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## Traumatic Brain Injury Treatment Internationally

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Running head: TRAUMATIC BRAIN INJURY INTERNATIONALLY

Traumatic Brain Injury Treatment Internationally:  
Surveying Speech Language Pathologist Around the World

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Program in Communication Disorders

Thesis

April 24, 2014

### Abstract

The purpose of this study was to investigate the prevalence and treatment priorities for Traumatic Brain Injury (TBI) internationally. The materials for this study included a questionnaire developed from literature and that was electronically distributed. Ten individuals from four countries that stretch across three continents completed the questionnaire. Results indicated According to the SLP's that answered the questionnaire, the minimum education level for a practicing SLP is a master's and some have obtained a Ph.D. The majority of SLP's internationally, have treated 1-5 TBI's in the last twelve months. According to the survey, SLP's around the world align closer to the ASHA standards in treatment priorities and procedures rather than ICF standards. The challenges an SLP will face in their service provision includes a patient's: lack of affordability and training, scheduling, transportation to therapy, education of family members/caregivers and an unwillingness to use particular devices.

## Traumatic Brain Injury Treatment Internationally:

### Surveying Speech Language Pathologist around the World

Speech-language pathology (SLP) is a discipline that works extensively with individuals who suffer a TBI. According to the American Speech-Language-Hearing Association (<http://www.asha.org>), speech pathologist: evaluate and diagnose speech, language, cognitive-communication and swallowing disorders. Children with traumatic brain injury, also known, as TBI, regardless of the severity of the injury, often face difficulties when living in home, school or community. A speech language pathologist working with TBI patients is responsible for assessing all aspects of communication, swallowing, treatment plans and programming, and determining individual's needs for functional recovery.

TBI is a worldwide condition that has long-term consequences in the lives of individuals. Due to the fact that speech-language pathology is a new or limited profession in many countries, some individuals with TBI receive limited services. According to the World Health Organization, TBI is a major cause of death and disability worldwide that will surpass many diseases as the major leading cause of disability or death by the year 2020. (Hyder, 2007). Levin (2004) points out differences in socio-economic status, diverse socio-cultural influences, and widely different education systems and educational attainment makes the management of TBI more difficult in some countries than in others. She points out that underdeveloped countries may have fewer services, less understanding of the condition, and fewer professionals to provide treatment. These are a few of the numerous factors that contribute to the high rates of TBI and lack of medical care in underdeveloped counties; however, even in well developed countries there can be differences in care and commitment to working with children who experience TBI. With this in mind, the purpose of this study was to determine the prevalence of TBI treatment around the world and examine the scope of SLP practice associated with this injury.

## Review of Literature

### What is Traumatic Brain Injury

According to the National Institute of Neurological Disorders and Stroke (<http://www.ninds.nih.gov/disorders/tbi/tbi.htm>), traumatic brain injury is a form of acquired brain injury that occurs when a sudden trauma causes damage to the brain. Both adults and children can suffer from TBI. According to the American Speech and Language Hearing Association, there are two types of TBI: penetrating injuries and closed

head injuries. Penetrating injuries occur when a foreign object enters the brain and causes damage to specific brain parts. Closed head injuries are the result of a blow to the head, for example a car accident when the head strikes the dashboard or windshield. These injuries cause two types of damage: Primary and Secondary brain damage (<http://www.asha.org>). Symptoms of a TBI can be mild, moderate or severe depending on the extent of damage to the brain. A person with a mild TBI may remain conscious or experience a loss of consciousness for a few seconds or minutes. Other symptoms may include headache, confusion, lightheadedness, dizziness, blurred vision or tired eyes, ringing of the ears, bad taste in the mouth, fatigue or lethargy, a change in sleep patterns, behaviors or mood changes, trouble with memory, concentration, attention, or thinking. Someone with a moderate to severe TBI may show these same symptoms, but may also have a headache that is worsening, repeated vomiting, nausea, convulsions or seizures, an inability to awaken from sleep, dilation to one or both pupils of the eyes, slurred speech, weakness or numbness in the extremities, loss of coordination, increased confusion, restlessness, or agitation (Hancock, 2010).

### **Functional Effects of a Traumatic Brain Injury**

After a brain injury, people usually experience cognitive and communication problems that significantly impair their ability to live independently. This can vary depending on how widespread the brain injury is and the location of the injury. Survivors of a brain injury may have a difficult time finding the words they need to express an idea or explain something. They may have trouble understanding both written and spoken messages, similar to trying to comprehend a foreign language. It may also become quite an effort to spell, write and read. Social communication can become very frustrating and unsuccessful as a result of a TBI. Difficulty while taking turns in conversation, maintaining a topic of conversation, using an appropriate tone of voice, responding to facial expressions and keeping up with a conversation may take place. A TBI could also affect a person's cognitive skills. Depending on the severity and location of the injury, problems may include trouble concentrating, processing information, recent memory recall, and setting goals and completing tasks, organization, solving problems and reacting to situations impulsively.

### **International Prevalence**

Traumatic brain injury in children presents challenges at the local, national and international levels (Savage, 2005). According to the World Health Organization (Hyder, 2007), TBI will surpass many diseases as the major leading cause of disability or death by the year 2020. TBI is a burden that has manifested itself throughout

the world and is most prevalent in low and middle-income countries due to a higher occurrence of risk factors. The issue with this is the lack of prepared health systems to address the associated health outcomes in these countries. Developing countries face the major problems of prevention, pre-hospital care and rehabilitation in their rapidly changing environments to prevent traumatic brain injuries from happening.

### **International Risk Factors**

The mortality rate for TBI is around 10 in Scandinavia, 20 in India, 30 in the United States, 38 in China, 81 in South Africa and 120 in Columbia (Tagliaferri, 2006). According to the World Health Organization, traumatic brain injury is the leading cause of disability in people less than 40 years of age. The three main causes of TBI are: road traffic accidents, falls, and violence. The relative occurrence of these varies from region to region as the exposure to certain hazards varies. There are about 3,000 people that die and 30,000 people that are seriously injured every day on the world's roads. Most of the victims are from the low to middle income countries with pedestrians, cyclist, and bus passengers usually being the ones at risk. According to WHO, traffic fatality rates among children are six times greater in developing countries than in high-income countries. While the number of road traffic accidents has steadily decreased in industrialized countries over the last two decades, for example, in three out of the four reported Nordic countries, the mortality rate decreased considerably between 1987 and 2000 due to the decrease in road traffic accidents, it has increased in undeveloped countries. Falls are the second most common cause of TBI, most frequently seen in Australia, India and northern Europe (Gururaj, 2002). In India, TBI is the leading cause of morbidity, mortality, disability and socioeconomic losses. Road traffic injuries are the leading cause of TBI in India at nearly 60% and falls are second at 20-25% (Gururaj, 2002).

***South African Risk Factors.*** South Africa's huge disparities in socio-economic status, diverse socio-cultural influences, and widely differing educational systems and educational attainment which characterize the country's population cause the management of TBI to be different than that of developed countries (Levin, 2004). The main cause of TBI can be attributed to the high rates of violence, and high rates of motor vehicle accidents. Additionally, insurance agencies are unavailable to most of the population and usually insufficient in most cases. The access to medical care and rehabilitation is unavailable to most of the population, even in the wealthiest areas of South Africa. The number of penetrating head injuries due to gunshots is increasing in certain areas of the country and children are often victims to adult-to-adult violence, including gang violence, taxi, and car hijacking. The reported child-rape patterns in South Africa are astounding and although this may not directly cause TBI, it can be

associated with it. South Africa has one of the highest motor vehicle accident rates in the world which can be directly associated with the number of TBI victims. The prevalence of HIV/AIDS in South Africa is one of the highest in the world. According to speech pathologist in the field, during 2002-2003 approximately 40-60% of their pediatric caseloads that had neurologic communication disorders including cerebral palsy and head injuries were also HIV positive (Levin, 2004). There is little literature on this subject, but it would seem that children who are HIV positive with a TBI show more severe symptoms of TBI and a more marked degeneration than children that test HIV negative. The socio-economic status of the family dictates the type of care the child is able to receive after a TBI. In South Africa, children from even the wealthiest homes are not afforded rehabilitation that is comparable to international practices and standards.

***European Studies on TBI.*** Tagliaferri's *Epidemiological Factors from European Studies* on TBI largely published in the last 20 years is reviewed in a report that used 23 found articles in published literature on the epidemiology of TBI in Europe (Tagliaferri, 2006). The Medline was searched and research was done on the incidence, severity, external cause, gender, mortality, prevalence, cost and related factors. The countries included Denmark, Sweden, Finland, Portugal, Germany, and regions within Norway, Sweden, Italy, Switzerland, Spain, Denmark, Ireland, The U.K. and France. A collective fatal TBI incidence rate of 235 per 100,000 was derived. An incidence is defined as a new diagnosis of TBI in a specified period of time (Morgan, 2010). This rate measures the risk of TBI in the population of interest. Usually the incidence rate will include hospitalized patients plus deaths identified from local authorities. Prevalence is defined epidemiologically as the measure of the total amount of TBI at a point in time or period interval in a population of a known size (Morgan, 2010). This includes those with TBI who have subsequent impairment, disability, handicap, or complaint plus the newly diagnosed cases at the defined time. A prevalence rate was not recorded from any European country. The recorded mortality rate was about 15 per 100,000 and case fatality rate of about 11 per 100 (Tagliaferri, 2006). The severity rate that was recorded was about 22:1.5:1 for mild verse moderate verse severe, accordingly. The outcome and disability findings were mixed and inconsistent. Due to the critical differences in methods across the European studies that have been done, it is recommended that the development of research guidelines to standardize definitions, case findings, and data reporting parameters to help establish a more precise utility of the epidemiology of TBI in Europe (Tagliaferri, 2006). Thirteen of the twenty-three studies gave data on external cause of mechanism of injury. Most reports show motor vehicle related causes as the most common leading to a TBI. The second most common leading injury is

falls. Outcome data shows that a person who survives a TBI has some consequences but no the reports are consistent in terms of severity distribution of the original study group, length of follow-up or types of outcomes identified. Any information on cost for treatment is quite limited.

### **Patient Outcomes Following TBI**

Patient outcomes are increasingly being used to determine effectiveness of treatment for individuals who have experienced a TBI. One study completed data on 8927 patients from 46 countries in efforts to explore whether outcomes 6 months after TBI differed between high-income countries and low and middle-income countries also known as LAMIC. The results showed that just under half of the patients experienced a good recovery, one-third moderate or severe disability, and one-quarter died within 6 months of their injury. Patients in LAMIC were more likely to die in severe TBI, but less likely to be disabled following mild to moderate TBI. The study concluded that lower death rates following severe TBI in high-income countries might be due to differences in medical care, which may result in a higher proportion of patients surviving with a disability. The lower levels of disability after mild and moderate TBI in LAMIC may be exemplified by socio-cultural factors (De Silva, 2008).

### **The Role of a Speech Language Pathologist**

A speech language pathologist plays a vital role in the diagnosis and treatment of a traumatic brain injury. According to ASHA, an SLP completes a formal evaluation of speech and language skills, an oral motor evaluation, and an understanding and use of grammar and vocabulary, reading and writing are evaluated as well. An SLP will also evaluate the social communication skills by being asked to interpret certain stories or jokes. Additionally, an SLP will assess a person's cognitive-communication skills for example the person may be asked if they are aware of their surroundings, their name, the date and a solution to a given problem. An SLP will also evaluate swallowing if problems are observed and may make recommendations for management and treatment. If necessary, an SLP may look into the benefit of a communication aid or device for the patient. The overall goal of an SLP working with a TBI patient is to create a treatment plan starting in the early stages immediately after the injury and going through as long as the patient needs rehabilitation (<http://www.asha.org>).

### **International Classification of Functioning, Health and Disability**

While TBI is prevalent around the world, the treatment and international communication on this topic has been recently enhanced given credit to one specific classification system. In order to assess the level of treatment for TBI internationally, a common framework and language of communication must be used. In May of 2001, the



World Health Organization approved the International Classification of Functioning, Disabilities and Health, more commonly known as ICF. ICF is a universal classification of disability and health for use in health and health related sectors. With ICF, data can now be compared across countries, health care disciplines, services and time. Before ICF, disability began where health ended; once you were disabled you were in a different category. ICF is named as it is because of its stress on health and functioning, not on disability. WHO's goal was to create a versatile tool that measures a person's functioning in society, no matter what the reason for impairment. ICF is a classification of health and health domains that can help to explain: changes in body function and structure, what a person can do in a standard environment- level of capacity, and what a person can do in their usual environment - level of performance (<http://www.cms.gov>[PDF]). For this reason, ICF is useful for people with all forms of disabilities; not only to identify their health care and rehabilitative needs, but also to identify and measure the effect of the physical and social environment on the disadvantages that they experience in their lives.

### **The ICF Biopsychosocial Model**

ICF is made up of two parts, each with two components that can be illustrated through the biopsychosocial model, an integration of medical and social. The first part is Functioning and Disability with two subgroups, the first being body function and structures and the second being activities and participation. The second part is Contextual Factors with two subgroups; environmental factors and personal factors (Geneva, 2002). The common terminology used in ICF allows for more effective communication among medical professionals and across cultures, age groups, genders and heterogeneous populations.

### **Summary and Questions of the Study**

From this review of literature, it can be seen that TBI is a worldwide medical condition that impacts both children and adults. Treatment for the cognitive-linguistic problems associated with the condition is provided by SLP's. However, little is known about the scope of practice for SLP's around the world that are expected to treat these individuals. The purpose of the study is to determine the prevalence of TBI treatment around the world and examine the scope of associated SLP practices. The specific questions of this study are as follows:

1. What are the education standards for SLP's in various countries?
2. How frequently do they treat individuals with TBI?
3. Do they use the ICF to guide diagnosis and treatment goals?
4. What challenges do SLP's face in their service provision to individuals with TBI?

## **Methodology**

### **Participants**

Sixty SLP's from around the world were sought as participants in this study. All were to be recognized as professionals in their country. There were no controls for length of experience, level of degree, or place of employment.

### **Materials**

A questionnaire that could be distributed electronically was used gather data for this study. The questionnaire included demographic data such as the education and experience of the SLP respondent, how long they have been working, where they have worked and the countries they have worked in. The questionnaire also included how many TBI's have they seen based on referral; if ICF is used as a basis for treatment; and what types of treatment and procedures they used with TBI patients.

### **Procedures**

The survey was distributed electronically to global and regional professional speech language organizations as well as individual therapists around the world through social media. Specifically, the survey was accessible through a link posted in an email or on social media sites. The survey took approximately ten minutes for a speech language pathologist to complete.

### **Analysis**

Description of the participants was used to frame the analysis. Their responses to the different questionnaire items were aligned with the specific questions of the study. Descriptive results sought to compare the responses of SLP's in various LAMIC as well as geographic regions.

## **Results**

### **Demographics**

Ten individuals from four countries that stretch across three continents completed the questionnaire. The individuals that responded to the questionnaires currently practice in: Sweden (1), Sri Lanka (3), Cyprus (3), Trinidad and Tobago (1) and the United States (2). All ten participants stated their professional title as a speech language pathologist or speech language therapist. The following ten participants have practiced speech pathology in either: Sweden, Sri Lanka, Greece, Cyprus, United Kingdom, Bulgaria, St. Lucia, America, Trinidad and Tobago,

or Uganda. In regards to their current place of employment, out of the nine that responded, four answered a hospital setting, one answered a clinical setting and four replied “other”. Additionally, when asked to check all settings they had worked in as an SLP, four answered school, five answered hospital, six responded clinic and three responded with “other”. When asked how many years of experience they had in the profession, five responded with more than ten years, three responded with six to ten years and one responded with one to five years of experience. (see Tables 1 and 2)

Table 1

*Years of experience in the field and past and current work settings*

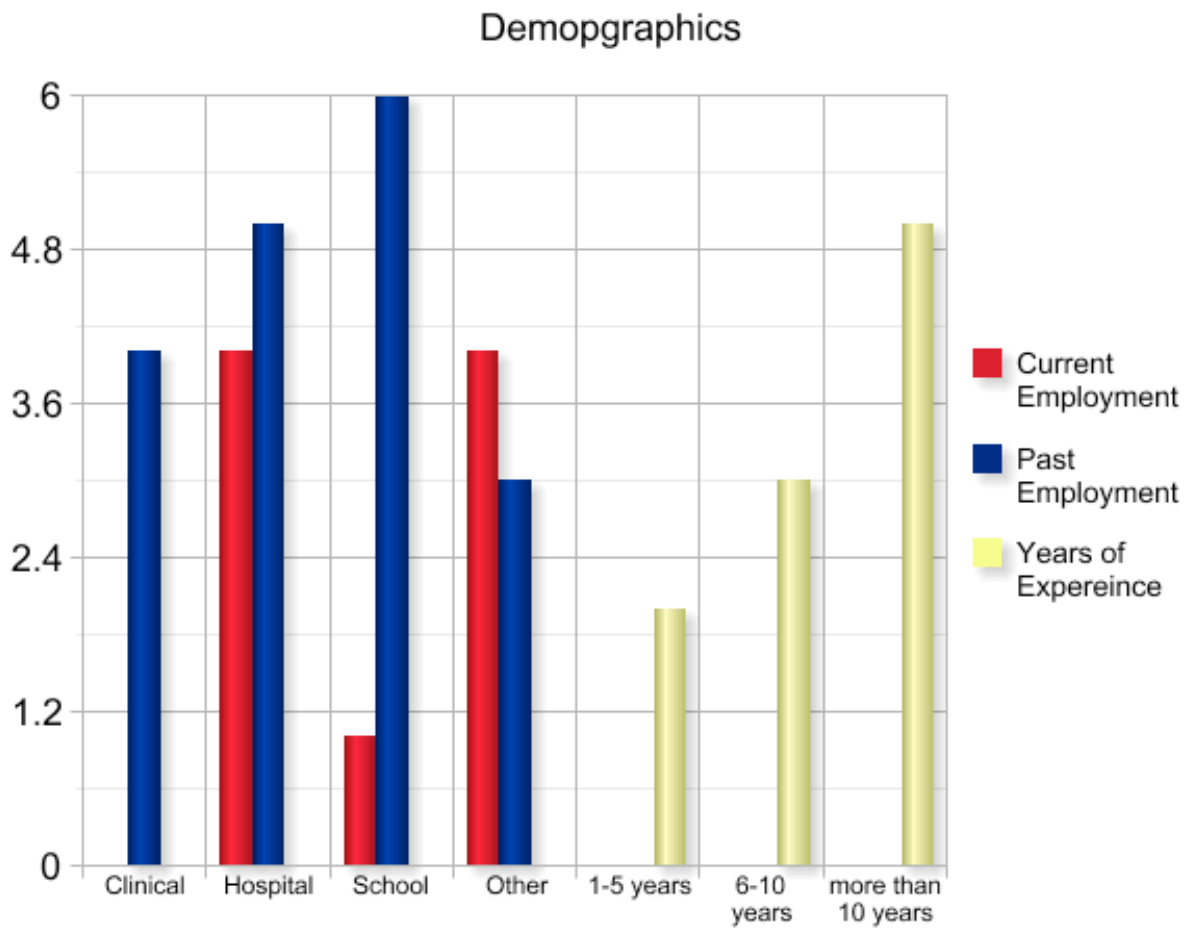
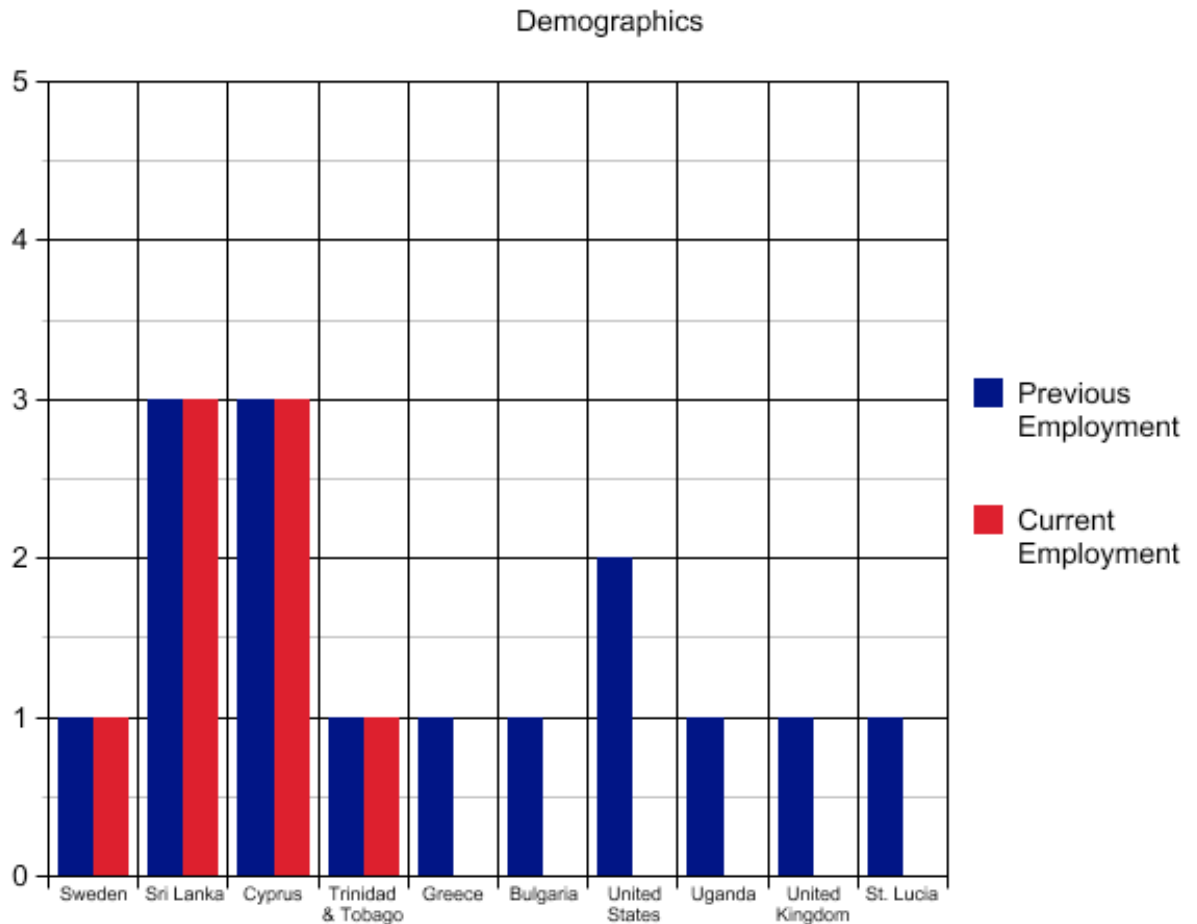


Table 2

*Location of Previous and Current Employment*



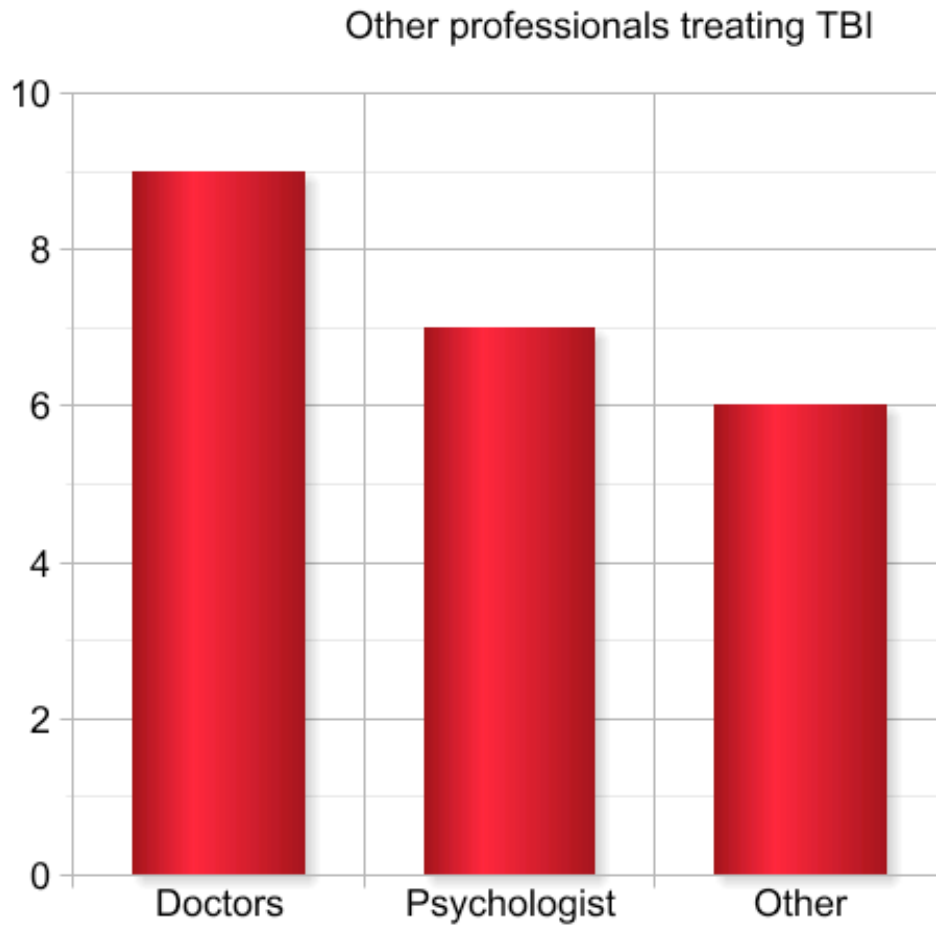
### Question One

The first question of this study asked what the educational standards for SLP's are in the various countries of practice. Items three and sixteen on the questionnaire were used to answer this question that asked participants to identify the name of their degree, level of degree and the country to which they received their degree. Out of the seven that answered what level of degree they received; three earned a B.S. in speech pathology, two earned a M.S. in speech pathology, one earned an M.A. in speech pathology and one earned a Ph. D. in speech pathology.

Additional insight about professional recognition came from a related item on the questionnaire that asked what other professionals treat patients with TBIs. Professional services associated with TBI, in addition to SLP, were doctors and psychologists. It should be noted that close behind psychologists was an undifferentiated category, others that included occupational therapist, physical therapist, social workers and neurologist. These results do suggest that SLPs are recognized as important service providers who are trained to work alongside other professional to service patients with TBI. (see Table 3)

Table 3

*Professionals Who Treat TBI*



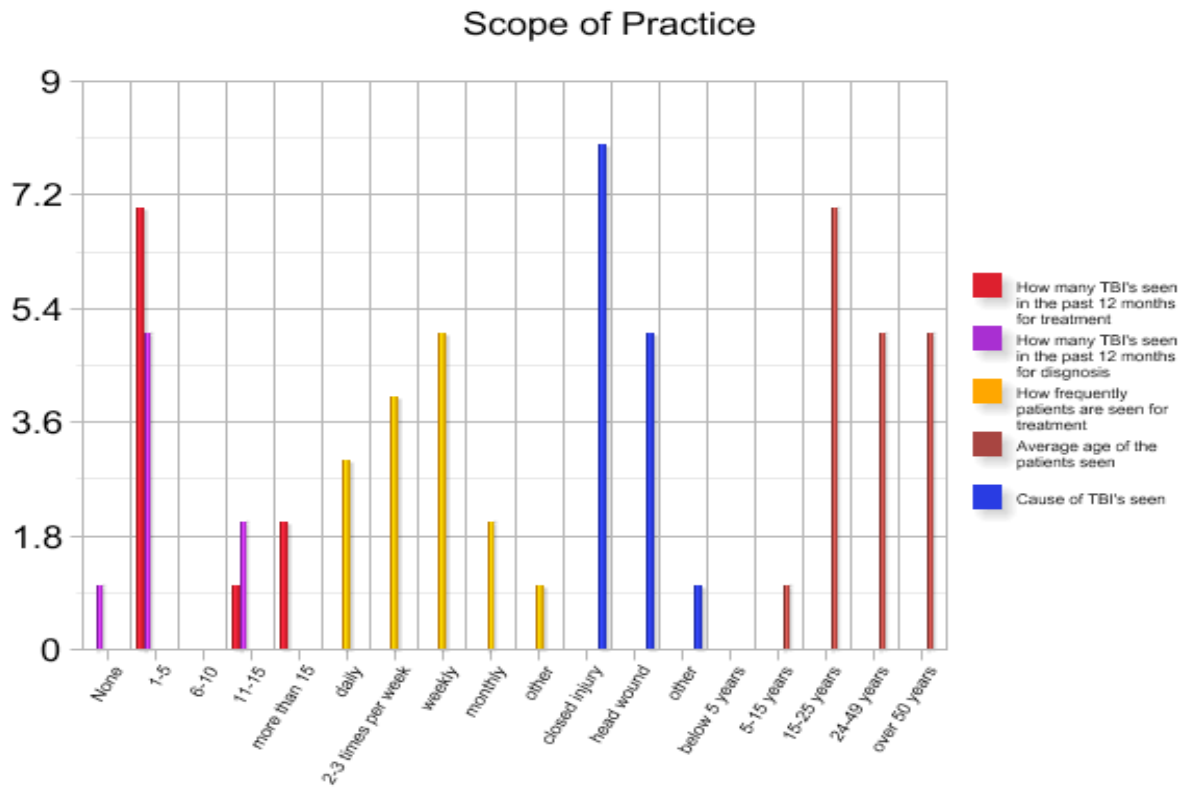
**Question Two**

The second question of this study asked how frequently the SLP’s treated TBI. Items on the questionnaire that asked about the number of patients seen, their ages, and the frequency and duration of treatment were used to answer this question. Seven out of the ten participants answered that they had seen 1-5 TBI’s for treatment. One SLP had seen 11-15 for treatment and two had seen more than 15 TBI’s over the last twelve months for treatment. Furthermore, of the eight SLP’s that responded regarding seeing patients for diagnosis, one had seen none, five had seen 1-5, and two had seen 11-15. The ages of the patients seen ranged from 5-15 years old (1), 15-25 years (7), 26-49 years (5) and above 50 (5). Frequency of treatment ranged covered a range from daily (3) to 2-3 times per week (4) to weekly (5) to monthly (2). One individual responded “other” suggesting a longer period of time.

In addition to the number and frequency of TBI's seen over the past twelve months, the questionnaire investigated how they receive patients and the causes of the TBI. Regarding how the SLP's receive patients, 70% answered doctoral referrals, 40% community agencies, 60% personal contact and 20% answered other. When asked the cause of the TBI's seen, 8 out of the 10 respondents had seen closed head injuries, 5 out of 10 had seen head wounds and 1 SLP responded with other. (see Table 4)

Table 4

*Assessment and Treatment by Age and Causation*



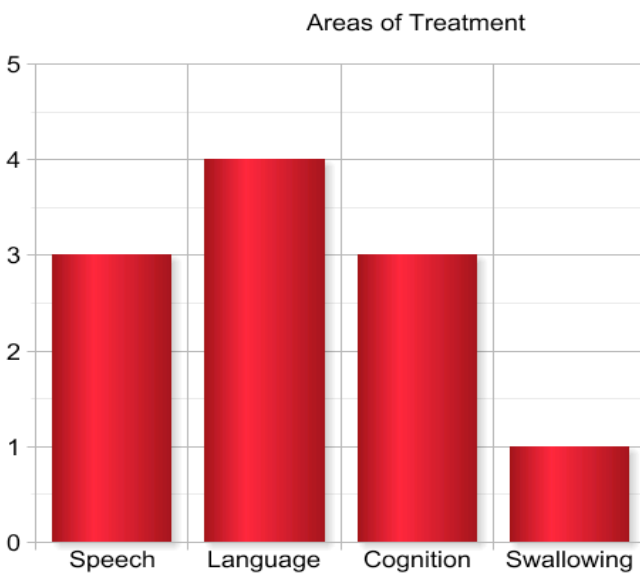
**Question Three**

The third question in the study asked whether or not the SLP's use ICF to guide diagnosis and treatment. Items fourteen and seventeen in the survey address this question. The first question asked what types of treatments and procedures the SLP had used for TBI, with the option to list their response. Out of the seven SLP's that

responded to this question, the areas of treatment covered fell into four major categories: speech, language, cognition and swallowing. A wide range of procedures was mentioned including: direct therapy, modeling, motor exercises, worksheets, word recall, word-finding activities and neuro feedback. In regards to the question regarding treatment priorities for TBI, each SLP responded differently. A few of the priorities included: physically stable, mobility, functionality and best possible communication whether verbal or non-verbal. (see Table 5)

Table 5

*Areas of Treatment*



**Question Four**

The last question of the study asked what challenges an SLP faces in their service provision to individuals with TBI. Of the ten SLP’s that took the survey, seven responded to this open ended question. One SLP, who practices in Sri Lanka, responded by saying, “the therapy is not in a medical setting, therefore getting the multidisciplinary team is a task.” Furthermore, this SLP said, “clients live away from the clinic which makes regular visits impossible.” A second SLP respondent from Sri Lanka mentioned, “the lack of specific/specialist training opportunities for learning on how to provide speech language therapy services to client with TBI” as a major difficulty. Additionally, this SLP stated that “due to the large client loads, in-ward care period is limited and clients from far off areas are sent home when medically fit, without being kept for rehabilitation.” A third difficulty mentioned by this SLP included the lack of therapy recourses and guidance from trained professionals is Sri Lanka.

An SLP respondent from Trinidad and Tobago said, “scheduling and the affordability of treatment because there are no public services in Trinidad” was their major difficulty. Lastly, an SLP from Sweden responded by addressing the difficulty of “a patient not willing to use augmentative communication since he has not accepted that he will not be able to speak again.” These comments suggest a wide range of difficulties are encountered by SLPs as they attempt to provide services to those with TBI.

### **Discussion**

The purpose of this study was to determine the prevalence of TBI treatment internationally and investigate the scope of associated SLP practices. Several points stand out. These include: the team approach of an SLP’s practice internationally, the broad range of their scope of practice, the variety of professionals that deal with the treatment for TBI, and the variety of difficulties an SLP faces.

The first point of interest was finding that globally, SLP’s work alongside other professionals in the treatment of TBI. According to ASHA, a speech language pathologist working with TBI patients is responsible for assessing all aspects of communication, swallowing, treatment plans and programming, and determining individual’s needs for functional recovery rehabilitation (<http://www.asha.org>). Although it was known that an SLP would be involved in the treatment of a TBI, it was found that internationally, several other professions contribute to therapy and even work with SLP’s in a team approach. According to the questionnaire, doctors, psychologist, occupational therapist, physical therapist, social workers and neurologist all play a role in treating TBI patients.

Furthermore, the questionnaire revealed that similar to the United States, SLP’s around the world cover language, cognition and speech production in therapy sessions. As seen in the literature, the international standard for treatment and procedures aligned closer to ASHA’s standards than the ICF standards. According to ASHA, the overall goal of an SLP working with a TBI patient is to create a treatment plan starting in the early stages immediately after the injury and going through as long as the patient needs (<http://www.asha.org>). On the other hand, ICF is a classification of health and health domains that can help to explain: changes in body function and structure, what a person can do in a standard environment- level of capacity, and what a person can do in their usual environment -level of performance ([http://www.cms.gov\[PDF\]](http://www.cms.gov[PDF])). With that in mind, the questionnaire revealed that SLP’s treatment priorities and procedures internationally closely aligned with ASHA’s standards.

Lastly, the variety of difficulties an SLP faces during treatment was an unexpected outcome of the study. The lack of affordability for therapy could be anticipated due to the known literature in which, the socio-economic



status of the family dictates the type of care the child is able to receive after a TBI. In South Africa, children from even the wealthiest homes are not afforded rehabilitation that is comparable to international practices and standards (Levin, 2004). The lack of training could be considered another expected outcome of difficulties faced by SLP's internationally. Unexpected responses included: scheduling, transportation to therapy, education of family members/caregivers and an unwillingness to use particular devices.

### **Limitations**

There are several limitations that impact the usefulness of the results of this study. One limitation in this study was a result of technological issues with distributing the online questionnaire. Due to the fact that the questionnaire was online, accessible control to ensure the participants understood the instructions and fully completed the survey was limited. With that in mind, out of the 129 surveys distributed: 34 were opened, 11 were started, and 10 were completed. Furthermore, after the survey had been distributed once, it was redistributed in an effort to fix a formatting glitch. Sending out the survey the second time to the same group may have limited the number of responses. In addition to technological issues, the lack of countries represented is a limitation. Out of the ten completed questionnaires, six countries are represented. Again, the fact that the questionnaire was online may have restricted SLP's in various countries from having the ability to receive the email or access a computer to respond. With that in mind, the results were limited to a smaller amount of participants and therefore a smaller sample of SLP's around the world.

### **Future Research**

In the future, the survey would not only be distributed to countries around the world, but to the United States and provinces as well. Therefore, information regarding worldwide treatment along with local and national SLP services and education levels would be collected. With this in mind, high and low TBI incidences worldwide could be compared to the United States. Another enhancement to the study would include a new way to distribute the surveys instead of electronically. Additionally, further research would be conducted to compare the amount of what SLP's do internationally is through ICF because of the importance in treatment worldwide.

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## Appendix A

## Base Survey Prior to Electronic Formatting

## TBI Survey:

1. Do you agree with this consent form?
2. In what country do you currently practice?
3. Indicate the degrees and institutions where you received your education.
4. What is your professional title?
5. How many years of experience in this profession do you have?
6. What countries have you worked in as an SLP?
7. What settings have you worked in as an SLP?
8. Where are you currently employed?
9. How do you receive patients?
10. How many TBI's have you seen over the last 12 months?
11. What were the ages of the patients with a TBI?
12. What was the cause of the TBI?
13. How frequently did you see the patient for treatment?
14. What types of treatments and procedures have you used for a TBI?
15. What difficulties do you have in treatment procedures?
16. What other kind of professionals treat patients with TBI in your country?
17. What are the treatment priorities for TBI in your country/professional community?

## Appendix B

## IRB Approval

October 30, 2013

## MEMORANDUM

TO: Erika Davee  
Fran Hagstrom

FROM: Ro Windwalker  
IRB Coordinator

RE: New Protocol Approval

IRB Protocol #: 13-10-200

Protocol Title: Traumatic Brain Injury Internationally: Roles and Responsibilities of Speech-Language Pathologists

Review Type: 1 EXEMPT 0 EXPEDITED 0 FULL IRB

Approved Project Period: Start Date: 10/30/2013 Expiration Date: 10/29/2014

Your protocol has been approved by the IRB. Protocols are approved for a maximum period of one year. If you wish to continue the project past the approved project period (see above), you must submit a request, using the form Continuing Review for IRB Approved Projects, prior to the expiration date. This form is available from the IRB Coordinator or on the Research Compliance website (<http://vpred.uark.edu/210.php>). As a courtesy, you will be sent a reminder two months in advance of that date. However, failure to receive a reminder does not negate your obligation to make the request in sufficient time for review and approval. Federal regulations prohibit retroactive approval of continuation. Failure to receive approval to continue the project prior to the expiration date will result in Termination of the protocol approval. The IRB Coordinator can give you guidance on submission times.

**This protocol has been approved for 200 participants.** If you wish to make any modifications in the approved protocol, including enrolling more than this number, you must seek approval prior to implementing those changes. All modifications should be requested in writing (email is acceptable) and must provide sufficient detail to assess the impact of the change.

If you have questions or need any assistance from the IRB, please contact me at 210 Administration Building, 5-2208, or [irb@uark.edu](mailto:irb@uark.edu).