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Development of Evidence-Based Practice Anesthesia Guidelines for Brain-Dead Organ Donors

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Final Scholarly Project: Development of Evidence-Based Practice Anesthesia Guidelines for Brain-Dead Organ Donors

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We have no conflicts of interest to disclose.

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Abstract

Organ donation is a gift of life for both donors and recipients that can come from living donors, donors after cardiac death, or brain-dead donors (BDDs). Treating the donors with optimal care throughout the entire donation process is crucial due to organ supply shortages. Organs from BDDs are a large contributor to the number of organs donated each year and require critical care from the time of admission, declaration of brain death, and throughout the organ procurement surgery. Although each BDD requires meticulous care for successful retrieval and donation, there is a lack of evidence-based practice (EBP) guidelines for anesthesia for BDDs during organ procurement surgery. This project encompasses the development, implementation, and evaluation plan of EBP anesthesia guidelines for BDDs. The problem was identified through an introduction to and background information regarding the organ donation process, from the declaration of brain death to organ procurement surgery, organ rejection, financial impact, and the significance of the problem to anesthesia. Next, a clinical person, intervention, comparison, outcomes, and time (PICOT) question was introduced which drove the objectives of the project and facilitated a thorough literature review. With the results from the literature search and recommendations from the Lifeline of Ohio Organ Procurement Agency (LOOP), guidelines for anesthesia for BDDs were created. The Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) Model was used to guide the development of and plan to implement the EBP anesthesia guidelines. Monitoring of outcomes will be completed by the QI department. Barriers, limitations, guideline improvement strategies, project timeline, and project budget are discussed, followed by a dissemination of the findings.

Keywords: organ donation, organ procurement, brain-dead donor, brain death, evidence-based practice, guidelines

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Problem Identification

Introduction of the Problem

Organ donation is a well-known and life-changing event for donors and recipients. Brain-dead donors (BDDs) comprise the most significant portion of available donor groups in the United States (Morse, 2017). Brain death occurs when cerebral function is terminated with a known cause (Kumar, 2016). The intact circulation of BDDs makes these donors an essential resource in organ preservation and organ transplantation (Townley, 2005). Potential organ donors are either declared brain dead or have irreversible damage to all cerebral functions (Anwar & Jae-Myeong, 2019). According to the American Association of Neurology (AAN), termination of the functions of the brain and brainstem, unresponsiveness, and apnea are three hallmark signs of brain death (Kumar, 2016). BDDs are an essential group in the organ donor population and assist in closing the gap between supply and demand.

The number of organs available for transplant compared to the number of recipients waiting for an organ transplant is alarming. In the United States, in 2016, 33,600 solid organs were transplanted, with most of the organs coming from BDDs (Souter et al., 2018). Over the last 19 years, organ donation from BDDs has doubled, and from 2019 to 2020, BDD donation has increased by 10.1 percent (UNOS, n. d.). In 2020, 6,000 Americans died waiting for an organ transplant (Donate Life America, 2022). The demand for organs for transplantation outweighs the supply. Although the extensive research and use of immunosuppressants have decreased morbidity and mortality in organ recipients, there is still the issue of an organ donation shortage (Bera et al., 2021). BDDs are an excellent alternative solution to living donor transplants, helping

decrease supply and demand issues. Therefore, it is essential to provide BDD patients with EBP care in order to preserve and optimize transplantable organs (Anwar & Jae-Myeong, 2019). Not only is optimal care for BDDs important to maintain and increase the supply of donated organs, but optimal care also can potentially decrease complications related to organ transplantation.

There are numerous complications related to organ transplantation, which include heart failure, hypertension, infection, acute kidney injury, diabetes mellitus, graft dysfunction and failure, malignancy, and death (Sen et al., 2019). The complications that occur from organ transplantation can lead to additional hospital care, which is an additional cost to the recipient and health care systems. For example, graft failure in recipients of kidneys; the most commonly transplanted organ, may lead to lifelong treatment on dialysis, additional transplant surgeries, death, lower quality of life, and increased medical costs to the patient (Sussell et al., 2020). On average, after an organ transplantation without complications, the cost of medications alone per recipient per year is $10,000 to $14,000 (James & Mannon, 2015). In addition to medications, organ recipients require follow up appointments and tests for the rest of their lives. If complications with an organ transplant arise, the cost of treating complications is an additional financial burden to the recipients that are already experiencing great financial burden.

In order to help avoid complications after organ transplant, there should be a systematic approach when caring for the organ donor. Standardized donor management goals help optimize the donor patient before organ recovery and increase the rates of organs transplanted (Franklin et al., 2010). After brain death declaration, organ procurement organizations (OPO) use donor management goal checklists in hopes of increasing the number of organs recovered and improving graft survival (Donor Management Goals Registry, n. d.). The Donor Management Goals online registry lists nine hemodynamic, laboratory value, and medication administration

benchmarks with the goal of OPOs to achieve at least seven of the benchmarks for optimal care (Donor Management Goals Registry, n. d.). Surveys show that intraoperative anesthetic practice during organ procurement aligns with intensive care unit (ICU) management and optimization of brain-dead organ donors (Champigneulle et al., 2019). Even with these recommendations within the organ procurement process, there are no specific intraoperative anesthesia guidelines (Champigneulle et al., 2019).

Evidence-based anesthesia practice for brain-dead organ donors is necessary to improve organ recipients' clinical outcomes such as rejection, infection, and death. The project aims to create evidence-based practice (EBP) anesthesia guidelines for brain-dead organ donors based on current studies and research and discuss ways in which clinical outcomes in the organ recipients are evaluated and measured. Anesthesia providers play an essential role in the continuity and maintenance of care from the ICU to the organ procurement process in the operating room (OR) (Morse, 2017). The lack of EBP guidelines for anesthesia for brain-dead organ donors provides many challenges, including a lack of standardized anesthesia care and difficulty in measuring the impact of anesthetic management on adverse clinical outcomes of the recipients (Champigneulle et al., 2019). To understand the issue's significance on a deeper level, a discussion of the pathophysiology of brain death, brain death testing, and the pathophysiology of organ rejection is needed.

Background

Although there have been many advances, organ transplantation is continually evolving and transforming today. In 1906, the first solid organ was unsuccessfully transplanted, with the first successful transplant being a kidney in 1954 (Milan et al., 2019; Morse, 2017). Between 1906 and 1983, a lack of regulation of organ procurement surgeries prevented advances in organ

transplants. However, in 1984, the National Organ Transplant Act (NOTA) was created (Morse, 2017). NOTA brings standards and supervision to organ transplantation and ultimately led to the birth of the Organ Procurement and Transplantation Network (OPTN). OPTN is operated by the United Network of Organ Sharing (UNOS) (Morse, 2017). Today, UNOS oversees 57 OPOs across the United States, which are organizations that assess donor potential, retrieve clinical data, and follow nationally mandated policies (United Network for Organ Sharing [UNOS], n. d. a). In order for UNOS and OPOs to begin assessing a patient for donation, the patient must be declared brain dead by the organization.

Pathophysiology of Brain Death

When a patient is declared brain dead, the impact on all organ systems is detrimental, causing hemodynamic instability and collapse (Kumar, 2016). During brain herniation, Cushing's reflex occurs within the cardiovascular system, resulting in reflex hypertension and bradycardia from medullary ischemia (Kumar, 2016). Following Cushing's reflex, there is an increase in circulating catecholamines which causes vasoconstriction and tachycardia. The vasoconstriction and tachycardia strain the heart, increasing the heart's susceptibility to myocardial ischemia (Kumar, 2016). Eventually, catecholamine stores run out, the central nervous vasomotor activity becomes ineffective, and hypotension occurs (Morse, 2017). In addition to hemodynamic instability, cardiac dysrhythmias frequently occur in brain-dead patients due to ischemia, hypoxia, increased intracranial pressure (ICP), and electrolyte or acid-base imbalances (Morse, 2017).

In addition to the heart, the lungs and pancreas are at risk of being damaged when a patient is brain-dead. Endogenous catecholamines, such as endogenous epinephrine, combined with a rise in pulmonary hydrostatic pressure, cause lung damage and pulmonary edema (Kumar,

2016). Polyuria and diabetes insipidus occur in brain-dead patients due to the loss of posterior pituitary function. Although the anterior pituitary continues to function longer than the posterior pituitary, thyroid levels decrease (Kumar, 2016). In addition to decreased insulin production in brain-dead patients, the stress exerted on the body causes hyperglycemia. Hyperglycemia can damage the pancreas and impact renal allografts (Kumar, 2016). Understanding brain death's effects on organs and how damaged organs can affect graft survival must be valued.

Other ways the body is impacted by brain death are temperature regulation, coagulopathy, and systemic inflammation (Morse, 2017). When brain death occurs, the hypothalamus malfunctions, resulting in the loss of temperature autoregulation, also known as poikilothermic activity (Morse, 2017). Hypothermia can result in dysrhythmias, coagulopathies, acute kidney injury, and a leftward shift in the oxygen dissociation curve (Kumar, 2016; Morse, 2017). In addition to hypothermia causing coagulopathy, depletion of catecholamines and release of tissue thromboplastin from ischemic brain tissue also cause coagulopathies (Morse, 2017). Finally, systemic inflammation occurs from many factors, such as brain ischemia, metabolic changes, and the brain-dead patient’s cardiovascular function (Kumar, 2016). Interleukin-6, released during inflammatory states, may cause graft damage (Kumar, 2016). Understanding the pathophysiology behind brain death brings about a better understanding of the damage that occurs to a BDD without proper treatment and management.

Brain Death Testing

Several prerequisites must occur before brain death testing can start for a patient. The prerequisites include unresponsiveness that is incompatible with survival, excluding medical conditions or drugs that could cause the unresponsiveness, core temperature greater than 32 degrees Celsius, and neurological imaging to confirm the diagnosis (Kumar, 2016). In addition,

ruling out all reversible factors and ensuring an improvement in the patient's physical exam does not occur within 24 hours are two criteria necessary for declaring brain death (Morse, 2017). More specifically, the patient must have an absence of multiple reflexes, including pupillary light reflex, corneal reflex, facial and maxillary reflexes, oculo-cephalic reflex, oculo-vestibular reflex, pharyngeal reflex, and laryngeal reflex (Kumar, 2016). The testing is qualitative and a definitive way to assess and diagnose brain death.

Although testing creates a streamlined and systematic process for declaring brain death, many barriers prevent every BDD from donating their organs. Once brain death is declared, the OPO for that region is notified within one hour so allocation of the BDD organs can begin (Souter et al., 2018). However, the allocation process is strict, and many BDD organs are eliminated from donation due to health history, allograft function, and size (Morse, 2017). The stringent process consequently results in a supply and demand issue, illuminating the value of optimal management of BDDs and their organs. Understanding the pathophysiological changes that happen after brain death must be appreciated since they can affect long term outcomes.

Pathophysiology of Organ Rejection

Both acute and chronic organ rejection exist and have an impact on the outcomes of organ transplantation. During the organ rejection process, T cells, leukocytes, and macrophages contribute to the cellular immune response and ultimately contribute to organ rejection (Morse, 2017). In acute rejection, when organ transplantation occurs, the host's T cells recognize donor cell antigens (Cajanding, 2018). T cells are the beginning of the process of antigen recognition and allograft destruction (Morse, 2017). An immune response occurs against the donor allogeneic major histocompatibility complex (MHC) molecules (Cajanding, 2018). The MHC antigens on the donor cells are seen as foreign by the recipient, causing an immune response and

destruction of the recipient tissue (Cajanding, 2018). The process is also known as the direct allorecognition pathway. The indirect allorecognition pathway occurs with acute and chronic organ transplant rejection (Cajanding, 2018). The indirect allorecognition rejection pathway involves the intracellular processing of the donor MHC molecules by the recipient's antigen-presenting cells (APCs). Next, T cells recognize the alloantigens on the APC's surface and identify the alloantigens for destruction (Cajanding, 2018). Immunoglobulins and B lymphocytes are vital parts of the humoral response to allograft rejection. Macrophages present antigens that activate B cells (Morse, 2017). B cells are a type of lymphocyte that create and secrete antibodies and amplify the alloresponse, playing a role in organ rejection (Cajanding, 2018). Antibodies promote inflammation and cell lysis, and complement activation causes cell injury, vascular inflammation, platelet thrombi formation, and organ rejection (Cajanding, 2018).

Financial Impact

A simulation study was conducted to compare the overall survival, lifetime costs, and years of quality of life between groups of kidney transplant recipients; one group with a risk of graft failure and another group with zero chance of graft failure (Sussell et al., 2020). The medical costs of graft failure in kidney transplant recipients were calculated to be $78,079 per recipient and a loss of 1.66 years of good quality of life per recipient. The study also estimated the lifetime costs of kidney graft failure to be 1.38 billion dollars and a loss of 29,289 years of quality of life based on the number of kidney transplants in 2017 (Sussell et al., 2020). The study reiterates the significance and importance of administering optimal anesthesia care for BDD during organ procurement surgery.

Even if complications do not occur, patients still have a financial and physical burden after organ transplantation surgery. Without complications, recipients of organ transplants are

required to receive life-long medical care related to follow-up appointments and immunosuppressant therapy (James & Mannon, 2015). After transplantation, the average cost of medications per recipient per year is $10,000 to $14,000, depending on the number of medications prescribed and insurance coverage. Per month, transplant recipients pay approximately $2,500 for medications such as immunosuppressants and other prescriptions needed for their care (James & Mannon, 2015). Not only are the costs to patients high, but the cost of organ transplantation for healthcare facilities is also noteworthy.

In addition to individual patient costs, there are extensive costs to health care organizations to consider related to the organ procurement process. Organ acquisition costs include any service that aids in the retrieval of organs from living, brain-dead, or donation after cardiac death donors (The Alliance, n. d.). Specifically, for BDDs, the organ acquisition costs are approximately one billion dollars annually (Held et al., 2021). Costs such as transportation of organs, OPO fees, donor registration fees, surgeon procurement fees, preadmission evaluations, donor and recipient diagnostic evaluation fees, preservation costs, perfusion costs, and any other inpatient service in connection with donation fall under the organ acquisition cost (The Alliance, n. d.). The Medicare Cost Report calculates that an estimated 3.3 billion dollars were spent on organ acquisition costs in 2016. The Medicare Cost Report encompasses 3,400 acute care hospitals across the United States (The Alliance, n. d.). The financial impact of organ transplantation, with and without complications, on healthcare facilities and patients is astounding. With a thorough understanding of different aspects of brain death and organ rejection, a discussion of the topic's significance to anesthesia is essential.

Significance to Anesthesia

The care given to both donors and recipients by the anesthesia team during organ procurement and transplantation surgery may affect the patients long term outcomes. In the perioperative setting, the anesthesia goal is to provide safe, excellent, and effective care to all patients. A mechanism to improve long term outcomes is the use of EBP during the perioperative management of anesthesia. EBP is a valuable way to provide up-to-date, high-quality, and safe patient care. Melnyk & Fineout-Overholt (2019) stated, "An evidence-based approach to care allows healthcare providers to access the best evidence to answer these pressing clinical questions in a timely fashion and to translate that evidence into clinical practice to improve patient care and outcomes" (p. 13). Although EBP implementation comes with challenges, EBP is vital to high-quality, safe, and effective care in all healthcare settings, including anesthesia. Creating and implementing EBP guidelines to optimize BDD's organs in the operating room may improve the demand for viable organs for donation and decrease adverse outcomes for the recipients through safe, effective, and high-quality care.

Person, Intervention, Comparison, Outcomes, & Time Question (PICOT)

A PICOT question follows, which will help guide the project from identification of a clinical problem all the way through outcome evaluation. Among brain-dead organ donors receiving anesthesia care, would the development and implementation of EBP guidelines for anesthesia, compared to traditional practice, impact clinical outcomes such as an increased number of organs transplanted per donor, reduced organ rejection, and decreased rates of death, for the recipient over a one-year period?

Project Objectives

The objectives for the development and implementation of anesthesia guidelines for BDDs include

- developing EBP guidelines for anesthesia for organ harvesting,
- developing a comprehensive plan to implement the EBP guidelines,
- developing a comprehensive plan on how to monitor and measure the EBP guidelines, and
- developing a comprehensive plan on how to adjust the EBP guidelines if the outcomes are less than desirable.

Literature Review

A thorough literature search of databases, including One Search, Academic Search Complete, PubMed, and Cumulative Index to Nursing and Allied Health Literature (CINHAL), was conducted using search terms inspired by the person, intervention, comparison, outcomes, and time (PICOT) question. During the literature search, the author used the same search terms within each database. The literature search began with One Search in January of 2022 and is still in progress due to the fluidity of the review. One Search is a database provided by Otterbein University that encompasses several databases. Due to the large volume of articles found within One Search, the author used the same search terms within the other three databases to ensure the discovery of the most relevant articles.

Search terms for all databases used included “brain death,” “organ donors,” “brain dead donor,” “anesthesia for brain dead patients,” “anesthesia for organ donors,” “organ donor anesthesia,” “reducing acute organ rejection,” “preventing organ rejection,” “organ donor optimization,” and “brain dead donor and study.” Filters for the searches were 2010 to present,

2017 to present, peer-reviewed, controlled trials, and Boolean phrases in all text. In addition, the author used articles referenced from the studies found during the primary literature search.

Inclusion criteria included randomized controlled trials, retrospective reviews, case studies, multi-center studies, single-center studies, prospective studies, clinical trials, and expert opinion. Other inclusion criteria included adults, humans, brain-dead organ donors, donation after brain death (DBD), hemodynamic goals and care in the ICU for brain-dead patients, strategies to improve organ viability, and plans to reduce organ rejection. Exclusion criteria included studies prior to 2010, pediatric patients, and studies conducted on animals. The following is a discussion and evaluation of each study found during the literature search, with a summary table of the literature review found in Appendix A.

Provider Preference Patient Care & Structured Patient Care

Although the project focuses on creating guidelines and not protocols, the following articles show that structure in health care settings is beneficial. Evidence shows that protocol-based care increases the number of donor management goals met for donor optimization. A quasi-experimental study was performed to analyze if using a treatment management protocol compared to no treatment protocol decreases cardiac arrest and death in brain-dead organ donors (Westphal et al., 2012). The study was divided into two stages, stage one being a retrospective review of patient records and treatment of BDDs without a protocol in place. Stage two involved a prospective study using a treatment protocol (Westphal et al., 2012). The focus of the study was not on the protocol itself but on if the use of a protocol aimed at optimization compared to treatment based on provider preference decreases cardiac arrest in potential donors (Westphal et al., 2012). The study found that five out of the 18 potential donors died of cardiac arrest without the use of a standard protocol for treatment. In the group, with the help of a protocol for

treatment, zero out of the 24 donors had a cardiac arrest (Westphal et al., 2012). The protocol used in phase two had 19 hemodynamic, ventilatory, time-based, and medication-related goals (Westphal et al., 2012). During phase one of the study, without using a standard protocol, healthcare providers treating the potential donors did not meet most of the 19 set goals. With the use of a protocol, many more goals were completed for each donor, optimizing donors and their organs for transplantation (Westphal et al., 2012). Limitations of the study included the small study population, lack of reported comorbidities in the phase one donors, and no assessment of the survival of the recipients of the organs (Westphal et al., 2012). The study is a level III on the evidence scale and shows the positive impacts of using protocol-based care.

Goal-directed checklists may decrease the number of BDDs that suffer from cardiac arrest. Similarly, a quality improvement project was conducted across 27 hospitals over two years to evaluate if using a goal-directed checklist for managing BDDs decreases cardiac arrest and increases the number of organs recovered per donor (Westphal et al., 2016). After exclusion criteria, 469 donors were included in the study; 385 received care based on the checklist, and 84 did not receive care based on the checklist. In addition, educational training on the guidelines occurred in eight hospitals, accounting for 54.9 percent of the patients in the study (Westphal et al., 2016). Without the checklist, the risk of cardiac arrest was 53 percent (Westphal et al., 2016). With the implementation of the goal-directed checklist, the risk of cardiac arrest was 25.4 percent (Westphal et al., 2016). Of the nine goals on the checklist, the risk of cardiac arrest decreased with an increasing number of goals met on the checklist. Some limitations of the study include the lack of assessment of organs and the recipients after transplant, the use of secondary records for the donors who did not receive the use of the checklist, and only inferences can be made due to the type of study (Westphal et al., 2016). The use of checklists, standardized care,

and achieving as many goals on the checklist as possible improves outcomes for BDDs. The study is a level VI on the level of evidence scale.

In addition to using a standard protocol for the care of brain-dead organ donors, standardization of measuring outcomes of the recipients of transplants is also essential. A systematic review of 22 randomized controlled trials focused on the outcomes measured based on the interventions and care of organ donors (Bera et al., 2021). The study was conducted on several databases from 1980 to 2021. The study identified 17,877 articles which, after screening and meeting eligibility criteria, were narrowed down to the 22 included articles (Bera et al., 2021). The systematic review revealed the unlimited number of ways outcomes could be measured in organ transplant recipients. A few ways to measure results include measuring specific organ outcomes rather than treatment, measuring the interventions in the ICU, and measuring immediate outcomes and not long-term graft survival or function (Bera et al., 2021). The study found that outcome measures can be divided into two categories; measuring interventions or measuring specific organ function. However, the review revealed a significant gap in the standardization of measuring outcomes. The study's limitations are the differences in each randomized controlled trial and the sole focus on BDD interventions before organ procurement (Bera et al., 2021). Standardizing outcome measures and choosing specific outcomes to measure is essential to avoid confusion when evaluating data. The study is a systematic review of randomized controlled trials rated as a level I on the level of evidence scale.

Organ Systems

Respiratory System

A multi-center randomized-controlled trial was conducted on the use of lung protective strategies versus conventional strategies on lung viability, the number of lungs transplanted, and

the survival rate of recipients six months after the transplant. In the trial, the lung protective strategies were tidal volumes of six to eight mL/kg of ideal body weight, positive end-expiratory pressure (PEEP) of eight to ten cmH2O, closed circuit for airway suctioning, and apnea tests using continuous positive airway pressure (CPAP) (Mascia et al., 2010). The traditional lung strategies for potential organ donors include tidal volumes of ten to 12 mL/kg of ideal body weight, PEEP of three to five cmH2O, open circuit for suctioning, and disconnecting from the ventilator for apnea tests (Mascia et al., 2010). The strategies were applied during the observational time for brain death declaration until the patient arrived in the operating room for harvesting (Mascia et al., 2010). At the end of the observational period of six hours, 95 percent of the patient's lungs in the protective strategy group were eligible to donate, whereas 54 percent of the lungs in the conventional strategy group were eligible (Mascia et al., 2010). The number of lungs harvested in the lung protective strategy group was 54 percent compared to 27 percent of lungs harvested in the conventional strategy group. There was no statistically significant difference between the groups when analyzing the six-month survival rates of the recipients of the lungs (Mascia et al., 2010). In addition, cytokines, hemodynamic variables, blood gas analyses, and average ventilatory variables were measured between the groups at the first hour, third hour, and sixth hour (Mascia et al., 2010). A drawback of the trial is that each lung protective strategy was analyzed as one whole intervention.

Furthermore, each intervention was not examined individually, proving difficult to determine which lung protective strategies were more effective and beneficial than others (Mascia et al., 2010). Lung protective strategies prove to increase the likelihood that donor lungs will be eligible for donation. The study is a randomized controlled trial and a high level of evidence, rated at level II.

Renal System

Evidence shows that therapeutic hypothermia may decrease the risk of delayed graft functioning. Delayed graft function is an adverse complication of renal transplantation that occurs in as many as 50 percent of renal transplant recipients (Niemann et al., 2015). Delayed graft function occurs when a renal recipient needs dialysis within seven days of the transplant. A randomized controlled trial was conducted to assess the effects of therapeutic hypothermia (34 to 35 degrees Celsius) versus normothermia (36.5 to 37.5 degrees Celsius) on delayed graft functioning (Niemann et al., 2015). After ineligible donors were eliminated, a total of 394 BDDs were enrolled and randomly assigned to the hypothermia group or normothermia group (Niemann et al., 2015). The donors were from the California Transplant Donor Network and OneLegacy. After other exclusion criteria occurred, 180 BDDs were assigned to the hypothermia group and 190 BDDs to the normothermia group (Niemann et al., 2015). Within the hypothermia group, there were 280 renal transplant recipients and 286 recipients in the normothermia group. Therapeutic hypothermia and normothermia were controlled by forced air or spontaneously by the donor (Niemann et al., 2015). The results showed statistical significance that recipients of kidneys within the normothermia group had delayed graft functioning in 39 percent of the recipients compared to 28 percent of the recipients having delayed graft function in the hypothermia group (Niemann et al., 2015). The other two outcomes measured, rates of organs transplanted in each group and number of organs transplanted per donor, were similar in each group and did not show statistically significant data. Limitations included the bedside healthcare providers not being blinded to the assigned groups, those with delayed graft functioning were treated at a different facility than their transplant, and the long-term outcomes of recipients and the organs were not assessed (Niemann et al., 2015). Although there are limitations, the study is

a high level of evidence at level II. Therapeutic hypothermia does not show an increase in adverse outcomes during kidney transplantation compared to normothermia.

Medications

Volatile Anesthetics

A ten-year retrospective study of adult organ recipients throughout several Cleveland hospitals was conducted to assess if the hypothesis that volatile anesthetics (VA) improve the survival of graft transplants (Perez-Protto et al., 2018). The study used Lifebanc, the organ procurement organization (OPO) for northeast Ohio, along with UNOS and hospital records of donors to retrieve necessary data. The study concluded that using VAs during organ procurement surgery of brain-dead organ donors does not significantly affect the outcome of graft survival, short or long-term, in recipients of kidneys, hearts, livers, or lungs (Perez-Protto et al., 2018). The study had a diverse donor pool, and each surgery was under the same OPO, so healthcare providers gave each patient a uniform standard of care. However, some weaknesses of the study are that the study was a small sample size, the study was not randomized, and the use of VA was not controlled for each patient (Perez-Protto et al., 2018). The retrospective cohort review is a level IV on the level of evidence rating scale. The use of volatile anesthetics is not required but is not prohibited during organ procurement surgeries.

The final study on inhalational agents shows benefits with VAs on BDDs during organ procurement surgery, but the evidence is inconclusive. A systematic literature review was performed on the indications for administering inhalational agents in brain-dead organ donors (Elkins, 2010). The review encompassed several databases and included some articles that used animal subjects. While the literature review concluded that more research needs to be done on the subject, some studies show the benefits of inhalational agents during organ procurement for

brain-dead organ donors (Elkins, 2010). The first benefit is that inhalational agents and anesthetic preconditioning can decrease the adrenergic response and reduce ischemia-reperfusion injury (Elkins, 2010). Anesthetic preconditioning involves giving 1.3 minimum alveolar concentration (MAC) of a volatile anesthetic for 20 minutes before ischemic episodes (Elkins, 2010). The second benefit found in the literature review is that the release of inflammatory substances and tumor necrosis factor-alpha is reduced with inhalational agents (Elkins, 2010). Adrenergic stimulation, ischemia-reperfusion injury, and inflammatory factors can cause organ rejection. The literature concludes that inhalation agents may improve organ transplant success because inhalational agents prevent the events previously discussed from occurring. The drawback of the literature search is the limited number of articles used within the inhalational agent part of the review and the lack of statistical significance behind the conclusions drawn (Elkins, 2010). In addition to the limitations, the study is a level V rating on the level of evidence scale. Because the evidence is not statistically significant, using VAs during organ procurement surgery will not be a guideline requirement but will be left as an option for use based on provider preference.

Nitric Oxide

Nitric Oxide (NO) may increase oxygen saturation in BDDs during organ procurement surgery. A single patient case study completed in Korea shows that using NO can help improve hypoxia in brain-dead organ donors suffering from neurogenic pulmonary edema (NPE) (Eun et al., 2014). During the organ procurement surgery, the pulse oximetry of the BDD was 91 percent, despite using pulmonary recruitment maneuvers. NO gas inhalation was started with a concentration of less than five ppm, and the pulse oximetry rose to 99 percent after 20 minutes (Eun et al., 2014). While the study is informative, the study has limitations of being a single-

patient study, not controlled, and the use of NO is not a standard of care in the United States (Eun et al., 2014). Although an informative article, NO will not be used in the author's guidelines. The study is a low level of evidence, rated as level VI as a single-patient case study.

Corticosteroids

Many different medications have proven effective in optimizing organs for transplant. In brain-dead organ donors, thyroxine, steroids, and vasopressin have been shown to help optimize organs for donation (Pinsard et al., 2014). However, steroids alone and their effects on organ recovery and function have not been studied significantly. Therefore, a comparative prospective multi-center cluster study in France was completed to assess the benefits of steroid administration alone on transplanted organs from brain-dead organ donors (Pinsard et al., 2014). The study included 208 brain-dead patients from 22 ICUs across a 15-month timeline to compare the groups; those who received steroids and those who did not (Pinsard et al., 2014). Across all hospitals, the same standard of care was given to each patient, including criteria for brain death, hemodynamic monitoring, thresholds for vasopressor use, and the time at which hydrocortisone was administered; within six hours after diagnosis of brain death. Half of the hospitals administered the low-dose, 300-500 mg hydrocortisone, and the other 11 did not (Pinsard et al., 2014). Two conclusions were drawn from the study. The first was that the use of steroids alone did not have any benefit related to the function and recovery of the organs transplanted from BDDs but is still beneficial in the multi-modal approach to brain-dead organ donor optimization (Pinsard et al., 2014). The second conclusion showed that in the patients that received low-dose steroids, the average amount of vasopressors used was less, and weaning of vasopressor support was 4.67 times more likely than in the BDDs who did not receive low-dose steroids (Pinsard et al., 2014). The study's strengths are the use of multiple ICUs, the time frame in which the study

was conducted for thorough comparison, and the standardization of care across all patients. Weaknesses of the study include that the study was not randomized and the past medical history of the organ recipients was not included (Pinsard et al., 2014). The prospective multi-center cluster study is rated as a level II, and the use of low-dose steroids will be added to the author's guidelines.

Vasopressors

Terlipressin is a vasopressor that may assist in providing hemodynamic stability to brain-dead organ donors. A single-center retrospective analysis was completed on 18 brain-dead patients, and the effects of intravenous administration of terlipressin on hemodynamics, renal function, and hepatic function were assessed (Zheng et al., 2021). All patients in the study were diagnosed brain-dead, were monitored with the same protocol, and received the same standards of care. Patients in the study were hemodynamically unstable after fluid resuscitation and a high dose of norepinephrine (Zheng et al., 2021). Based on urine output, a low dose infusion at 0.02-0.06 mcg/kg/min of terlipressin was started on the patients in the study. Once the patient was stable, the norepinephrine infusion was weaned to keep the patient's mean arterial pressure (MAP) between 65 mmHg and 105 mmHg (Zheng et al., 2021). The patient's hemodynamics, renal function, and hepatic function were assessed before administering terlipressin, 24 hours after the beginning of the terlipressin infusion, 72 hours after the onset of infusion, and right before organ procurement (Zheng et al., 2021). The study showed that the MAP, systolic blood pressure, serum creatinine, urine output, estimated glomerular filtration rate, and creatinine clearance rate improved with terlipressin administration (Zheng et al., 2021). In addition, from baseline to immediately before organ procurement, the norepinephrine dose was able to be decreased from 0.6-1.0 mcg/kg/min to 0.07-0.11 mcg/kg/min, and the terlipressin dose was able

to be reduced from 0.04-0.06 mcg/kg/min to 0.01-0.03 mcg/kg/min (Zheng et al., 2021). However, some limitations of the study include the small study size, a single center study, most of the patients were young, and the study did not have information about the recipients of the transplanted organs (Zheng et al., 2021). Terlipressin has recently been approved by the Food and Drug Administration (FDA) for use in hepatorenal syndrome. Terlipressin will be added to the guidelines and may be used pending full FDA approval. The retrospective single-center study is a medium level of evidence at level IV.

Fluid Administration

A standardized approach for fluid resuscitation in brain-dead patients is an ongoing debate due to the variety of patient circumstances. For example, if a BDD receives too much fluid, their lungs may not be viable for transplantation due to edema and reduced oxygenation (Marklin et al., 2020). On the other hand, if a BDD is hypotensive and not given enough fluids, vasopressors might be used, which can cause ischemia to organs. Organ ischemia decreases the viability of organs to be transplanted (Marklin et al., 2020). A single-center prospective study used a stroke volume-based fluid resuscitation approach on 64 of 94 patients in the study to examine the amount of fluid administered, average time spent on vasopressors, and the number of organs transplanted from each brain-dead organ donor (Marklin et al., 2020). A 500 mL fluid bolus of 0.9 percent normal saline or lactated ringers was administered to each patient following a baseline stroke volume. The stroke volume was measured with an esophageal doppler or the FloTrac system (Marklin et al., 2020). After the first fluid bolus, if the stroke volume was responsive and increased by ten percent within 30 minutes, the BDD received another bolus (Marklin et al., 2020). If the stroke volume did not increase by ten percent within 30 minutes, the patient was not fluid-responsive, and another bolus was not given. However, in non-fluid

responsive patients, if the stroke volume decreased by ten percent in the next 30 minutes, a 500 mL fluid bolus was administered (Marklin et al., 2020). The process occurred every 30 minutes for four consecutive hours, with a maximum administration of 4,000 mL. The vasopressors were titrated down every ten minutes for a MAP goal greater than 65 mmHg. The vasopressors, if on multiple, were weaned in the same order and by the same dose increments (Marklin et al., 2020).

After four hours, several outcomes were measured. In the fluid resuscitation group, 1,031.2 to 2,843.8 mL of fluid was given compared to 404.5 to 2,242.9 mL in the control group (Marklin et al., 2020). BDDs in the non-control group were on the vasopressor norepinephrine for 94.1 minutes to 258.5 minutes compared to 371.4 to 1,543.8 minutes in the control group. In addition, 39.1 percent of patients in the non-control group were weaned off vasopressors after four hours, compared to only 6.7 percent of patients in the control group (Marklin et al., 2020). Finally, the protocol group had an average of 3.39 organs transplanted per brain-dead organ donor compared to the average of 2.93 organs transplanted per organ donor in the control group (Marklin et al., 2020). The study has limitations, including the size of the study, the high variability between how many vasopressors each patient was on before the study began, the analysis of organ function after being transplanted into the recipients was not measured, and the continued conflicting evidence surrounding the subject (Marklin et al., 2020). The prospective study discussed is a level III on the level of evidence scale. The use of stroke volume-based fluid resuscitation will be added to the guidelines but requires the use of FloTrac or esophageal doppler.

In broader terms, protocol-based fluid resuscitation may increase the number of organs donated per donor and the one-year survival rates of recipients. A multi-center randomized controlled trial was conducted to evaluate if a fluid management protocol improved organ

recovery in BDDs compared to traditional fluid management therapy (Al-Khafaji et al., 2015). The protocol involved administering 250 to 500 mL fluid boluses depending on the brain-dead organ donor's pulse pressure variation, cardiac index, and MAP. Within the protocol-based group, an average of 1,229.1 mL of fluids were infused, compared to an average of 986.18 mL of fluids infused in the conventional fluid management group (Al-Khafaji et al., 2015). The study showed no statistically significant difference between the two groups related to the number of organs donated per donor and one-year survival rates (Al-Khafaji et al., 2015). An average of 3.39 organs were recovered per donor in the protocol-based group and 3.29 organs per donor in the conventional management group.

Similarly, in the first year post-transplant, 7.8 percent of recipients of organs from the protocol-based group did not survive, and 7.9 percent of recipients of organs from the conventional group did not survive (Al-Khafaji et al., 2015). Drawbacks to the study include the lack of specification of the type of fluids administered and the hemodynamic monitoring system used. LiDCO is a non-invasive monitoring system implemented on BDDs in the protocol-based fluid management group (Al-Khafaji et al., 2015). During the trial, many facilities struggled with using the LiDCO due to its complex nature and frequent malfunctioning. Because of these complications, the use of the LiDCO rendered 24 percent of the protocol-based group unable to receive the intervention (Al-Khafaji et al., 2015). Although the study has limitations, the multi-center randomized controlled trial is a level II study, and protocol-based fluid resuscitation will be incorporated into the guidelines.

Hemodynamics

A multivariate analysis was conducted on two groups of organ donors, and the number of organs transplanted per donor was analyzed. The study occurred in UNOS region 11, involving

two groups of organ donors and two phases: phase one and phase two (Franklin et al., 2010). Phase one of the study involved using eight different donor management goals that are commonly used in practice today for organ donors (Franklin et al., 2010). After results were obtained from phase one, some of the donor management goals were modified and used as the donor management goals for phase two. The donors included in the trial were BDDs and donors after cardiac death, with brain-dead organ donors making up most of the patients (Franklin et al., 2010). The eight parameters used within both phases included MAP, average central venous pressure (CVP), pH, final partial pressure of oxygen in arterial blood (PaO2), final sodium level, final glucose level, vasopressor use, and urine output (Franklin et al., 2010). During analysis, phase one had 2.96 organs transplanted per donor, and phase two had 3.34 transplanted per donor. In addition, within the modified phase two donor management goals, there were several donor management goals with statistical significance ($P \leq 0.05$) that increased the number of organs transplanted (Franklin et al., 2010).

The donor management goals with statistical significance included final CVP, PaO2, final sodium, low vasopressor use, and glucose control (Franklin et al., 2010). Keeping CVP between four and 12 mmHg, PaO2 greater than 80 mmHg on less than or equal to 40 percent fraction of inspired oxygen (FiO2), final sodium level less than 160 mEq/L, final glucose level less than 200 mg/dL, and low vasopressor use were the donor management goals that improved the number of organs transplanted. The study defines low vasopressor use as using one or no vasopressors, with dopamine at less than ten mcg/kg/min, phenylephrine less than 60 mcg/min, or norepinephrine less than ten mcg/min (Franklin et al., 2010). The other three donor management goals, MAP, pH, and urine output, although they showed no statistical significance in the study, the use of a MAP of 60 to 100 mmHg, a pH of 7.3 to 7.45, and urine output of 0.5 to

7 mL/kg/hr over four hours showed improvement in the probability of the number of transplanted organs (Franklin et al., 2010). Some limitations of the study included variation in the medical history and demographics of the patients in each phase, the protocol which each hospital used to achieve the donor management goals, and not assessing organ and recipient survival or function after transplant (Franklin et al., 2010). Using optimal hemodynamic and laboratory value parameters may increase the number of organs transplanted per donor and will be used within the author's guidelines. The multivariate analysis discussed is a level III study.

A systematic review was conducted with a search of Medline and Embase to investigate the best blood pressure goals for optimal organ function and survival in organ transplant recipients and the number of organs transplanted per patient. A total of 107 articles were found eligible for the study, but after exclusion criteria, twelve cohort studies were included for investigation during the literature review (Basmaji et al., 2020). Three studies found no statistical significance between hypotension and graft survival or function, while seven found that hypotension may cause graft dysfunction (Basmaji et al., 2020). The literature review concluded that no clinically significant blood pressure goal was found to improve graft function and survival and improve transplanted organs per donor. In addition, six of the 12 studies in the systematic review showed bias (Basmaji et al., 2020). Although the review did not support the literature review thus far, including the studies assists in showing the variability in the outcomes of patients.

A narrative literature review was conducted on anesthetic considerations during organ procurement surgery of BDDs and donors after cardiac death. For the project, the focus will be on the BDD organ procurement portion of the review (Anderson et al., 2015). The review used articles and studies from PubMed, Pubget, and Embase (Anderson et al., 2015). The literature

review concluded that anesthesia providers must know how each organ is affected by brain death and what organs are being procured during each surgery so anesthesia can be tailored to optimize the function of the organs being donated (Anderson et al., 2015). The review divided the anesthetic considerations by each organ system based on the evidence and data.

For cardiac optimization, the recommended management during anesthesia includes restoring intravascular volume and using vasopressors to maintain organ perfusion (Anderson et al., 2015). Adequate organ perfusion requires maintaining systolic blood pressure greater than 100 mmHg, MAP greater than 70 mmHg, and a heart rate between 60 and 120 beats per minute (Anderson et al., 2015). Pulmonary recommendations include a tidal volume of six to eight mL/kg of ideal body weight and positive end-expiratory pressure of eight to ten cmH2O, also known as a lung protective strategy. The second respiratory recommendation is to keep the CVP between four and eight mmHg by intravenous fluid administration (Anderson et al., 2015). The literature review found that for the endocrine system, vasopressin should be administered to manage polyuria from diabetes insipidus and support hemodynamics, insulin should be given to keep serum glucose less than 180 mg/dL, and administration of hormone replacement with thyroxine, T3 infusion, or corticosteroids should occur (Anderson et al., 2015). Hematological recommendations included transfusing if the hemoglobin is less than seven or eight g/dL, administering platelets for bleeding, and administering clotting factors for coagulopathies (Anderson et al., 2015). Finally, for the musculoskeletal system, the review recommended using skeletal muscle relaxants to prevent spinal reflex movements (Anderson et al., 2015). The literature review suggests many donor management goals that will be considered while developing the author's guidelines. The study is a narrative review and a low level of evidence at level V.

Relevant Incomplete Trials

Two trials were discovered during the literature review that are not yet completed but are essential to discuss due to the strength and relevance of the studies. First, a multi-center randomized placebo-controlled trial is being conducted to assess the effects of intravenous thyroxine on heart transplants (Dhar et al., 2021). Additional measured outcomes include the time to wean the donor off vasopressors and improve ejection fraction on echocardiography. The study involves 800 BDDs across the United States that are eligible to donate their hearts. The thyroxine infusion will be administered for 12 hours versus a saline placebo infusion with random assignment to each group (Dhar et al., 2021). Although the study is rated as a level II on the level of evidence scale and has the potential to be included in the future, the study is not yet completed and unable to be utilized. The second ongoing trial is a pragmatic, registry-based, multi-center, double-blind, randomized controlled trial assessing the use of Plasma-Lyte 148 compared to 0.9 percent normal saline on delayed graft function in kidney transplants from BDDs (Collins et al., 2020). The study will use 800 BDDs, 400 receiving Plasma-Lyte 148 infusions and 400 receiving 0.9 percent saline infusions. The recipients of the kidneys from the BDDs will have follow-up evaluations one week and one-year post-transplant (Collins et al., 2020). Outcome measures will include delayed graft function, which is the requirement of dialysis within seven days of the transplant, hyperkalemia, mortality, graft function and survival, cost-effectiveness, and quality of life (Collins et al., 2020). As previously discussed, the debate on fluid management in BDDs is ongoing, and the trial will bring more clarity to the controversy.

Overall, the literature review revealed many ways in which BDDs can be managed to optimize organ recovery. The current project outcomes are supported by the literature, with some gaps in the literature and inconclusive findings. With the results from the literature search,

guidelines for anesthesia for BDDs can be created. Any gaps in the literature and the level of evidence of each study will be considered during the creation, implementation, and evaluation of the guidelines. In addition, the author will use the anesthesia recommendations created by the Lifeline of Ohio Organ Procurement Agency (LOOP) to supplement any gaps or missing information found during the literature review.

Model Identification

To successfully implement EBP, a systematic and organized approach is necessary. A plan and a step-by-step approach to implementing the project plan will be beneficial when challenges arise. Due to the many individual and organizational challenges, models and frameworks help assist and guide healthcare providers to implement EBP successfully (Melnyk & Fineout-Overholt, 2019). Based on the project's goals, the author can choose a theoretical framework, a conceptual framework, an EBP model, or a combination of these to implement a project.

Understanding theoretical frameworks or EBP model will assist in choosing the appropriate model for the project. Theoretical frameworks use theory to help outline the implementation stage of a project (Moran et al., 2020). According to Moran et al. (2020), "theory helps to explain or predict the relationships around the phenomenon of interest" (p. 138). A conceptual framework helps project implementation by identifying the main ideas (Moran et al., 2020). EBP models use research evidence, availability of healthcare resources, patient preferences and actions, clinical circumstances, and clinical expertise to drive implementation (Melnyk & Fineout-Overholt, 2019). The author will use an EBP model to assist with planning the implementation of the project.

Within the final scholarly project, the author utilizes the Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) Model to guide the development and plan for implementing EBP anesthesia guidelines for BDDs. Melnyk & Fineout-Overholt (2019) state, "the JHNEBP Model guides bedside nurses in translating best evidence into practice for clinical, learning, and operational practice" (p. 412). Any area of nursing, including undergraduate students, graduate students, and nurses, can use the JHNEBP Model (Melnyk & Fineout-Overholt, 2019). The JHNEBP Model is a step-by-step model that will bring structure, organization, and clarity to project implementation.

There are multiple steps involved in the JHNEBP Model (Appendix B). The first step of the JHNEBP Model is to inquire about a problem within the healthcare system (Melnyk & Fineout-Overholt, 2019). The inquiry of the author's project is the lack of guidelines for anesthesia for BDDs during organ procurement surgery. A three-step process follows inquiry, including creating a *practice* question, seeking *evidence*, and *translating* the evidence into practice (PET). The practice question is the PICOT question of the project, which is: among BDDs receiving anesthesia care, would the development and implementation of EBP guidelines for anesthesia, compared to traditional practice, impact clinical outcomes such as an increased number of organs transplanted per donor, reduced organ rejection, decreased rates of death, for the recipient over a one-year period? The evidence portion of the PET process involves a literature review, which synthesizes literature based on the quality and strength of studies (Melnyk & Fineout-Overholt, 2019). The literature review within the project shows varying evidence, both supportive and inconclusive, of the problem and PICOT question. Translation, the third step of the PET process, begins with a plan to implement the guidelines for anesthesia for

BDDs (Melnyk & Fineout-Overholt, 2019). The PET process is surrounded by reflection arrows, signifying the need for continual reflection throughout the PET steps.

After the PET process is complete and project implementation is in process, evaluation and modification of the guidelines, if necessary, occur. Within the JHNEBP model, the final two steps after inquiry and PET are best practices and practice improvements (Melnyk & Fineout-Overholt, 2019). Outcomes, revision, and reassessment will be discussed later in the final scholarly project. Although displayed in a systematic step-by-step framework, the JHNEBP Model is fluid, and modifications can occur at any stage (Melnyk & Fineout-Overholt, 2019). The author is permitted to use the JHNEBP Model (Appendix C).

Guideline Development

After a thorough literature review, collection of data from the literature review, and supplemental use of the LOOP Guidelines, the development of EBP guidelines for anesthesia for BDDs can be created. The guidelines created include intravenous access, hemodynamic goals, laboratory value goals, miscellaneous goals, medications required during organ procurement, medications useful in maintaining suggested goals, and other medications to have on hand. The use of the guidelines must also take into consideration the transplant surgeon, critical care physicians, and the anesthesia provider's clinical judgement.

The guidelines, as outlined in Appendix D, discuss the sequence of events that occur during an organ procurement surgery and outline the goals for organ optimization. Explaining the order of events during an organ procurement surgery in the guidelines will assist the anesthesia provider in knowing when to give certain medications that are within the guidelines and when to anticipate events and changes. Several goals are outlined in the guidelines, with a range of numbers for some parameters. The guidelines display as much EBP information as

possible based on the information available, and the gaps in methods for treating specific parameters are up to the anesthesia provider or surgeon's preference.

If possible, LOOP guidelines suggest one central line or two large-bore peripheral IVs above the waist (Lifeline of Ohio, 2014). The hemodynamic goals found to improve outcomes within the literature review include MAP, systolic blood pressure, heart rate, CVP, temperature, and oxygen saturation. Optimal laboratory values include serum sodium, serum glucose, PaO2, and serum pH. Other goals include urine output, tidal volume, PEEP, and hemoglobin transfusion threshold.

Several medications were found during the literature review to be beneficial in donor optimization, including paralytic of choice, Hydrocortisone, Mannitol, Betadine, Prostaglandin, and Heparin. To keep the hemodynamic parameters within their ranges, vasopressors such as Dopamine, Phenylephrine, Norepinephrine, and Terlipressin can be used. Fluid resuscitation is another alternative to attempt to maintain hemodynamic goals, as explained in Appendix D. Other drugs to have on hand include Vasopressin, Thyroxine or T3 infusion, and blood on hold. Specific doses and hemodynamic parameter goals can be found in Appendix D and will be displayed in the guidelines.

Guideline Implementation

Method & Design

The project utilizes an EBP implementation model. Implementation science is used to close the “know-do” gap, which is what one knows about the problem and what one does about the problem. Closing the “know-do” gap helps address barriers and facilitate the use of EBP by healthcare providers (University of Washington, n. d.). The purpose of implementation science is to implement a plan with speed, efficiency, strategy, quality, and great reach (University of

Washington, n. d.). In combination with the JHNEBP Model, implementation science will help guide, plan, and discuss the project's design. Within the JHNEBP Model, the inquiry, practice question, and evidence stages have all already been completed. The next step in the model is the translation stage, which involves translating the evidence found in the literature review into practice (Melnyk & Fineout-Overholt, 2019). The plan for translation includes ethical considerations, setting, target population, implementation plan, and project team.

Ethical Considerations

Ethical considerations of the project are within the families of the brain-dead organ donors and healthcare providers. Implementation of standardized brain death testing is not only required before the declaration but reassures families that care for their loved one is best practice and high-level quality care (Schweikart, 2020). Another ethical consideration is within the Hippocratic Oath for healthcare providers to do no harm. The brain-dead diagnosis relieves healthcare providers from breaking their oath (Schweikart, 2020). Human subject privacy and protection will be provided by eliminating identifying information of the BDD and recipients when collecting and analyzing data. Due to the hypothetical implementation of the project, approval from both Otterbein University and Ohio Health IRB are not necessary.

Setting & Target Population

The proposed setting is an urban level-one trauma center. On-call anesthesia staff will be necessary because organ procurement surgeries are often delayed until later in the night due to operating room availability and staff needs. In addition, level-one trauma centers in urban areas receive higher acuity patients, such as those suffering from brain death due to strokes, motor vehicle accidents, and overdoses. The target population for the project is BDDs, with additional monitoring of the patients who are the recipients of the organs for outcome measurement. BDDs

and recipients of all genders, ages, marital statuses, racial or ethnic groups, socioeconomic classes, and levels of education will be included in the project. The guidelines will not be used on organ donors after cardiac death or living donors. The target population for education will be the anesthesia staff, pharmacy, and OR nurses.

Implementation Plan

The project leader designed a proposed plan for implementation. To implement the project, the project team should complete the following steps. First, the project leader must create a project team and collaborate with members of the project team, as implementation cannot be done alone. High-level leadership and communication are necessary to guide the project team to successful implementation (Moran et al., 2020). Many factors must be tackled to accomplish the project goals. The project leader must demonstrate the purpose of the project and how the project will benefit the team members and stakeholders. Keeping lines of communication open with full transparency will create a trusting relationship between team members and the team leader (Moran et al., 2020). Building a trusting relationship can be done by holding multiple meetings to explain every aspect of the project, including anticipated barriers, and build rapport with the project team.

Before staff education sessions, project team meetings will occur once a week for one month. During team meetings, the project leader should explain why they chose each team member and how their unique skill set will help successfully implement the project (Moran et al., 2020). During the team meetings, explaining each person's roles and responsibilities in the project is vital. Lastly, although the project leader holds most of the responsibility, the project leader must be open to suggestions and ideas from the project team. Project decision-making involves the entire team, not just the project leader (Moran et al., 2020). Using team-based

decision-making will bring fresh ideas to the forefront that the team leader may not have thought of before.

After collaborating with the project team and implementing the guidelines, educating all staff involved on the new guidelines is necessary. Healthcare providers that require education include physicians, surgeons, ICU nurses, OR nurses, LOOP coordinators, and all anesthesia staff (certified registered nurse anesthetists (CRNAs), anesthesiologist assistants, and anesthesiologists). Over a one-month period, the project leader will give brief educational sessions in the involved staff's common areas, such as the breakrooms and central unit desks. To ensure every staff member is aware of the project and guidelines, each staff member will be listed on a sheet and must sign their name after participating in the educational session. In addition to the educational sessions, flyers will be placed in the locker rooms and break rooms and emails will be sent with a brief description of the project and when and where staff members can receive education and sign their names. If all staff members have not received the education after one month, additional time will be allotted for education along with question-and-answer sessions if needed.

While the educational sessions are occurring, technological additions will be made to ensure the guidelines are available and utilized. The guidelines will be made available on the electronic medical record system's desktop, printed out and displayed on the medication carts of each OR, and emailed to all involved employees. In addition, to ensure accessibility to the guidelines during surgery, once the organ procurement surgery has been scheduled, a notification will be added to the chart. Similar to an allergy or a difficult airway notification, the organ procurement notification will pop up on the patient's electronic chart.

When the anesthesia staff opens the chart, the guidelines (Appendix D) appear on the screen once the organ procurement notification link is clicked. In addition to the guidelines being one click away, once the organ procurement button is clicked, the hemodynamic parameters listed in the guidelines will automatically populate in the chart. A reminder will flash on the screen if the hemodynamic goals are not met. The reminder will ensure that the anesthesia provider is notified and corrects the patient's hemodynamics according to the guidelines. Once every staff member is aware of the project, when the project will start, their role in the project and the guidelines are easily accessible, implementation can begin.

Before organ procurement surgery, the anesthesia provider will collaborate with the OR nurse to ensure all medications used in the guidelines are within reach of the anesthesia provider. The anesthesia provider will open the chart, see the organ procurement notification, and click on the link to open the guidelines and activate the hemodynamic parameters in the chart, as explained during their educational sessions. After each organ procurement surgery with the BDD, the electronic record will be stored and reviewed during the data collection phase. The organ recipients must also have their charts stored for future data collection. The main project team will meet every other week throughout the guideline implementation phase to review workflow, address any barriers, and assess outcomes. During the follow-up meetings, discussing the strengths and weaknesses of the project thus far and putting a hold on the guidelines if outcomes are less than desirable is necessary.

Project Team & Stakeholders

While many staff members must be involved in the project, the project team will encompass managers and leaders of each department of involved staff members. As explained earlier, the project team will attend meetings held by the project leader and show support for the

project to their department staff. The project team includes department heads of OR nurses, pharmacists, anesthesia staff, transplant surgeons, and the OPO.

The project leader will ultimately be responsible for ensuring each member of the team completes their assigned tasks. The OPO staff is responsible for coordinating care with the ICU staff and finding recipients for the viable organs of the BDD. Information technology (IT) is responsible for adding the organ procurement notification with hemodynamic monitoring integration to the chart once the organ procurement surgery is scheduled. IT will be notified about organ procurement surgery by the OPO.

The anesthesia staff is responsible for gathering necessary medications for the BDDs and providing anesthesia based on the guidelines during organ procurement surgery. The anesthesia staff must communicate with the OR nurses and pharmacy to ensure all the medications listed in the guidelines are readily available. In addition to the other responsibilities of the team leader, the team leader will create and display the flyers, print, and add the guidelines to each anesthesia medication cart, and schedule, run, and receive signatures for the educational sessions.

In addition to the project team, stakeholders must be identified. Stakeholders are those who may be affected by the project's outcomes, positively or negatively, and have an interest in the project (Moran et al., 2020). Bringing new ideas and change to healthcare is challenging. Still, with the identification and support of stakeholders, some of these challenges can be mitigated, easing some of the vital processes of the project, such as introduction and implementation. In the project, some of the stakeholders include healthcare staff involved in the project, the OPO, and the hospital financial department. Based on current EBP, the implementation of the created guidelines has the potential to save lives, reduce costs, and streamline anesthesia care.

Outcome Monitoring & Analysis

Data Collection

After implementing the guidelines based on the projected timeline, the quality improvement (QI) department can begin collecting data. According to Moran (2020), "The data collection phase of the Doctor of Nursing (DNP) project is action-oriented and involves collaborators to assist with participant recruitment, instrument development, and data collection" (p. 175). The methods for data collection for the project include chart auditing, chart extraction, and checklists. The checklist will be used to guide the data collector(s) through their chart data extraction. The information to collect from the BDD's charts for data analysis includes the following:

- time of brain death declaration
- organs viable for donation according to the OPO
- medical interventions for hemodynamic stability pre-operatively (drips, fluids, etc.)
- pre-operative vital signs, labs, and urine output since brain death declaration
- intra-operative interventions for hemodynamic stability
- the number of guideline goals met during surgery (if applicable)
- what goals were not met during surgery (if applicable)
- any additional interventions that deviated from the guidelines (if applicable)

The information gathered from patient charts will be helpful during data analysis to evaluate the effectiveness of the guidelines on hemodynamic stability and organ optimization.

The second area of data collection involves chart auditing, data extraction, and a checklist for the recipients of the BDD's organ(s). The information to extract from the recipient's charts for data analysis includes the following:

- organ(s) transplanted
- patient history
- preoperatively medical interventions for hemodynamic stability (dialysis, ECMO, medications, etc.)
- pre-operative vital signs, labs, and urine output
- any complications intra-operatively
- 24-hour, 48-hour, seven-day, six-month, and one-year post-transplant graft function (labs, rejection, infection, immunosuppressant medications, other treatments)

The data from the lists above should also be collected on previous organ procurement surgeries before guideline implementation to gather baseline data. Baseline data will be helpful during analysis and evaluation to assess if the guidelines are causing worse outcomes than the outcomes of baseline data.

Tools for Analysis

After data collection, data analysis can occur. The QI department will assist in analyzing the data collected, which will help determine what worked within the project, what did not, what needs to change, and if the guidelines need to be withdrawn (Moran et al., 2020). Data analysis will occur in the form of descriptive statistics using the QI department's data analysis tools or software. Descriptive statistics organize data and help describe different components of the data (Salkind & Frey, 2020). Every item on the checklists above will need a mean computed to determine if the outcomes are trending in the right direction and are meeting optimal goals. The data, outcomes, and patient demographics can be assessed from the information to assist in project evaluation.

Evaluation & Guideline Adjustment

After data analysis, an evaluation of the project can occur. The JHNEBP Model's final two steps are best practices and practice improvements, which occur during the evaluation and modification stages of the project (Melnyk & Fineout-Overholt, 2019). The team leader, project team, and QI department will come together to evaluate each objective and the overall success of the guidelines and their implementation. Guideline evaluation determines if and what adjustments need to be made to the guidelines, the implementation plan, or both. The two main groups of patients, the BDDs and the transplant recipients, will be reviewed to determine what parts of the guidelines met the objectives of the project, what parts of the guidelines did not, and if the outcomes are trending in the right direction.

The outcome goals of the project are an increased number of organs transplanted per donor, reduced rate of organ rejection, and decreased rates of death up to one-year post-transplant. Considering the national goals for organ transplantation, UNOS has a few overarching goals based on trends rather than static metrics. For example, the relevant goals UNOS has in their OPTN for the project are to increase the number of transplants and improve transplant recipient outcomes (United Network for Organ Sharing [UNOS], n. d. b). Although there are not specific numerical national standards and goals for transplant outcomes, it is important to assess and ensure that positive outcomes are increasing, and negative outcomes are decreasing. The JHNEBP Model involves continuous monitoring of outcomes. Not only can the key outcomes be evaluated, but specific parts of the guidelines can also be assessed to determine if some of the guideline goals work better than others. The team can also evaluate whether the number of goals met on the guidelines during organ procurement improves outcomes (i.e., the more goals completed, the better the outcomes were for the recipient). Lastly, the project team

will evaluate how often the guidelines are being followed when applicable, assess cases when the guidelines are not being used, and, if applicable, determine why guideline compliance is insufficient.

If, based on the evaluation, the project outcomes are less than desirable, adjustments must be made. Some ways to adjust the guidelines include medication dosages, lab value ranges, changes in lung protective strategies, the integration technique of the guidelines in the electronic medical record, altering the implementation plan, and adding or removing members from the team. More specifically, the limit for the dose of the vasopressors can be increased, the lab value ranges can be narrower, the transfusion threshold can be increased or can be based on hemodynamic stability and hemoglobin trend, and tidal volume and positive end expiratory pressure ranges can be altered. If there are technological issues, IT can be utilized to assist in streamlining the integration of the guidelines into the charting system. One struggle with implementation may be the number of people on the project team. If team members express that they are stretched too thin, the project leader can reassess and add team members as necessary. In addition, if outcomes are found to be less than desirable at any point during implementation of the project, the implementation of the guidelines into practice should be held until further evaluation is completed.

Dissemination

After project implementation and outcome measurement, the project findings can be disseminated. Dissemination involves telling a story, sharing the information, and giving meaning to the project's results with the stakeholders (Moran et al., 2019). The project can be presented as a PowerPoint presentation for each department involved in the project (anesthesia, nursing, IT, QI, etc.). The meetings will be scheduled based on the availability of each

department, with invitations to the meetings sent via email to all employees for attendance and participation. Discussing the project's successes and limitations is essential for future development. In addition, other similar EBP implementation projects can be examined for comparison, inspiration, and ways for improvement. After the presentation, time for questions, comments, and concerns will occur so the team members and team leader can receive feedback and listen to new ideas from employees for project or guidelines modification. Overall, dissemination should show how, if implemented, the project plan and guidelines can contribute to the future of evidence-based advanced practice nursing.

Limitations & Barriers

Several barriers and limitations can occur during guideline implementation that affects the project's outcomes. Limited funding is a barrier that can strain the resources available for guideline implementation. Without adequate funding, the project may have to sacrifice team members, technological implementation, or staff education, which are all factors that may decrease the success of implementation. A barrier may exist with the compliance and efficiency of the IT staff. Because IT is responsible for adding the notification set to the chart once OPO informs IT, due to turnover, limited staff, or urgency of the task, it may be difficult to add the notification into the charting system before the surgery. Although not ideal, if this happens, the guidelines are posted in every OR and are found on the desktops of each OR computer. Another barrier involves the healthcare providers responsible for using the guidelines. There are many reasons why the guidelines would not be implemented when they should have been; resistance to change, lack of time to gather supplies, and lack of proper education on how to use the guidelines. If the guidelines are not being used properly or being used at all, there will be a lack of data for proper data collection, analysis, and evaluation. Lastly, the project requires many

follow-up visits for organ recipients. If the organ recipients do not attend their follow-up visits, the lack of data collected from no-show visits can alter outcome measures and create limitations. All the barriers and limitations discussed could prevent the guidelines from improving outcomes for organ recipients.

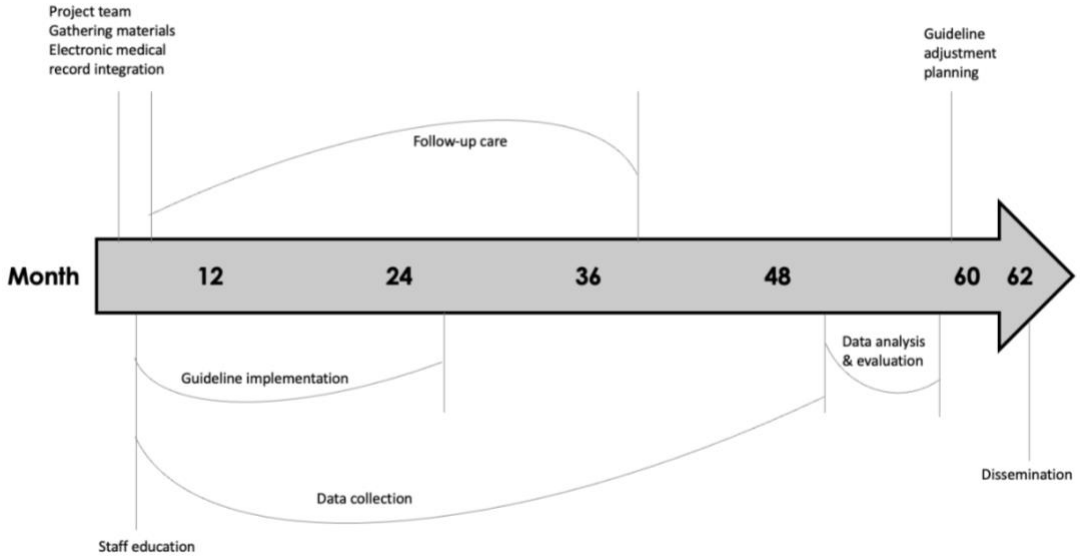
Timeline

The total estimated project implementation time is five years and two months and is displayed in Figure 1. The first two months involve gathering and creating a strong project team, printing materials, and integrating guidelines into the electronic medical record system. Months three and four are dedicated to educating all staff involved in implementing the guidelines and their roles and responsibilities in the project. The following two years consist of using the guidelines in organ procurement surgeries.

Follow-up care of the transplant recipients will start the first day after the first transplant recipient surgery through one year after the last patient receives an organ transplant. Follow-up care will end at approximately month 40. Data collection will continuously occur throughout implementation, with an extended window of one year after the last follow-up visit of the transplant recipients, bringing the timeline to month 52. Data analysis and evaluation will occur over six months in months 52 through 58. Month 59 is for the planning of guideline adjustments, if necessary. Finally, months 60, 61, and 62 are for the dissemination and presentation of the findings.

Figure 1

Image Depicting the Timeline of the Project



Budget

The estimated budget for implementing the project includes supplies and labor costs for the IT department, CRNA salary, and QI department salary. The supplies needed for the project include paper and ink for the flyers and display of guidelines in each OR. Printing the guidelines and flyers includes the cost of paper and ink. One ream, 500 pages, of inkjet paper costs approximately $24.99 (Office Depot, n.d. b). One ink cartridge costs approximately $89.00 (Office Depot, n.d. a). Labor costs for the project include department heads of IT, CRNAs, and QI for project guidance, preparation, implementation, and evaluation. Assistance from the IT department is necessary to integrate the guidelines into the electronic medical record system. The average salary of an IT technician in Ohio is $62,210 (Indeed, n.d.). IT assistance will be needed for two months, so the cost for IT will be estimated at $10,368.33. Third, the project leader, a CRNA, will be in charge of education sessions. The average salary of a CRNA in Ohio is $90.10 per hour (Incredible Health, n.d.). An estimated hour a day, five days a week, for two months has

been allotted for education preparation and the education itself, totaling $3,604.00. Finally, the QI department is needed for outcome measures. The average salary of a QI department specialist is $78,919 per year, which is the estimated allotted time for data analysis (Salary, n.d.). The total estimated budget for the project is $93,005.32. Unrealized costs include additional supplies and additional staff participation that was not anticipated. If the project were to be implemented, understanding that the budget may change based on unrealized costs is necessary.

Conclusion

Overall, implementing EBP guidelines is a meticulous process but has lasting impacts. Specifically, creating anesthesia guidelines and developing a guidelines implementation plan for BDDs for organ procurement surgeries has the potential to change the lives of organ recipients through improved outcomes. The problem, the lack of EBP guidelines for anesthesia for BDDs, was identified with a discussion of the significance and background of the problem. A PICOT question was created and used to facilitate the literature search, create objectives, and develop EBP guidelines. Using the JHNEBP Model, a plan for guideline implementation was created, including identifying methods, identifying the target population, gathering a project team, identifying stakeholders, discussing logistics, creating a timeline, and producing a budget for implementation. Finally, a plan for collecting, measuring, analyzing, and evaluating data and project implementation was discussed, including project barriers and dissemination. If implemented, anesthesia guidelines for BDDs may improve outcomes of organ recipients, bring high-quality, evidence-based care to organ procurement surgeries, and have lasting impacts on the hospitals that use the guidelines and the patients receiving organs.

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Appendix A

Citation	Conceptual Framework	Design/Method	Sample/Setting	Major Variables	Outcome Measurement	Data Analysis	Findings	Level of Evidence
Al-Khafaji, A., Elder, M., Lebovitz, D. J., Murugan, R., Souter, M., Stuart, S., Wahed, A. S., Keebler, B., Dils, D., Mitchell, S., Shutterly, K., Wilkerson, D., Pearse, R., & Kellum, J. A. (2015). Protocolized fluid therapy in brain-dead donors: The multi-center randomized MOnIToR trial. *Intensive Care Medicine, 41*(3), 418-426. https://doi.org/10.1007/s00134-014-3621-0	Trial to analyze if protocolized fluid management in BDDs improves organ recovery	Multi-center randomized controlled trial	603 donors screened, 556 enrolled, 508 participated in the study; 249 received protocol fluid management, 259 received usual fluid management care	Fluid protocolized care Conventional fluid management	Number of organs transplanted per donor, number of organs recovered, observed vs. expected organs transplanted, recipient survival six months post-transplant	Wilcoxon's test, X2 tests, Fisher's test, two-sided t-test,	No significant difference in organs transplanted per donor, the survival rates were not significantly different in each group	II
Anderson, T. A., Bekker, P., M. D., & Vagefi, P. A., M. D. (2015). Anesthetic considerations in organ procurement surgery: A narrative review. *Canadian Journal of Anesthetics, 62*(5), 529-539. https://doi.org/10.1007/s12630-015-0345-8	Review anesthesia considerations for organ procurement surgery on BDDs	Systematic narrative review	PubMed, Pubget, and Embase databases were searched	n/a	Optimize donor organs, maximize the number of organs donated, improve long-term graft viability	n/a	Tailoring the anesthetic to optimize the organs being donated and knowing how brain death affects each organ may improve graft survival in recipients	V

							and increase the number of organs donated	
Basmaji, J., Reed, C., Rochwerg, B., & Ball, I. M. (2020). The impact of neurologically deceased donors' blood pressures on clinical outcomes in transplant recipients: A systematic review. *Canadian Journal of Anesthesia = Journal Canadien d'anesthesie, 67*(9), 1249-1259. https://doi.org/10/1007/s12630-020-01731-3	Review of literature to assess target blood pressure goals for BDDs for optimal outcomes	Systematic review	Searched Medline and Embase; two-step review process	n/a	Optimize organ function, survival, and organs transplanted per donor	n/a	Systolic blood pressure less than 90 mmHg may cause graft dysfunction in recipients of kidneys, but is of low certainty	V
Bera, K. D., Shah, A., English, M. R., & Ploeg, R. (2021). Outcome measures in solid organ donor management research: A systematic review. *BJA: The British Journal of Anaesthesia, 127*(5), 745-759. https://doi.org/10.1016/j.bja.2021.07.008	Review of outcome measures and interventions in randomized controlled trials	RCTs systematic review	Searched MEDLINE, Embase, CENTRAL, Web of Science, and trial databases from 1980-2021	n/a	Types of outcomes measured from donor management interventions	n/a	Outcome measures were focused on care in the ICU and single organ survival or function. There is a need for outcomes measures of recipients and standard reporting of outcomes	I

Collins, M. G., Fahim, M. A., Pascoe, E. M., Dansie, K. B., Hawley, C. M., Clayton, P. A., Howard, K., Johnson, D. W., McArthur, C. J., McConnochie, R. C., Mount, P. F., Reidlinger, D., Robinson, L., Varghese, J., Vergara, L. A., Weinberg, L., & Chadban, S. J. (2020). Study protocol for better evidence for selecting transplant fluids (BEST-Fluids): A pragmatic, registry-based, multi-center, double-blind, randomized controlled trial evaluating the effect of intravenous fluid therapy with Plasma-Lyte 148 versus 0.9% saline on delayed graft function in deceased donor kidney transplantation. *Trials, 21*(1), 1-19. https://doi.org/10.1186/s13063-020-04359-2	A trial evaluating the use of 0.9% normal saline versus Plasma-Lyte 148 on delayed graft function in kidney transplants from BDDs	A pragmatic, registry-based, multi-center, double-blind, randomized controlled trial	800 brain-dead donors, 500 receiving plasma-Lyte 148, 400 receiving 9% saline	Plasma-Lyte 148 group 0.9% saline group	Delayed graft function, early kidney function, hyperkalemia, mortality, graft survival, graft function, cost-effectiveness, quality of life	Wilcoxon rank-sum test; Poisson regression models; Kaplan-Meier curves; log-rank test; Cox regression	TBD	II
Dhar, R., Klinkenberg, D., & Marklin, G. (2021). A multi-center randomized placebo-controlled trial of intravenous thyroxine for heart-eligible brain-dead organ donors. *Trials, 22*(1), 1-11. https://doi.org/10.1186/s13063-021-05797-2	A trial assessing the effects of a 12 hr IV thyroxine infusion on heart transplants from BDDs	Multi-center randomized placebo-controlled trial	800 donors enrolled, 400 in the IV thyroxine group, 400 in the placebo saline group	IV thyroxine infusion IV placebo saline infusion	Number of hearts transplanted, hearts do not have a worse outcome than those without IV thyroxine, time to wean vasopressors, ejection fraction on echo	Chi-square test	TBD	II
Elkins, L. J. (2010). Inhalational anesthesia for organ procurement: Potential indications for administering inhalational anesthesia in the brain-dead organ donor. *AANA Journal, 78*(4), 293-299.	Review of current literature on the use of inhalational agents during	Systematic review	Searched available literature in Ovid, Medline, Medscape, and CINAHL	n/a	n/a	n/a	Inhalational anesthetics can decrease adrenergic response to	V

	organ procurement of brain-dead organ donors						a noxious stimulus, reduce ischemia-reperfusion injury, and suppress the effects of tumor necrosis factor-alpha and other inflammation products	
Eun P. S., Hee S. W., A-Ran L., Sang L. H., An K. S., Soon P. E., & Young C. W. (2014). Inhaled nitric oxide for the brain dead donor with neurogenic pulmonary edema during anesthesia for organ donation. *Korean Journal of Anesthesiology*, *67*(2), 133-138. https://doi.org/10.4097/kjae.2014.67.2.133	A review of the use of Nitric Oxide (NO) on a brain-dead organ donor with neurogenic pulmonary edema (NPE) during organ procurement	Single-patient case study	One brain-dead organ donor with NPE	n/a	The use of inhaled NO with hypoxic NPE brain-dead organ donors	n/a	During organ procurement, the use of NO can improve NPE hypoxemia in brain-dead organ donors	VI
Franklin, G. A., Santos, A. P., Smith, J. W., Galbraith, S., Harbrecht, B. G., Garrison, R. N. (2010). Optimization of donor management goals yields increased organ use. *American Surgeon*, *76*(6), 587-594. https://doi.org/10.1177/000313481007600621	An analysis of the best donor management goals for successful organ transplantation and organs	Multivariate analysis	Eight hundred five donors were studied; 2,685 organs were transplanted. 338 donors for phase I, 467 donors for phase II	Phase I: standard clinical parameters Phase II: adjustments from phase I	Number of organs transplanted per donor compared from phase I to phase II	SPSS version 17.0; Student *t* test; Pearson X2 test; Fisher exact test	Limiting vasopressor use and PaO2 are most significant for a successful transplant, tight	III

	transplanted per donor						glucose control is essential, MAP, CVP, pH, Na, and urine output had little effect on a successful transplant	
Marklin, G. F., Klinkenberg, W. D., Helmers, B., & Ahrens, T. (2020). A stroke volume-based fluid resuscitation protocol decreases vasopressor support and may increase organ yield in brain-dead donors. *Clinical Transplantation*, *34*(2), e13784. https://doi.org/10.1111/ctr.13784	A study on the use of a goal-directed fluid resuscitation protocol on organ ischemia, number of organs transplanted, and time on vasopressors	Prospective study	94 patients were included in the study, 64 received fluid resuscitation protocol, 30 did not	Treated with protocol Treated without protocol	The total volume of fluid administered over four hours, percent of donors off vasopressors in four hours, the average time to wean off vasopressors, and number of organs transplanted per donor	t-test; Mann-Whitney U test; chi-square test; Fisher's exact test; two-tailed tests	Patients in the protocol group received more fluid ($p = .003$), average time on vasopressors was reduced ($p = <.001$), had more off of vasopressors after four hours ($p = <.0013$), and were more likely to donate more organs than the control group	III

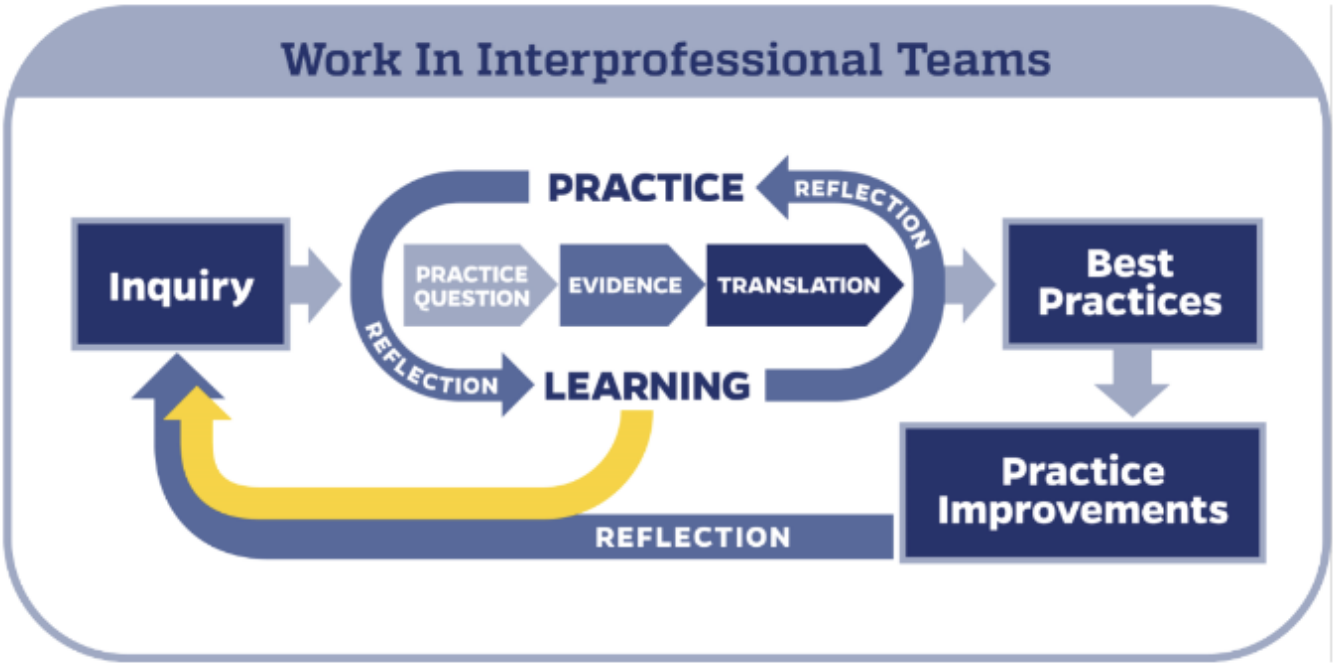
Mascia, L., Pasero, D., Slutsky, A. S., Arguis, M. J., Berardino, M., Grasso, S., Munari, M., Boifava, S., Cornara, G., Bella Corte, F., Vivaldi, N., Malacarne, P., Del Gaudio, P., Livigni, S., Zavala, E., Filippini, C., Martin, E. L., Donadio, P. P., Mastromauro, L., & Ranieri, V. M. (2010). Effect of a lung protective strategy of organ donors on eligibility and availability of lungs for transplantation: A randomized controlled trial. *JAMA: Journal of the American Medical Association, 304*(23), 2620-2627. https://doi.org/10.1001/jama.2010.1796	Trial on if lung protective strategies improve lung donor eligibility, number of lungs donated, and 6-month function of recipients	Randomized controlled trial	118 patients; 59 in control (conventional ventilatory strategy); 59 in protective ventilatory group	Conventional ventilatory support Lung protective ventilatory support	Number of donor lungs eligible for donation, number of lungs procured, the survival rate of recipients 6-months post-transplant	T-test, Wilcoxon rank sum test, X2 test, Fisher exact test, McNemar test	More lungs were eligible and harvested in the lung protective support group, there was no clinically significant difference in 6-month recipient survival rates	II
Niemann, C. U., Feiner, J., Swain, S., Bunting, S., Friedman, M., Crutchfield, M., Broglio, K., Hirose, R., Roberts, J. P., & Malinoski, D. (2015). Therapeutic hypothermia in deceased organ donors and kidney-graft function. *New England Journal of Medicine, 373*(5), 405-414. https://doi.org/10.1056/NEJMoa1501969	A trial to assess if hypothermia has an impact on delayed graft functioning	Randomized controlled trial	370 donors; 180 in the hypothermia group, 190 in the normothermia group; 572 recipients	Therapeutic hypothermia Normothermia	Delayed graft function in kidney recipients, rates of organs transplanted in each group, total organs transplanted per donor	Wilcoxon rank-sum test; chi-square test; Fishers exact test	Delayed graft functioning occurred in 28% of the hypothermia group and 39% of the normothermia group	II
Perez-Protto, S., Nazemian, R., Matta, M., Patel, P., Wagner, K. J., Latifi, S. Q., Lebovitz, D. J., & Reynolds, J. D. (2018). The effect of inhalational anaesthesia during deceased donor organ procurement on post-transplantation graft survival. *Anaesthesia & Intensive Care*, *46*(2), 178-184. https://doi.org/10.1177/0310057x1804600206	A review of OPOs and patient records to conclude if the use of volatile anesthetics (VA) improves	Retrospective cohort review	235 total, 151 donors received VA, 84 did not receive VA. Excluded for missing data, age criteria, and DCD criteria. Used kidney, liver,	VA No VA	The difference in graft survival (from transplant to failure) for organs obtained from VA and non-VA exposed donors	t-test; Wilcoxon-Mann-Whitney test; Chi-square test; Fisher's exact test	There were no significant differences between VA and non-VA groups with short or long-term graft	IV

	graft survival		heart, and lung graft recipients				survival of kidneys, heart, liver, or lungs	
Pinsard, M., Ragot, S., Mertes, P. M., Bleichner, J. P., Zitouni, S., Cook, F., Pierrot, M., Dube, L., Menguy, E., Lefèvre, L. M., Escaravage, L., Dequin, P.-F., Vignon, P., & Pichon, N. (2014). Interest of low-dose hydrocortisone therapy during brain-dead organ donor resuscitation: The CORTICOME study. *Critical Care*, *18*(3), R158. https://doi.org/10.1186/cc13997	A study on the impact of steroid use alone on primary function recovery of transplanted organs	Prospective multi-center cluster study	259 subjects included, 157 did not receive steroids, 102 received steroids. 128 of control included in the analysis, 80 of steroid group included in the analysis	Steroid administration No steroid administration (control)	Benefits of steroid administration on function and recovery of transplanted organs and the benefits of steroid administration in hemodynamic instability	Student t-test; Mann-Whitney U-test; chi-square test	There were no benefits with the use of steroids on primary function and recovery of transplanted organs, but the use of steroids had a 4.67 times higher probability of vasopressor weaning than the control group	II
Westphal, G. A., Coll, E., de Souza, R. L., Wagner, S., Montemezzo, A., Cani de Souza, F. C., Torres, G., Halla, S., Carnin, T. C., Machado, M. C., Berbigier, E., Busetto, F., Bittencourt, I., Gerent, K., de Souza, B. S., Tassinari, M., & de Andrade, J. (2016). Positive impact of a clinical goal-directed protocol on reducing cardiac arrests during potential brain-dead donor maintenance. *Critical Care (London, England)*, *20*(1), 323.	A project that measures the effects of the use of a checklist for the care of a brain-dead donor on cardiac arrest and organs	Quality improvement project	767 total, 41 excluded; 324 actual donors, 141 cardiac arrests, 226 family refusals, 35 contraindications; 83 had no checklist used, 382 had checklist used	Use of checklist No use of a checklist	Occurrence of cardiac arrest, actual donations, average organs retrieved per donor, donor loss from family refusal, or medical contraindicati	Kolmogorov-Smirnov test; student t-test; Mann-Whitney test; chi-square test	The use of a goal-directed checklist decreases donor losses and increases organs transplanted per donor	VI

https://doi.org/10.1186/s13054-016-1484-1	transplanted per donor				ons. Measured every four months over two years			
Westphal, G. A., Zaclikevis, V. R., Daberkow, V. K., De Brito Cordeiro, R., Horner, M. B. W., de Oliveira, T. P., Duarte, R., Sperotto, G., da Silveira, G., Caldeira, F. M., Coll, E., & Yus-Teruel, S. (2012). A managed protocol for treatment of deceased potential donors reduces the incidence of cardiac arrest before organ explant. *Revista Brasileira de Terapia Intensiva*, *24*(4), 334-340.	A study that compares the incidence of cardiac arrest in brain-dead donors when using a protocol for treatment versus no protocol	Quasi-experimental	42 donors; 18 in phase I and 24 in phase II	Phase I: conventional treatment Phase II: use of a protocol for treatment	Number of occurrences of cardiac arrest in brain-dead organ donors with the use of a treatment protocol versus no protocol	Student t-test; chi-square test	Using a managed protocol may decrease the death of donors from cardiac arrest	III
Zheng, D., Liu, G., Chen, L., Xie, W., Sun, J., Wang, S., & Tai, Q. (2021). Effects of terlipressin on management of hypotensive brain-dead patients who are potential organ donors: A retrospective study. *Frontiers in Pharmacology*, *12*, 716759. https://doi.org/10.3389/fphar.2021.716759	A review of the effects of Terlipressin administration on hemodynamics, renal function, and liver function of brain-dead organ donors with hypotension	Retrospective single-center study	18 patients of 294 were enrolled. Hemodynamically unstable and diagnosed brain-dead	Terlipressin administration	Parameters were measured at baseline, 24 hours and 72 hours after administration, and right before organ procurement	SD; variance; two-tailed test	Terlipressin administration increased MAP and systolic blood pressure, decreased heart rate, and improved renal function	IV

Table adapted from (Melnyk & Fineout-Overholt, 2019).

Appendix B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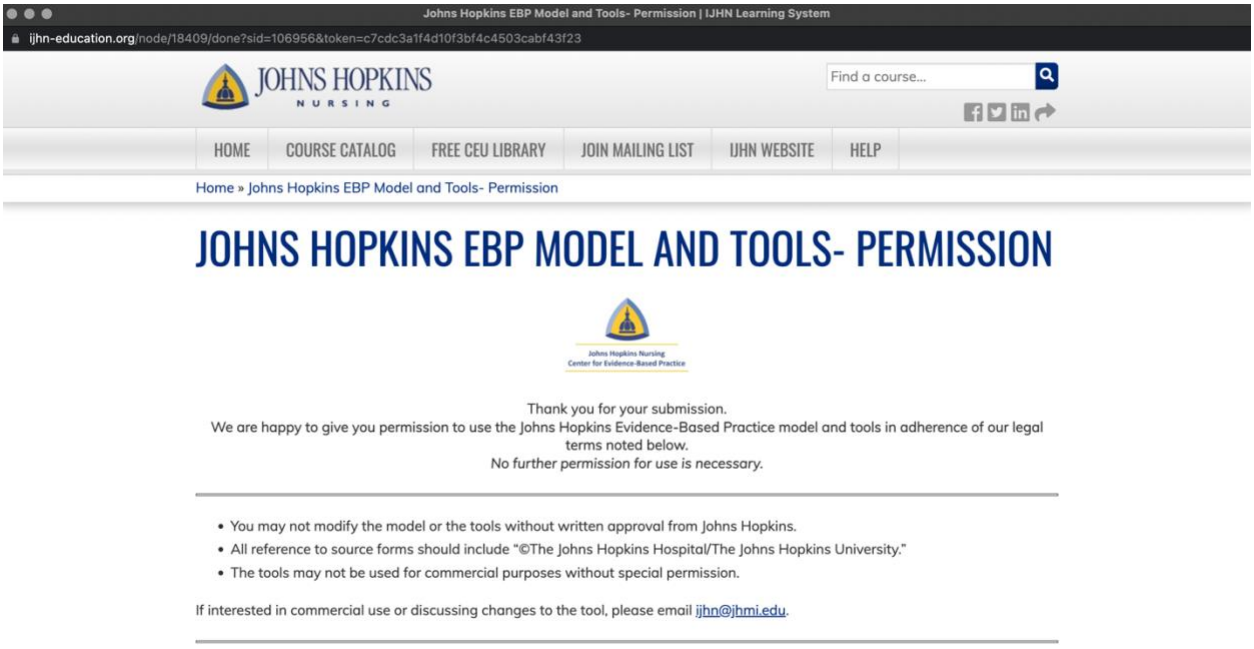
Appendix C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Appendix D

OhioHealth	GUIDELINE DRAFT
TITLE: Anesthesia for Brain-Dead Organ Donors	**NUMBER:**
ISSUE DATE:	**EFFECTIVE DATE:**
DEVELOPED / REVISED BY: Kelly Dzialowski, SRNA	
REVIEWED BY:	**DATE REVIEWED:**
APPROVED BY:	

SCOPE - This guideline is in effect for the following OhioHealth system business units:

STATEMENT OF PURPOSE:
The purpose of this guideline is to provide evidence-based practice guidelines regarding anesthesia for brain-dead organ donors. Donor management goals are used in intensive care units to guide critical care of brain-dead donors and optimize care. Achieving as many donor management goals as possible is shown to improve the quality of organs and the number of organs transplanted per brain-dead organ donor. Because management of brain-dead donors in the intensive care unit is similar to the management necessary in the operating room during organ harvesting, the use of donor management goals in the form of anesthesia guidelines may impact the number of organs transplanted per donor, organ rejection and death, and long-term survival in the recipients. Consideration generally includes:

a) Obtaining appropriate pre-op assessment of the patient
b) Collaborating with the OPO and ICU nurses to evaluate current patient status
c) Addressing patients' consents and surgeons' preferences
d) Availability of anesthesiologists or CRNAs to address complications

POLICY:
The guideline applies to brain-dead organ donors undergoing organ procurement surgery and assists anesthesia providers in the administration, selection, and management of anesthesia for brain-dead organ donors. It is intended to provide the most current evidence-based care and is not a substitute for clinical judgment and surgeon preference/instruction.

ORDER OF ORGAN PROCUREMENT SURGERY EVENTS

- Abdominal team begins dissection
- Heart and lung teams perform gross examination
- Lung team may perform procedures based on their protocols
- After abdominal team is finished, Heparin is administered (dose per surgeon request) , aorta is cannulated
- Anesthesia pulls back central line before application of cross clamp
- After cross clamp applied
    - Anesthesia turns off anesthesia machine and discontinues monitors and drips, unless donor is donating

GUIDELINES

1. Intravenous (IV) Access
    a. One central line or two large bore peripheral IVs above the waist when able
2. Hemodynamic Goals
    a. Mean arterial pressure
        i. 60-105 mmHg
    b. Systolic blood pressure
        i. >100 mmHg
    c. Heart rate
        i. 60-120 bpm
    d. Central venous pressure
        i. 4-12 mmHg
    e. Temperature
        i. 34-35° Celsius
    f. O2 saturation
        i. 100%

3. Laboratory Value Goals
    a. Serum Na
        i. <160 mEq/L
    b. Serum glucose
        i. <200 mg/dL
    c. PaO2
        i. > 80 mmHg with <40% FiO2
    d. pH
        i. 7.3-7.45
4. Other Goals
    a. Tidal volume
        i. 6-8 mL/kg (IBW)
    b. Positive end expiratory pressure (PEEP)
        i. 8-10 cmH2O
    c. Transfuse
        i. Hgb <7-8 g/dL
    d. Urine Output
        i. 0.5-7 mL/kg/hr
5. Required Medications
    a. Paralytic
        i. Provider choice prior to incision
    b. Hydrocortisone
        i. 300-500 mg if within six hours of brain death declaration
    c. Mannitol
        i. 100 G of 20% over 1-2 hours
    d. Pancreas donor
        i. Betadine 120 mL via nasogastric (NG) tube, then clamp NG
    e. Lung donor
        i. Prostaglandin 500 mcg
    f. Heparin
        i. 10,000-30,000 units three minutes before cross clamp
6. Medications to Maintain Hemodynamic Goals
    a. Dopamine infusion
        i. <10 mcg/kg/min
    b. Phenylephrine infusion
        i. <60 mcg/min
    c. Norepinephrine
        i. <10 mcg/min
    d. Terlipressin
        i. 0.02-0.06 mcg/kg/min
        ii. If on high dose norepinephrine drip and still unstable, start infusion
    e. Fluid Resuscitation
        i. Stroke volume based (use esophageal doppler or FloTrac)
            1. Obtain baseline stroke volume
            2. Give 500 mL fluid bolus of 0.9% NS or LR
            3. If stroke volume increases by 10% within 30 minutes, give another 500 mL bolus
            4. If stroke volume does not increase by 10% within 30 minutes, do not give another bolus
                a. Reevaluate in 30 minutes
                b. If stroke volume decreases by 10% within the next 30 minutes, administer another 500 mL fluid bolus
            5. Continue to reevaluate and treat accordingly every 30 minutes, with a max fluid administration of 4,000 mL
            6. Titrate vasopressors, if on any, to mean arterial pressure goal displayed in 2ai
7. Have on hand
    a. Blood on hold
    b. Vasopressin
    c. Thyroxine or T3 infusion