Characterization, Implementation, and Impact of Low Stimulation Precautions in Acute Neurological Injury

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CHARACTERIZATION, IMPLEMENTATION, AND IMPACT OF LOW STIMULATION PRECAUTIONS IN ACUTE NEUROLOGICAL INJURY

by
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A dissertation submitted to the Graduate College in partial fulfillment of the requirements for the degree of Doctor of Philosophy Interdisciplinary Health Sciences Western Michigan University June 2021

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CHARACTERIZATION, IMPLEMENTATION, AND IMPACT OF LOW STIMULATION PRECAUTIONS IN ACUTE NEUROLOGICAL INJURY

Alexis Kurek, Ph.D.

Western Michigan University, 2021

Recommendations provided by clinical and professional organizations that encourage providing patients with a low stimulation environment following acquired brain injury are prevalent but supported by expert opinion only. Such recommendations are based on extrapolation of what is known about physiological response to environmental stimuli, however such findings are not specific to the patients with acquired brain injury. Recommendations for low stimulation environments lack guidance for their application and implementation of precautions, and there have been no studies investigating their effectiveness at improving clinical outcomes.

The objective of this study is to determine what patient characteristics are associated with prescription of low stimulation environments in an acute hospital setting, to determine if the precautions are effective at reducing environmental stimulation, and to determine if the implementation of the precautions contribute to improved patient outcomes. To answer these questions, retrospective review of patients admitted to the ICU with a stroke or TBI diagnosis was first conducted. Descriptive statistics were utilized to evaluate the patterns related to the ordering of low stimulation precautions, while logistic regression was used to determine correlation between clinical factors and the prescription of low stimulation precautions. Next, observational data was collected on light and sound levels, as well as the frequency with which people entered a patient’s room in order to quantify the levels of stimulation in low stimulation rooms on the neurological ICU, non-low stimulation rooms on the neurological ICU, and general
ICU rooms. Finally, the relationship between low stimulation precautions orders and the clinical outcomes of change in GCS score, ICU and total length of stay, and discharge disposition in the retrospective cohort are analyzed through regression analysis.

Predictive indicators of low stimulation precautions included an admitting stroke diagnosis, benzodiazepine use, and a plan of care involving the Severe TBI order set identified. There were no significant differences in the stimulation levels of general ICU, low stimulation, and non-low stimulation rooms. Significant relationships between change in GCS score and discharge disposition were identified, however these associations were weak and thought to lack clinical significance.

The findings of this study indicate that application and implementation of low stimulation precautions is inconsistent and is not systematically guided by clinical indicators. In their current state, they are also ineffective at reducing environmental stimuli. Not surprisingly, clinical outcomes suggest that there is little clinical benefit to their use at the research setting, in which application was inconsistent. However, further studies are warranted to examine the posed questions in the context of a structured protocol that is systematically utilized for patients with ABI.
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CHAPTER I

INTRODUCTION

During the phase immediately following acquired brain injury there is a great deal of uncertainty surrounding the patient with many unknowns related to their recovery (Graham, 2020). Patients are typically disoriented, while their families have questions that are unable to be answered by physicians at the onset of injury, as diagnosis and prognostication requires time as test results filter in and patient response to different interventions is assessed (Brain Injury Association of America [BIAA], 2020). During this acute phase of recovery, brain-injured patients are more prone to sensory hypersensitivity and fatigue (Belmont et al., 2006; Callahan, 2018; Chaudhari and Behan, 2004). In efforts to reduce the level of stimulation that patients are subjected to during this time, “low stimulation” precautions (LSP) or guidelines are frequently recommended. These precautions typically consist of environmental modifications such as “low lights”, “soft voices”, and limitations on visitors (Giacino et al., 2018; Ontario Neurotrauma Foundation [ONF], 2016; Turner-Stokes, 2014). The purpose of these restrictions is to help prevent the patient from becoming overstimulated, which can trigger sympathetic activity and therefore result in increased agitation and changes in vital signs such as blood pressure or intracranial pressure (ICPs), and result in the need for additional medical interventions (Dünser & Hasibeder, 2009). These recommendations are frequently found informally in family and nursing brain injury resource guides, such as referenced in American Nurse Today, as well as in more formal, published guidelines (Ryan, 2009). Such recommendations are readily accepted
despite rarely being accompanied by studies to support them. Additionally, there are no detailed
guidelines for whom these recommendations are appropriate or criteria for their discontinuation:
this leaves providers and other professionals left to interpret and implement them based on their
own clinical judgement. This burden on individual providers or facilities contradicts the ever-
growing trend of the use of evidence-based care pathways and protocols in the care of
neurological populations, which promote standardized care that have been shown to improve
outcomes (Rotter, 2019; Rotter, 2012).

A review of the literature produces only level C evidence as the foundation for the use of
low stimulation precautions, relying heavily on expert opinion for their inclusion in
recommendations or guidelines. Notably, low-stimulation recommendations are frequently left
out of more rigorous clinical guidelines that inform medical practice in brain injury. This is
presumed to be due to the lack of evidence of their effectiveness, as well as the lack of
specificity in terms of implementation surrounding their use. Due to the pervasiveness of low
stimulation recommendations and the increasing call for evidence-based care, this topic warrants
further research to both characterize the “low stimulation” precautions as they are implemented
in the ICU as well as to determine their effectiveness at improving patient outcomes.

Background of the Problem

Acquired brain injuries are those that result in acute neurological changes due to a
precipitating event, such as traumatic blunt force resulting in intracranial hemorrhage, anoxia, or
ischemia following a cerebrovascular accident (CVA). These injuries are the leading cause of
death and disability worldwide in the adult population (Chan et al., 2013). Traumatic brain injury
and stroke account for the largest share of these patients, with global incidence of 69 million and
15 million respectively, while the collective incidence of other etiologies of acquired brain injuries has not been quantified (Dewan et al., 2019; World Health Organization [WHO], 2002). While the standard of care for patients with ABI has evolved and significant advances have been made that have resulted in improved diagnostics and interventions, morbidity from these injuries remains a substantial global burden (Katan, 2018; James et al., 2019), These advances have also not resulted in significantly reduced mortality rates in recent decades, as increasingly fatal mechanisms of injury related to TBIs (e.g. motor vehicle accidents) and pervasive associated risk factors such as obesity and diabetes continue to drive fatalities (Boehme, 2017; Stein, 2010). Another mechanism of ABI, seizures, specifically status epilepticus (SE) results in neurological change through structural cerebral damage as well as hypoxia. Whether SE is the result of uncontrolled epilepsy or is a part of the sequelae of injury from a TBI or CVA, these patients are at particular risk of heightened sensitivity to stimulation and are responsive to sensory stimulation even when in comatose states (Dan, 2006; Fernández-Torre, 2012).

The high financial and sociological burden of these acquired injuries and the well-evolved medical disciplines responsible for their care provide a population that is primed for ongoing optimization of diagnostics and intervention. The neurosciences realm of medicine has heartily embraced evidence-based practice (EBP), as evidenced by the dedication to the development of clinical practice guidelines by nearly every professional and clinical organization within the field. A concept rooted in clinical epidemiology and popularized in the early 1990s, evidence-based medicine seeks to incorporate the “current best evidence in making decisions about the care of individual patients” (Guyatt, 1991). The integration of EBP into medical education and practice coincided with the development of clinical research hierarchies, as physician-scientists became more discerning about the level of evidence accepted as ‘truth’. A
concerted effort by these parties to neutralize bias, avoid duplication, and promote quality care in clinical research provided the foundations on which EBP was able to grow (Sur, 2011). While there have been many arguments made about the drawbacks of EBP in terms of contextualizing the patient’s needs and the potential for payors to ‘weaponize’ it in efforts to reduce reimbursement, it is generally now considered a cultural and professional requirement that interventions provided have sound evidence to support them.

While the importance of EBP is well-accepted, the dissemination and implementation of such faces many logistical and cultural barriers. In order to improve access and therefore increase incorporation of EBP into clinical practice, many professional and clinical organizations have taken to developing clinical practice guidelines (CPGs). These CPGs synthesize the best available research and evidence-base into practical recommendations related to the diagnostic and intervention processes for specific diagnoses. They often differentiate between ‘options’, ‘recommendations’, and ‘guidelines’, based on the level of evidence supporting a specific diagnostic or treatment modality. The implementation of such guidelines has been proven to be an effective means of improving patient outcomes and reducing costs (Rotter, 2019; Rotter, 2012).

Despite the commitment to EBP in the medical field, many interventions provided continue to be done so on the basis of tradition or expert opinion only, which is considered to be the lowest level of evidence. This is often due to a gap in the research, creating the need for clinical extrapolation on the part of the practitioner. Such is the case when considering LSP: while there has been no research that directly seeks to study the effects of low stimulation environments in patients with ABI, there are significant bodies of work in clinically adjacent areas that provide insight into the impact of stimulation on physiological functioning. This has
led to the inclusion of LSP in more informal guidelines directing the care of patients with ABI, and more specifically, TBI, but not the more rigorous CPGs. These informal guidelines typically provide a general overview of care and lack clinically specific information. Those that do include recommendations for LSP in the care of patients with ABI, such as those published by the Ontario Neurotrauma Foundation, do not attempt to provide guidance related to inclusion or exclusion criteria for their use or implementation methods. This lack of specificity creates a need for providers to individually interpret them and fails to provide the structure that individual facilities benefit from when implementing interventions. This also limits further research attempts, as there is not a consistent operational definition of LSP.

The inclusion and acceptance of LSP in the care of patients with ABI despite the lack of evidence base can be attributed to the body of work in clinically relevant areas. These include research investigating the impact of environmental stimulation, including noise, light and tactile stimuli, on physiological response in a variety of patient populations. It is well documented that noise levels in ICU environments frequently exceed the recommended levels put forth by regulatory bodies, and that this type of noxious stimuli may contribute to physiological and psychological stress that could further impact a patient’s recovery (Hsu, 2010). Such stimuli are known to negatively impact sleep quality, which has been tied to the development of delirium, poor respiratory function, and dysfunctional immunological processes (Meyer, 1994; Walder et al., 2004). Initiatives aimed at reducing noise levels and light levels in the ICU environment and implementing mandatory rest periods have been shown to be effective both at diminishing stimulation, improving sleep quality, as well as improving job satisfaction amongst nursing staff (Khan, 1998; Lei, 2011; Reimer, 2015). The provision of a low stimulation environment may also facilitate general rest and reduce agitation, which have been shown to be closely linked in
studies with patients with TBI in both acute and post-acute settings (Giacino, 2017; Nott, 2010). Sleep disturbance and agitation are common complications in patients with disordered consciousness, and preventing these, potentially through the use of LSP, is considered to be an important part of optimizing care (Giacino, 2017). The impact of auditory and tactile stimuli on physiological response has also been a topic of interest to researchers: multiple studies have been conducted investigating physiological response via ICPs and cerebral perfusion pressure (CPP) measurements and various types of auditory and tactile stimuli. While the results of these studies have been mixed in terms of significant effects, causal relationships have been identified linking touch and environmental sounds to lowering ICPs.

Stimulation as an intervention aimed at improving alertness in patients with disordered consciousness has also been an area of significant study. The purposeful application of specific stimuli or, “Coma stimulation” programs or protocols, as these are referred to, seek to use stimulation to derive a physiological response in patients with disordered consciousness. Under these protocols, patients are exposed to specific stimuli, including auditory, olfactory, visual, and/or tactile stimuli, in a structured, purposeful manner with the aim of improving arousal and facilitating transition out of minimally conscious or vegetative states. These protocols are based on the premise that environmental stimuli can increase neurological activity and have been shown to be effective at altering behavior in patients in a vegetative or comatose state. However, the long-term impact of these programs and whether or not they lead to superior clinical outcomes is unknown and the rigor of studies demonstrating a positive clinical effect has ultimately been lacking (Tinga, 2016).

While the aforementioned studies are certainly supportive of the notion of environmental stimuli’s ability to impact physiological response, the populations included in the samples have
not been fully representative of the spectrum of patients to which LSP is typically applied to, nor do they attempt to relate the physiological changes with long-term clinical outcomes.

Statement of the Problem

While prior evidence clearly links environmental stimuli to physiological response, the functional impact of this, both long term and short term, is not yet established. Nor has this link been studied in the context of reducing stimulation in patients with acute neurological injury. Clinical extrapolation to the benefit of reduced stimulation in patients with acute brain injury is reasonable, but without outcomes that support this claim, it is considered a gap in EBP brain-injury care. Additionally, the lack of specificity related to the implementation of LSP regarding qualifying patient characteristics and explicit environmental restrictions contribute to a haphazardness with which they are applied. If low stimulation precautions are beneficial, then the lack of an operational definition and guidelines prevents this benefit from being fully realized.

Purpose of the Study

The purpose of this study is to investigate how low stimulation guidelines are applied on the neurological and surgical ICUs, specifically examining application patterns based on patient characteristics, including admitting diagnosis, GCS scores, need for medical intervention (e.g., necessity of specific medications), and eventual discharge disposition. Anecdotally, the prescription and implementation of low stimulation precautions is not standardized and is highly subject to provider preference within the setting in which the research was conducted. It is anticipated that findings will reflect this lack of consistency.
Research Question and Methods

The aim of this research is to explore the efficacy of low stimulation precautions by answering the following questions:

1. How are low stimulation precautions currently utilized in the research setting, and what type of patient receives them?
2. Do low stimulation precautions as implemented in their current state result in a reduction in environmental stimuli as measured by frequency of interruptions to patient and light and sound levels?
3. Do low stimulation precautions impact clinical outcomes for patients with ABI as measured by LOS, discharge disposition, and change in GCS?

To answer the above questions, retrospective data will be taken from the hospital electronic medical record (EMR) for patients admitted with specific diagnoses, including stroke, traumatic brain injury, tumor, epilepsy and anoxia. A random sample will be generated from all patients meeting inclusion criteria between January 1, 2013 and November 1, 2017, with a target sample of 500 patients. Descriptive statistics will be utilized to gain insight into the most common demographics and diagnoses prescribed low stimulation precautions. Comparisons between type of injury, age, gender, discharge disposition and age severity will be made. Logistic regression will be used to analyze the relationship between the prescription of low stimulation precautions and several variables, including admitting RASS, NIHSS, APACHE, and/or GCS score, the utilization of specific medications including benzodiazepines, opioids, and anti-epileptics, the presence of neuropsychology on the unit to which they were admitted, the completion of a neuropsychology consult, and intracranial pressure instability. Pending these results, the use of
propensity scoring will facilitate comparison between those who were subject to LSP and those who were not to identify any significant differences in age, severity, or diagnosis. This will be completed to ensure that comparison between the two groups outcomes cannot be attributed to meaningful differences in clinical factors that impacted their group assignment. T-tests will be utilized to identify significant differences between the control and experimental group as they relate to admitting GCS score and patient age. Logistic regression will be utilized to assess the effect of low stimulation precautions on patient outcomes as measured by discharge disposition, length of stay (both total and ICU), and GCS scores.

Lastly, quantitative measurements of decibel and light levels (low, average, peak) and the frequency of interruptions to patients throughout the day will be taken to assess the extent to which stimulation in designated low stimulation rooms is reduced when compared to non-low stimulation rooms. Light and sound measurements will be taken via a lux-meter and decibel recorder respectively in 24-hour increments in three different low stimulation Neuro ICU, non-low stimulation Neuro ICU and non-Neuro ICU rooms, for a total of 120 hours of measurements for each group. The inclusion of the non-Neuro ICU room will allow for comparison of stimulation between a typical ICU environment and one that potentially regularly offers lower stimulation. This information will help to contextualize the differences, or lack thereof, in stimulation identified in low stimulation rooms when compared with rooms without that designation. Frequency of interruptions will be measured via observational methods in increments of 4 hours at staggered points in the day, representing a total of 24 total hours observed per group. Analysis of variance (ANOVA) will be utilized to identify significant differences in these measures between groups. This data will allow for the evaluation of


differences in stimulation levels between low stimulation and non-low stimulation rooms, which is suggestive of the effectiveness of the low stimulation order on reducing environmental stimuli in designated rooms. Additionally, it will provide context to the results indicating whether or not low stimulation environments are effective at improving patient outcomes, and either support or refute these conclusions. Altogether, this information will provide insight into whether or not the application of low stimulation precautions as they currently exist in the research location have an impact on patient recovery.

Significance of the Research

This research will contribute to evidence base for patients with acquired brain injury by improving the level of evidence associated with LSP recommendations. The outcomes of this study will provide the first step in establishing the effectiveness of LSP and help to provide a framework under which further investigations of related interventions may be applied. By understanding LSP prescription patterns and their effectiveness at both reducing environmental stimuli and improving patient outcomes, clinicians will be able to better focus their resources to provide optimal healing environments. Without this research, patients will continue to be subjected to unproven interventions, or interventions provided in a sub-optimal manner.

Definition of Terms

Acquired Brain Injury (ABI) – An injury to the brain that is not hereditary, congenital, degenerative, or induced by birth trauma. Etiologies include tumor, stroke, blunt force trauma, alcohol or drug use, oxygen deprivation, and others (BIA, 2021)

Traumatic Brain Injury (TBI) - An alteration in brain function, or other evidence of brain pathology, caused by an external force. Traumatic impact injuries can be defined as closed (or non-penetrating) or open (penetrating) (BIA, 2021)
**Evidence-Based Medicine** - The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. Requires (Guyatt, 1991).

**Evidence-Based Practice (EBP)** – Equivalency of Evidence-Based Medicine as it relates to other fields or disciplines

**Clinical Practice Guidelines (CPG)** – Recommendations on how to treat and diagnose a specific condition. CPGs summarize current medical knowledge, weigh the benefits and harms of diagnostic procedures and treatments, and give specific recommendations based on this information, as well as provide information about the scientific evidence supporting these recommendations (InformedHealth.org, 2016)

**Glasgow Coma Scale (GCS)** - A commonly used 15-point scale developed in 1974 to assess, classify and track progress/regression in patients with acquired brain injury based on eye opening, verbal responses and motor responses. Categorizes brain injuries as mild (score of 13-15), moderate (12-9), or severe (3-8) in nature (Teasdale, 2014).
CHAPTER II

BACKGROUND AND LITERATURE REVIEW

The investigation into the history and supporting evidence of low stimulation precautions is multi-faceted given the numerous clinical and sociological factors that contribute to their current use in care of patients with ABI. Given that the premise of this research is questioning the place of LSP in evidence-based care, the history of evidence-based practice and the development and efficacy of clinical guidelines is explored. As previously mentioned, there is startlingly little research that has been conducted to investigate the use of LSP in ABI; thus, the investigation into adjacent clinical populations and interventions was required to find relevant evidence related to the impact of environmental stimuli on physiological functioning.

Search Terms and Description

Scopus, PubMed, and Google Scholar databases were utilized in the online searches for this literature review between January 2019 and February 2021. English and non-English with translation publications were reviewed from a variety of medical, nursing, psychology, rehabilitation and other scientific journals. The search terms utilized for the literature review included numerous combinations of the following: “low stimulation environments”, “low stimulation precautions”, “reduced stimulation environments”, “ICU noise levels”, “ICU light levels”, “stimulation protocols”, “brain injury stimulation levels”, “Glasgow coma scale”, “stroke”, “history of evidence-based medicine”, “evidence-based practice”, “development of clinical practice guidelines”, “clinical pathways stroke”, “clinical pathways brain injury”,

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Conceptual Framework

The conceptual framework of this study is rooted in the relationships between the impact of environmental stimuli on physiological response, and how what is known about this relationship is incorporated into clinical practice (see Figure 1).

Figure 1: Conceptual framework of evidence around low stimulation environments in ABI

![Diagram](image)

Literature Review

Acquired brain injury is the leading cause of death and disability worldwide in the adult population (Chan et al., 2013). Traumatic brain injury and stroke account for the largest share of
these patients, with global incidence of 69 million and 15 million, while the collective incidence of other etiologies of acquired brain injuries has not been quantified (Dewan et al., 2019; WHO 2002) respectively.

Traumatic brain injury (TBI), or intracranial injuries caused by blunt force to the head, may range from mild concussions to severe, life-threatening injuries. The physical effects may last from several days to the remainder of a person’s life, and may include changes to a person’s cognitive abilities, personality or emotional functioning, and physical capabilities (Center for Disease Control [CDC], 2014). The Glasgow Coma Scale (GCS) has been utilized to systematically rate and classify brain injury severity level since its introduction in 1974. The 15-point scale assesses eye opening, best verbal response and best motor response to categorize injury as mild (score of 13-15), moderate (12-9), or severe (3-8) in nature (Teasdale, 2014). The scale is used not only to initially assess and classify, but also to track progress or regression and outcomes over the course of a patient’s recovery. While the majority of TBIs are mild in nature, TBI in general still accounts for nearly 60,000 deaths per year in the United States (National Center for Injury Prevention and Control, 2003). Due to the disproportionate impact on the elderly and children, falls are the leading cause for ED visits and hospitalizations related to TBI, accounting for nearly fifty percent of ED visits among children and over 80% for those over the age of 64 (Peterson, 2019). The CDC further reports that motor vehicle accidents account for the second largest share of TBI-related hospitalizations, approximately 20%, and are the leading cause of TBI-related death for persons between 15-34 and over the age of 74. Intentional self-harm, homicide and being struck by or against an object are other identified causes of TBI, with high variation in incidence between age groups. Despite prevention efforts, the number of TBI-
related emergency department visits was observed to increase by 53% between 2001 and 2014, with an average of 155 deaths per day (Peterson, 2019).

A systematic review conducted by Stein et al. (2010) investigated observed mortality rates in patients with severe TBI and identified trends that have amounted to a nearly 50% decrease in mortality since 1885. Improvement in survival was not noted to be uniform across the time span: a 3% decrease was noted per decade between 1885-1939, with no improvement between the years 1930-1970, followed by a 9% decrease per decade between 1970-1990, and no significant improvement noted until the time of publication in 2010 (Stein, 2010). While the research is not forthcoming regarding the intermittent nature of progress, the authors speculate that progress during the earliest epoch studied could be attributed to the abandonment of ‘ill-advised techniques’, such as prolonged dehydration and routine trephination of skull fractures, and that technical innovations in the later part of the 1990s related to the head imaging (e.g. CT scanning) and intracranial pressure (ICP) monitoring, both of which facilitated more aggressive management of TBIs, contributed to improved survival rates between 1970-1990 (Stein, 2010).

The lack of progress between 1930-1970 is notable given technical advances in the mid-1900s, including improved respiratory management and support methods (e.g., cuffed tracheostomy tubes, positive-pressure ventilators) and visualization methods (e.g., echoencephalography and arteriography). The authors postulate that this lack of improvement may be due to the increasing incidence of motor vehicle collisions as a TBI-etioloogy, which has been noted to cause a more severe injury that is less amendable to treatment when compared to other types of injury (Stein, 2010). The relative flattening of mortality rates since 1990 is notable given the rise in use of evidence-based medicine and the development of clinical guidelines
related to TBI care. The authors identify the increase in falls among the elderly and improved initial resuscitation interventions and more aggressive life-saving treatments, which produce a patient population with more severe injuries and worse prognoses compared to previous epochs, as well as generally more inclusive data-sets which include a greater number locations with historically higher mortality rates (e.g. those from developing countries, low volume trauma centers) when compared to previous epochs, as potential contributing factors to this finding.

Symptoms of a traumatic brain injury vary widely depending on the severity and mechanism of injury. Patient suffering from a mild TBI often experience a constellation of symptoms, including headache and/or pain localized to injury, confusion or disorientation, dizziness, changes in vision or hearing, emotional lability, difficulty performing cognitive tasks requiring memory or attention, increased sensitivity to light and sound, increased fatigue or lethargy, nausea and/or vomiting, as well as dizziness or balance problems (CDC, 2019). The duration of symptoms may range from several hours to months; however, most patients see resolution of their symptoms within 2-6 weeks (Yang et al., 2007). Extended experience of these symptoms beyond three months is typically referred to as post-concussive syndrome and is closely associated with psycho-social risk factors, such as depression, anxiety, or PTSD (Katz, 2015). Mild injuries are most frequently noted in patients without radiological evidence of neurological changes (e.g., intracranial hematoma or hemorrhage), but some cases are considered ‘mild-complicated’, in which small amounts of bleeding in the brain is visualized. Those with moderate to severe injuries are prone to the above symptoms, as well as seizures, prolonged disordered consciousness, numbness in their extremities, physical discoordination, profound confusion, restlessness, agitation, and pupil enlargement (CDC, 2019). These injuries are
associated with bleeding in the subdural, subarachnoid and intraparenchymal regions of the brain, fractures of the skull, and axonal sheering injuries, and (Tenny, 2020). The location of the bleed or injury has an impact on intervention and treatment course, as well as prognosis. The recovery period for moderate to severe injuries is typically prolonged, requiring hospitalization and rehabilitation.

Stroke is the fifth leading cause of death in the United States, responsible for nearly 150,000 deaths per year, and is the leading cause of serious long-term disability (CDC, 2019). While stroke mortality has been observed to have decreased over the past 20 years, more recent figures suggest a leveling off or even reversal in these trends, as obesity and associated diabetes and reduction in initial case fatality contribute to increase in overall incidence and mortality (Boehme, 2017). Caused by brain cell death due to lack of oxygenation that is attributable to ischemia or hemorrhage, stroke by definition has radiological or clinical evidence of permanent injury (Sacco, 2013). Ischemic infarcts account for approximately 80% of clinically identified strokes, with a variety of contributing etiologies including cardioembolic, atherosclerotic, lacunar or other specific causes such as vertebral dissections (Sacco, 2013). Hemorrhagic strokes occur in the intraparenchymal or subarachnoid cranial spaces and are most frequently caused by ruptured aneurysms or arteriovenous malformations. Further, patients with an acute ischemic infarct may go on to experience hemorrhagic transformation, especially those at high risk due to use of anticoagulation agents (e.g., warfarin) or those that undergo alteplase administration (Maier, 2020). Risk factors for both ischemic and hemorrhagic stroke can be classified as modifiable and non-modifiable, and include age, sex, race, cardiovascular disease, hypertension,
diabetes, alcohol consumption, waist to hip ratio, lack of physical activity, poor diet, tobacco abuse, high cholesterol, and psychosocial stress and depression (Boehme, 2017).

Regardless of etiology, hemorrhage in the subarachnoid or intraparenchymal regions is typically cause for significant medical intervention. Usually identified clinically with subsequent radiographic confirmation via CT, initial management of hemorrhage begins with medical stabilization, including respiration and blood pressure, and the reversal of anticoagulation if necessary. Placement of an ICP monitor may also be required for patients who are at high risk for elevated ICPs. Neurosurgical consultation typically results in a recommendation for observation and monitoring or intervention including extra-ventricular drain (EVD) placement, burr holes, surgical evacuation, craniectomy/craniotomy (Tenny, 2020). If non-ruptured aneurysms are identified, coiling or clipping may be required in stabilized patients or in patients already undergoing surgical intervention. Complications of cerebral hemorrhage include focal neurological defects, cerebral edema, additional infarcts, rebleeding, vasospasm, seizures and brain herniation resulting in the suppression of the brain stem and the subsequent loss of vital respiratory and circulatory function leading to death (Tenny, 2020). Prognosis is often dependent on multiple factors, including the age of the patient, comorbidities and/or other injuries, location and size of the bleed, initial GCS, delay in surgical intervention, and presence of antiplatelets or anticoagulants (Tenny, 2020).

Seizure represents another cause of acute neurological injury. Seizure activity that persists for greater than 30 minutes or multiple seizures without the regaining of consciousness between them is considered to be status epilepticus (SE), a condition which is associated with high rates of morbidity and mortality, reaching 76% in elderly patients (Cherian, 2009). In the
United States, there are thought to be up to 40,000 hospital admissions due to SE per year with an estimated mortality rate between 9% and 20% (Chin, 2004; Trinka, 2012). SE may result from seizures activity caused by CVAs, traumatic brain injuries, infections, brain tumors, and sub-therapeutic levels of antiepileptic drug levels in patients with epilepsy. Seizure activity is typically characterized by an increase in autonomic activity including hypertension, hyperglycemia, sweating, salivation, and hyperpyrexia, and is associated with increased cerebral blood flow. Following the initial seizure activity, patients experience a failure in cerebral autoregulation and blood flow, an increase in intracranial pressure and systemic hypotension (Cherian, 2009). Treatment of SE is geared toward the protection of vital functions, establishing medical stability and the physical safety of the patient to prevent injury through use of anticonvulsants and environmental modifications, followed by identification of the cause of SE and determining a plan of care for ongoing management to prevent further recurrence (Cherian, 2009). Patients may require endotracheal intubation and/or administration of benzodiazepines, as well as a host of other pharmacological interventions. Patients who do not respond to initial interventions are thought to experience refractory status epilepticus (RSE), and are at higher risk of experiencing complications, increased length of stay, structural cerebral damage, cerebral hypoxia, and mortality (Cherian, 2009). All patients who experience SE, but particularly those with RSE, are at risk for experiencing long-term sequelae including impairments in neurological, cognitive, and behavioral function and decline in quality of life (Sculier, 2018). Whether SE is the result of uncontrolled epilepsy or is a part of the sequelae of injury from a TBI or CVA, these patients are at particular risk of heightened sensitivity to stimulation and are responsive to sensory stimulation even when in comatose states (Dan, 2006; Fernández-Torre, 2012). Therefore, seizure precautions, implemented both in the hospital and in the home setting, have
historically included the avoidance of environmental triggers such as bright or flashing lights, an inclusion which acknowledges the impact of visual stimulation on neurological function (Al Sawaf, 2020).

These acquired injuries can have profound and lasting effects on a patient, impacting their physical, cognitive, and social well-being. Because of their high prevalence and impact on public health, extensive research has been conducted and subsequent guidelines have been published that are meant to standardize best practice interventions in these populations. While several aspects of the care of these patients have been effectively standardized, exposure to sensory stimulation in the context of reducing stimulation to improve outcomes in the hospital environment has not been.

**Evidence-Based Medicine**

The term “evidence-based medicine” (EBM) was coined in 1990 by Gordon Guyatt, and first appeared in the *Journal of the American Medical Association (JAMA)* in 1992 (Zimerman, 2013). Defined as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients”, EBM is now both a ubiquitous term and concept that is accepted in modern medicine (Guyatt, 1991). Synonymous with evidence-based practice (EBP), EBM is rooted in modern epidemiology, sharing its methods of quantification, surveillance, and controlled experiments, which themselves are traced back to the eighteenth- and nineteenth-century European development of statistics and probability methods (Zimerman, 2013). Clinical epidemiology in North America was propelled by John R Paul who coined the term in 1938 and encouraged a multifaceted approach to observing disease in individual patients that included both social and environmental factors, as well as that of their close community.
(Zimmerman, 2013). The field was further advanced by Alvan R. Feinstein, a physician with a background in mathematics, who introduced the use of statistical research methods and Boolean logic into the evaluation of clinical practice and outcomes and the study of the medicine decision-making process (Zimmerman, 2013). Citing his belief that public health studies lacked rigor related to hypotheses, data collection, bias, and casual attribution, Feinstein worked to incorporate the use of scientific criteria in the classification, diagnosis, and treatment of disease he encountered as a physician (Sur, 2011).

The move toward socialization of medicine in the Canadian health system in the 1960s lead to the creation of new medical schools that were charged with integrating public health into medicine and employed “problem-based learning” methods that integrated basic sciences and medicine using clinical problems (Seidel, 1992; Zimmerman, 2013). David Sackett, director of clinical epidemiology and biostatistics at one such school, McMaster University, partnered with Feinstein in integrating the problem-based learning curriculum with the most novel concepts in clinical epidemiology. By the late 1970s, these methods evolved into the inclusion of short courses on the “critical appraisal of the literature” within the medical school curriculum. Aimed at teaching students to identify, assess, interpret, and incorporate research findings into their development of patient care plans, this method encouraged clinicians to rely less on their intuition and experience (Zimmerman, 2013). Originally termed “Scientific Medicine”, the concept was initially met with resistance from colleagues due to the inherent implication that their current clinical decision making was unscientific (Sur, 2011). Re-branded as “evidence-based medicine”, the instructional method and content were first published in the Canadian Medical Association Journal in 1981 and underwent several iterations until appearing in JAMA in 1992 as
a nine-article series. A colleague of Sackett, Guyatt’s first article in the series calls for a radical shift towards objectivity and scientific methods: “a new paradigm for medical practice is emerging. Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research” (Guyatt, 1992; Zimerman, 2013). The editorial staff at JAMA worked with Sackett, Guyatt, and other academicians in the U.S., publishing the first articles as the anonymous Evidence-Based Medicine Working Group in efforts to give it the authority of a consensus paper. The EBM Working Group identified the need to not only address the importance of critical appraisal of literature, but the application of it into clinical practice as well, which previous publications related to the concept had failed to adequately do (Sur, 2011). This resulted in the creation of a “User’s Guide” to EBM, which provided explicit instruction for clinicians in the application of research of varying levels of rigor or quality. It should be noted that this publication format became the basis for the User’s Guide to the Medical Literature, which continues to provide clinicians with a straightforward resource to understand and apply the latest scientific literature related to specific topics or diagnoses (Sur, 2011). The series on EMB by the EBM Working Group continued for 8 years with a total of 32 articles, with JAMA demonstrating significant commitment and advocacy for the new methods (Zimerman, 2013). Other journals began to publish articles with the same terms and content by other McMaster faculty, however given the attention it received in JAMA and other dissemination methods, the term and methods were becoming popularized and by 1995 less than of half publications with the term “evidence-based medicine” were published by McMaster faculty (Zimerman, 2013).
The integration of the term and concept into medical discourse in the 1990s was aided in part by the cultural and technological shifts toward the incorporation of computers and other technologies such as digital databases, bioinformatics, and new clinical research methodologies (Zimerman, 2013). Additionally, there was an increasing awareness of weaknesses of standard clinical practice and their impact on patient outcomes and cost of care, and EBM offered a method of bringing more certainty to the clinical decision-making process (Sur, 2011). Historically considered to be an ‘art’, the use of statistical modeling and scientific methodology were rare in a field that relied on “expert opinion, experience, and authoritarian judgement” (Sur, 2011). EBM provided a practical bridge in terms of both concept and application in joining the knowledge base of scientific research and clinical bedside application by physicians.

This same decade also saw the formation of the Cochrane Collaboration, formed by Murry Enkin, Ian Chalmers, and Tom Chalmers in 1993. Named for Archie Cochrane, a physician who led pioneering efforts to eschew bias in clinical research and promote randomized controlled trials (RCT), the collaboration sought to improve the quality of medical research in hopes of bringing more benefit to patients (Cochrane, 1989). The members of the collaboration recognized the importance of RCTs and their place as “the foundation of a hierarchy of evidence that pooled data from multiple trials”, as well as the impact of publication bias on medical practice (Sur, 2011). Having first-hand experience with the consequences of relying on medical dogma, they committed themselves to compiling a database of published, unpublished, ongoing and planned trials and meta-analyses. Eventually the group evolved into a collaboration involving other medical specialties that committed themselves to ten principles: collaboration, building on enthusiasm of individuals, avoiding duplication, minimizing bias, keeping up to date,
striving for relevance, promoting access, ensuring quality, continuity, and worldwide participation (Sur, 2011). The work of such scientist-physicians made it possible for EBM to have a scientific knowledge base from which to draw upon.

Despite the more overt benefits of increasing the use of scientific methods and objectivity in the field of medicine, the reliance on EBM has been met with critiques. Critics of the approach, including Feinstein himself, have argued that an over-reliance on RCTs may lead to the exclusion or dismissal of valuable, beneficial information pertaining to interventions that are potentially lifesaving, citing the known benefits of insulin for diabetic acidosis and penicillin for bacterial endocarditis, both of which were introduced through single study articles (Sur, 2011). It has also been argued that EBM attempts to take the complex decision-making process and reduce it to an algorithm that may negate experience, extrapolated knowledge, intuition, and that decontextualizes and does not account for the patient’s psychosocial needs, or their personal values and beliefs. “Soft” data, such as severity of symptoms and rate of illness growth are also hard to capture within EBM algorithms (Feinstein, 1997). Additionally, critics of EBM cite concern for potential abuses by payors: the lack of adherence to “best available evidence” may be used to justify lack of reimbursement, manipulate provision of care, and marginalize interventions that do not adhere to what is identified as “best practice” (Sur, 2011). From a logistical or practical standpoint, the time required for dissemination of research findings translation into clinical practice is lengthy, noted to be up to 17 years from first publication to ubiquitous application (Balas, 1998)

These arguments in defense of traditional medicine offer important counterpoints to the standardization of medical treatment and reliance on EBM. Indeed, the incorporation of LSP into
the care of brain injured patients relies on such clinical intuition and extrapolated knowledge that EBM is unable to account for. Despite the validity of such arguments, the importance of seeking truth as it relates to the effectiveness or efficacy of interventions remains a vital and worthy pursuit, as patient outcomes and resources are at stake.

The use and pursuit of EBM or EBP has expanded outside the field of medicine into other clinical realms, including nursing, psychology, and rehabilitation specialties such as physical, occupational, and speech therapy. Its importance is codified in the American Speech-Language Hearing Association (ASHA) practice standards, which require that all clinicians engaging in the practice of speech-language pathology “demonstrate knowledge of processes used in research and the integration of research principles into evidence-based clinical practice…(and) must demonstrate comprehension of the principles of basic and applied research and research design. In addition, the applicant should know how to access sources of research information and have experience relating research to clinical practice” (ASHA, 2005, p.6). This mandate acknowledges several realities as it relates to professional clinical practice. The first of these is that clinical fields are dynamic, and that the training received during an academic career will not be sufficient to provide a clinician with the required skills to provide the most efficacious care for the entirety of their career. It is estimated that research relevant to EBP doubles in under ten years and failing to engage with the literature on a routine basis will undoubtedly result in the provision of substandard or outdated care (Hess, 2010; Ratner, 2006). The obligation of competency in identifying and incorporating EBP into clinical care also speaks to the importance of providing value to the patient as it relates to their resources and outcomes. Payors are
increasingly insistent on providers demonstrating the worth of their billable charges via patient outcomes, and preferential outcomes are linked to EBP by the nature of their effectiveness.

Evolution of a field and the incorporation of EBP into clinical practice are closely tied. Technological advances over the past several decades, such as those achieved in brain imaging, have completely transformed the neuroscience fields. Disciplines such as neuropsychology have seen paradigm shifts in their practice based on these advances, as reliance on the profession to localize lesions was reduced; this shift provided space for the discipline to engage in other professional pursuits requiring their clinical expertise, such as characterizing cognitive strengths and weaknesses (Bilder, 2010). The use of EBP facilitates shifts such as these as new advances arise, and clinical professions are pushed to the limits of their current knowledge base. As these limits are approached, researchers and clinicians search the adjacent possible for further diagnostic tools and interventions that could provide additional benefit to patients.

It is difficult to measure the impact of EBM or EBP on the health care system as a whole, as the factors involved to be measured are too numerous to effectively quantify. A systematic review conducted by Simons et al. (2018) that investigated the evidence related to the correlation between EBM training and physician’s knowledge, skills, attitudes, practice patterns and patient outcomes found that short term knowledge and skills were improved, but that there was little reliable evidence suggesting changes in practice patterns and no information related to impact on patient outcomes. Study heterogeneity, small samples sizes, and varying degrees of bias were noted to prevent meaningful comparisons and limited study validity. The authors note that the overall quality of evidence evaluated was poor due to methodological weaknesses, and cite Coomarasamy and Khan (2004) in their explanation of the difficulty in linking EBM to patient
outcomes, given the “many different factors in the clinical context [making it] difficult to unravel the contribution of EBM among these many factors”, and go on to indicate that the effect of EBM training on patient outcomes may not be apparent for months to years (Simons, 2018)

The Development of Clinical Pathways

The development and promotion of standardized clinical care pathways, which was first developed in the 1980’s, has been gaining momentum since the early 2000’s. The aim of these pathways or protocols is described by Rotter et al. (2019) as “(1) it is used to translate guidelines or evidence into local structures; (2) it details the steps in a course of treatment or care in a plan, pathway, algorithm, guideline, protocol or other “inventory of actions”; and (3) it aims to standardize care for a specific clinical problem, procedure or episode of healthcare in a specific population”. Their use has demonstrated improvements in patient outcomes, reductions in length of stay, reduced hospital costs and in-hospital complications, as well as improvement in professional documentation (Busse, 2019; Rotter, 2012). They accomplish this by operationalizing EBM and/or clinical practice guidelines as developed by professional associations and the best available research. Care pathways are typically multidisciplinary in nature and are targeted to a specific population, procedure or diagnosis, facilitating coordinated and consistent care to all patients (Institute for Quality and Efficiency in Health Care, 2016). The clinical practice guidelines from which they are formulated are frequently created regionally by professional associations, leading to multiple sets of guidelines for the same population or diagnosis. A systematic review of practice guidelines related to stroke completed by Platz (2019) revealed 49 publications that aimed to present best practice in stroke care and rehabilitation. Among these, there was wide variation related to the scope and structure of the guidelines. The
influence of geographically based factors (e.g., low availability of rehabilitation professionals such as physical or occupational therapists) was also noted to impact the recommendations reported. Likewise, a systematic review of traumatic brain injury clinical practice guidelines conducted by Patel et al. (2016) noted similar findings: 24 published guidelines met inclusion criteria for review and comparison, with wide variation in populations targeted, settings of care, resources assumed, rigor of development, etc. Despite the differences with which these guidelines are developed and subsequent care pathways are formulated, the demonstrated positive impact of consistent, evidence-based care delivery ensures that this method of care guidance and provision will continue to be the standard going forward, and that current and future interventions should be incorporated into this model as able.

*Inclusion of Low Stimulation Precautions in Clinical Guidelines*

The effectiveness of care pathways demonstrates the importance of standardization in care delivery as it relates to the specificity with which care is provided and interventions are applied. Despite their frequent mention in non-guideline publications related to brain injury, such standardization has not been applied to the use of LSP. Of the published guidelines reviewed, only those put forth by the Ontario Neurotrauma Foundation (ONF) gives mention to the use of low stimulation environments, a recommendation that is limited to the phrases “Avoid overstimulation” and “consider use of low stimulation rooms” and does not attempt to further direct clinicians in the implementation of such precautions (ONF, 2016). This absence of specificity or guidelines related to LSP reflects the lack of research that has been conducted investigating their use despite their prevalence in brain injury care. ONF cites only the expert opinion of INCOG contributors in their publication on the management of post-traumatic
amnesia as rationale for their inclusion of LSP, which in turn does not offer external supporting evidence for their recommendation (Ponsford, 2014). While expert opinion is of value, it is considered to be the lowest level of evidence or support in research related to evidence-based practice in healthcare (Sackett, 2000). There are no published recommendations that specify who is appropriate for a low stimulation environment, that provide an exhaustive list of restrictions should be in place, how they should be enforced, or any criteria for the reintroduction of normal environmental stimuli.

Despite this lack of evidence, the inclusion of LSP in brain injury care is not without merit. Clinical intuition leads us to believe that a less stimulating environment would be more conducive to neurological healing as it promotes rest and may reduce agitation. In their study evaluating agitation in patients post-TBI, Nott (2010) found that increased levels of agitation were associated with decreased structured activity and visiting hours, which created higher levels of environmental stimuli. This suggests a strong causal link between environment and behavior. Giacino et al. (2017) identify sleep disturbance and agitation as two of the most common complications of prolonged reduced consciousness in brain injured patients, and that reducing or preventing these complications is an important part of optimizing care. While Giacino and Nott do not specify methods to accomplish this, Becker (2013) advocates for environmental modifications such as limitations on television, visitors and activity in order to encourage periods of rest and reduce agitation. Likewise, Lombardi and Zafonte (2005) recommend a low stimulation environment for patients that have suffered a traumatic brain injury based on the impact of environmental stimuli on the development of delirium. Such recommendations are also included in the practice guidelines put forth by INCOG in regard to the management of post-
traumatic amnesia and delirium, citing Level C, specifically expert opinion, as evidence (Ponsford, 2014). A controlled environment and enforcement of sleep/rest periods are also advocated for in the practice guidelines put forth by Andrews (2005). While these recommendations seem intuitive, they are not ubiquitous and are absent from more rigorous practice guidelines (Giacino et al., 2017; Powers, 2018). Additionally, no studies were identified during an exhaustive literature search that evaluated the effectiveness of such guidelines.

While the rationale for such recommendations in the aforementioned studies is not explicitly stated as such, they are likely informed by the known effect of traumatic brain injury on sensory processing. Hypersensitivity to light and sound is a well-documented phenomenon following mild TBI, or concussion, with reports of up to 50% and 10% prevalence post-injury, respectively (Capo-Aponte, 2012; Greenwald, 2012; Hall, 2005; Landon, 2012). While the exact physiology of sensitivity is unknown, such symptoms are so prevalent that they are included in patient reported outcome measures and are an important consideration when classifying degree of post-concussion syndrome (Greenwald, 2012). While this common finding of mild TBI is not frequently discussed in the context of stroke or severe brain injury, it does give credence to the notion that those with neurological impairment or changes may experience environmental stimuli to a heightened degree due to disordered processing when compared with those without ABI. This lends further support to the concept of reducing environmental stimuli in this population.

Despite the lack of evidence that specifically investigates low stimulation precautions in neurological injury, there have been multiple studies conducted that evaluate the impact of physical environment and stimuli on physiological factors that contribute to a patient’s medical stability and recovery. The majority of this research investigates the impact of different stimuli
on sleep quality, as insufficient sleep is associated with the development of ‘ICU psychosis’ or delirium, poor respiratory function, and dysfunctional immunological processes, and thus contribute to prolonged hospitalizations and poor outcomes (Meyer et al., 1994; Walder, Francioli, Meyer, Lançon, & Romand, 2004). Specifically, noise levels and their effect on hospitalized patients have historically been an area of interest for researchers. It is well documented that noise in ICUs frequently exceed the recommended levels put forth by regulatory bodies such as the EPA, often averaging 20-25 dB above the recommended levels, and in some cases up to 10 times the maximum decibel levels (Hsu 2010; Khan, 1998; Lisle, 1986). These elevated noise levels were found to be associated with increased physiological and psychological stress, suggesting that they may negatively impact a patient’s recovery (Hsu, 2010). They can also contribute to sleep fragmentation, as even short tone bursts, such as those produced by monitors and alarms, have been shown to produce transient EEG arousal during all stages of sleep (Carly, 1997). Because of this, several researchers have set forth to study the effect of behavior and environmental modification programs aimed at reducing noise and noxious light levels in hospital settings. These studies have determined that the majority of noise sources are amendable to behavior/environmental modification and that such programs are effective at reducing noise levels in the ICU (Khan, 1998). Expanding on this theme, Li et al. (2011) investigated the impact of reducing noise, light and care-related interruptions on sleep quality in surgical ICU patients. Results indicated that reducing environmental stimuli and enforcing a ‘do not disturb’ rest period were effective at improving patient’s sleep quality. Reimer (2015) found that similar guidelines were also effective at reducing stress levels in nursing staff when enforced for short periods of time during the day, thus potentially improving the quality of nursing care received by patients. The positive results of stimulation-reducing
studies are not universal, however, as reducing baseline light in the patient’s rooms has also been associated with decreased sleep quality, likely due to greater fluctuations in lux levels creating disruptions in patient’s arousal state (Walder et al., 2004). It should be noted again that the aforementioned studies investigated the impact of typical environmental stimuli in cardiac and post-surgical patients, where the assumption of neurological typicality is presumed but not guaranteed.

Environmental stimuli have also been observed to impact physiology outside of sleep quality in hospitalized patients. Schinner (1995) examined the effects of auditory stimuli in comatose patients, comparing the physiological response as measured by intracranial pressure (ICP) and cerebral perfusion pressure (CPP) when subjects were exposed to classical music, environmental background noise, or noise reduction methods (application of ear plugs). This study found no significant change in ICP or CCP when interventions were applied. Common nursing interventions and their impact on ICPs were further investigated by Olson, Mcnett, Lisa, Riemen, & Bautista (2013): they found that neither draining cerebrospinal fluid or limiting stimulation had an effect on ICP levels at any time interval. However, results did indicate that having family members talking in the room and repositioning patients were effective at lowering ICPs after five minutes. This suggests a causal relationship between auditory and tactile stimuli and physiological response in hospitalized patients.

Further contributing to the notion of environmental impact on patient outcomes, there is a considerable body of work investigating the effects of controlled sensory stimulation exposure in patients with disorders of consciousness. “Coma stimulation” programs or protocols, as these are referred to, seek to use stimulation to derive a physiological response in patients with disordered
consciousness. In these studies, patients are exposed to specific stimuli, including auditory, olfactory, visual, and/or tactile stimuli, in a structured, purposeful manner with the aim of improving arousal and facilitating transition out of minimally conscious or vegetative states. These programs, therefore, investigate the impact of increasing stimulation in neurological injury, as opposed to the aim of low stimulation precautions, which is reducing stimulation. A systematic review conducted by Wilson & McMillan (1993) determined that sensory stimulation can alter behavior in patients with disorders of consciousness, as judged by changes in physiological measurements, behavior and outcome statistics. However, the long-term impact of these changes, and whether or not they lead to superior clinical outcomes, is unknown. While not designed specifically for use with acquired brain injured patients, the Snoezelen® multi-sensory environment has also been shown to be effective at promoting oscillatory activity which may reflect the state of relaxation as demonstrated on EEG (Poza et al., 2013). Despite these findings, a systematic review conducted by Lombardi (2002) concluded that multiple studies have found such programs to be effective at improving arousal in patients with disorders of consciousness, but that the overall quality of these studies is largely inadequate and therefore the results cannot be generalized or translated into recommended practice. These findings were supported in a later systematic review conducted by Tinga et al. (2016) which concluded that while a large majority of studies found a positive significant difference in patients exposed to purposeful sensory stimuli vs controls, there is a need for more rigorous randomized, controlled clinical trials before such interventions can be deemed effective. However, since the completion of these reviews, Moattari, Shirazi, Sharifi, & Zareh (2016) conducted a RCT examining the effect of a structured sensory protocol administered 2 times daily to comatose patients and found a significant, positive correlation between administration of the protocol and improved recovery as measured by the
Rancho Los Amigos and Glasgow Coma Scale rating scales. These findings strongly support the notion that environmental stimuli have the ability to impact physiological response and function in patients with neurological impairment. However, because the nature of these studies is limited to patients in vegetative or minimally responsive states, the results cannot be generalized to patients in more responsive states.

A complicating clinical factor in this population that is difficult to control for in experiments is the considerable amount of spontaneous improvement that occurs in this population during the acute phase of recovery, and therefore interventional causation is difficult to prove (Grosswasser, 1990). Additionally, none of these studies detail or describe baseline environments that the stimulation protocols are meant to contrast.

Additional support to the notion of environmental impact on cognitive or neurological function are the multitude of positive findings surrounding the use of “enriched environments” in patients during the acute recovery phase following stroke. Environments that provide cognitive, physical and social activity opportunities are known to facilitate structural changes required for the process of neuroplasticity, including production of dendritic spines, normalized astrocyte-neuron ratios, and supporting optimal levels of brain derived neurotrophic factor (BDNF) (Johansson, 2000; Johansson, 2002; Komitova, 2002; Nygren, 2006). Studies have found that providing patients with cognitively stimulating items and tasks in both acute care and sub-acute environments may result in a greater degree of engagement in activity and recovery as demonstrated by reduced length of stay (LOS) and reduction in adverse events than those who were not provided similar experiences (Janssen, 2014; Rosenbergen, 2017). It should be noted, however, that these benefits did not translate to reduced disability at three months post-stroke.
(Animal models demonstrate benefit to exposure to such stimuli as soon as 24 hours following stroke (Johansson, 1996).
CHAPTER III

RESEARCH METHODOLOGY

Attempting to control and quantify the amount of stimulation that a patient is subjected to in an acute care hospital setting is a task that faces many barriers. The number of people involved in the care of the patient is not limited to physicians, nurses, and nursing aides, but includes ancillary staff such as phlebotomists, radiology technicians, respiratory, physical, occupational and speech therapists, dietitians, and staff from nutrition and janitorial services. Patient friends and family are also often a constant presence in the ICU setting, and while the conduct of hospital employees can typically be relied on to remain professional and appropriate to the setting, that of friends and family cannot be. The degree to which each interaction disrupts the patient is variable and highly dependent on the state of consciousness of the patient and the manner in which conversations are held. The degree of disruption may also be impacted by whether or not physical contact with the patient is made, such as during the physical examination of the patient by a nurse or a loved one holding the patient’s hand. Such contact may be experienced as benign, pleasant, or painful by the patient, depending on their physical injuries and neurological status.

Disruptions may also be caused by environmental noise, such as those produced by malfunctioning IVs, bed alarms, and other monitoring devices at the patient bedside. These may be consistent or progressive in decibel level and their duration is typically dependent on the availability of nursing staff to attend to the source. Factors such as distance from the patient, duration of alarms, number of alarms sounding, and the level of consciousness of the patient
contribute to the degree of disruption to the patient. Other external sources of environmental noise include the moving of equipment, loud conversations held outside the patient room, TV being watched by visitors, and overhead announcements. Depending on the conscious state and neurological status of the patient, these sounds may be perceived as benign, noxious, pleasant, or may not register into their consciousness at all.

Similarly, the patient’s experience of exposure to light is also dependent on the source of light, the intensity, and the patient’s level of consciousness and associated sleep/wake cycle. Many ICU rooms have multiple sources of light with varying degrees of intensity that can range from direct light projected downward at the patient’s head of bed to ambient light in the vestibule to the room. Daylight from windows may be bright with the patient directly in its path or muted from drawn shades. Other sources of environmental light such as that from monitors or TV being watched by visitors may also register with the patient, depending on their sensitivity to stimulation.

For the above reasons, attempting to fully control and quantify the degree to which a patient is stimulated by their environment is a formidable task that is predisposed to error. Despite this, there are several variables that contribute to the level of stimulation within the environment that are quantifiable. Furthermore, the degree to which a patient experiences a favorable outcome is dependent on many factors, including their pre-existing and newly acquired comorbidities, risk factors such as age, mechanism of injury, the quality of interventions performed, and others. All these serve as confounding factors that make it difficult to evaluate the impact of a low stimulation environment on a patient recovery.
**Research Design**

This observational study employed both retrospective cohort and cross-sectional designs. The first and third of the research questions, which require analysis of prescription patterns and patient characteristics of those prescribed LSP and the comparison of clinical outcomes between those prescribed LSP and those who were not, utilized a retrospective cohort data, as the population sample, dependent and independent variable outcomes are those of past patients and are well documented. The second of the research questions, which investigates the quantification of stimulation of patients prescribed LSP in comparison with those who are not, utilized a cross-sectional model, with observational data obtained from current patients from each of the sample groups (low stimulation, neurological ICU non-low stimulation rooms, and general ICU non-low stimulation rooms). This research model was necessary given the lack of quantifiable data of the environments of those patients included in the sample of the first and third investigations.

**Research Questions and Hypotheses**

The aim of this research is to explore the efficacy of low stimulation precautions by answering the following questions:

1. How are low stimulation precautions utilized in the research setting, and what type of patient receives them?
2. Do low stimulation precautions as implemented in their current state result in a reduction in environmental stimuli as measured by frequency of interruptions to patient and light and sound levels?
3. Do low stimulation precautions impact clinical outcomes for patients with ABI as measured by LOS, discharge disposition, and change in GCS?

Given the knowledge of the research setting, it was hypothesized that while there is likely a greater ratio of patients with TBI who are prescribed LSP compared to other ABI etiologies, that few definitive trends in prescription of LSP will be identified due to the lack of protocolization of LSP use. This same lack of protocol informs the hypothesis regarding the second research question: it is the postulation of the researcher that while there will likely be a difference in stimulation between neurological ICU and general ICU rooms, that there will be no significant difference between LSP and non-LSP rooms within the neurological ICU. This hypothesis further informs the last research question, as it is hypothesized that the lack of efficacy of LSP at reducing stimulation will contribute to a lack of significant difference identified in the clinical outcomes of the LSP and non-LSP sample groups.

*Population and Sample*

To answer the first and third questions, retrospective data was taken from the EMR of a Level 1 trauma hospital and designated Comprehensive Stroke Center in West Michigan for patients between the ages of 18 and 99 admitted to the neurological ICU with a primary diagnosis of stroke, traumatic brain injury, or anoxia. Additional inclusion criteria include eventual discharge from the hospital (i.e., did not expire). Vulnerable populations including pregnant women, incarcerated persons, and ethnic minorities were not excluded from this study, however minors (i.e., patients under the age of 18) were, as they were infrequently admitted to the adult ICU. A power analysis was deferred due to lack of studies for comparison and presumed adequacy. A random sample was generated through the use of the Honest Broker from
all patients meeting inclusion criteria between January 1, 2013 and November 1, 2017, with a
target sample of 500 patients. The second question was addressed through convenience samples,
including both the random selection of current patients hospitalized in the neurological ICU or
general ICU and the consecutive sampling of patients with LSP orders admitted during the data
collection timeframe.

Instrumentation

Cerner PowerChart, the EMR utilized during the timeframe from which the retrospective
data was extracted from, serves as the primary source of retrospective data for this study. Light
levels of all sample group rooms were collected via the HOBO Pendent MX Temperature/Light
Data Logger device with data logging facilitated by the use of a designed Apple iPad. The
reading and recording of decibel levels were accomplished through the use of the CDC’s Noise
and Hearing Prevention (NOISH) Sound Level Meter application, which permits the reading,
recording, and analysis of sound without the need or function of voice recording. No sound or
voice recordings were collected during this study, only the analytical reports related to dB levels.
A PowerDeWise professional grade, omnidirectional lavalier microphone was used to optimize
sound/decibel capture. Microsoft Excel was utilized to help manage data extracted from both the
NIOSH and HOBOConnect applications installed on the designated iPad. SAS Studio statistical
software and Microsoft Excel were utilized to conduct all statistical analyses related to this
study.
Data Collection

Retrospective required for this study was acquired through the use of the research setting’s available Honest Broker and extracted from Cerner PowerChart EMR application. Deidentified extracted data was managed in Microsoft Excel in a password protected folder on the local drive and was only accessible by approved individuals involved in the research. Data from patients within the sample included the following variables: presence of an order for LSP, primary diagnosis upon admission, age, gender, discharge disposition, admission and discharge GCS, the presence of a TBI order set (a set of order pre-grouped due to likelihood of use based on diagnosis), admitting RASS, NIHSS, APACHE, the administration of benzodiazipines, opioids, and anti-epileptics, the availability of neuropsychology on the unit to which they were admitted (i.e. admission prior to or following the data of the integration of neuropsychology service to the neurological ICU), the completion of a neuropsychology consult, and intracranial pressure instability. Greater than 100 unique admitting ICD-10 coded diagnoses were noted in the sample upon extraction; these were grouped into 10 clinically meaningful diagnoses groups based on like ICD-10 codes, with the diagnoses with the highest frequencies serving as the diagnostic labels.

Quantitative data related to the stimulation levels with the patient rooms were collected through the observational methods described above. Collection of light and decibel levels was conducted simultaneously through the above-described applications. A password protected iPad designated for research purposes was placed as near the head of the patient’s bed as feasible to best capture the light and sound experienced by the patient. Data collection occurred for continuous 24-hour periods (+/- 2 hours), capturing both day and night levels of sound and light.
exposure. This data was collected in five separate rooms for each of the non-low stimulation sample groups (non-low stimulation neurological ICU and general ICU), and for a total of 121:36 and 151:48 hours, respectively. Data from low stimulation rooms were collected in a similar fashion, however given the low patient population in this group, 1 room was sampled more than once for a total of 151:45 hours cumulatively. Data extracted from the apps was downloaded into password protected Microsoft Excel spreadsheets and further managed and organized for analysis.

Data related to the frequency of interruption to patient rest was collected at 1-hour intervals through the direct observation of the number of times staff enter a patient’s room for a novel purpose. Such interactions included, but are not limited to, evaluation by consulting services, daily rounds, services provided by ancillary staff, vital checks conducted by nursing staff, janitorial services, and lab draws. Staff leaving and reentering for the same purpose (e.g., retrieving additional supplies) was counted as the same encounter. The number of staff involved in the interaction was not considered consequential and therefore not recorded (e.g., a bed change requiring two staff). Observations took place between the hours of 7:00 am and 4:30 pm and were equally dispersed throughout the day to ensure that the entirety of a day’s workflow was captured and no one period of time was over-represented (e.g., physician rounds, shift change, etc.). Observation of patients who left the floor for testing or other purposes was discontinued and not included in final analysis. Observers were in discrete locations and did not alert care staff to their purpose to ensure no behavior changes were elicited. This information was also recorded and managed through a password protected Microsoft Excel spreadsheet and helped to inform the frequency with which a patient’s rest was disturbed.
Data Analysis

To answer the research questions, a combination of descriptive statistics, logistic regression, propensity scoring, and t-tests were performed. An alpha level of .05 was maintained for all analyses. Descriptive statistics were used to characterize the sample population in terms of demographics and clinical characteristics including diagnosis, admitting GCS, presence of LSP order, and discharge disposition. They were also used to visualize comparisons between frequency of prescription of LSP between certain groups within the sample. Logistic regression was utilized within this first investigation due to its ability to identify correlation between multiple independent variables and a categorical dependent variable, in this case, the presence of LSP orders. This approach was used to analyze the relationship between the prescription of low stimulation precautions and several variables, including admitting RASS, NIHSS, APACHE, GCS score, the utilization of specific medications including benzodiazepines, opioids, and anti-epileptics, the presence of neuropsychology on the unit to which they were admitted, the completion of a neuropsychology consult, and intracranial pressure instability to determine which of the aforementioned variables represent a significant predictor of LSP prescription.

Following these results, propensity scoring was conducted to compare the LSP and non-LSP groups. Given the non-randomized and retrospective nature of the sample population, and the unknown degree to which patients were purposefully or meaningfully assigned LSP, propensity scoring identified the degree to which the two groups were matched in clinically meaningful ways that have the ability to impact their group assignment or outcomes. The groups underwent matching on diagnosis, neuropsychology involvement, LOS, use of specific medications, and discharge disposition to ensure that groups were equivalent in terms of
diagnostic distribution and clinical characteristics. However, no significant differences were identified, and the full data set was used for subsequent analysis. To further ensure the appropriateness of comparison between the control and experimental groups, t-tests were utilized to identify significant differences between the groups in terms of admitting GCS score and patient age, as this approach facilitates identification of significant differences in means of continuous variables (e.g., age and severity score). This ensured that the two groups were appropriate to compare in terms of clinical outcomes and that one group did not represent a more medically frail or prognostically worse off group than the other.

Quantification data related to frequency of interruptions, light and decibel (dB) levels underwent descriptive analysis to compare the findings between the non-low stimulation neurological ICU, low-stimulation neurological ICU, and general ICU rooms. No rooms in which the patient was in isolation precautions due to infection were selected for observation, as this would have likely impacted several measurements. Given the relatively small sample size to be obtained for these observations, Student’s t-tests were used to compare the observational findings between each group as follows. Light, or lux, measurements included average lux readings (near-24-hour continuous increments), peak lux readings during that timeframe, and daytime average lux readings (0700-2100). Decibel measurements included average decibel readings (total weighted average, or TWA), max decibel reading, which represents the mean square root of the peak readings, and the C-weighted peak decibel readings (LCPeak). Observation data of frequency interruptions were averaged for each group. Separate analyses were conducted for all of the above variables between the three groups in pairs. These analyses allowed for identification of significant differences between each of the groups and thus
determine if LSP precautions in their current state are efficacious in reducing stimulation levels. This information provides context and contributes to the validity of the conclusions when interpreting the results of the final research question.

Following this, logistic regression was again utilized to analyze the relationship between the prescription of LSP and the patient outcome measures of discharge disposition and length of stay (both total and ICU). These variables were identified as clinically meaningful as they represent the degree to which a patient requires medical care and physical assistance and can be considered a reflection of regained functional independence. Change in GCS score was also selected as an outcome variable due to its use as a measure to classify functional neurological status, as a positive change in GCS is indicative of neurological recovery. A stepwise approach was utilized, and non-significant variables removed as determined to be appropriate. Chi-square was utilized to specifically evaluate discharge disposition and LSP orders independent of other significant variables. The association between ICU LOS and discharge disposition was also explored independently through nonparametric one-way ANOVA analysis to identify potential relationships between these two factors.

Conclusion

While there are multiple confounding variables that are difficult to control for, the variables identified are thought to be the best available representation of a patient’s clinical context and experience. The statistical approaches mentioned were chosen for their ability to best manage the variable types utilized in the study and for their applicability to the research questions at hand. The above methods were meant to provide a comprehensive evaluation of all
relevant data related to the use of LSP in the ICU setting and provide meaningful evidence as to their efficacy.
CHAPTER IV

RESULTS

Subject Characteristics

Four hundred ninety-nine (n=499) patient records were extracted for retrospective review and analysis. Of the 499 patients included in the study, 36.7% had orders for LSP, whereas 63.3% did not (see Figure 2). Of the total sample population, 65% of patients were discharged to acute rehab, 18% to sub-acute rehab (SAR), 4% to long-term acute care (LTACH) and 14% were discharged home (See Figure 3). Forty-seven percent (47%) of patients had a Glasgow Coma Scale (GCS) score of 15 at time of admission, 31% had a GCS score between 10-14, and 22% had a GCS of 9 or less (see Figure 4). Seventy-eight percent (78%) of patients were admitted with a primary stroke diagnosis compared with 22% admitted with a traumatic brain injury. Forty-two percent (42%) of patients admitted with a stroke diagnosis received low stimulation precaution (LSP) orders, compared to 18% of patients admitted with a TBI diagnosis (see Figure 5). Forty percent (40%) of the sample was admitted following the introduction of neuropsychology on the ICU (after August 2017), however only 5% of the patients were noted to have undergone a neuropsychological consult. The majority of patients were treated with opioids and/or anesthetics, whereas a small minority received stimulants or anti-epileptic agents. Five percent (5%) of patients within the total sample were admitted under a severe TBI order set, and 9.81% experienced unstable or elevated ICPs during their admission (see Table 1).
Figures 2-4: Sample Characteristics - Presence of LSP orders, Discharge disposition, Admission GCS score, n = 499

**Figure 2**

- LSP Orders
  - Low Stim Orders: 63%
  - No Low Stim orders: 37%

**Figure 3**

- Discharge Setting
  - Home: 18%
  - Acute Rehab: 4%
  - SAR: 14%
  - LTACH: 64%

**Figure 4**

- GCS on admission
  - 15: 15%
  - 10-14: 34%
  - <9: 51%

**Figure 5: Frequency of LSP by diagnosis, n = 499**

- Frequency of LSP by Diagnosis Type
  - TBI
    - LSP: 20
    - Non-LSP: 89
  - Stroke
    - LSP: 163
    - Non-LSP: 227

Frequency of LSP by Diagnosis Type

- 0 50 100 150 200 250 300 350 400 450

- LSP
- Non-LSP
Table 1: Sample clinical characteristic frequencies, n = 499

<table>
<thead>
<tr>
<th>Clinical Characteristic</th>
<th>Frequency</th>
<th>% of Total Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of opioids</td>
<td>365</td>
<td>73.15</td>
</tr>
<tr>
<td>Use of anesthetics</td>
<td>250</td>
<td>50.1</td>
</tr>
<tr>
<td>Neuropsychology Available</td>
<td>203</td>
<td>40.68</td>
</tr>
<tr>
<td>Use of benzodiazepines</td>
<td>139</td>
<td>27.86</td>
</tr>
<tr>
<td>Use of antipsychotics</td>
<td>102</td>
<td>20.44</td>
</tr>
<tr>
<td>Use of anti-hypertensives</td>
<td>66</td>
<td>13.23</td>
</tr>
<tr>
<td>ICPs greater than 20</td>
<td>49</td>
<td>9.82</td>
</tr>
<tr>
<td>Use of Severe TBI order set</td>
<td>25</td>
<td>5.01</td>
</tr>
<tr>
<td>Neuropsychology Evaluation</td>
<td>23</td>
<td>5.21</td>
</tr>
<tr>
<td>Use of stimulants</td>
<td>11</td>
<td>2.2</td>
</tr>
<tr>
<td>Use of anti-epileptics</td>
<td>11</td>
<td>2.2</td>
</tr>
</tbody>
</table>

Diagnoses Characteristics

A plurality of patients was admitted with a primary diagnosis of nontraumatic hemorrhage (22.85%, n=114), with 42% (49/114) of these patients receiving LSP; this is in contrast to patients admitted with non-subarachnoid hemorrhage following injury (n=43) and subarachnoid hemorrhage following injury (n=28), in which LSP was only ordered in 4.6% (2/43) and 14.3% (4/28), respectively (see Tables 2-3). Those patients admitted with a primary diagnosis of cerebral infarct due to embolism of MCA had the highest ratio of LSP orders (79%, 19/24), however those admitted with a TBI diagnosis, including subarachnoid hemorrhage (n=5), non-subarachnoid hemorrhage (n=1), cerebral contusion (n=3), and closed fracture w/ bleed (n=12) with the Severe TBI order set applied collectively received LSP in 19 out of 21 instances (90.5%) (see Table 3).
Table 2: Distribution of diagnoses, n=499

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Frequency</th>
<th>% of Total Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nontraumatic hemorrhage</td>
<td>114</td>
<td>22.85</td>
</tr>
<tr>
<td>Cerebral infarction d/t occlusion/stenosis of carotid/vertebral artery</td>
<td>104</td>
<td>20.84</td>
</tr>
<tr>
<td>Infarct d/t occlusion of MCA/PCA, unspecified</td>
<td>61</td>
<td>12.22</td>
</tr>
<tr>
<td>Nontraumatic SAH</td>
<td>50</td>
<td>10.02</td>
</tr>
<tr>
<td>Hemorrhage following injury (non-subarachnoid)</td>
<td>43</td>
<td>8.62</td>
</tr>
<tr>
<td>Unspecified CVA</td>
<td>36</td>
<td>7.21</td>
</tr>
<tr>
<td>Subarachnoid hemorrhage following injury</td>
<td>28</td>
<td>5.61</td>
</tr>
<tr>
<td>Closed fracture w/ bleed</td>
<td>28</td>
<td>5.61</td>
</tr>
<tr>
<td>Cerebral infarct d/t embolism of MCA</td>
<td>24</td>
<td>4.81</td>
</tr>
<tr>
<td>Cerebral/brain stem contusion, unspecified cerebral laceration/contusion</td>
<td>11</td>
<td>2.2</td>
</tr>
</tbody>
</table>

Table 3: Frequency of LSP and concurrent TBI order set use by diagnosis, n=499

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Freq. of LSP order</th>
<th>% w/ LSP orders</th>
<th>Freq. of concurrent TBI OS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cerebral infarct d/t embolism of MCA</td>
<td>19/24</td>
<td>79.0%</td>
<td>0</td>
</tr>
<tr>
<td>Unspecified CVA</td>
<td>19/36</td>
<td>52.0%</td>
<td>0</td>
</tr>
<tr>
<td>Closed fracture w/ bleed</td>
<td>12/28</td>
<td>42.0%</td>
<td>12</td>
</tr>
<tr>
<td>Nontraumatic hemorrhage</td>
<td>49/114</td>
<td>42.0%</td>
<td>1</td>
</tr>
<tr>
<td>Nontraumatic SAH</td>
<td>21/50</td>
<td>42.0%</td>
<td>3</td>
</tr>
<tr>
<td>Cerebral infarction d/t occlusion/stenosis of carotid/vertebral artery</td>
<td>37/104</td>
<td>35.0%</td>
<td>0</td>
</tr>
<tr>
<td>Infarct d/t occlusion of MCA/PCA, unspecified</td>
<td>18/61</td>
<td>29.5%</td>
<td>0</td>
</tr>
<tr>
<td>Cerebral/brain stem contusion, unspecified cerebral laceration/contusion</td>
<td>2/11</td>
<td>18.0%</td>
<td>3</td>
</tr>
<tr>
<td>SAH following injury</td>
<td>4/28</td>
<td>14.3%</td>
<td>5</td>
</tr>
<tr>
<td>Hemorrhage following injury (non-subarachnoid)</td>
<td>2/43</td>
<td>4.6%</td>
<td>1</td>
</tr>
</tbody>
</table>
*Propensity Score and Bias Assessment*

To ensure the low stimulation and non-low stimulation groups were not significantly different in clinically meaningful ways, propensity matching was performed using the previously identified significant variables and reduced the overall sample to 301 patients with no significant differences found between them, therefore the entire sample was utilized for the remainder of the analysis. Additional t-tests were conducted to ensure comparability between the groups in terms of patient age and admitting GCS, which also revealed no significant differences, with p-values of .5763 and .1003, respectively (see Table 4).

Table 4: Comparison of means between LSP and non-LSP groups, age and admitting GCS score – T-tests

<table>
<thead>
<tr>
<th>Variable</th>
<th>DF</th>
<th>t-statistic</th>
<th>Pr &gt; t</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>300</td>
<td>0.56</td>
<td>0.5763</td>
</tr>
<tr>
<td>Admitting GCS</td>
<td>300</td>
<td>1.65</td>
<td>0.1003</td>
</tr>
</tbody>
</table>

*Analyses of Associations Between Clinical Characteristics and LSP Orders*

Significant relationships were found between diagnosis (Wald $X^2_9 = 32.0217$, $p=.0002$) use of benzodiazepines (Wald $X^2_1 = 14.7192$, $p=.0001$), use of the severe TBI order set (Wald $X^2_1 =23.7041$, $p=<.0001$), the availability of neuropsychological evaluation on the ICU Wald $X^2_1$, 4.4104, $p=.0357$) and the presence of LSP orders. (see Table 5). When non-significant variables were removed from the model, probabilities remained largely unchanged.
Table 5: Relationship between clinical characteristics and likelihood of LSP prescription - Binary Logistic Regression, n=499

<table>
<thead>
<tr>
<th>Parameter</th>
<th>DF</th>
<th>Wald Chi-Square</th>
<th>Pr&gt;ChiSq</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neuropsychology Availability</td>
<td>1</td>
<td>4.4104</td>
<td>0.0357</td>
</tr>
<tr>
<td>Severe TBI order set use</td>
<td>1</td>
<td>23.7041</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Use of Benzos</td>
<td>1</td>
<td>14.7192</td>
<td>0.0001</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>9</td>
<td>32.0217</td>
<td>0.0002</td>
</tr>
</tbody>
</table>

No specific diagnosis was related to an increased likelihood of receiving LSP, however, a TBI-related diagnosis was associated with a reduced likelihood of having LSP orders applied (p=.0002). When diagnoses were recoded as binary (i.e., stroke or TBI), analysis revealed that patients admitted with a stroke-related diagnosis were more likely to receive LSP than those admitted with a traumatic injury ($X^2 = 22.5489$, p= <.0001). T-tests for patient age and admitting GCS were not significant ($F_{50} = 1.07$, p=.669 and $F_{150} = 1.11$, p=.531) (see Table 6). Odds ratio for the same variables demonstrated wide confidence intervals (see Table 7).
### Table 6: Relationships between significant variables including specific diagnoses and LSP prescription – Binary logistic regression, n=499

<table>
<thead>
<tr>
<th>Analysis of Maximum Likelihood Estimates</th>
<th>Parameter</th>
<th>DF</th>
<th>Estimate</th>
<th>Standard Error</th>
<th>Wald Chi-Square</th>
<th>Pr&gt;ChiSq</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td></td>
<td>1</td>
<td>5.576</td>
<td>1.029</td>
<td>29.3458</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Neuropsych Available</td>
<td></td>
<td>1</td>
<td>-0.516</td>
<td>0.2457</td>
<td>4.4104</td>
<td>0.0357</td>
</tr>
<tr>
<td>Severe TBI OS</td>
<td></td>
<td>1</td>
<td>-4.615</td>
<td>0.948</td>
<td>23.7041</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Benzo use</td>
<td></td>
<td>1</td>
<td>-0.973</td>
<td>0.254</td>
<td>14.7192</td>
<td>0.0001</td>
</tr>
<tr>
<td>Nontraumatic hemorrhage</td>
<td></td>
<td>1</td>
<td>-0.321</td>
<td>0.401</td>
<td>0.6406</td>
<td>0.4235</td>
</tr>
<tr>
<td>Cerebral infarction d/t occlusion/stenosis of carotid/vertebral artery</td>
<td></td>
<td>1</td>
<td>-0.382</td>
<td>0.434</td>
<td>0.7742</td>
<td>0.3789</td>
</tr>
<tr>
<td>Infarct d/t occlusion of MCA/PCA, unspecified</td>
<td></td>
<td>1</td>
<td>-0.716</td>
<td>0.461</td>
<td>2.4187</td>
<td>0.1199</td>
</tr>
<tr>
<td>Cerebral infarct d/t embolism of MCA</td>
<td></td>
<td>1</td>
<td>1.046</td>
<td>0.614</td>
<td>2.9056</td>
<td>0.0883</td>
</tr>
<tr>
<td>Nontraumatic SAH</td>
<td></td>
<td>1</td>
<td>-0.745</td>
<td>0.48</td>
<td>2.4081</td>
<td>0.1207</td>
</tr>
<tr>
<td>Hemorrhage following injury</td>
<td>subdural, etc</td>
<td>1</td>
<td>-3.33</td>
<td>0.931</td>
<td>12.8005</td>
<td>0.0003</td>
</tr>
<tr>
<td>SAH following injury</td>
<td></td>
<td>1</td>
<td>-3.859</td>
<td>1.186</td>
<td>10.5893</td>
<td>0.0011</td>
</tr>
<tr>
<td>Cerebral/brain stem contusion, unspecified cerebral lacertian/contusion</td>
<td></td>
<td>1</td>
<td>-4.505</td>
<td>1.474</td>
<td>9.3436</td>
<td>0.0022</td>
</tr>
<tr>
<td>Closed fracture w/ bleed</td>
<td></td>
<td>1</td>
<td>-2.522</td>
<td>0.933</td>
<td>7.3</td>
<td>0.0069</td>
</tr>
<tr>
<td>Unspecified CVA</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

### Table 7: Relationships between significant clinical variables and LSP prescription – Odds ratio, n=499

<table>
<thead>
<tr>
<th>Odds Ratio Estimates</th>
<th>Effect</th>
<th>Point Estimate</th>
<th>95% Confidence Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Neuropsych Availability</td>
<td>0.0597</td>
<td>0.369</td>
</tr>
<tr>
<td></td>
<td>Severe TBI OS</td>
<td>0.01</td>
<td>0.002</td>
</tr>
<tr>
<td></td>
<td>Benzo use</td>
<td>0.378</td>
<td>0.23</td>
</tr>
<tr>
<td></td>
<td>Diagnosis 1 v 10</td>
<td>0.726</td>
<td>0.331</td>
</tr>
<tr>
<td></td>
<td>2 v 10</td>
<td>0.683</td>
<td>0.292</td>
</tr>
<tr>
<td></td>
<td>3 v 10</td>
<td>0.489</td>
<td>0.198</td>
</tr>
<tr>
<td></td>
<td>4 v 10</td>
<td>2.846</td>
<td>0.855</td>
</tr>
<tr>
<td></td>
<td>5 v 10</td>
<td>0.475</td>
<td>0.185</td>
</tr>
<tr>
<td></td>
<td>6 v 10</td>
<td>0.036</td>
<td>0.006</td>
</tr>
<tr>
<td></td>
<td>7 v 10</td>
<td>0.021</td>
<td>0.002</td>
</tr>
<tr>
<td></td>
<td>8 v 10</td>
<td>0.011</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>9 v 10</td>
<td>0.08</td>
<td>0.013</td>
</tr>
</tbody>
</table>

Diagnoses: (1) Nontraumatic hemorrhage, (2) Cerebral infarction d/t occlusion/stenosis of carotid/vertebral artery, (3) Infarct d/t occlusion of MCA/PCA, unspecified, (4) Cerebral infarct d/t embolism of MCA, (5) Nontraumatic SAH, (6) Hemorrhage following injury (subdural, etc.), (7) SAH following injury, (8) Cerebral/brain stem contusion, unspecified cerebral lacertian/contusion, (9) Closed fracture w/ bleed, (10) unspecified CVA
Comparisons of Stimulation Levels

Stimulation quantification data analysis resulted in no significant differences between any of the three identified groups in any of the variables of interest: dB max, LC Peak, TWA, total average lux, daytime average lux, peak lux levels, or frequency of patient interruptions (see Table 8). While not statistically significant, LSP rooms were noted to have the highest readings in light-related variables observed, while the non-LSP neurological ICU rooms had the lowest. LSP rooms were also noted to have the highest rate of interruptions per hour (see Table 9).

Table 8: Comparison of quantifiable stimulation means between room types - T-tests

<table>
<thead>
<tr>
<th>Group 1 n=151:45 (hours)</th>
<th>Group 2 n=151:48 (hours)</th>
<th>Group 3 n=121:36 (hours)</th>
<th>Measure</th>
<th>t-statistic</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Stim General ICU</td>
<td>dbmax</td>
<td>0.556699968</td>
<td>0.593</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Stim General ICU</td>
<td>dBmax</td>
<td>-0.284328366</td>
<td>0.784</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Stim General ICU</td>
<td>LC Peak</td>
<td>0.298110492</td>
<td>0.772</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Stim General ICU</td>
<td>LC Peak</td>
<td>-0.797010824</td>
<td>0.446</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Stim General ICU</td>
<td>dB TWA</td>
<td>1.429363555</td>
<td>0.191</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Stim General ICU</td>
<td>dB TWA</td>
<td>-0.396242524</td>
<td>0.706</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Stim General ICU</td>
<td>Avg lux</td>
<td>0.633655556</td>
<td>0.542</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Stim Neuro ICU</td>
<td>Avg lux</td>
<td>1.693483546</td>
<td>0.125</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Stim General ICU</td>
<td>Peak lux</td>
<td>0.882720177</td>
<td>0.403</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Stim General ICU</td>
<td>Peak lux</td>
<td>0.852805045</td>
<td>0.416</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Stim General ICU</td>
<td>Daytime lux</td>
<td>0.515673435</td>
<td>0.620</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Stim Neuro ICU</td>
<td>Daytime lux</td>
<td>0.798092089</td>
<td>0.445</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1 n=16 (hours)</td>
<td>Group 2 n=18 (hours)</td>
<td>Group 3 n=18 (hours)</td>
<td>Measure</td>
<td>t-statistic</td>
<td>p value</td>
</tr>
<tr>
<td>Low Stim General ICU</td>
<td>Interruptions</td>
<td>0.75243139</td>
<td>0.458</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Stim Neuro ICU</td>
<td>Interruptions</td>
<td>1.183736395</td>
<td>0.246</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General ICU Neuro ICU</td>
<td>Interruptions</td>
<td>0.506340311</td>
<td>0.616</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 9: Averaged light, sound, and interruption data by room type (by hour)

<table>
<thead>
<tr>
<th>Room Type</th>
<th>Max (dB)</th>
<th>LC Peak (dB)</th>
<th>TWA (dB)</th>
<th>Lux Average (lx)</th>
<th>Lux Peak (lx)</th>
<th>Lux Daytime Average (lx)</th>
<th>Freq of Interrupt.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Stimulation</td>
<td>101.5</td>
<td>121.27</td>
<td>60.03</td>
<td>5.79</td>
<td>33.5</td>
<td>9.08</td>
<td>5.14</td>
</tr>
<tr>
<td>n=151:45</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General ICU</td>
<td>99.9</td>
<td>120.1</td>
<td>56.1</td>
<td>4.64</td>
<td>25.8</td>
<td>7.52</td>
<td>4.33</td>
</tr>
<tr>
<td>n=151:48</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurological ICU</td>
<td>102.28</td>
<td>124.3</td>
<td>61.64</td>
<td>3.2</td>
<td>24</td>
<td>6.98</td>
<td>3.11</td>
</tr>
<tr>
<td>N=121:36</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Max dB – highest averaged reading; LC Peak (dB) – highest single dB reading; TWA (dB) – total average dB; Lux average (lx) – total average for 24 time period; Lux peak (lx) – highest single lx reading in 24-hour period; Lux daytime average – average lx for hours between 700-2100; Freq of interrupt – number of times a person entered the room for a novel purpose

Despite the relatively small sample size these findings reflect, they do support the notion that low stimulation precautions in their current form are functionally ineffective at reducing stimulation levels in a patient room, and this context should be considered in the interpretation of the remaining analyses.

Analyses of Associations Between LSP Orders and Clinical Outcomes

In response to the third research question, a binary logistic regression was performed to identify significant relationships between LSP orders and the clinically meaningful outcomes of LOS (ICU and total), discharge disposition, and change in GCS (see Table 10). Neither total (OR .985, p=.4353) nor ICU LOS (OR 1.043, p=.0969) reached statistical significance. Change in GCS score (OR 1.061, p=.0425) and discharge disposition (OR 1.010, p=.006) were noted to be significant, however near-even odds ratios were observed with both variables.
Table 10: Relationship between clinical outcome variables and LSP prescription - Logistic regression, n=499

<table>
<thead>
<tr>
<th>Parameter</th>
<th>OR (95%CI)</th>
<th>Wald Chi-Square</th>
<th>Pr &gt;ChiSq</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total LOS</td>
<td>.985 (.947-1.024)</td>
<td>0.6087</td>
<td>0.4353</td>
</tr>
<tr>
<td>ICU LOS</td>
<td>1.043 (.992-1.097)</td>
<td>2.7554</td>
<td>0.0969</td>
</tr>
<tr>
<td>Change in GCS</td>
<td>1.061 (1.002-1.124)</td>
<td>4.1135</td>
<td>0.0425</td>
</tr>
<tr>
<td>Discharge Disposition</td>
<td>1.010 (1.003-1.018)</td>
<td>7.5584</td>
<td>0.006</td>
</tr>
</tbody>
</table>

Differences in discharge disposition were significant ($X^2_3 = 11.559$, $p=.0091$), however the overall impact did not appear to be clinically significant. Chi-square analysis revealed that the majority of difference between expected and observed findings ranged between 1-4% of the total sample (see Table 11). The exception to this was that the group receiving LSP saw 7% less than expected (15 v 24.2/183) patients discharge to home care and 6% more patients than expected (131 v 119.56/183) discharge to acute rehab. There was also a significant relationship between ICU LOS and discharge disposition ($X^2_3 62.846, p=<.0001$) with those discharging home averaging the shortest ICU LOS, followed by those discharging to acute rehab, sub-acute rehab and LTACH (see Figure 6).

Table 11: Chi-Square analysis of discharge disposition, $X^2_3 = 11.559$, $p=.0091$, n=499

<table>
<thead>
<tr>
<th>No Low Stimulation</th>
<th>Sub-acute Rehabilitation</th>
<th>Home</th>
<th>Acute Rehabilitation</th>
<th>LTACH</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>62</td>
<td>51</td>
<td>195</td>
<td>8</td>
<td>316</td>
</tr>
<tr>
<td>Expected</td>
<td>56.361</td>
<td>41.796</td>
<td>206.44</td>
<td>11.399</td>
<td></td>
</tr>
<tr>
<td>Total %</td>
<td>12.42</td>
<td>10.22</td>
<td>39.08</td>
<td>1.6</td>
<td>63.33</td>
</tr>
<tr>
<td>Low Stimulation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency</td>
<td>27</td>
<td>15</td>
<td>131</td>
<td>10</td>
<td>183</td>
</tr>
<tr>
<td>Expected</td>
<td>32.639</td>
<td>24.204</td>
<td>119.56</td>
<td>6.6012</td>
<td></td>
</tr>
<tr>
<td>Total %</td>
<td>5.41</td>
<td>3.01</td>
<td>26.25</td>
<td>2</td>
<td>36.67</td>
</tr>
</tbody>
</table>
**Figure 6: Relationship between discharge disposition and ICU length of stay (LOS) - One-way ANOVA, n = 499**

Distribution of Wilcoxon Scores for ICU

**Conclusion**

In summary, while there were some significant factors impacting the prescription of LSP, implementation of precautions did not appear to result in meaningful change in outcomes for patients admitted to the neurological ICU. Stroke-related admitting diagnosis, use of benzodiazepines, the availability of neuropsychology on the ICU, and increased LOS were predictive of having LSP ordered. Once ordered, LSP did not significantly impact the amount of stimulation that a patient was exposed to, as measured by dB and lux levels, nor did it reduce the frequency of staff entering the room. Despite this, the presence of LSP orders was significantly associated with an increased change in GCS and preferable discharge disposition, however these associations were identified to be weak and likely resulted in minimal clinical impact.
CHAPTER V

DISCUSSION

This single center observational study reflects the current practice patterns and subsequent outcomes related to low stimulation protocols in a neuro-intensive care population. It was the attempt of the researcher to identify how LSP was being applied, their impact on stimulation levels in the ICU, and to determine if they were effective at improving patient outcomes in ABI. While there are many confounding factors to consider in this population, including degree of spontaneous recovery, pre-existing conditions and comorbidities, patient motivation and support systems, and the high degree of influence individual care team members have on the variables explored, the study findings are thought to adequately reflect the functional impact of LSP on patients admitted to the neurological ICU.

Summary of Findings

Of all the clinical variables explored, only four were identified to be significantly associated with the prescription of LSP: stroke-related admitting diagnosis, use of benzodiazepines, the availability of neuropsychology on the ICU, and LOS. The presence of an LSP order did not significantly impact the amount of stimulation that a patient was exposed to, as measured by dB and lux levels, nor did it reduce the frequency of staff entering the room. However, the presence of LSP orders was significantly associated with a greater change in GCS
and preferable discharge disposition. Despite reaching statistical significance, these associations were weak and suggestive of minimal clinical impact.

Conclusions of Hypotheses

1. How are low stimulation precautions utilized in the research setting, and what type of patient receives them?

The study findings reflect no clear pattern of prescription related to the ordering of LSP in the research setting. The lack of protocol around LSP at the research setting creates the need for providers to make decisions related to the inclusion of LSP in a patient’s plan of care without any supportive decision-making tools, which appears to translate into inconsistent ordering. In general, hemorrhagic stroke patients were most likely to receive LSP, as well as those who had longer lengths of stays. These associations are clinically intuitive, as these clinical characteristics are indicative of medically and neurologically fragile patients whose recovery course is complex. Patient’s requiring benzodiazepines as a sedating agent were also identified as more likely to receive LSP than those who were not. Lastly, patients who were admitted following the introduction of neuropsychology services on the ICU (i.e., After August of 2017) were also more likely to receive LSP than their counterparts admitted prior to that date. Patients admitted that had the Severe TBI order set applied to their plan of care were also more likely to receive LSP, as the order is embedded in the order set.

2. Do low stimulation precautions as implemented in their current state result in a reduction in environmental stimuli as measured by frequency of interruptions to patient and light and sound levels?

The presence of LSP orders and a “Low Stimulation Room” sign on the door which detailed restrictions were not effective at reducing dB or lux levels, nor at reducing the frequency
with which staff entered the patient room. This suggests that patients with LSP orders were exposed to similar light and sound environmental stimuli as their counterparts in other ICU settings, and that staff attempts to cluster care to increase the patient’s uninterrupted rest time were ineffective, if made at all.

3. Do low stimulation precautions impact clinical outcomes for patients with ABI as measured by LOS, discharge disposition, and change in GCS?

Low stimulation precautions were determined to not be effective at reducing LOS (total or ICU) for patients admitted with ABI when compared with their non-LSP counterparts. While statistically significant relationships between change in GCS and discharge disposition were identified during analysis, the associations were weak and deemed to be clinically insignificant. Therefore, it is the conclusion of this study that LSP in their current form are ineffective at improving outcomes in patients admitted to the ICU with ABI.

Discussion

As previously mentioned, the population studied in this research is complex and highly varied in their clinical composition and needs. There are multiple confounding factors to consider when attempting to interpret the recovery patterns of patients with acute neurological injury; however, the above findings do offer some valuable insight into the originally posed research questions.

Given the lack of protocol around LSP at the research setting, it is unsurprising that the significant relationships found were limited. While the greater frequency of LSP for stroke patients vs. those with TBI is reasonable, the statistical relationship indicating a greater likelihood for stroke vs. TBI patients was unexpected, given that traditionally low stimulation
environments have typically only been promoted as an intervention for patients with TBI. This indicates a willingness of providers to consider the full clinical picture of the patient and not rely solely on diagnosis to develop plans of care. However, the lack of LSP use in the TBI population outside of those admitted under the diagnosis of ‘closed fracture w/ bleed’, was unanticipated. The strong correlation between use of the Severe TBI order set and LSP was expected, as the order set in the EMR at the research setting includes the LSP order, increasing the likelihood of it being applied to the patient. Upon further review of the data, every patient admitted under a TBI diagnosis that had LSP orders also had the Severe TBI order set applied; likewise, there were only four patients admitted during this time frame that had the Severe TBI order set applied and not LSP orders. This suggests that LSP was not utilize in the TBI population outside of the use of the Severe TBI order set. Anecdotally, it is known that nursing staff at the research setting have been observed to initiate LSP (i.e., utilize the door signage) without a provider order; while impossible to capture the rate of occurrence in a retrospective review, it is possible that this practice impacted provider ordering patterns (i.e., LSP was not ordered because the sign was already on the door). It is also within reason to suspect that the patient sample did not capture a portion of the patients admitted to the research setting with a TBI should their primary admitting diagnosis have been related to polytrauma or orthopedic injuries, as the sample was extracted from the EMR based on primary diagnosis only. The increased likelihood of LSP ordering following introduction of neuropsychology services to the ICU is thought to stem from two factors: the influence of the neuropsychologist’s education to the providers related to low stimulation environments and their own ordering privileges on the unit, as their training likely facilitated heightened awareness of LSP as an ABI intervention compared to the physicians. The lack of significant relationship between neuropsychological evaluation and LSP suggests that the
impact of the former had greater influence than the latter. The last of the significant relationships identified, that between LSP and use of benzodiazepines, can possibly be attributed to the likelihood that a patient who requires continuous sedation is identified by providers as requiring a less stimulating environment. However, given the wide range of dosing and utility of this drug class on the ICU, this correlation was the least anticipated among the significant variables.

The lack of correlation between LSP and several of the clinical variables, most notably GCS on admission, ICP instability and use of anti-epileptics, was thought to be remarkable. A lower GCS score, especially those indicating severe injury regardless of etiology, would have been anticipated to be indicative of LSP being an appropriate intervention. Given that GCS was a measure used across all diagnoses and prescription of LSP was not limited to any particular population, the lack of correlation between score and LSP use suggests that patients admitted with severely compromised neurological status were not at higher likelihood of receiving LSP than those with less profound deficits. Likewise, ICP instability is thought to be reflective of poor regulation in addition to profound neurological injury, for which reduced environmental stimuli would likely be perceived as beneficial. Despite this, those with ICP instability were not more likely to receive LSP than patients without such instability.

There are several factors that likely contributed to the correlations, or lack thereof, identified. Because use of LSP is not standardized, with the exception of the inclusion of the LSP order promoted within the Severe TBI order set, their use was subject to individual provider preferences, which were no doubt influenced by their education, training, and experience, which varied provider to provider. This would lead to inconsistencies between like patients based on their attending physician. Upon review of the individual charts, LSP orders did not appear to be actively managed. A chart review of 25% of the included sample patients revealed
documentation of environmental restrictions by nursing in only 4 occasions, and LSP was discontinued prior to discharge in only 13 patients. This suggests that providers only considered the ordering of such precaution orders on admission, prior to clinical characteristics such as ICP instability manifesting or being recognized. This restricted timing of precaution ordering would result in the failure to order LSP for patients who would otherwise be deemed appropriate for them at later points in their care.

The findings related to quantifiable stimulation levels within the patient room types were as hypothesized by the researcher. While the general principles of “low stimulation” are well known, the lack of formal protocol around their use allows for variable levels of adherence. Rooms with LSP patients are identified with door signage, but standardized education to patients and their families or specialized care flows are not in place, therefore enforcement of LSP is largely the responsibility of nursing staff. Anecdotally it was noted that not all patients for whom LSP were ordered had the room sign applied, nor were signs routinely removed once the LSP order was discontinued. In these cases, the researcher took steps to apply or remove door signage as appropriate. This suggests that there is a lack of communication between providers and nursing staff related to the order, as well as a lack of importance placed on ensuring its active enforcement. Nursing staff at the research setting identified multiple barriers to providing a low stimulation environment, including poor compliance by patient visitors, poorly coordinated care by ancillary services, and lack of support in enforcing restrictions (e.g., limiting the number of visitors, quiet voices only, etc.). Anecdotally, these factors likely contribute to the limited additional effort put forth by nursing staff to enforce precautions. Additionally, it is likely that usual care provided by nursing staff inherently involves the reduction of extraneous stimulation to promote rest to patients, especially on the neurological ICU, further limiting any meaningful
reduction in environmental stimulation. Upon review of the data, there was noted to be a single set of light measurements per room type that was considered to be an outlier, however given the equal distribution, these measurements were not excluded from analysis. Extraneous factors that may have potentially contributed to environmental stimuli include room/window orientation relative to patient bed position (i.e., if the patient’s head of bed received direct sunlight), the number of alarms and mechanical devices the patient required, the frequency of visitors to the patient room, the amount of time the patient spent outside of the room for additional diagnostics or procedures, and whether or not the patient was orally intubated. Specifically related to frequency of interruptions and decibel levels, COVID-19 visitor restrictions were in place for the entirety of the observational data collection period which allowed only 1 visitor per patient. Of the rooms observed, visitors appeared to have very little impact on the frequency of interruptions, however it is possible that they had a greater impact on dB levels, as frequent conversation with patients not orally intubated would contribute to higher dB averages. This, however, is only hypothesized, as observation of this did not occur simultaneously with the collection of dB measurements. There did not appear to be any concerted efforts to cluster care among staff for patients in LSP, nor did staff behavior while in the room appear to change based on room type. These measurements and subsequent findings, however, do not account for all staff and visitor interactions and potential behavior modifications.

This lack of meaningful reduction in environmental stimuli for patients designated as low stimulation is extremely important to consider when interpreting the results of the final question related to their effectiveness at improving clinical outcomes. While the sample size of rooms in which quantitative measures were taken was small, it was thought to be representative of the enforcement of low stimulation precautions as a whole and is therefore generalized to the sample
population in which retrospective data was retrieved. While these findings do not invalidate the final research question, they do require the reader to accept that there is little clinical premise on which to assume that LSP would be effective at improving outcomes in patients with ABI at the research setting. Unfortunately, it is not known whether or not LSP effectively enforced in a way which reduced environmental stimuli compared with usual care is an efficacious intervention for patients with ABI.

The significant findings related to the determination of the effectiveness of LSP on patient outcomes are likely influenced by a number of factors. While a low admitting GCS score was not associated with a higher likelihood of LSP orders, the patient groups for which LSP order rates were the highest, hemorrhagic injuries and those admitted under the Severe TBI order set, are at higher risk of fluctuation in neurological status and thus GCS score. This tendency likely contributed to the significant association, while the low efficacy of LSP as a whole limited the effect.

There are several factors that may have influenced the significant findings related to discharge disposition and LSP orders, including patient demographics and injury type. If LSP were effective at reducing environmental stimuli, then the higher likelihood of discharge to acute rehab would likely be attributed to a greater level of independence and function reached during the acute hospitalization, which is required for this setting. However, in the context of ineffective LSP, it is more likely that this observed finding is related to the association between diagnoses correlated with LSP orders and patient demographics. Some studies have found that hemorrhagic stroke patients tend to be younger than those with ischemic infarcts, as are patients hospitalized with TBI (Zhang, 2011). This younger demographic would likely have higher baseline function, adequate support systems, and greater prognosis for improvement, all of which are typically
criteria for admission to acute rehabilitation centers. Likewise, it is anecdotally observed that younger patients typically demonstrate greater rehabilitation potential and of the four possible discharge locations, home offers the least intensive rehabilitation opportunities: this actuality likely accounts for the lower than anticipated percentage of patients discharged to home vs. an inpatient rehabilitation setting.

Lastly, the association between ICU LOS and discharge disposition is clinically intuitive, as those requiring the least amount of ICU care would be less medically complex and deconditioned, and therefore most appropriate and most likely to discharge home. As ICU LOS increases, the level of deconditioning increases: this trend is reflected in the progression of discharge setting from acute rehab (3 hours of active therapy required daily), to sub-acute rehab (1-3 hours of therapy daily) to LTACH, which is indicative of ongoing complex medical needs that require active management.

Assumptions, Limitations and Delimitations

Due to these circumstances and the nature of the variables, several assumptions must be made when addressing the research questions at hand. The first of these is that the presence of an order in the EMR for low stimulation precautions is the singular indicator that a patient is in low stimulation precautions. This assumption may be faulty, as anecdotally it is known that patients within the research setting are sometimes informally placed in LSP through the use of a sign indicating such precautions on the door without the placement of a formal order. Likewise, it is assumed that patients with an LSP order in place in the EMR had active steps taken to enforce such an environment, including communication between staff and family and door signage to indicate to staff and visitors that stimulation should be kept to a minimum. This must be assumed
due to the lack of required documentation of such communication in the EMR. Again, this may be a faulty assumption given the lack of protocol regarding LSP within the research setting, a notion that is further supported by the lack of significant differences in stimulation levels found between room types. Additionally, it is assumed that patients who are designated to be in LSP are done so until they discharge from the ICU. This assumption is due to preliminary data that identified that only 3 patients within the first 180 of the sample had their order for low stimulation precautions discontinued prior to their discharge from the hospital. This indicates a lack of active management of the order, as it is unlikely that all patients who required LSP continued to do so until discharge. However, given the lack of documentation regarding LSP interventions provided and communication of such interventions, the actual duration of LSP for each individual patient is unknown.

An additional assumption of this study is that there were no significant practice changes in the implementation of LSP between the timeframe of the retrospective cohort data (2013-2017) and when collection of data related to the quantification of stimulation occurred (2021). While there were no practice changes during this time gap identified in the preliminary design of this study, lack of correspondence between the data does represent a potential weakness regarding validity of findings related to LSP use and outcome correlation. Anecdotally, COVID-19 restrictions or related barriers (e.g., higher staffing ratios) did not appear to impact care staff practice patterns as it related to patient environments, however it is possible that this created an inconsistency between groups. While unlikely, it is possible that the enforcement of LSP in the retrospective cohort was not congruent with cohort from which quantitative measurements were taken. If this were the case, then the conclusions reached by this researcher regarding the final
research question related to the effectiveness of LSP in improving patient outcomes would be faulty.

Primary limitations of the study include the lack of diversity in research setting and population sampled. Practice patterns and lack of guidelines observed at the research setting are not thought to be generalizable to all sites and settings, as lack of guidelines or practice patterns at one site does not imply the same for others. Therefore, the findings related to the prescription of LSP may not be reflective of the hospitals across the nation. Similarly, the way in which LSP are implemented are setting-specific and it is reasonable to assume that implementation likely impacts effectiveness. Findings related to clinical outcomes therefore may not be reflective of outcomes at hospitals with more stringent application and enforcement methods. It is thought, however, that the clinical context that this research was conducted in is not unique to the research setting and similar contexts exist across different medical settings.

Considerations for Future Research

While these findings contribute to the evidence-base for treatment of ABI, there are many unanswered questions. Additional exploration of the impact of environmental stimuli on patients with neurological injury would further inform the premise of LSP in this population, as the majority of research previously conducted on this topic has not been specific to this population. Formalized and enforceable LSP protocols that are effective at reducing environmental stimuli should be developed, and these patient outcomes should be compared with the baseline findings of this study. This would better speak to the efficacy of LSP as a worthwhile intervention in the care of ABI patients, as this research is unable to provide this answer given the lack of significant differences in stimulation levels in LSP and non-LSP rooms. Future exploration of
this topic should include both acute and post-acute settings (i.e., inpatient rehab), as elements of low stimulation precautions are found in literature related to all settings. It should also be inclusive of a greater range of neurological diagnoses, including not just TBI, but stroke, seizure, and injuries stemming from metabolic dysfunction (e.g., encephalopathy).

Conclusion

Study limitations include the sample of practice patterns in a single center, the heterogeneity of the population in terms of diagnoses, a lack of standardized practice for prescribing or implementing LSP. Despite these limitations, there were interesting trends noted for future research and hypothesis generation. The availability of neuropsychology in the ICU increased the likelihood that LSP was ordered. This occurred irrespective of actual evaluation of the patient by the neuropsychology service, suggesting that the presence of neuropsychologists increased awareness regarding the inclusion of LSP as a non-pharmacological treatment modality. The correlation between use of benzodiazepines and LSP is likely due to the generally accepted association between agitation and need for reduced stimulation; however, it is worth noting that agitation may not have been present on admission when LSP were ordered. The association between the presence of the severe TBI order set and LSP order is attributed to the way in which the two orders are linked in the electronic medical record at the research setting, a connection likely supported by the close association between TBI and LSP in the literature.

Overall, it is apparent that the absence of guidelines or policy related to the prescription of LSP, either in the literature or at the facility level, lead to the inconsistent assignment of LSP at the research setting. And while it must be assumed that the prescription of LSP devoid of formal policy was guided by provider clinical judgement, the overall picture is that patient
selection for LSP is largely arbitrary. The lack of differences identified in the matching process and t-tests between the low stim and non-low stim groups also speaks both to how the criteria for LSP application is ill-defined. Quantitative measurements revealed no differences in LSP vs non-LSP rooms. These findings and lack of guidelines, both at the research setting and in the literature, suggest that it is unlikely that LSP were enforced in a routine and systematic manner.

The findings related to the clinical outcomes of the LSP and non-LSP groups suggest that there is no significant clinical benefit to ordering LSP in their current state at the research setting. Both total and ICU LOS were unaffected by use of LSP, and variance in discharge disposition was minimal and inconsistent. The lack of meaningful change in GCS between the two groups also suggests that LSP were not effective at facilitating greater neurological recovery. However, similar to the application of LSP, the implementation and enforcement of low stimulation environments was not well-defined. The research setting lacked a formalized protocol for the implementation and enforcement of LSP, resulting in inconsistent experiences for the patient. While it was expected that patients with LSP ordered had a sign placed on their door outlining the precautions (“quiet” voices, limited number of visitors, no TV or music), anecdotally this did not occur consistently, nor was there any formalized support or method to enforce the precautions. Previous studies provide a clear link between environment and physiologic response, however the clinical impact of this link in terms of functional outcomes should be fully investigated in the context of a more structured LSP protocol in which application and implementation is reliable and consistent. This would further inform the efficacy of LSP and provide supporting evidence for their inclusion, or exclusion, from clinical practice guidelines related to ABI.
In summation, the findings of this study suggest that LSP in their current state at the research setting are not prescribed systematically, that they are ineffective at reducing environmental stimuli, and that they do not offer clinical value in terms of improved patient outcomes to patients with ABI. While these findings cannot be generalized to low stimulation environments as a whole, this experience is not thought to be unique to the hospital in which the research was conducted. Haphazard application and implementation are thought to contribute to the lack of effectiveness, which is reflective of the lack of guidelines around low stimulation environments found in the literature. While the argument for low stimulation environments as an intervention in ABI is clinically sound, the functional impact of them is not yet proven to be significant. Previous studies provide a clear link between environment and physiologic response, however the clinical significance of this link in terms of improved function and recovery should be fully investigated in the context of a more structured LSP protocol in which application and implementation is reliable and consistent. These findings should be incorporated into the development of future clinical pathways related to ABI care to promote evidence-based practice, should they be deemed appropriate and of clinical value.

Given the burden of ABI worldwide, further investigation into the impact of stimulation on neurological recovery is a worthwhile and judicious use of effort and resources. While implementation of specialized environments does require collaboration and effort, if proven effective, they would provide a cost-effective, non-pharmacological method of promoting recovery in ABI survivors.
REFERENCES


Guyatt GH. Evidence-based medicine. *ACP J Club*. 1991;114(suppl 2): A-16


https://www.ncbi.nlm.nih.gov/books/NBK390308/


APPENDIX A
Human Subjects Institutional Review Board Letter of Approval

WESTERN MICHIGAN UNIVERSITY

Date: March 22, 2021
To: Rob Lyerla, Principal Investigator
    Alexis Kurek, Student Investigator for dissertation
From: Amy Naugle, Ph.D., Chair

Re: Approval not needed for IRB Project Number 21-03-20

This letter will serve as confirmation that your project titled “Characterization, Implementation, and Impact of Low Stimulation Environments in Acute Neurological Injury” has been reviewed by the Western Michigan University Institutional Review Board (IRB). Based on that review, the IRB has determined that approval is not required for you to conduct this project because you are not collecting personal identifiable (private) information about an individual.

Thank you for your concerns about protecting the rights and welfare of human subjects.

A copy of your protocol and a copy of this letter will be maintained in the WMU IRB files.