upsetting. If participation in this study does cause you some distress and you'd like to have some follow-up support from the NICU Social Worker, Monette Boudreau-Roth, I can provide her with your contact information before you leave. Do you have any questions before we begin?

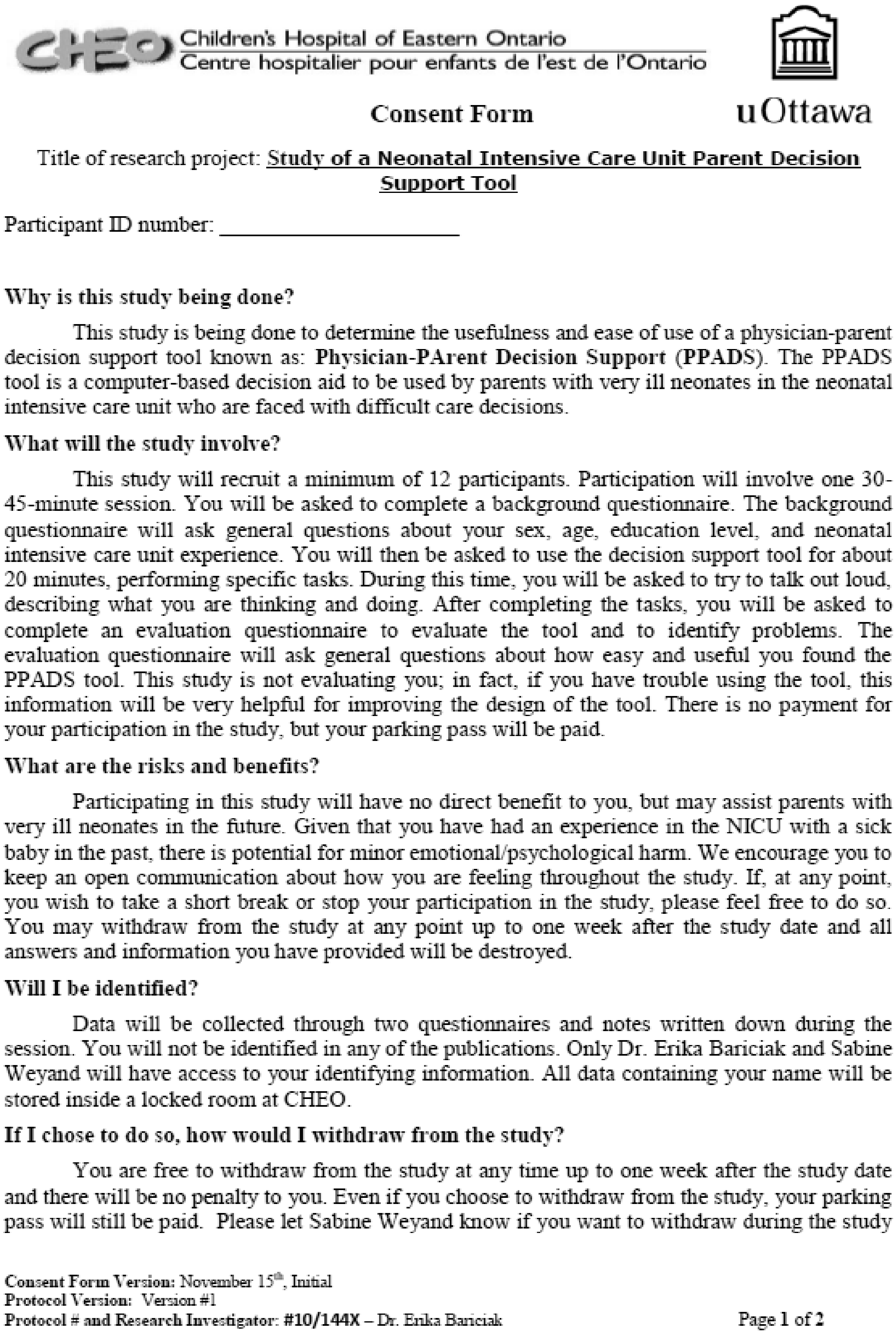
Please take a moment to read and complete this consent form. At this point I would like to remind you that you may withdraw from this study at any point. [Wait] Thank you.

Next, could you please complete the Background Questionnaire? [Wait] Thank you.

Next, I would like to ask you to please complete three tasks. I ask that you please perform one task at a time, do not skip any tasks, and do not to look ahead. You can check of the boxes as you complete the tasks. Please let me know when you have finished. [Wait] Thank you.

Finally, I ask that you fill out the evaluation questionnaire. [Wait] Thank you very much for your participation in this research study. "

Appendix F: Parent Consent Forms



Children's Hospital of Eastern Ontario
Centre hospitalier pour enfants de l'est de l'Ontario

uOttawa

Consent Form

Title of research project: **Study of a Neonatal Intensive Care Unit Parent Decision Support Tool**

Participant ID number: ____________________

Why is this study being done?

This study is being done to determine the usefulness and ease of use of a physician-parent decision support tool known as: **Physician-PArent Decision Support** (**PPADS**). The PPADS tool is a computer-based decision aid to be used by parents with very ill neonates in the neonatal intensive care unit who are faced with difficult care decisions.

What will the study involve?

This study will recruit a minimum of 12 participants. Participation will involve one 30-45-minute session. You will be asked to complete a background questionnaire. The background questionnaire will ask general questions about your sex, age, education level, and neonatal intensive care unit experience. You will then be asked to use the decision support tool for about 20 minutes, performing specific tasks. During this time, you will be asked to try to talk out loud, describing what you are thinking and doing. After completing the tasks, you will be asked to complete an evaluation questionnaire to evaluate the tool and to identify problems. The evaluation questionnaire will ask general questions about how easy and useful you found the PPADS tool. This study is not evaluating you; in fact, if you have trouble using the tool, this information will be very helpful for improving the design of the tool. There is no payment for your participation in the study, but your parking pass will be paid.

What are the risks and benefits?

Participating in this study will have no direct benefit to you, but may assist parents with very ill neonates in the future. Given that you have had an experience in the NICU with a sick baby in the past, there is potential for minor emotional/psychological harm. We encourage you to keep an open communication about how you are feeling throughout the study. If, at any point, you wish to take a short break or stop your participation in the study, please feel free to do so. You may withdraw from the study at any point up to one week after the study date and all answers and information you have provided will be destroyed.

Will I be identified?

Data will be collected through two questionnaires and notes written down during the session. You will not be identified in any of the publications. Only Dr. Erika Bariciak and Sabine Weyand will have access to your identifying information. All data containing your name will be stored inside a locked room at CHEO.

If I chose to do so, how would I withdraw from the study?

You are free to withdraw from the study at any time up to one week after the study date and there will be no penalty to you. Even if you choose to withdraw from the study, your parking pass will still be paid. Please let Sabine Weyand know if you want to withdraw during the study

Consent Form Version: November 15th, Initial
Protocol Version: Version #1
Protocol # and Research Investigator: **#10/144X** – Dr. Erika Bariciak

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session, and if you decide to withdraw after the study session you can contact Sabine by calling her at [redacted] and leaving a message in the confidential voice mail.

Consent

By signing this form, I acknowledge that I have volunteered to participate in a study to determine the usefulness and ease of use of the PPADS tool. I acknowledge that the research procedure described above, and of which I have a copy, has been explained to me, and that all my questions have been answered to my satisfaction. Additionally, I feel that I have been provided with sufficient time to reflect on my decision to participate.

I have been assured that I will not be identified in any published material. I understand that I am free to withdraw from the study at any time up to one week after the study date, and there will be no penalty to me. Any personal information about me will be coded so that I cannot be identified by name.

Thank you very much for participating!

Signature of Participant: ________________________________ Date:____/____/____

Name of Participant (Please print): ________________________________

Signature of Witness:________________________________

I HAVE EXPLAINED THIS STUDY TO THE ABOVE SIGNED PERSON AND I AM SATISFIED THAT IT IS UNDERSTOOD.

Signature of Investigator or Designate: ________________________________

If you should have any concerns regarding this study please contact: Sabine Weyand by email at [redacted] or by telephone at [redacted] or Dr. Erika Bariciak by email at [redacted] or by telephone at [redacted]

The CHEO Research Ethics Board (REB) has reviewed and approved this research project. You may contact the Chair of the Research Ethics Board, Dr. Carole Gentile, for information regarding patient's rights in research studies at [redacted]

CHEO Children's Hospital of Eastern Ontario
Centre hospitalier pour enfants de l'est de l'Ontario

uOttawa

Formulaire de Consentement

Titre du projet de recherche: **Étude d'un système d'aide à la décision pour les parents de nouveaux-nés admis aux soins intensifs**

Numéro de Participant: ___________________

Pourquoi cette étude?

Cette étude a pour but de déterminer l'utilité et la facilité d'usage d'un système de support de décision pour les parents de nouveaux-nés admis aux soins intensifs (**PPADS**). PPADS utilise un ordinateur et un programme pour aider les parents à prendre des décisions difficiles au sujet des soins d'un nouveau-né très malade à l'unité de soins intensifs.

Qu'implique cette étude?

L'étude va devoir recruiter un minimum de douze personnes et une session va durer de 30 à 45-minutes. Vous devrez premièrement compléter un questionnaire de base qui va poser des questions sur votre sexe, age, niveau d'éducation et votre experience au sein de l'unité de soins intensifs néonataux. Puis on vous demandera d'utiliser le système d'aide à la décision pour une vingtaine de minutes, avec des tâches spécifiques. Durant cet exercice, on vous demandera d'essayer de faire vos commentaries de vive-voix, décrivant ce que vous pensez et faites. Après avoir complété ces tâches, on vous demandera de compléter un questionnaire pour évaluer l'outil et pour identifier des problèmes. Le questionnaire pour évaluer l'outil vous demandera si l'outil est facile à utiliser, et si vous le trouvez utile. Cette étude ne vous évalue pas; en effet, si vous avez des difficultés à utiliser l'outil, ces renseignements seront très utiles pour que nous apportions des améliorations au système. Il n'y aura pas compensation pour votre participation à cette étude, mais nous payerons votre stationnement.

Quels sont les risques et les bénéfices?

Une participation à cette étude n'aura pas de bénéfices directement pour vous, mais elle pourra aider d'autres parents dans l'avenir. Il est possible qu'il y ait des effets mineurs émotifs ou psychologiques. Nous vous encourageons à communiquer vos sentiments durant toute la session. Si vous désirez faire une pause ou arrêter complètement, sentez vous libre de le faire. Vous pouvez vous retirer de l'étude à n'importe quel moment, jusqu'à une semaine après la fin de la session, et toutes les réponses et informations que vous avez fournies seront détruites.

Est ce que je serai identifié?

La collecte de données se compose de deux questionnaires et de notes prises durant la session. Vous ne serez pas identifié dans les publications. Il y aura seulement Dr. Erika Bariciak et Sabine Weyand qui auront accès aux renseignements qui vous identifient. Toutes les données qui contiennent votre nom vont être entreposées dans un bureau, sous clef, à l'Université Carleton.

Formulaire de Consentement

Si je decide de retirer ma participation, que dois-je faire?

Vous êtes libre de vous retirer de l'étude à n'importe quel moment, jusqu'à une semaine après la fin de la session, et il n'y aura aucune consequence pour vous. Si vous décidez de vous retirer du projet, nous paierons votre stationnement. Nous vous prions d'informer Sabine Weyand si vous voulez vous retirer durant la session, et si vous décidez de vous retirer à un autre moment, après la session, vous pouvez contacter Sabine au numéro suivant [redacted] et laisser un message dans la boîte vocale confidentielle.

Consentement

En signant ce formulaire, je reconnais que je me suis porté volontaire pour participer à cette étude, pour aider à déterminer l'utilité et la facilité d'usage d'un nouvel outil. Je reconnais qu'on m'a bien expliqué la procedure à suivre, j'en ai reçu une copie, et on a répondu à toutes mes questions de manière satisfaisante. De plus, on m'a donné suffisamment de temps pour réfléchir à ma décision de participer.

On m'a assuré que je ne serai pas identifié dans les publications. Je comprends que je peux me retirer de cette étude à n'importe quel moment, jusqu'à une semaine après la fin de la session, et qu'il n'y aura aucune consequence pour moi. Toute information personnelle va être codée, donc je ne serai pas identifié par mon nom.

Un grand merci pour votre participation!

Signature du participant: ________________________________ Date:____/____/____

Nom du participant (Imprimer): __________________________________

Signature du témoin:__________________________________

J'AI EXPLIQUÉ CETTE ÉTUDE À LA PERSONNE QUI A SIGNÉ CI-HAUT ET JE SUIS SATISFAITE QU'ELLE EST BIEN COMPRISE.

Signature du chercheur ou personne désignée: _______________________________

Si vous avez une préoccupation au sujet de cette étude, veuillez contacter: Sabine Weyand par email:[redacted] ou par téléphone: [redacted] ou Dr. Erika Bariciak par courriel à [redacted] ou par téléphone à [redacted].

Le CHEO Research Ethics Board (REB) a reçu et approuvé ce projet de recherche. Vous pouvez contacter Dr. Carole Gentile, présidente du Research Ethics Board, pour des renseignements au sujet des droits des participants dans un projet de recherche: [redacted]

Appendix G: Parent Background Questionnaire

Background Questionnaire for PPADS Tool

Title of research project: **Study of a Neonatal Intensive Care Unit Parent Decision Support Tool**

Participant ID: ____________________

The purpose of this survey is to determine some background information that will be used for the data analysis. The questionnaire should take about 5 minutes. Please be aware that you are under no obligation to complete this questionnaire, and you may withdraw from the study at any point in time until one week after today.

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

2. Your gender:
   ☐Female
   ☐Male

3. Is another member of your family also participating in this study?
   ☐Yes
   ☐No

4. Your highest level of education:
   ☐Less than High school diploma
   ☐High school diploma
   ☐Some university or college years
   ☐University degree
   ☐Other, specify _______

5. How many of your children have been admitted to the NICU:
   ☐0
   ☐1
   ☐2
   ☐3
   ☐Other, specify _______

6. Length of time elapsed since last infant in NICU
    ☐< 3 months
    ☐4-6 months
    ☐7-9 months
    ☐10-12 months
    ☐> 12months

7. Were any of the following scenarios presented to you while your neonate was in the NICU:
    ☐Withdrawal of life support
    ☐Non-escalation of care
    ☐Do not resuscitate order
    ☐None of the above

8. Were any of these scenarios undertaken:
    ☐Withdrawal of life support
    ☐Non-escalation of care
    ☐Do not resuscitate order
    ☐None of the above

9. Do you have a computer at home?
    ☐Yes
    ☐No

10. How often do you use a computer per week?
    ☐ Never
    ☐ Rarely
    ☐ Every once in a while
    ☐ Often

11. What is your computer skill level?
    ☐ Expert
    ☐ Advanced
    ☐ Beginner
    ☐ Novice

Thank you for your participation. You may provide any additional comments below:

____

____

____

Appendix H: Parent Evaluation Tasks

Evaluation Tasks for PPADS Tool

Title of research project: **Study of a Neonatal Intensive Care Unit Parent Decision Support Tool**

Participant ID: __________________

Thank you for taking the time to help us evaluate our parent decision support tool (PPADS). This tool has been developed to help parents who have very ill infants in the NICU. This tool is intended to be used in addition to parent-physician meetings, to help parents gather information and help them make difficult care decisions with their doctor.

During the evaluation, we ask you to provide your opinion of the tool and perform a few short simple tasks to evaluate it. We ask that you think out loud as you interact with the tool to provide us with more information. Feel free to ask questions at any time. You are not obliged to complete this experiment and you may withdraw at any time until one week after today.

Please complete each of the tasks below. You may use the checkboxes to keep track of which tasks you have completed. The tasks should take about 30 minutes to complete.

Task 1:
Imagine that you are the parent of a baby girl, Jane, born 2 weeks ago at 24 weeks gestation (3 months early).

She needed help to breathe right at birth and was placed on a breathing machine (ventilator). She has very immature, injured lungs, and each attempt to remove her from the ventilator has failed.

She now has bleeding into her lungs from a problem with her heart called a PDA; this has made her lungs even sicker. She is now on the maximum level of ventilator support but is still not doing well.

She has needed blood transfusions for this lung bleeding. Her blood pressure is low and she needs medication to help keep it normal.

She has stopped voiding (producing urine) because her kidneys are failing. Her salts in her blood are severely unbalanced putting her at risk for heart rhythm problems.

An xray of her intestines has shown that she has a severe gut infection called NEC. She has been started on antibiotics for this.

The doctor looking after Baby Jane has met with you to discuss her situation. The medical team feels that Jane will likely not survive, despite ongoing therapy. They feel that even if she did survive, she would most likely suffer from severe handicaps including cerebral palsy (CP) and intellectual deficits. They recommend changing her direction of care to palliative care and withdrawing all painful, invasive, life support.

Please use this PPADS Program to help you understand your options when considering this decision.

Steps:

1) ☐ Log in using:
   User name: 1234567
   Password: 123
2) ☐ View home page
3) View medical information
   - ☐ View the current conditions
   - ☐ View the note from the clinician
   - ☐ View the current treatments
   - ☐ Find and read the definition of at least two of the current treatments
   - ☐ View the medical outcome predictions (ie. Risk of mortality, Risk of BPD, Risk of IVH)
4) Go to the decision support page
   - ☐ View the different direction of care options
   - ☐ View the reason a change in direction of care was suggested
5) Complete a new decision support form
   - ☐ Fill out the decision support form (assume information when not known)
6) ☐ Print the decision support form
7) ☐ Go to homepage
8) ☐ Log out

Task 2:
Imagine that you are the parent of a baby boy, Bob, who was born at term gestation 1 week ago.

He did fine for the first few days of life, but then became pale and stopped feeding. He quickly got sicker and had trouble breathing and had to be placed on a ventilator. He is still on the ventilator.

He developed low blood pressure and needed medications to keep his blood pressure normal. He continued to get worse and he developed heart and kidney failure.

An echocardiogram (ECHO) was done, which showed that he has congenital heart disease, which requires open-heart surgery. A medication was started to help his heart pump blood more easily throughout his body, and this stabilized him.

His kidneys remain damaged and he is still not voiding (producing urine). This has resulted in a severe imbalance of the salts in his blood.

An MRI of his head showed that his brain did not receive enough blood flow or oxygen and now he has widespread injury to the brain.

The doctor looking after Baby Bob would like to meet with you to discuss his current clinical status. He is worried that Baby Bob has had some irreversible injuries to many of his organs as a result of being so sick and worries about whether Bob will be able to tolerate the surgery.

Please use this PPADS Program to help you understand Bob's current issues before you meet with the medical team.

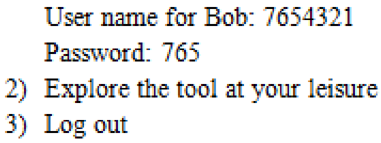
Steps:

1) ☐ Log in using:
   User name: 7654321
   Password: 765
2) ☐ View home page
3) View medical information
   - ☐ View the current conditions
   - ☐ Find and read the definition of at least two of the current conditions
   - ☐ View the note from the clinician
   - ☐ View the current treatments
   - ☐ View the medical outcome predictions (ie. Risk of mortality, Risk of BPD, Risk of IVH)
4) ☐ View the glossary
5) ☐ Search glossary for "IVH"
6) ☐ Log out

Task 3:
For this task you may log back in to either Baby Jane or Baby Bob's account and explore the tool at your leisure.

Steps:

1) Log in using:
   User name for Jane: 1234567
   Password: 123



User name for Bob: 7654321
Password: 765

2) Explore the tool at your leisure
3) Log out

Appendix I: Parent Evaluation Questionnaire

Evaluation Questionnaire for PPADS Tool

Title of research project: **Study of a Neonatal Intensive Care Unit Parent Decision Support Tool**

Participant ID: _________________

The purpose of this study is to determine whether the PPADS tool is easy to use, useful, and has the potential to be used by parents while their baby is admitted in the neonatal intensive care unit. The questionnaire will assess your opinion about the tool and should take about 5 minutes to complete. Please be aware that you are under no obligation to complete this questionnaire and you may withdraw from the study at any point in time until one week from today.

1. Your overall view of PPADS:
   ☐Exceptional
   ☐Satisfying
   ☐Frustrating
   ☐Unacceptable

2. The organization of information in PPADS is:
   ☐Very clear
   ☐Moderately clear
   ☐Somewhat confusing
   ☐Very confusing

3. Navigation through PPADS is:
   ☐Very easy
   ☐Moderately easy
   ☐Somewhat difficult
   ☐Very difficult

4. For you to understand the meaning of the pages and buttons in PPADS is:
   ☐Very easy
   ☐Moderately easy
   ☐Somewhat difficult
   ☐Very difficult

5. Using PPADS to perform the assigned tasks is:
   ☐Always easy
   ☐Mostly easy
   ☐Sometimes easy
   ☐Never easy

6. The amount of information used in PPADS is:
   ☐ Too much information
   ☐ Just right
   ☐ Too little information

7. The length of the decisions support form is:
   ☐ Too long
   ☐ Just right
   ☐ Too short

8. The terms used in PPADS are:
   ☐ Always easily understood
   ☐ Mostly easily understood
   ☐ Sometimes easily understood
   ☐ Never easily understood

9. Please mark how much you agree or disagree with the following statements:

	Strongly Disagree 1	Disagree 2	Agree 3	Strongly Agree 4
1. I would find it easy to learn to use the tool	☐	☐	☐	☐
2. Using the tool would not add stress	☐	☐	☐	☐
3. I was able to find the information I was looking for	☐	☐	☐	☐
4. I found I could navigate the tool quickly	☐	☐	☐	☐

10. Please mark how much you agree or disagree with the following statements:

	Strongly Disagree 1	Disagree 2	Agree 3	Strongly Agree 4
1. The list of the neonate's current medical condition was useful	☐	☐	☐	☐
2. The list of the neonate's current medical conditions were easy to understand	☐	☐	☐	☐

	Strongly Disagree 1	Disagree 2	Agree 3	Strongly Agree 4
3. The list of the neonate's current treatments was useful	☐	☐	☐	☐
4. The list of the neonate's current treatments were easy to understand	☐	☐	☐	☐
5. The neonate's risk predictions were useful	☐	☐	☐	☐
6. The neonate's risk predictions were easy to understand	☐	☐	☐	☐
7. The reason a change in direction of care was suggested was useful	☐	☐	☐	☐
8. The reason a change in direction of care was suggested was easy to understand	☐	☐	☐	☐
9. The decision support form was useful	☐	☐	☐	☐
10. The decision support form was easy to understand	☐	☐	☐	☐
11. The information about the different directions of care were presented in a balanced way	☐	☐	☐	☐
12. The glossary descriptions provided for the different medical terms were useful	☐	☐	☐	☐
13. The glossary descriptions provided for the different medical terms were easy to understand	☐	☐	☐	☐
14. After using the PPADS tool I would feel more informed	☐	☐	☐	☐
15. After using the PPADS tool I would have a better understanding of the direction of care options	☐	☐	☐	☐
16. After using the PPADS tool I would feel more certain about my decision	☐	☐	☐	☐

	Strongly Disagree 1	Disagree 2	Agree 3	Strongly Agree 4
17. After using the PPADS tool I would feel clearer about how my values affect my decision	☐	☐	☐	☐
18. If given the opportunity I would use the tool	☐	☐	☐	☐

Thank you very much for your participation. Please list any other comments including: overall opinion of the tool, positives, negatives, problems you had, and suggestions for improvements below:

____

____

____

____

Appendix J: Physician Recruitment Letter

To all neonatologists at CHEO,

We are contacting you to ask if you would be interested in participating in a study of the usefulness and ease of use of a tool we are designing to help parents make difficult decisions about their sick baby admitted to the NICU. The study will be conducted at the Children's Hospital of Eastern Ontario during NICU Research Rounds.

Sabine Weyand is a master's student at the University of Ottawa and will be conducting the study under the supervision of Dr. Erika Bariciak. She is investigating the development of a parent decision support tool known as PPADS. The PPADS tool is a computer-based, interactive decision aid to be eventually used by parents with very ill neonates in the neonatal intensive care unit.

Participation will involve a 20-30 minute session at CHEO where you will be given a demonstration of the PPADS tool and asked to complete an evaluation questionnaire. Although participating in this study would not have any direct benefit to you, it may benefit parents with very ill neonates and neonatologists in the future. There is no payment for your participation in the study. You will not be identified in any published materials related to this study.

Participation in this research study is voluntary and is very much appreciated. **Please indicate your interest and return this letter in the prepaid envelope provided by** [redacted]

☐ **I am interested. Please contact me at the following email or phone number.**

Email:

Phone Number:

☐ **I am interested and will contact Sabine Weyand at** [redacted] **or** [redacted]

Sincerely,

Dr. Thierry Lacaze,

Chief of Neonatology, Children's Hospital of Eastern Ontario

Appendix K: Physician Prototype Demonstration Script

Demonstration Script and Tasks:

Thank you for taking the time to help us evaluate our parent decision support tool (PPADS). This tool has been developed to help parents who have very ill infants in the NICU. This tool is intended to be used in combination with parent-physician meetings, to help parents gather information and aid them in making difficult care decisions with the medical team.

We will present you with a scenario of a sick baby in the NICU. We will then demonstrate how the tool would be used in this scenario. During the demonstration feel free to ask questions and provide feedback. After the demonstration we ask you to fill out a brief questionnaire to evaluate the tool. You are not obliged to complete this study and you may withdraw at any time until one week after today.

Scenario:

Baby girl Jane was born 10 days ago at 24 weeks gestation weighing 750g. She was flat at birth and needed a brief period of CPR, then was placed on a ventilator.

She remains ventilated as each attempt to extubate her has failed.

She now has a pulmonary hemorrhage secondary to a large PDA. She is now HFO but her lungs are still failing.

She has needed blood transfusions for the pulmonary hemorrhage. Her blood pressure is low-normal after fluid boluses and dopamine and epinephrine infusions.

She is anuric and has a catheter in place. Her sodium is low and her potassium is starting to climb, putting her at risk of arrhythmias.

An abdominal x-ray has revealed severe, extensive NEC. She has been started on antibiotics for this.

The doctor looking after Baby Jane has met with her parents to discuss her situation. The medical team feels that Jane will likely not survive, despite ongoing therapy. They feel that even if she did survive, she would most likely suffer from severe handicaps including cerebral palsy (CP) and intellectual deficits. They recommend changing her direction of care to palliative care and withdrawing all painful, invasive, life support.

The parents of Baby Jane have been provided with the option of using the PPADS tool to help them understand the decision options and aid in decision-making.

We will start the demonstration from the perspective of Jane Doe's doctor by logging into the PPADS tool as Clinician 1.

1) ☐ Log in as a Clinician using:
   User name: Clinician1
   Password: 123
2) ☐ View home page
3) ☐ View Jane Doe's patient file
4) ☐ Write a note to Jane Doe's Parents
5) ☐ Activate Jane Doe's parent account

Next, we will observe the tool from the perspective of the parent by logging in as the parent of Jane Doe.

1) ☐ Log in as a parent using:
   User name: 1234567
   Password: 123
2) ☐ View home page
3) ☐ View the current conditions page
4) ☐ Find and read the definition of at least two of the current conditions
5) ☐ View the note from the clinician
6) ☐ View the current treatments page
7) ☐ Find and read the definition of at least two of the current treatments
8) ☐ View the medical outcome predictions (ie. Risk of mortality, Risk of BPD, Risk of IVH)
9) ☐ Go to the decision support page
10) ☐ View the different direction of care options
11) ☐ View the reason a change in direction of care was suggested
12) ☐ Look at parent decision support form
13) ☐ View Glossary
14) ☐ Search Glossary for IVH
15) ☐ Go to homepage
16) ☐ Log out

Appendix L: Physician Questionnaire

Title of research project: **Study of a Neonatal Intensive Care Unit Parent Decision Support Tool**

Participant ID: ____________________

The purpose of this study is to determine whether the PPADS tool is easy to use, useful, and has the potential to be used by parents while their baby is admitted in the neonatal intensive care unit. Please be aware that you are under no obligation to complete this questionnaire, and you may withdraw from the study at any point in time until one week after today.

Part A. Background Information

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

2. Your gender:
   ☐Female
   ☐Male

3. 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

4. What is your computer skill level?
   ☐ Expert
   ☐ Advanced
   ☐ Beginner
   ☐ Novice

Part B. Evaluation Questionnaire

	Strongly Disagree 1	Disagree 2	Agree 3	Strongly Agree 4
5. My overall view of the PPADS tool is positive	☐	☐	☐	☐
6. I would find it easy to integrate the tool into the current delivery of care	☐	☐	☐	☐
7. I would find it easy to learn to use the tool	☐	☐	☐	☐
8. I find the organization of information in PPADS to be clear	☐	☐	☐	☐
9. I think the tool would be helpful to parents	☐	☐	☐	☐
10. I think the tool provides the right amount of information to parents	☐	☐	☐	☐
11. I think the tool would help parents feel more informed	☐	☐	☐	☐
12. I think the tool would help parents understand their neonate's conditions	☐	☐	☐	☐
13. I think the tool is easy for parents to use	☐	☐	☐	☐
14. I think the tool would help with physician-parent communication	☐	☐	☐	☐
15. I think the decision support aid would help parents come to a decision about change of care needs	☐	☐	☐	☐
16. I think the decision support aid would help me better understand the parents' views on their decision	☐	☐	☐	☐
17. I think the decision support form would help guide physician-parent consultation	☐	☐	☐	☐

	Strongly Disagree 1	Disagree 2	Agree 3	Strongly Agree 4
18. If given the opportunity, I would offer parents of neonates in the NICU to use the PPADS tool	☐	☐	☐	☐
19. I can see the tool being useful in my role as physician in the future	☐	☐	☐	☐

Thank you very much for your participation. Please list any other comments including: overall opinion of the tool, positives, negatives, problems you had, and suggestions for improvements below:

Appendix M: Physician Consent Form

English Consent Form

Title of research project: **Study of a Neonatal Intensive Care Unit Parent Decision Support Tool**

Participant ID number: ____________________

Why is this study being done?

This study is being done to determine the usefulness and ease of use of a physician-parent decision support tool known as: **Physician-PArent Decision Support** (**PPADS**). The PPADS tool is a computer-based decision aid to be used by parents with very ill neonates in the neonatal intensive care unit who are faced with difficult care decisions.

What will the study involve?

This study will recruit a minimum of four neonatologists. Participation will involve one 20-30 minute session. A demonstration of the PPADS tool will be performed and you will be asked to fill out a questionnaire to evaluate the tool. There is no payment for your participation in the study.

What are the risks and benefits?

Participating in this study will have no direct benefit to you at this time, but may assist parents with very ill neonates and neonatologists in the future. There are no predicted risks of participating in this study. You may withdraw from the study at any point up to one week after the study date and all answers and information you have provided will be destroyed.

Will I be identified?

Data will be collected through an evaluation questionnaire and notes written down during the session. You will not be identified in any of the publications. Only Dr. Erika Bariciak and Sabine Weyand will have access to your identifying information. All data containing your name will be stored inside a locked room at CHEO.

If I chose to do so, how would I withdraw from the study?

You are free to withdraw from the study at any time up to one week after the study date and there will be no penalty to you. Please let Sabine Weyand know if you want to withdraw during the study session, and if you decide to withdraw after the study session you can contact Sabine by calling her at [redacted] and leaving a message in the confidential voice mail.

Consent

By signing this form, I acknowledge that I have volunteered to participate in a study to determine the usefulness and ease of use of the PPADS tool. I acknowledge that the research procedure described above, and of which I have a copy, has been explained to me, and that all my questions have been answered to my satisfaction. Additionally, I feel that I have been provided with sufficient time to reflect on my decision to participate.

I have been assured that I will not be identified in any published material. I understand that I am free to withdraw from the study at any time up to one week after the study date, and there will be no penalty to me. Any personal information about me will be coded so that I cannot be identified by name.

Thank you very much for participating!

Signature of Participant: ________________________________ Date:____/____/____

Name of Participant (Please print): __________________________________

Signature of Witness:__________________________________

I HAVE EXPLAINED THIS STUDY TO THE ABOVE SIGNED PERSON AND I AM SATISFIED THAT IT IS UNDERSTOOD.

Signature of Investigator or Designate: _______________________________

If you should have any concerns regarding this study please contact: Sabine Weyand by email at [redacted] or by telephone at [redacted] or Dr. Erika Bariciak by email at [redacted] or by telephone at [redacted].

The CHEO Research Ethics Board (REB) has reviewed and approved this research project. You may contact the Chair of the Research Ethics Board, Dr. Carole Gentile, for information regarding patient’s rights in research studies at [redacted]

Française Formulaire de Consentement

Titre du projet de recherche: **Étude d'un système d'aide à la décision pour les parents de nouveaux-nés admis aux soins intensifs**

Numéro de Participant: ___________________

Pourquoi cette étude?

Cette étude a pour but de déterminer l'utilité et la facilité d'usage d'un système de support de décision pour les parents de nouveaux-nés admis aux soins intensifs (**PPADS**). PPADS utilise un ordinateur et un programme pour aider les parents à prendre des décisions difficiles au sujet des soins d'un nouveau-né très malade à l'unité de soins intensifs.

Qu'implique cette étude?

L'étude va devoir recruiter un minimum de quatre néonatologues à une session va durer de 20 à 30-minutes. Il y aura une démonstration de l'outil PPADS et on vous demandera de remplir un questionnaire pour évaluer cet outil. Il n'y a pas de remuneration pour votre participation dans cette étude.

Quels sont les risques et les bénéfices?

Une participation à cette étude n'aura pas de bénéfices directement pour vous, mais elle pourra aider des parents et des néonatologues dans l'avenir. Nous n'anticipons pas de risqué pour la participation dans cette étude. Vous pouvez vous retirer de l'étude à n'importe quel moment, jusqu'à une semaine après la fin de la session, et toutes les réponses et informations que vous avez fournies seront détruites.

Est ce que je serai identifié?

La collecte de données se compose d'un questionnaire et de notes prises durant la session. Vous ne serez pas identifié dans les publications. Il y aura seulement Dr. Erika Bariciak et Sabine Weyand qui auront accès aux renseignements qui vous identifient. Toutes les données qui contiennent votre nom vont être entreposées dans un bureau, sous clef, à l'Université Carleton.

Si je decide de retirer ma participation, que dois-je faire?

Vous êtes libre de vous retirer de l'étude à n'importe quel moment, jusqu'à une semaine après la fin de la session, et il n'y aura aucune consequence pour vous. Nous vous prions d'informer Sabine Weyand si vous voulez vous retirer durant la session, et si vous décidez de vous retirer à un autre moment, après la session, vous pouvez contacter Sabine au numéro suivant [redacted] et laisser un message dans la boîte vocale confidentielle.

Consentement

En signant ce formulaire, je reconnais que je me suis porté volontaire pour participer à cette étude, pour aider à déterminer l'utilité et la facilité d'usage d'un nouvel outil. Je reconnais qu'on m'a bien expliqué la procedure à suivre, j'en ai reçu une copie, et on a répondu à toutes mes questions de manière satisfaisante. De plus, on m'a donné suffisamment de temps pour réfléchir à ma décision de participer.

On m'a assuré que je ne serai pas identifié dans les publications. Je comprends que je peux me retirer de cette étude à n'importe quel moment, jusqu'à une semaine après la fin de la session, et qu'il n'y aura aucune consequence pour moi. Toute information personnelle va être codée, donc je ne serai pas identifié par mon nom.

Un grand merci pour votre participation!

Signature du participant: ________________________________ Date:____/____/____

Nom du participant (Imprimer): __________________________________

Signature du témoin:__________________________________

J'AI EXPLIQUÉ CETTE ÉTUDE À LA PERSONNE QUI A SIGNÉ CI-HAUT ET JE SUIS SATISFAITE QU'ELLE EST BIEN COMPRISE.

Signature du chercheur ou personne désignée: _______________________________

Si vous avez une préoccupation au sujet de cette étude, veuillez contacter: Sabine Weyand par email: [redacted] ou par téléphone: [redacted] ou Dr. Erika Bariciak par courriel à [redacted], ou par téléphone à [redacted]

Le CHEO Research Ethics Board (REB) a reçu et approuvé ce projet de recherche. Vous pouvez contacter Dr. Carole Gentile, présidente du Research Ethics Board, pour des renseignements au sujet des droits des participants dans un projet de recherche: [redacted] [redacted]