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Reliability and validity of the Clinical Neurologic Assessment (CNA) Tool in children with head trauma

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The University of Arizona, 1990

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RELIABILITY AND VALIDITY OF THE CLINICAL NEUROLOGIC ASSESSMENT (CNA) TOOL IN CHILDREN WITH HEAD TRAUMA

by

Stephanie Marie Gillespie

A Thesis Submitted to the Faculty of the

COLLEGE OF NURSING

In Partial Fulfillment of the Requirements
For the Degree of

MASTER OF SCIENCE

In the Graduate College

THE UNIVERSITY OF ARIZONA

STATEMENT BY AUTHOR

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Leanna Crosby
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12/10/90

Date

DEDICATION

This thesis is dedicated to my mother in appreciation for her love, support, and encouragement during my educational and professional endeavors.

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TABLE OF CONTENTS

TABLE OF CONTENTS (Continued)

TABLE OF CONTENTS (Continued)

LIST OF TABLES

ABSTRACT

Head trauma remains a major health care problem in the United States. Individuals who have sustained head trauma require accurate and precise assessments of their neurologic status. The early detection of subtle changes in the neurologic status enables the health care team to provide prompt treatment which may decrease the morbidity and mortality associated with head trauma.

The Clinical Neurologic Assessment (CNA) Tool is a 21 item instrument designed to assess subtle neurologic changes that often accompany head trauma. Reliability and validity of the CNA has been previously assessed in adults who have sustained head trauma. This descriptive study was designed to test the reliability and validity of the CNA in children with head trauma.

Interrater reliability of the CNA was assessed by determining Cohen's Kappa values for each item. Kappa values ranged from .74 to 1.00. Internal consistency of the CNA was assessed using Cronbach's alpha. The total CNA alpha was estimated to be .98 with subscale alphas ranging from .89 to .96.

Concurrent and construct validity of the CNA were also assessed. Concurrent validity was estimated by determining Pearson's Product-Moment Correlation Coefficients for the

CNA and the Glasgow Coma Scale (GCS) ($r = .93$, $p = .001$). Pearson's correlation coefficients were also estimated based on severity of head trauma ($r = .57$ to $.74$, $p \leq .017$) and the age of the subject ($r = .89$ to $.99$, $p \leq .001$).

Construct validity was assessed using exploratory factor analysis which demonstrated a three factor solution. These factors reflected the following: a general overview of the level of consciousness, overall body and extremity position and movement, and muscle tone of the extremities.

CHAPTER 1

INTRODUCTION

Accidental injuries are the leading cause of childhood morbidity and mortality in the United States (National Safety Council, 1988). It has been estimated that between one million (Eiben et al, 1984) and five million (Raphaely et al, 1980) children sustain head trauma each year. Of those children, approximately 200,000 are hospitalized and one in 10,000 will die (Annegers, 1983).

The incidence of head trauma increases with the age of the child. Frankowski, Annegers, & Whitman (1985) estimated the incidence among 0 - 4 year olds to be 150 per 100,000 versus 550 per 100,000 among the 15 - 19 year olds. Males are twice as likely to sustain head trauma as females (Klauber, Barrett-Connor, Marshall, & Bowers, 1981; Kraus, 1980; Kraus et al, 1984). These statistics illustrate that head trauma is a major health care problem in the United States.

Monitoring Cerebrovascular Status following Head Trauma

A critical aspect in the care of a head traumatized patient is monitoring their cerebrovascular status. Monitoring is essential not only at the time of injury but also during the acute and recovery phases as well.

Clinical decisions, regarding treatment, are frequently based on the observed symptoms gained through cerebrovascular monitoring.

A variety of clinical instruments are available to assess and monitor the neurological status of head trauma patients following injury. The Glasgow Coma Scale (GCS) is the most frequently used instrument and one which was developed specifically to assess level of consciousness (Jennett & Teasdale, 1981). The GCS consists of three sub-scales designed to assess eye opening, motor response, and verbal response. The GCS provides a quick and simple method of assessing the level of consciousness. However, there are several disadvantages in its use. The primary disadvantage is the inability to detect subtle neurophysiologic changes that occur during the acute phase of head trauma. This is the time during which treatment is dependent on accurate detection of subtle symptoms signifying a deterioration in the cerebrovascular status. For example, a patient may only be confused to the time of day and therefore receive four points on the verbal response subscale. This same patient may become confused to place and person as time progresses and still receive four points on the verbal response subscale.

Morray, Tyler, Jones, Stuntz, and Lemire (1984)

demonstrated that 38% of 451 head traumatized patients were unable to be evaluated by one or more of the GCS sub-scales. For example, if the eye lids are severely swollen, the patient may not be able to open their eyes. If they have sustained limb fractures, motor responses may not be accurately assessed. Verbal responses may not be evaluated because of endotracheal intubation.

Another disadvantage is that the GCS does not reflect the true neurological status of patients who are aphasic, hemiplegic, or have suffered a spinal cord injury in addition to a head injury (Ingersoll & Leyden, 1987).

Finally, children who are too young to communicate verbally, or those who speak a foreign language are unable to be completely evaluated by the GCS, which results in an inaccurate representation of the obtained score.

The Children's Orthopedic Hospital and Medical Center (COHMC) coma scale (Morray, Tyler, Jones, Stuntz, & Lemire, 1984) was developed to provide a more accurate neurological assessment of brain injured children, including those who had sustained head trauma. The COHMC scale eliminates evaluation of verbal communication and assesses cortical function in terms of motor response and brain stem function (i.e. pupillary, corneal, oculovestibular, and oculocephalic reflexes). One disadvantage of the COHMC

scale is that it completely excludes the assessment of verbal response even in children who may be able to converse. A second disadvantage is that assessment of brain stem function does not specifically address level of consciousness. Therefore, utilization of the COHMC scale may delay the detection of subtle neurological changes.

The Clinical Neurologic Assessment (CNA) instrument (Crosby & Parsons, 1989) is a 21 item instrument divided into six subscales:

1. Response to Verbal Stimulation
2. Response to Tactile Stimulation
3. Ability to Follow Commands
4. Assessment of Muscle Tone and Resistance
5. Assessment of Body and Extremity Position/Movement
6. Assessment of Chewing, Yawning, and Verbalization

The CNA was developed using a multidisciplinary approach and included suggestions and recommendations from neuroscience nurses, neurosurgeons, neurologists, physical and occupational therapists, and speech pathologists. It was developed to detect and assess early neurological changes in patients with head trauma.

The CNA has been extensively pilot tested on adult head traumatized patients and has a reported Cronbach's

alpha of .96 (Crosby & Parsons, 1989). Concurrent validity using the GCS, revealed a strong positive correlation, r = .94 (Crosby & Parsons, 1989). The CNA has been reported to be easy to use as well as a reliable and valid instrument for detecting and documenting subtle changes in the neurological status of adult head traumatized patients. However, the instrument has not been tested with children who have sustained head trauma.

In summary, head trauma in the pediatric population remains a major health care concern. A priority for nurses caring for head traumatized patients, especially during the acute care phase, is to provide comprehensive patient care including the completion of serial neurologic assessments. Currently, a clinically reliable and valid neurological assessment instrument which is sensitive and specific to the pediatric head traumatized population does not exist.

Purpose of the Study

The purpose of this study was to test the reliability and validity of the Clinical Neurologic Assessment (CNA) tool when used to assess the level of consciousness in children who had sustained head trauma.

Conceptual Framework

The physiological basis of consciousness was used as

the conceptual framework to guide this study. Consciousness is a complex physiological and behavioral phenomenon defined as "the state of awareness of the self and the environment " (Plum & Posner, 1982, p.1). Coma is the opposite of consciousness and is defined as "the total absence of awareness of self and environment even when the subject is externally stimulated" (Plum & Posner, 1982, p.1). Consciousness has two basic components: arousal and content (Plum & Posner, 1982). Arousal is the "excitation of behavior by internal or external stimuli" (Mitchell, 1988, p.68). Content is associated with a higher level of cerebral functioning and includes both cognitive and affective functions (Plum & Posner, 1982).

A central nervous system (CNS) structure which is essential for maintaining consciousness is the reticular formation (RF). The RF is a mass of neurons and nerve fibers located within the central portion of the brain stem and extends from the caudal medulla to the rostral midbrain with fibers extending into the diencephalon (Afifi & Bergman, 1986). The overall functions of the RF include: somatic motor function, somatic sensory function, visceral motor function, arousal, and sleep (Afifi & Bergman, 1986).

The arousal component of consciousness depends on a functioning ascending reticular activating system (ARAS).

The ARAS is an area located within the medial reticular formation extending up to the diencephalon and cerebral cortex. A state of arousal, alertness, and attentiveness, of the cerebral cortex to incoming sensory stimuli, occurs when the ARAS is stimulated (Afifi & Bergman, 1986).

Loss of or a decrease in the level of consciousness, related to dysfunctioning of the RF and ARAS, is a commonly observed phenomena following head trauma. It is a direct result of the mechanical forces applied to the head and are generally categorized as acceleration/deceleration injuries, compression or pressure gradient injuries from skull distortion, and/or stretching of the cervical spine (Gennarelli, 1986). The result is stress and injury to cerebral tissue.

The Centripetal Theory has been utilized by some researchers to explain the underlying mechanisms of head trauma. This theory states that strains (distortions and deformations of cerebral tissue) are likely to occur at the surface of the brain and tend to decrease radially from the outer to inner cerebral tissue (Gennarelli, 1986). In other words, the more severe strains occur on the surface of the cerebral tissue below the impact site followed by the dispersion of kinetic energy toward deeper tissue resulting in less strain. Strains to the upper brain stem

can be seen with increased frequency, in relation to the Centripetal Theory, due to the unique anatomy of the brain stem and cerebral hemispheres. There is only a small area of interface connecting the brain stem to the cerebral hemispheres. In addition, there is a large difference in mass ratio between the cerebral hemisphere and the brain stem. Together these factors can produce torque between the hemispheres and the brain stem resulting in severe strains occurring at the upper brain stem level (Gennarelli, 1986).

The arousal component of consciousness is closely associated with a wakeful state characterized by opening of the eyes. Other behaviors that demonstrate a state of arousal include the orienting response which involves the head turning toward the source of the stimulation, an increased sympathetic nervous system response following stimulation, and an increase in muscle tone (Mitchell, 1988). Reactions to specific stimuli are characterized behaviorally by directional movements of the body and by obeying simple and complex commands (Mitchell, 1988). The CNA items evaluate each of these behaviors which are indicative of the arousal component of consciousness. These items are found in the following subscales: Response to Verbal Stimulation, Response to Tactile Stimulation,

Ability to Follow Commands, Muscle Tone and Resistance, and Body and Extremity Position/Movement.

The second component of consciousness, content, is associated with higher levels of cerebral functioning including both cognitive and affective domains (Plum & Posner, 1982). Content is assessed by observing an individual's ability to receive and interpret incoming communication and their ability to converse. Five CNA items measure the content component of consciousness. These include the entire Chewing, Yawning, and Verbalization subscale and item eight which evaluates subjective behavior.

In summary, the conceptual framework used to guide this research was the knowledge that consciousness has two components: arousal and content. The physiological basis of consciousness is complex and requires the functioning and integration of a variety of cerebral and brainstem structures. Loss of or decreased levels of consciousness can be attributable to injury of a large area of the cerebral cortex as well as to brain stem structures (Plum & Posner, 1982). Serial neurological assessments measuring the level of consciousness, are critically important if one is to detect a change in the neurologic condition. The CNA is a 21 item instrument which measures a person's level of

consciousness.

Problem Statement

Health care providers need a simple and accurate method in which to detect subtle changes in the level of consciousness of patients with head trauma. Currently, there is lack of a valid and reliable neurological assessment instrument which is able to detect subtle changes in the neurologic condition of pediatric head traumatized patients.

Research Question

The research question investigated in this study was: is the Clinical Neurologic Assessment (CNA) tool a reliable and valid instrument when used to assess the level of consciousness of children who have sustained head trauma?

Definition of Terms

1. Clinical Neurologic Assessment Tool (CNA) (Crosby & Parsons, 1989): A neurological assessment tool developed to assess the level of consciousness of head injured adults. The CNA was designed to assess the subtle neurologic changes which occur following head trauma and evaluates cognitive, motor and verbal functions, body position, muscle tone, and the presence of spontaneous chewing and yawning (Crosby & Parsons, 1989).

2. Consciousness: "A state of awareness of the self and the environment" (Plum & Posner, 1982, p. 1) which encompasses two components: arousal and content. Arousal is closely associated with the concept of wakefulness whereas content reflects the cognitive and affective aspects of cerebral functioning.

3. Head Trauma: A blow to the head that alters the level of consciousness.

Significance To Nursing

Head trauma continues to be a major health care problem in the United States. Nurses who care for head traumatized patients are responsible for conducting and documenting neurological assessments that are accurate and precise. It is imperative that one be able to detect subtle changes in the neurologic status and level of consciousness. Early detection of neurologic changes enables a more rapid response or change in medical and nursing therapy which may lead to a decreased incidence of morbidity and mortality associated with head trauma. The purpose of this study was to test the reliability and validity of the CNA tool when used to assess the level of consciousness in pediatric head trauma victims.

Summary

This chapter provided a description and general overview of the research problem investigated in this study. The conceptual framework used to guide the study and the significance relative to nursing were also discussed.

Head trauma remains a major health care problem in the United States today. Nurses are responsible for assessing the neurologic status of head trauma victims. Early detection of subtle changes in the level of consciousness of head trauma patients is imperative to decrease morbidity and mortality rates in this population. This study will contribute to the development of a tool that can assist nurses with this important responsibility.

CHAPTER 2

REVIEW OF THE LITERATURE

A review of the literature demonstrated a wide variety of instruments which have been developed to assess the neurologic status of patients who have experienced head trauma. Some instruments have been developed specifically for use during the acute phase following head trauma (Jennett & Teasdale, 1974; Morgan, Koch, Lee & Aldag, 1988; Cote, Battista, Wolfson, Boucher, Adam, & Hachinski, 1989; Geisler & Salcman, 1986; Starmark, Stalhammar, Holmgren,& Rosander, 1988; Sugiura, Muraoka, Chishiki, and Baba, 1983). Others are used during the less acute phases of recovery when the patient's neurologic status is more stable. Such instruments are focused on higher levels of cognitive and motor assessment which assist in determining rehabilitation potentials (Turner, Kreutzer, Lent, & Brockett, 1984, Kiernan, Mueller, Langston, & Van Dyke, 1987, Rappaport, Hall, Hopkins, Belleza & Cope, 1982). In addition, there are instruments specifically designed to assess pediatric patients with impaired neurological states (Morgan, Koch, Lee, & Aldag, 1988, and Morray, Tyler, Jones, Stuntz, & Lemire, 1984).

GCS and Similar Instruments

The most commonly utilized instrument for the assessment of patients with acute neurologic disorders is the Glasgow Coma Scale (GCS) developed by Teasdale and Jennett (1974). The GCS was developed to quantitatively measure various levels of consciousness regardless of the neurologic condition, i.e. trauma, cerebrovascular accident, etc. (Teasdale & Jennett, 1974). Prior to the GCS, a standardized method of evaluating a patient's neurologic condition was not available.

The GCS consists of three separate categories for evaluating eye opening, motor response, and verbal response. Each category has a variety of responses from which to choose, enabling one to select a numerical value based on a specific observed response. The total GCS score is calculated by adding the three sub-scale values. The range of possible scores is 3 to 15 with higher numerical values indicating an increase in the level of consciousness.

The GCS has been a popular assessment tool because of its ease of use and high degree of interrater reliability (Teasdale, Knill-Jones and Van Der Sande, 1978). Interrater reliability was established in three phases in which nurses, neurosurgeons, and general surgery residents

participated as observers of neurologically impaired patients. In phase one, 27 observers assessed 16 patients and wrote brief descriptions regarding their neurologic status and recorded the presence or absence of various levels of impaired consciousness and motor abnormalities. Additionally, observers recorded assessments of certain ocular features and determined GCS total scores. In reviewing the brief descriptions provided by each observer, there were widely varying views about descriptions and classifications of impaired consciousness. There were also ambiguities and inconsistencies among terms used to describe impaired levels of consciousness. For example, the same patient could be described as "somnolent", "difficult to arouse", or "deeply comatose" by different observers.

In phase two of the study, eighteen observers assessed twelve patients utilizing the GCS (Teasdale & Jennett, 1974). Each patient was assessed on two successive days resulting in 24 sets of data. The following disagreement rates were determined for each of the following sub-scales: eye opening was .089, verbal response was .091, and motor response was .081.

In phase three of the study, the observers were shown a film of the motor responses elicited (using painful

stimuli) from 14 patients. The observers scored the patients responses using the GCS. The disagreement rates on the combined sub-scales for the nurses, neurosurgeons, and general surgeons were .072, .085, and .073 respectively.

Although some variability in the assessment of patient responses using the GCS existed, it was lower than those reported with alternative systems (Teasdale, et al, 1978). The authors found two main sources of variability within assessments by the observers. First, there may have been differences in patients' responses because of a fluctuating condition or because of a difference in the manner in which the assessment was performed. Secondly, there may have been variations in the interpretation of the same response observed by different clinicians.

Comprehensive Level of Consciousness Scale

Stanczak and his associates (1984) conducted a study to compare the psychometric qualities and research utility of the GCS and the Comprehensive Level of Consciousness Scale (CLOCS). The CLOCS is divided into eight subscales which include posture, eye position at rest, spontaneous eye-opening, general motor functioning, abnormal ocular movements, pupillary light reflexes, general responsiveness, and best communicative effort. The CLOCS

incorporates an instruction paragraph for each subscale and a glossary of terms in which to guide the observer. Based on a particular response, a numerical value is assigned to each subscale and tallied to obtain a total score from 0-45.

Stanczak et al (1984) evaluated 101 subjects (45% head trauma patients) admitted to a neurosurgery service with a GCS of 13 or less. The subjects were evaluated every 12 hours for seven days and then daily for three weeks or until their GCS score was > 13. A Cronbach's alpha coefficient was calculated for each item on the GCS and the CLOCS, however, these values were not reported. A reliability coefficient of 0.69 ($p<0.0001$) was calculated for the total GCS score and a reliability coefficient of 0.86 for the CLOCS ($p<0.0001$).

Interrater reliability was established by three pairs of raters who performed 20 simultaneous evaluations of the same subjects. The Pearson product-moment correlation for the total GCS score was 0.95 and 0.96 for the CLOCS ($p<0.001$). Test re-test reliability of the GCS and CLOCS, based on the scores obtained on the initial evaluation and those obtained 12 hours later, rendered correlations of 0.85 ($p<0.0001$) and 0.89 ($p<0.001$) respectively.

Stanczak et al (1984) assessed concurrent validity of

the GCS by comparing responses from nurses on 100 evaluations utilizing a 0 - 6 scale which rated levels of consciousness from coma to alert and oriented. Validity and reliability of the 0-6 scale was not reported. Pearson product-moment correlations were then calculated between these ratings and the scores on the GCS and CLOCS. This analysis yielded a Pearson correlation of 0.68 ($p<0.001$) for the GCS and a 0.71 ($p<0.001$) for the CLOCS.

Although the GCS is a popular neurological assessment instrument, it has several disadvantages. First, the instrument does not allow for detection of subtle changes in the neurological status of patients during the acute phase following head trauma. Examples of these subtle changes include the presence or absence of voluntary spontaneous movements as opposed to evaluating motor responses only to command or to noxious stimulation. Such detection is critical if one is to avoid delaying medical and nursing treatment that may prevent additional neurologic damage.

A second disadvantage of the GCS is that many patients can not be assessed by one or more of the components of the scale. Gale et al (1983) reported that 38% of 451 head traumatized patients were unable to be evaluated utilizing all components of the scale. This occurs when patients

have other injuries, such as periorbital edema, which renders the eye opening component untestable as well as spinal cord injuries which prevent evaluation of motor responses. Medical treatments such as the administration of skeletal muscle paralyzing agents and extremity immobilization also prevent motor response assessments while verbal assessments can be precluded by endotracheal intubation.

In addition, it was reported by Starmark et al (1988) following the review of 166 papers, published in neurosurgery journals between 1983 and 1985, that 79% of those utilizing the GCS did not report how untestable features were handled. Some authors excluded patients who could not be assessed by the entire GCS while others adopted "pseudoscoring" in place of actual scoring for untestable features (Starmark, Holmgren, & Stalhammar, 1988).

Finally, the GCS does not provide for developmental differences based on the age of the patient. This results in the omission of items because children may be too young to converse or are too young to understand simple commands.

Although Stanczak and his associates (1984) reported the CLOCS to be a more reliable instrument than the GCS it also had several disadvantages. The CLOCS is a lengthy

instrument which incorporates a variety of terms not commonly used in the clinical setting i.e. athetoid (slow, sinuous, writhing movements) and cerea flexibilitas (waxy flexibility commonly seen in catatonia). Also, the CLOCS has the same disadvantages as the GCS in that untestable items are not eliminated and the age of the patient is not considered.

Disability Rating Scale

There have been a variety of other neurologic assessment tools developed which either include the entire GCS, components of the GCS, or adaptations of the GCS. One such instrument is the Disability Rating Scale (DRS) developed by Rappaport, Hall, Hopkins, Belleza, & Cope, (1982). The purpose of the DRS was to quantitatively assess the disability of severe head trauma patients from the time of injury through recovery and into the rehabilitative phase.

The DRS consists of 8 items divided into 4 categories: arousal and awareness, cognitive ability to handle self-care functions, physical dependence upon others, and psychosocial adaptability for work, housework or school. The arousal and awareness subscale is evaluated using the GCS, although the authors reversed the numerical values to reflect higher degrees of impairment with higher scores.

The other components of the DRS have numerical values as well and are summed allowing the total score to be categorized into one of ten levels of disability.

Rappaport et al (1982) conducted a study in which four raters (a psychiatrist, a psychologist, a psychology master's degree student, and an evoked potential technician) derived disability rating scores, using the DRS, on 88 patients admitted within 90 days of injury to a rehabilitation program. Patients were evaluated at admission and 12 months after their injury.

Their findings demonstrated an interrater reliability of 0.98 ($p<0.01$). Inter-item correlations ranged from 0.23-0.95 ($p<0.01$). Correlations between the admission disability rating (DR) and the outcome DR (one year after injury) was 0.53 ($p<0.01$) reflecting that the final outcome is directly related to the initial disability rating. The researchers also found significant positive correlations, ranging from 0.35-0.73 ($p<0.01$), between abnormal evoked potential scores and the admission DRS score.

Although the researchers found the DRS to be a useful instrument to assess head traumatized individuals, the DRS like the GCS, did not reflect subtle changes in the neurological condition of head traumatized patients during the acute care phase. The DRS is a helpful instrument in

tracking the progress of head traumatized patients who exhibit neurological deficits by providing a mechanism to follow their readiness for specific rehabilitative efforts.

Maryland Coma Scale

The Maryland Coma Scale (MCS) developed by Geisler and Salcman (1986) is another neurological assessment instrument which incorporates an adaptation of the GCS. It consists of a total of 10 items. The MCS items include: eye opening, orientation, pupillary and corneal reflexes, facial grimace, oculovestibular testing, the type of stimulus required to elicit responses, verbal response, and upper and lower extremity motor responses. Six of the above items are scored separately for each side of the body. They include pupillary and corneal reflexes, facial grimace, oculovestibular response, and upper and lower extremity motor responses. Each of the 10 items have numerical values according to responses elicited, which are summed, providing a scoring range of 0-43. Scoring on the MCS accounts for untestable items by grading the final score as a percentage of testable functions.

The researchers compared the MCS and the GCS in 120 patients admitted to a large teaching hospital with the diagnosis of head trauma. Patients' neurological impairments were measured utilizing each scale for a

minimum of two weeks. Results demonstrated that the two scales generally agreed on determining the neurological status when measured the first 3-4 days post injury. They found that when the MCS score was greater than the GCS score, the MCS score more accurately reflected a favorable outcome. In addition, the MCS more accurately predicted a negative outcome in 20 of 26 patients with scores of 35% or less ($X^2 = 27.63$, $p<.001$). They found the MCS raw scores to be more reliable in addition to not being affected by untestable items. Methods and specific statistical results were not provided in the literature.

The MCS does have some advantages over the GCS in assessing impaired levels of consciousness. For example, if patients have an endotracheal tube but demonstrate signs of consciousness then orientation is evaluated by written responses versus being determined untestable. Secondly, untestable items are deleted from the total possible responses thus allowing a more accurate raw score. Lastly, recording extremity movement on each side of the body separately could provide a means of detecting further deterioration in the neurological status by assessing motor responses more thoroughly.

One difficulty in scoring the MCS is related to the item evaluating the type of stimulus required to elicit

verbal and motor responses. If the type of stimulus utilized to elicit both verbal and motor responses are different, observers may select either response which will result in the selection of a higher or lower numerical value and a different total score. Secondly, the methods utilized to determine validity and reliability when comparing the MCS and GCS were not reported by the authors.

Canadian Neurological Scale

The Canadian Neurological Scale (CNS) [Cote, Battista, Wolfson, Boucher, Adam, & Hachinski, 1989] is a more recent instrument designed to quantify measurements of neurological deficits observed in stroke patients. The instrument items focus on the categories of mentation and motor function. Mentation is evaluated using three sub-categories: level of consciousness, orientation, and speech. The sub-categories item responses are divided based on the amount of deficit exhibited. Numerical values correspond to each potential deficit ranging from 0-3 and are weighted relative to their perceived importance (pre-determined by the authors). For example, the sub-category of speech has three possible responses: normal (1.0 points), expressive deficit (0.5 points), and receptive deficit (0 points).

The portion of the CNS that evaluates motor function

is divided into two sub-categories depending on the patient's capacity to cooperate and comprehend verbal commands. Motor function is measured in the proximal and distal areas of the arms and legs as well as the face. The maximum score possible on the CNS is 11.5.

To determine validity and reliability of the CNS, the researchers studied 157 patients with the diagnosis of acute (<48 hours) cerebrovascular event including transient ischemic attacks, cerebral infarction, and intracerebral hemorrhage. Patients were assessed upon admission by two observers utilizing the CNS and two observers performing standard neurological examinations. Those performing the neurological examinations selectively categorized the patients into one of four pre-determined groups depending on their neurological deficits (none, mild, moderate, or severe). This was used as the standard against which the CNS was compared on the basis of independent scoring of each patient by the observers using the CNS. In those patients admitted to the ICU, the CNS was administered every 4 hours for 48 hours. The functional status, (utilizing the Katz activities of daily living index) and the associated morbidity and mortality rates were examined at one week, one month, three months, and six months time.

Cronbach's alpha demonstrated an internal consistency

of 0.792 for the CNS. Kappa statistics were utilized to measure the agreement among observers over and above that expected by chance alone. They ranged from 0.535 (95% CI, 0.372 to 0.698) for level of consciousness to 0.835 (95% CI, 0.672 to 0.988) for orientation.

In determining concurrent validity, the CNS was correlated to appropriate sections of the standard neurologic examination. Spearman rank correlations (with the exception of the level of consciousness) were from 0.69 to 0.78 with $p<0.001$. Predictive validity was assessed at three end points: death at 6 months (0.73), any vascular event with 6 months (0.70), and independence in activities of daily living (ADL's) at a minimum of 5 months after entry into the study (1.60) with $p<0.001$.

Construct validity was evaluated by correlating the GCS and the CNS with the standard neurologic examination. They reported higher correlation coefficients for each item separately, and for the total score between the CNS and the standard neurological examination ($r_S=0.77$; 95%CI, 0.68 to 0.86) than for the same comparisons using the GCS (.56; 95% CI, 0.42 to 0.71).

Although the CNS demonstrated validity and reliability it may not be as useful in the head traumatized population who exhibit more diffuse injury as opposed to localized

insults observed in stroke patients. In addition, the CNS may not be suitable for detection of subtle changes in the level of consciousness since the only options for the response on that item are alert or drowsy. Also there is the continued problem of how to score untestable items.

Edinburgh-2 Coma Scale

The Edinburgh-2 Coma Scale (E2 CS) [Sugiura, Muraoka, Chishiki, & Baba, 1983] was designed to assess impaired levels of consciousness. The E2 CS is an ordinal scale with a range from 0 (no impairment of consciousness) to 9 (coma). Scoring is based on the best response which reflects the degree of integration occurring within the central nervous system and is estimated by the levels within the scale.

The E2 CS begins with two orientation questions; knowledge of the correct month of the year and age of the patient. Scores of 0-2 are obtained depending on how many of the questions were answered correctly (0 for 2 correct answer, 1 for 1 correct answer, and 2 for two incorrect responses). If the patient is unable to answer the questions correctly, the individual's motor responses are evaluated by providing two commands. They include opening and closing of the hands and the eyes. Scores on this portion of the scale range from 3 to 5. Obeying both

commands scores a 3, obeying one of the two commands scores a 4 and not following either command scores a 5. If the patient cannot follow commands, painful stimulation is utilized to obtain either a localizing (score of 6), abnormal flexion (score of 7), or abnormal extension (score of 8) response. If no movement to pain is noted the patient receives a score of 9.

The authors studied 55 patients who demonstrated impaired states of consciousness after neurosurgical surgery. Diagnoses included intracerebral hemorrhage, subdural hematoma, epidural hematoma, and cerebral aneurysm. The E2 CS and GCS were both administered during the post-operative course and rendered a total of 5300 pairs of data.

The researchers reported a positive correlation (although no statistics were provided) between the E2 CS and the GCS ($p<0.005$). The disagreement rate was not assessed in this study but was reported at 32% for an earlier version of the scale. Although specific methods and statistics were not presented in the literature, the authors reported that the E2 CS had a high correlation with the functional and survival outcome as measured by the Glasgow Outcome Scale (GOS) (Jennett & Bond, 1975). They also reported that a change greater than 2 levels in either

direction of the E2 CS corresponded to a change in the patients' outcome (measured by the GOS).

Although the E2 CS demonstrated some utility, the disadvantages in utilizing the E2 CS are similar to those using the GCS: lack of ability to detect subtle changes in the cerebrovascular status, limited use with children, and more commonly a high percentage of untestable items related to injuries and endotracheal intubation.

Reaction Level Scale

The Reaction Level Scale (RLS85) [Starmark et al, 1988] is a single scale divided into eight levels for assessment of overall patient responsiveness. The eight levels of the RLS are: alert, drowsy or confused, very drowsy or confused, unconscious but localizes, unconscious and withdraws to pain, unconscious with flexion movements to pain, unconscious with extension movements to pain, and unconscious with no response to painful stimuli. Directions for scoring, illustrations, and definitions of the types of responses at each level are provided on the scoring sheet.

Starmark et al compared the RLS85 to the GCS for rating neurosurgical patients in the following areas: ranking order of deficit severity, interobserver variability, and coverage of relevant factors.

Four physicians, four registered nurses and four assistant nurses performed 72 paired ratings using the RLS85 and the GCS on 47 neurosurgical patients resulting in a total of 288 assessments. The primary diagnoses included head trauma, brain tumors, and vascular disorders.

Spearman rank correlation demonstrated that the GCS and RLS85 were highly correlated relative to ranking the patient according to severity (0.94). Results of the 72 paired observations demonstrated that the observers agreed on the assessments using both the GCS and the RLS85 on 31 test occasions and disagreed using both scales on 22 occasions. Of the remaining 19 test occasions two more were excluded due to patient extubations between assessments. The authors reported that there were 11 disagreements utilizing the GCS summed score compared to two using the RLS85 of the remaining 17 observations. Disagreements, which occurred in both scales, were evenly distributed over the entire range of responsiveness levels. Lastly, the RLS85 demonstrated more complete coverage (100%) of relevant factors, while the GCS summed score demonstrated only 40%. The GCS summed score also demonstrated untestable features in 43 of 72 test occasions (60%).

One advantage of using the RLS85 is that it provides

clear directions on eliciting and interpreting specific patient responses resulting in decreased errors during its utilization. The RLS85 also decreases the amount of untestable items by providing alternative assessments which can be evaluated.

The disadvantage of the RLS85 is that it may still not be sensitive enough to detect subtle changes in the cerebrovascular status i.e. spontaneous and purposeful motor movements and does not consider the developmental abilities of the pediatric age group.

Pediatric Instruments

A neurological assessment tool specific to pediatric patients, the Children's Orthopedic Hospital and Medical Center (COHMC) Coma Scale (Morray, Tyler, Jones, Stuntz, & Lemire, 1984) was developed to assess children with a variety of central nervous system disorders.

Children's Orthopedic Hospital and Medical Center Coma Scale

The COHMC Coma Scale is divided into two subscales with the total point value ranging from 0-9. The first subscale measures cortical function on a six point scale by evaluating motor responses to a variety of stimuli. The second sub-scale measures brain stem function and has a maximum point value of three. Brain stem function is

determined by the presence or absence of several reflexes including pupillary, corneal, oculovestibular, and oculocephalic as well as the presence of spontaneous breathing. The points calculated for the two subscales are summed yielding the total scale value.

The researchers completed a retrospective chart review of 100 children that had been monitored and treated for intracranial hypertension within a pediatric intensive care unit (ICU). The diagnoses of the children varied, although the highest percentage involved neurological insults attributable to hypoxic events (31%) and trauma (29%). The admission neurological examination was utilized to complete the COHMC Coma Scale. Outcome was measured six months following admission using a tool adapted from the GOS (Jennett & Bond, 1975).

Utilizing Pearson's correlation coefficients the authors reported moderately good correlations between the coma score and GOS in patients with the diagnoses of head trauma (.67) and hypoxic encephalopathy (.69), $p<0.001$.

Although the COHMC Coma Scale was designed to take the needs of children into consideration, it does have some disadvantages. First, the COHMC Coma Scale completely excludes the verbalization assessment even in children who may be able to converse. Secondly, the assessment of brain

stem reflexes, while important in the neurologic examination of patients without cortical functioning, does not provide specific information regarding the level of consciousness.

Neonatal Neurobehavioral Examination

A second pediatric assessment tool is the Neonatal Neurobehavioral Examination (NNE) [Morgan, Koch, Lee & Aldag, 1988) designed to provide a quantitative assessment of a newborn's neurologic status. The NNE consists of 27 items divided into three categories: motor patterns and tone, primitive reflexes, and behavioral responses. Each section evaluates 9 parameters on a three point scale.

The purpose of this study was to norm-reference the scale so that neonates of different gestational ages, as well as those with developmental disabilities, could be objectively assessed.

The interrater reliability of the NNE was determined to be 88% by item and 95% by total score in each section. The authors reported highly significant differences in the examination scores between infants > 36 weeks gestation (mean = 66.45 and SD = 7.45), those between 34-36 weeks gestation (mean = 60.65 and SD = 8.00), and those < 34 weeks gestation (mean = 51.14 and SD = 9,49). Other statistical analysis were not included in their report.

The NNE may be utilized to identify developmental deficiencies in infants but does not contain items which directly measure the level of consciousness.

Cognitive and Rehabilitative Instruments

Neurobehavioral Cognitive Status Examination

The Neurobehavioral Cognitive Status Examination (NCSE) [Kiernan, Mueller, Langston, & Van Dyke, 1987] and the Brief Neuropsychological Mental Status Exam (BNMSE) [Turner, Kreutzer, Lent & Brockett, 1984] are instruments designed to assess the cognitive and rehabilitative promise of neurologically impaired individuals.

The NCSE was designed to allow clinicians to determine the cognitive abilities of patients in the acute care setting. The NCSE is divided into two sections. The first section assesses level of consciousness, attention and orientation. The second section assesses language, constructional ability (reconstructing drawings), memory, calculations, and reasoning.

The authors used the instrument on 60 people with no neurologic deficit between the ages of 29 and 66 years and on 59 geriatric subjects between the ages of 70 and 92. They then administered the NCSE to 30 neurosurgical patients with documented brain lesions (between the ages of

25 and 88 years).

The authors found that the "normal" geriatric population had lower mean scores in the areas of constructional ability, memory and similarities (a test for verbal reasoning). The neurosurgical patients, with documented brain lesions, had significantly lower scores than those in the geriatric group with the exception of the test for judgment which demonstrated no statistical difference.

The NCSE has utility in detecting specific cognitive dysfunctions but is not useful in assessing subtle changes in the neurological status of acute head traumatized patients, since a high level of cognitive functioning is required for the NCSE to be administered. Another disadvantage of the NCSE is that patients must have a high level of arousal before it can be administered. It also can not be utilized in patients who can not converse fluently, such as aphasic or intubated patients and young children.

Brief Neuropsychological Mental Status Exam

The BNMSE (Turner, Kreutzer, Lent, & Brockett, 1984) was developed to assess baseline cognitive functioning of acutely brain injured adult patients. The BNMSE evaluates concentration, sustained attention, orientation, insight,

right-left orientation, receptive/expressive language functions, verbal memory, and arithmetic reasoning. Components of several accepted instruments were incorporated in the BNMSE including the: Wechsler Adult Intelligence Scale, Wechsler Memory Scale, Babock Story Recall, Rey Auditory Verbal Learning Test, and the Halstead-Wepman Aphasic Screening Test.

Turner et al (1984) selected 18 subjects from the neurosurgical and rehabilitative units of a large teaching hospital in which to evaluate the BNMSE. Fifty per cent of the patients had notable impairments in 3 major areas: immediate and delayed story recall; attention, concentration and mental tracking; and immediate auditory memory.

Although the BNMSE has potential usefulness for nurses providing acute care to neurologically impaired individuals, it measures deficits in cognition, not impaired levels of consciousness. The BNMSE like the NCSE cannot be administered to aphasic patients or portions of the pediatric population. Further pilot testing utilizing a larger sample size is also required based on the number of items in the BNMSE.

Although there are numerous neurological assessment instruments in the literature, the primary limitations

include untestable items, insensitivity in detecting subtle changes in the cerebrovascular status, and decreased utility with various patient populations based on age. However, one instrument which accounts for the cited limitations is the Clinical Neurologic Assessment Tool (CNA) (Crosby & Parsons, 1989). This instrument has demonstrated validity and reliability in assessing the level of consciousness of the adult head traumatized patient.

Clinical Neurologic Assessment Instrument

The CNA is a 21 item instrument specifically designed to detect subtle changes in neurologic functioning that may indicate transitions in the comatose state. The instrument is divided into six subscales with items that assess responses to verbal and tactile stimulation, ability to follow commands, muscle tone, body position, movement, chewing, yawning, and verbalization. The items were derived by consulting with people experienced in caring for head traumatized patients including neuroscience nurses, neurosurgeons, neurologists, physical therapists, occupational therapists, and speech pathologists. The maximum possible score on the CNA is 101 points. The score is based on the percent of testable items that can be evaluated. Therefore, when calculating the percent for a

given individual (assessed points/total possible points), an item which cannot be evaluated is subtracted from total possible score.

The CNA was extensively tested on 187 adult head traumatized patients who were hospitalized within a large trauma center. A total of 226 assessments were completed. Interrater reliability of the CNA was determined by two persons simultaneously and independently evaluating 20 head traumatized patients. An exact agreement of 93% was reported. Internal consistency of the CNA was demonstrated by the Cronbach's alpha of 0.96.

Concurrent validity was demonstrated by correlating the CNA with the GCS and was reported to be .96. The sample was divided according to severity of injury to determine concurrent validity while considering the severity of head injury. A correlation of 0.80 was identified in the severely head injured group (GCS 3-8), 0.50 in the moderately head injured group (GCS 9-12), and 0.74 in the mildly head injured group (GCS 13-15).

Predictive validity was demonstrated when the CNA correctly predicted a patient's GCS category in 215 out of 226 (95%) subjects.

The CNA has demonstrated reliability and validity in the adult head traumatized patient however, additional

evaluation is necessary to determine the reliability and validity among other patient populations, especially children.

Summary

A review of the literature on currently available instruments developed for assessing an individual's neurologic status was included in this chapter. Although the literature is fairly replete with studies that have used various instruments to assess neurologic function, most of the instruments are inadequate for assessing the level of consciousness of head trauma victims. The instruments included in this review were divided into three categories: 1. the GCS and similar tools, 2. pediatric instruments, and 3. instruments used for cognitive evaluation and rehabilitative potential.

Deficiencies of the GCS and similar instruments included failure to detect subtle changes in the neurologic status, inability to assess one or more components of the subscales due to injuries or medical therapy, inconsistency in scoring untestable items, and lengthy amounts of time required to perform assessments. The instruments developed for the pediatric population either did not include assessments of verbalization in children who were able to speak or determined developmental deficiencies but not

neurologic impairments. Lastly, the tools measuring the cognitive status or rehabilitative potential of patients could only be used on those with a high level of neurologic functioning.

CHAPTER 3

METHODOLOGY

Introduction

The purpose of this study was to test the reliability and validity the Clinical Neurologic Assessment (CNA) tool when used to assess the level of consciousness in three to fifteen year old children with recent head trauma. The research design, variables, data analysis, subjects and setting, instruments, procedure, assumptions, limitations, and the protection of human subjects pertaining to this study are presented in this chapter.

Research Design

This study was based on a descriptive research design. The purpose was to test the reliability and validity of the CNA in children who had sustained head trauma.

Variables

Consciousness is a complex physiological concept dependent upon the intact functioning of many interacting central nervous system structures. Consciousness is measured indirectly by observing a variety of parameters such as spontaneous eye opening, motor movement,

cognition, and verbalization. The CNA contains 21 items observing these parameters which reflect consciousness. The items are categorized into six subscales:

1. Response to Verbal Stimulation.
2. Response to Tactile Stimulation.
3. Ability to Follow Commands.
4. Muscle Tone and Resistance.
5. Body and Extremity Position/Movement.
6. Chewing, Yawning, and Verbalization.

Data Analysis

The data were coded and analyzed using the Statistical Package for the Social Sciences-X(SPSSX). Descriptive statistics were used to evaluate the demographic data.

Reliability Testing

Reliability is concerned with the extent to which a measurement is repeatable (Nunnally, 1978). Internal consistency is based on the average correlation among items in an instrument (Nunnally, 1978). Internal consistency is also a reliability estimate of the homogeneity of an instrument's items (Carmines & Zeller, 1979).

Internal consistency of the CNA was estimated using

Cronbach's alpha (Cronbach, 1951). Alpha coefficients were computed for the total CNA and for each subscale. Alpha coefficients were also calculated for the total CNA and subscales based on severity of head trauma (severe = GCS of 3 to 8, moderate = GCS of 9 to 12, and mild = GCS of 13 to 15) and age (3 to 8 and 9 to 15). Reliability of the CNA was also examined by determining inter-item, item-to-subscale, and item-to-total scale correlations.

Interrater reliability of the CNA was determined by the investigator and a neuroscience Clinical Nurse Specialist (CNS) simultaneously and independently assessing 23 subjects. Cohen's Kappa values were determined for each of the CNA items. Kappa values reflect the consistency in observations between the two raters beyond which is expected by chance.

Validity Testing

Validity is the extent to which an instrument measures what it is intended to measure. Validity is a matter of degree and is not a reflection of the instrument itself, but rather a reflection of the instrument relative to its specific use (Nunnally, 1978). There are three types of validity: content, criterion, and construct (Carmines & Zeller, 1979).

The original CNA items were based on behavioral

responses of patients with closed head injuries. Content validity of the CNA was assessed in the previous study with adult head trauma victims. Experts in neuroscience nursing, neurology, neurosurgery, physical therapy, occupational therapy, and speech pathology were consulted to evaluate and revise the original CNA items.

Concurrent validity is considered a type of criterion validity. An instrument is said to have concurrent validity when a concept being measured by one instrument is compared to and has a high correlation with a previously established criterion (Brink & Wood, 1988). Concurrent validity was examined by determining the relationship between the CNA and GCS scores using Pearsons Product-Moment Correlation Coefficients. Correlations between the CNA and GCS were also computed in relation to severity of head trauma and ages of the subjects.

Construct validity is the degree to which an instrument measures the construct for which it was intended (Burns & Grove, 1987). Construct validity was assessed in this study using exploratory factor analysis.

Setting

Data were collected at two regional Level I trauma centers in a southwest metropolitan area. Neurologic assessments using the CNA and GCS were conducted in either

the emergency department, pediatric intensive care unit, general pediatric unit, or general neurological-neurosurgical units.

Subjects

Subjects included in this study were children who had sustained recent (within 72 hours) head trauma (mild, moderate, or severe) and were admitted to one of the two trauma centers. The following two criteria were used to determine subject eligibility:

1. Between ages 3 and 15
2. Documented evidence of head trauma within 72 hours of admission to the trauma center

Subjects were excluded if they had received paralytic agents within six hours prior to the time of the neurologic evaluation.

Instruments

The CNA (Appendix A) and the GCS (Appendix B) were used to collect data on the subjects included in the study. The CNA was scored based on a percentage of testable items. In other words, if an item was unable to be tested, it's total point value was deleted from the possible total score. The number of points accumulated during the assessment was then divided by this "adjusted" total score. The GCS was scored by evaluating the three

subscales individually and summing the subscale scores to obtain a total GCS score.

Clinical Neurologic Assessment Tool

The CNA has been extensively pilot tested in adult head traumatized patients and has a reported alpha reliability of 0.96 and an interrater reliability of 93% (Crosby & Parsons, 1989). Concurrent validity was determined by correlating the CNA and GCS scores. Correlations were reported to be 0.80 in patients with a GCS of 3 to 8, 0.50 in patients with a GCS of 9 to 12, and 0.74 in patients with a GCS of 13 to 15. Predictive validity was determined by calculating the percent of subjects correctly classified into three GCS categories using scores on the CNA. Ninety five percent of the subjects (n = 226) were correctly classified (Crosby & Parsons, 1989).

Glasgow Coma Scale

The GCS, developed by Teasdale & Jennett (1974), has also demonstrated reliability and validity. Teasdale et al (1978) reported interrater reliability to be .89 on the eye opening sub-scale, 0.91 on the verbal response subscale, and 0.81 on the motor response subscale. Stanczak et al (1984) reported a reliability coefficient

of 0.69 ($p<0.0001$) for the total GCS which is marginally acceptable (Nunnally, 1978). Stanczak et al (1984) also assessed the concurrent validity of the GCS using Pearson Product-Moment correlations to compare the GCS with a 0 to 6 scale rating levels of consciousness from alert and oriented to a state of coma. They reported an $r = .68$ ($p<0.001$) for the GCS.

Procedure

Prior to initiating data collection, the investigator explained the purpose of the study and subject criteria for inclusion to the nursing and medical staff at both trauma centers. This step in the procedure facilitated the study by allowing members of the hospital staff to notify the investigator of potential subjects identified at the respective institutions.

Emergency department personnel notified the investigator of potential subjects that were admitted to the hospital or were going to be discharged home. In addition, daily visits and/or phone calls were made to the general pediatric units and pediatric intensive care units in each facility.

After determining that a potential subject met the eligibility criteria, the child and his or her parents were approached by the investigator. Informed consent was

obtained after a thorough explanation of the purpose and procedure involved in conducting the CNA and GCS.

Once signed consent was obtained, the investigator reviewed the child's medical record in order to complete the demographic data form (Appendix C). The investigator then assessed the neurologic status of the child using first the CNA followed by the GCS. Consistency in data collection was attempted in children between the ages of three and eight by utilizing toys to examine motor movement and assessing orientation by asking the subject names of siblings and/or pets.

Assistance with interrater reliability was elicited from a neuroscience CNS at one of the trauma centers who was familiar with the CNA instrument. Twenty-three subjects were simultaneously and independently assessed by the investigator and the neuroscience CNS during the initial phase of data collection.

Subjects determined as having a moderate or severe head trauma upon admission (determined by GCS scores of 9 to 12 and 3 to 8 respectively) were reassessed throughout their recovery phases. Reassessments were conducted at varying intervals according to evidence of significant neurological improvements (increasing levels of consciousness). This period of time ranged from one to

fourteen days. A maximum of three assessments per subject were used in the data analysis.

The initial assessments required approximately one hour to complete. This included providing explanations of the study, answering questions, obtaining consent, reviewing the medical record and performing the CNA and GCS assessments. Subsequent assessments required 20 to 30 minutes to complete.

Assumptions

For the purposes of this investigation, the following assumptions were made:

1. The subjects' neurologic status remained constant during the time required to conduct a single assessment of the level of consciousness using the CNA and GCS.
2. Subjects did not purposely alter or fabricate any observed behaviors during a single assessment period which could have changed the CNA and GCS scores.
3. Reassessments were considered separate independent observations.

Limitations

Limitations of this study included:

1. A smaller than optimal sample size limiting statistical evaluation of reliability and validity.
2. Inability to evaluate an equal distribution of head trauma subjects based on GCS scores. This limitation was due first to the inability to obtain consent from emotionally upset parents of severely injured children, and second to the rapid improvement in the neurologic status of the child prior to the investigator being able to admit the child to the study.

Protection of Human Subjects

All subjects and their parents received a comprehensive explanation of the purpose and procedure involved in the study. They were reassured that the assessment using the CNA and GCS would not have any adverse effect on the outcome of the injury. Subjects and their parents were encouraged to ask questions about the study. Additional time was scheduled during the initial interview to answer questions and discuss concerns. Subjects and their parents were assured that they could withdraw from the study at any time without any negative repercussions.

Subject anonymity was ensured by assigning each

subject an identification number on the data collection form. Only the investigator and the CNS were aware of the identity of each subject.

Summary

The research methodology proposed for reliability and validity testing of the CNA instrument in children with head trauma was presented in this chapter. Subjects included children between the ages of three and fifteen with documented evidence of recent head trauma (within 72 hours) who were admitted to one of two regional trauma centers.

The CNA and GCS were used by two assessors to evaluate the level of consciousness of each subject.

Reliability of the CNA was measured by: estimating its internal consistency using Cronbach's alpha, determining interrater agreement using Cohen's Kappa for each CNA item, and determining inter-item, item-to-subscale, and item-to-total scale correlations. Construct validity of the CNA was assessed using exploratory factor analysis. Concurrent validity was examined by determining the relationship between the CNA and GCS scores using Pearsons Product-Moment Correlation Coefficients.

CHAPTER 4

RESULTS OF DATA ANALYSIS

The purpose of this study was to test the reliability and validity of the Clinical Neurologic Assessment (CNA) Tool in children with head trauma. Assessments were completed in the emergency room, pediatric intensive care units or the general pediatric units of two southwest regional Trauma Centers.

Demographic data were collected on each subject followed by neurological examinations using the CNA tool and the GCS (Appendices A and B respectively).

The results of the data analysis are presented in this chapter. A discussion of the findings is organized into three sections: 1) description of the sample, 2) reliability testing of the CNA Tool, and 3) validity testing of the CNA Tool.

Description of the Sample

In this study, 78 assessments utilizing the CNA and GCS were conducted on 41 subjects. Subject ages ranged from 3 to 15 years, with a mean of 9.98 years and a standard deviation of 4.0 years (Table 1). Nearly half (51.2; n = 21) of the children were male and half female (48.8%; n = 20) were female (Table 2).

Table 1

Age of Subjects N = 41

Age	Frequency	Percentage
3	3	7.3
5	3	7.3
6	3	7.3
7	3	7.3
8	5	12.2
9	4	9.8
10	2	4.9
11	2	4.9
12	1	2.4
13	2	4.9
14	5	12.2
15	8	19.5
Total	41	100.0

Note. Mean = 10.0 years, standard deviation = 4.0 years.

Table 2

Sex of Subjects N = 41

Sex	Frequency	Percentage
Male	21	51.2
Female	20	48.8
Total	41	100.0

Motor vehicle accidents were the most common mechanism of head injury (46.3%; n = 19) followed by falls (19.5%; n = 8) and bicycle accidents (17.1%; n = 7) (Table 3). Seven subjects (17.1%) had mechanisms of injury classified as "other" which are also listed in Table 3.

Types of injuries to the cranium were categorized as acceleration/deceleration injuries, compression injuries, or other. Thirty-eight of the subjects (92.7%) obtained acceleration/deceleration types of injuries while 4.9% (n = 2) obtained compression injuries (Table 4). One subject (2.4%) was unable to be classified. The most common sites of cranial injuries were the left frontal lobe (29.3%; n = 12) and the left temporal lobe (29.3%; n = 12) (Table 5). Eleven of the subjects (26.8%) sustained trauma to the right frontal and the left parietal areas.

Twelve children (29.2%) had blood alcohol levels drawn on admission. Two of those subjects (4.8%) tested positive with one reported at .03 milligrams per deciliter and one at .75 milligrams per deciliter.

Admission GCS scores, indicative of severity of head trauma, were generally calculated by pre-hospital care providers and the emergency room staff. The GCS scores ranged from 3 (2.4%; n = 1) to 15 (39%; n = 16), with a mean of 12.40, a mode of 15.0, a median of 14.0, and a

Table 3

Mechanism of Injury N = 41

Mechanism of Injury	Frequency	Percentage
MVA	19	46.3
Fall	8	19.5
Bicycle	7	17.1
Other	7	17.1
Pedestrian	(1)	(14.3)
Skateboard	(1)	(14.3)
Go-cart	(1)	(14.3)
Motorcycle Accident	(1)	(14.3)
Horseshoe Accident	(1)	(14.3)
Falling Tree	(1)	(14.3)
All Terrain Vehicle	(1)	(14.3)
Total	41	100.0

Note: MVA = Motor Vehicle Accident. Numbers in parentheses reflect frequencies of "Other" category only.

Table 4

Types of Injury N = 41

Type of Injury	Frequency	Percentage
Acceleration/Deceleration	38	92.7
Compression	2	4.9
Unknown	1	2.4
Total	41	100.0

Table 5

Site of Cranial Impact N = 41

Site of Impact	Frequency	Percentage
Left Frontal	12	29.3
Left Temporal	12	29.3
Left Parietal	11	26.8
Right Frontal	11	26.8
Right Temporal	7	17.1
Left Occipital	6	14.6
Right Parietal	3	7.3
Right Occipital	3	7.3
Right Basilar	1	2.4
Left Basilar	0	0.0

Note: Totals not included since subjects had more than one site of impact.

standard deviation of 3.53 (Table 6). Four subjects (10%) did not have GCS scores calculated upon admission.

Reliability Testing of the CNA

The CNA has a possible range (summed scores) of 21 to 101 points. The final score is based on a percentage of the actual acquired points divided by the total possible points for that particular patient. This allows items which can not be observed to be deleted from the patient's possible score and ultimately the total score. This unique feature of the CNA provides a more accurate measurement and avoids erroneously low estimations of the patient's level of consciousness.

The CNA scores ranged from 32% to 100% with a mean of 84% and a standard deviation of 23% Thirty-seven assessments were scored as 100% on the CNA. Five assessments were scored as 99%. The remaining assessments were evenly distributed and ranged from 32% to 98%.

Interrater Reliability

Twenty-three subjects were evaluated simultaneously and independently by two raters using the CNA. Cohen's Kappa values were computed for each CNA item to assess interrater reliability in this study.

Cohen's Kappa (K) is the proportion of persons

Table 6

Admission Glasgow Coma Scale Scores N = 41

Admission GCS Scores	Frequency	Percentage
3	1	2.4
5	1	2.4
6	1	2.4
7	3	7.3
8	2	2.9
10	1	2.4
11	2	4.9
12	2	4.9
14	8	19.5
15	16	39.0
Missing	4	9.8
Total	41	100.0

Note: GCS = Glasgow Coma Scale.

consistently classified in the same category on two occasions beyond which is expected by chance (Waltz, Strickland, & Lenz, 1984). The following equation was used to manually calculate Cohen's K for each CNA item:

$$K = \frac{P_o - P_c}{1 - P_c}$$

where

P_o = Observed Agreements

P_c = Chance Agreements

P_o was calculated by the following equation:

$$P_o = \sum_{k=1}^{m} P_{kk}$$

where

m = the number of classification categories

P_{kk} = the proportion of items consistently classified in the k^{th} category

P_c was calculated by the following equation:

$$P_c = \sum_{k=1}^{m} P_k P_k$$

where

m = the number of classifcation categories

$P_k P_k$ = the proportion of items assigned to category k on each measurement occasion, respectively.

The value for K can range from -1.00 (complete inconsistency of test results) to 1.00 (total consistency of results) (Waltz, Strickland, & Lenz, 1984). An acceptable level of interrater agreement is K = .75 (Waltz, Strickland, and Lenz, 1984). The calculated Kappa value for each CNA item ranged from .74 for one item (item 2) to 1.00 for 12 items (Table 7).

Internal Consistency

Reliability testing of the CNA included an estimation of the CNA's internal consistency by computing Cronbach's Alpha. Overall reliability of the CNA was 0.98. Reliability of the instrument was further assessed by examining each of the six subscales and their respective items.

The CNA subscales are as follows:

1. Response to Verbal Stimulation
2. Response to Tactile Stimulation
3. Ability to Follow Commands
4. Assessment of Muscle Tone and Resistance
5. Assessment of Body and Extremity Position/Movement
6. Assessment of Chewing, Yawning, and Verbalization

Table 7

Cohen's Kappa Values for Each CNA Item

Item	Kappa Value
1	.92
2	.74
3	1.00
4	1.00
5	.95
6	.95
7	1.00
8	1.00
9	1.00
10	1.00
11	1.00
12	1.00
13	.94
14	.91
15	1.00
16	1.00
17	1.00
18	.87
19	1.00
20	.95
21	.95

Response to Verbal Stimulation Subscale. The Response to Verbal Stimulation subscale consists of CNA items one and two. This subscale's computed alpha coefficient was .96 (Table 8). The scale mean was 8.22, with a possible range of 2 to 10, and a standard deviation of 3.1. The item-to-total scale correlation was .91 and .87 for items one and two respectively. Item-to-subscale correlations were each .92. Item one positively correlated with five of the other 20 CNA items (criteria .30 - .70) and item two correlated with eight.

Response to Tactile Stimulation Subscale. The Response to Tactile Stimulation subscale contains CNA items 3, 4, and 5. The computed alpha was .92 (Table 9). The scale mean was 15.5, with a range of 3 to 19, and a standard deviation of 4.9.

Item-to-total scale correlations were .78 (item 3), .83 (item 4) and .93 (item 5). Item-to-subscale correlations were .81 (item 4), .84 (item 3) and .88 (item 5). Item 3 had the highest number of inter-item correlations meeting the criterion level of .30 - .70 (correlated with 11/20). Item four positively correlated with nine out of the 20 CNA items while item five correlated with six of 20 CNA items.

Table 8

Reliability of the Response to Verbal Stimulation Subscale (Items = 2, N = 76)

CNA Item	Item-to-Total Scale Correlation (≥ .50)*	Item-to-Subscale Correlation (≥ .50)*	Inter-item Correlations (< .30)	(.30 - .50)*	(> .70)	Standardized Alpha
1	.91	.92	0	5	15	.96
2	.87	.92	0	8	12	

Note: N = observations, *Criterion levels.

Table 9

Reliability of the Response to Tactile Stimulation Subscale (Items = 3, N = 76)

CNA Item	Item-to-Total Scale Correlation (≥ .50)*	Item-to-Subscale Correlation (≥ .50)*	Inter-item Correlations (< .30)	(.30 - .50)*	(> .70)	Standardized Alpha
3	.78	.84	1	11	8	.92
4	.83	.81	0	9	11	
5	.93	.88	0	6	14	

Note: N = observations, *Criterion levels.

Ability to Follow Commands Subscale. Table 10 illustrates the reliability indices of the Ability to Follow Commands subscale which consists of items 6, 7, and 8. The computed alpha was .94. The scale mean was 11.0, with a range of 3 - 14, and a standard deviation of 4.4.

Item 7 had the lowest item-to-total scale correlation (r = .81) and item 6 had the highest (r = .95). Item-to-subscale correlations for items 6 and 7 were .83 while item 8 was .93. In terms of inter-item correlations as estimates of internal consistency, item seven had the highest number of correlations with 11 out of 20. Item eight correlated with seven other CNA items while item six correlated with three.

Assessment of Muscle Tone and Resistance Subscale. The Assessment of Muscle Tone and Resistance subscale contains items 9 - 12. The Cronbach alpha for this subscale was .89 (Table 11). The scale mean was measured at 15.7, with a range of 4 to 17, and a standard deviation of 2.7.

The item-to-total scale correlations ranged from .53 (item 9) to .81 (item 12). Item-to-subscale correlations ranged from .73 (item 12) to .82 (item 10). Items 9 and 11, which assess muscle tone of the upper and lower extremities, had the highest number of inter-item

Table 10

Reliability of the Ability to Follow Command Subscale (Items = 3, N = 73)

CNA Item	Item-to-Total Scale Correlation (≥ .50)*	Item-to-Subscale Correlation (≥ .50)*	Inter-item Correlations (< .30)	(.30 - .50)*	(> .70)	Standardized Alpha
6	.95	.83	0	3	17	.94
7	.81	.83	0	11	9	
8	.89	.93	0	7	13	

Note: N = observations, *Criterion levels.

Table 11

Reliability of the Assessment of Muscle Tone and Resistance Subscale (Items = 4, N = 78)

CNA Item	Item-to-Total Scale Correlation (≥ .50)*	Item-to-Subscale Correlation (≥ .50)*	Inter-item Correlations (< .30)	(.30 - .50)*	(> .70)	Standardized Alpha
9	.53	.74	1	17	2	.89
10	.77	.82	0	13	17	
11	.60	.74	1	18	1	
12	.81	.73	0	8	12	

Note: N = observations, *Criterion levels

correlations for this subscale (17/20 and 18/20 respectively). Item 12 had the lowest number of inter-item correlations with 8 out of 20 meeting the specified criteria.

Assessment of Body and Extremity Position/Movement Subscale. Table 12 contains the reliability measurements of the Assessment of Body and Extremity Position/Movement subscale which contains CNA items 13 - 17. The computed subscale alpha was .96. The subscale mean was measured at 22.3, with a range of 5 - 25, and a standard deviation of 5.4.

Item 17 had the lowest item-to-total scale correlation (.78) while item 16 had the highest (.89). Item-to-subscale correlations varied with a maximum of .93 for item 14 and a minimum of .77 for item 17. Inter-item correlations ranged from 6 out of 20 (item 16) to 11 out of 20 (item 15).

Assessment of Chewing, Yawning and Verbalization Subscale. The Assessment of Chewing, Yawning, and Verbalization subscale contains four items (18 - 21) with reliability indices presented in Table 13. The subscale standardized alpha was .91. The subscale mean was 12.2, with a range of 4 - 16, and a standard deviation of 4.5.

Table 12

Reliability of the Body and Extremity Position/Movement Subscale (Items = 5, N = 76)

CNA Item	Item-to-Total Scale Correlation (≥ .50)*	Item-to-Subscale Correlation (≥ .50)*	Inter-item Correlations (< .30)	(.30 - .50)*	(> .70)	Standardized Alpha
13	.87	.90	0	7	13	.96
14	.80	.93	0	10	10	
15	.83	.91	0	11	9	
16	.89	.90	0	6	14	
17	.78	.77	0	10	10	

Note: N = observations, *Criterion levels.

Table 13

Reliability of the Chewing, Yawning, and Verbalization Subscale (Items = 5, N = 78)

CNA Item	Item-to-Total Scale Correlation (≥ .50)*	Item-to-Subscale Correlation (≥ .50)*	Inter-item Correlations (< .30)	(.30 - .50)*	(> .70)	Standardized Alpha
18	.83	.87	0	10	10	.91
19	.55	.60	2	10	8	
20	.93	.90	0	6	14	
21	.83	.89	0	12	8	

Note: N = observations, *Criterion levels.

Item 19 had the lowest item-to-total scale correlation (.55) and item-to-subscale correlation (.60). However, if item 19 was deleted, the corrected alpha of this subscale would be = .86.

Items 18 and 21 had the highest item-to-total scale correlations (.83) and item 21 also had the highest item-to-subscale correlation (.89). Inter-item correlations in this subscale ranged from 6 out of 20 (item 20) to 12 out of 20 (item 21).

It is worth mentioning that the majority of CNA inter-item correlations in all of the subscales that did not meet the specified criterion (.30 to .70) was primarily due to correlations exceeding the upper limit. Very few inter-item correlation values were below the .30 level (Tables 8 through 13).

Alpha Coefficients Relative to Severity of Head Trauma

Standardized Alpha Coefficients for the CNA and its subscales were also computed in relation to severity of head trauma. The sample was divided into three groups: those with severe head trauma (GCS scores of 3 - 8), moderate head trauma (GCS scores of 9 - 12) and mild head trauma (GCS scores of 13 - 15). Table 14 displays the calculated standardized Alpha for the CNA and subscales for each group.

Table 14

Reliability of CNA Relative to Severity of Head Trauma

	GCS 3-8 N = 17 Alpha Coefficients	GCS 9-12 N = 14 Alpha Coefficients	GCS 13-15 N = 47 Alpha Coefficients
Total CNA	.87	.94	.92
Subscale: Response to Verbal Stimulation	.89	.92	---
Subscale: Response to Tactile Stimulation	.48	.85	.95
Subscale: Ability to Follow Commands	.65	.83	---
Subscale: Muscle Tone & Resistance	.82	.85	---
Subscale: Body & Extremity Position/Movement	.93	.62	---
Subscale: Chewing, Yawning, & Verbalization	.49	.74	.65

Severe Head Trauma Group. In the severe head trauma group (n = 17), the CNA alpha coefficient was 0.87 for the total scale while the subscale coefficients ranged from 0.48 (Response to Tactile Stimulation) to 0.93 (Assessment of Body and Extremity Position/Movement). The Response to Tactile Stimulation and the Assessment of Chewing, Yawning, and Verbalization subscales did not meet the established alpha coefficient criteria of .50 but all were assessed based on N = 17.

Moderate Head Trauma Group. In the moderate head trauma group (n = 14) the overall alpha coefficient was 0.94. The Response to Verbal Stimulation subscale had the highest coefficient of .92 and the Assessment of Body and Extremity Position/Movement had the lowest coefficient (.62).

Mild Head Trauma Group. The overall CNA alpha coefficient in the mild head trauma group (n = 47) was 0.92. Only two subscale coefficients could be calculated due to zero variance among the items. The Response to Tactile Stimulation subscale alpha was 0.95 and the Assessment of Chewing, Yawning, and Verbalization subscale alpha was 0.65.

Alpha Coefficients Relative to Age of Subjects

Since the subjects of interest in this particular study involved children of varying ages with varying neurological development, the internal consistency of the CNA was also evaluated based on years of age. The subjects were divided into two groups. Group 1 included subjects between the ages of 3 and 8 (N = 27). Group 2 included subjects between the ages of 9 and 15 (N = 51).

Ages 3 to 8. Cronbach's alpha coefficients for the total CNA and for the subscales of each group are displayed in Table 15. The overall CNA alpha coefficient for ages 3 - 8 (N = 27) was 0.98 with a range in subscale values between 0.88 (Assessment of Chewing, Yawning, and Verbalization) and 0.99 (Ability to Follow Commands).

Ages 9 to 15. The overall CNA alpha for this group (n = 51) was 0.97 with subscale alpha coefficients ranging from 0.89 (Ability to Follow Commands) and 0.96 (Body and Extremity Position/Movement).

Validity Testing of the CNA

Validity is defined as the extent or degree to which an instrument measures what it is intended to measure (Zeller & Carmines, 1979). Construct and concurrent validity were examined in this study.

Table 15

Reliability of the CNA in Relation to Age Groups

	Ages 3 - 8 (N = 27) Alpha Coefficient (≥.70)*	Ages 9 -15 (N = 51) Alpha Coefficient (≥.70)*
Total CNA	.98	.97
Subscale: Response to Verbal Stimulation	.97	.95
Subscale: Response to Tactile Stimulation	.97	.90
Subscale: Ability to Follow Commands	.99	.89
Subscale: Assessment of Muscle Tone and Resistance	.92	.77
Subscale: Body and Extremity Position/ Movement	.96	.96
Subscale: Chewing, Yawning, and Verbalization	.88	.92

*Criterion levels

Concurrent Validity

Pearson's Product-Moment Correlation Coefficients were calculated to determine the relationship between the CNA and GCS as an estimation of concurrent validity. Using a Pearson's $r \geq .50$ and a $p < .05$ (Burns & Grove, 1987) a significantly positive correlation ($r = .93$, $p < .001$) was found to exist between CNA and GCS for the total sample (Table 16).

Pearson's correlations were also computed between the CNA and GCS based on severity of head trauma. The sample was divided in the same manner as before: severe (GCS = 3 to 8), moderate (GCS = 9 to 12), and mild (GCS = 13 to 15). Statistically significant positive correlations were found between the CNA and GCS in all three groups with correlations ranging from $r = .57$ ($p = .017$) to $r = .74$ ($p < .001$) (Table 16).

Table 16 also displays Pearson's correlation coefficients for the CNA and GCS based on age groups. Significantly positive correlations between the CNA and GCS were evident in the 3 - 8 age group ($r = .99$, $p < .001$) and in the 9 - 15 age group ($r = .89$, $p < .001$).

Construct Validity

Exploratory factor analysis using varimax rotation

Table 16

Concurrent Validity of the CNA

Group	Pearson's Product-Moment Correlation Coefficients
Overall CNA and GCS	$r = .93$ $p < .001$
GCS 3 - 8 and CNA	$r = .74$ $p < .001$
GCS 9 - 12 and CNA	$r = .57$ $p = .017$
GCS 13 - 15 and CNA	$r = .67$ $p < .001$
Ages 3 - 8	$r = .99$ $p < .001$
Ages 9 - 15	$r = .89$ $p < .001$

was utilized to examine the construct validity of the CNA. Eigenvalues of $\geq$ 1.00 were the criteria used for determining extracted factors (Kim & Mueller, 1978). A factor loading of $\geq$ .50 was used to determine which items to retain on a given factor and an interval of $\geq$ .20 between factors was required to maintain an item within the factor (Armor, 1974).

Factor analysis demonstrated a three factor solution. Eigenvalues for each factor ranged from 14.14 to 1.09 and are presented in Table 17 with percentages of variance and each item's factor loading value. All of the CNA items met the loading criterion of $\geq$ .50, although four of the items did not meet the interval criteria of $\geq$ .20 to keep them on the factor in which they loaded the highest (items 1, 2, 4, and 6). Three of these four items (2, 4, and 6) assessed eye movement in response to a variety of stimuli. The fourth item (1) assessed the overall response to verbal stimulation. The majority of remaining items loaded as they had in the previous factor analysis conducted by Crosby & Parsons (1989).

Factor 1 was comprised of items 3, 5, 7, 8, 18, 19, 20, and 21. These items were from the Response to Tactile Stimulation and Ability to Follow Command subscales. Items in this factor assessed cognition, affective

Table 17

Factor Analysis of the CNA (N = 73)

Item Number	Factor 1 (≥.50)*	Factor 2 (≥.50)*	Factor (≥.50)
1	.671	.561	---
2	.568	.731	---
3	.835	---	---
4	.680	.512	---
5	.808	---	---
6	.731	.551	---
7	.734	---	---
8	.662	---	---
9	---	---	.862
10	---	.651	---
11	---	---	.889
12	---	.668	---
13	---	.669	---
14	---	.843	---
15	---	.748	---
16	---	.692	---
17	---	.795	---
18	.856	---	---
19	.538	---	---
20	.828	---	---
21	.959	---	---
Eigenvalue	14.14	1.88	1.09
Per Cent of Variance	67.3	9.0	5.2
Cumulative Per Cent of Variance	67.3	76.3	81.5

*Criterion Levels.

behavior, and responses to environmental stimuli which give a "general" overview of a patient's level of consciousness.

Factor 2 loaded items 10, 12, 13, 14, 15, 16, and 17 and comprised the entire Assessment of Body and Extremity Position/Movement subscale and the two items assessing muscle resistance from the Assessment of Muscle Tone and Resistance subscale. The items in this factor assess "overall body and extremity position and movement" and are generally examined without stimulating the patient. Items 9 and 10 loaded onto Factor 3 which assess muscle tone of the extremities.

Summary

Forty-one subjects were included in the data analysis resulting in a total of 78 assessments using both the CNA and GCS. Interrater reliability was assessed by determining Cohen's Kappa values for each of the 21 CNA items. Kappa values ranged from .74 to 1.00. Internal consistency of the CNA was estimated using Cronbach's alpha. The computed alpha for the entire CNA was .98. Alpha values for the six CNA subscales ranged from .89 to .96.

Concurrent validity of the CNA was assessed by correlating the CNA and GCS in relation to severity of the

head trauma (GCS = 3 to 8, GCS = 9 to 12, GCS = 13 to 15) and by age groups (3 to 8 and 9 to 15). Pearson's Product-Moment Correlation Coefficients ranged from .57-.93 ($p \leq .017$) for the groups based on severity of head trauma. The three to eight year old age group correlation was .99 while the nine to fifteen year old group was .89 ($p<.001$).

Construct validity of the CNA was examined using exploratory factor analysis. Seventeen of the 21 CNA items loaded onto one of three factors. Items in factor 1 assessed cognition, affective behavior, and responses to environmental stimuli. Factor 2 loaded items which assessed "overall body and extremity position and movement". Factor 3 loaded the two items assessing muscle tone of the extremities.

CHAPTER 5

DISCUSSIONS AND CONCLUSIONS

A discussion of the findings is presented in this chapter and is divided into the following sections: background and purpose of the research, discussion of the findings, limitations, recommendations, conclusions, and implications for nursing practice.

Background and Purpose of the Research

The Clinical Neurologic Assessment (CNA) Tool was developed to detect changes in the neurologic status of individuals who have sustained head trauma. The CNA has demonstrated reliability and validity when tested in an adult population. The purpose of this study was to test the reliability and validity of the CNA when utilized to assess children who have experienced head trauma.

The conceptual framework used for this study involved the physiological concept of consciousness. Consciousness is an awareness of one's self and the environment (Plum & Posner, 1982). Consciousness is divided into two components: arousal and content.

Arousal is the level of wakefulness observed in response to internal or external stimulation (Mitchell, 1988). Content involves the cognitive and affective

portions of consciousness and involves higher levels of cerebral functioning. The 21 CNA items were designed to assess subtle changes in patients' levels of consciousness reflected in a variety of behaviors.

The CNA's items are divided into the following six subscales:

1. Response to Verbal Stimulation
2. Response to Tactile Stimulation
3. Ability to Follow Commands
4. Assessment of Muscle Tone and Resistance
5. Assessment of Body and Extremity Position/Movement
6. Assessment of Chewing, Yawning, and Verbalization

Review of the Research Protocol

The sample was comprised of forty-one subjects who were recruited from two regional Trauma Centers. The subjects met three criteria: 1. were between the ages of three and fifteen, 2. had sustained head trauma within 72 hours of their initial assessment, and 3. were not receiving paralytic agents at the time of the assessment. All subjects were evaluated by the investigator after obtaining informed consent.

Discussion of the Findings

Reliability

The overall internal consistency of the CNA was estimated at .98 using Cronbach's alpha. Although meeting the minimum established criterion of $\geq$.70 there is concern that the higher than expected alpha may be reflecting redundancy among the items. It is reasoned however, that the high alpha is a result of measuring a complex, integrated, and functional unit: the human body and its associated neurologic structure. This complex integration of cognitive, sensory, and motor systems results in an inability to measure each component separately. The consequence is an overlap in components being assessed in order to examine the entire level of consciousness of an individual.

The internal consistency of each subscale also met the established criteria of Cronbach's alpha $\geq$.70. Subscale alpha coefficients ranged from .89 (Assessment of Muscle Tone and Resistance subscale) to .96 (Response to Verbal Stimulation and Assessment of Body and Extremity Position/Movement subscales).

CNA item-to-total scale correlations demonstrated a high degree of reliability. The criteria used for the item-to-total scale correlation was $\geq$.50. All of the CNA

items met this criteria with ranges in correlations from .53 (item 9 assessing muscle tone) to .95 (item 6 evaluating the ability to follow eye movement commands). Items having the lowest item-to-total scale correlations included items 19 (.55) and 11 (.60). Items 9 and 11 assess muscle tone of the upper and lower extremities respectively. Item 19 evaluates the presence or absence of yawning.

The more severe head injured patients tended to exhibit increases in muscle tone (abnormal posturing) on admission. As these patients progressed through the head trauma recovery phase, their levels of consciousness tended to increase (measured by other CNA items) while their muscle tone remained constant (increased). Therefore, muscle tone may play a more important role in determining levels of consciousness in the acute stages of head trauma and have less emphasis during the recovery phase. Item 19, which assesses the presence of yawning, may have had a lower correlation due to yawning being present but not witnessed by the assessor or staff.

All of the CNA items met the criteria of $\geq .50$ for the item-to-subscale correlations. The correlations ranged from .60 (item 19 assessing the presence of yawning) to .93 (item 8 assessing subjective behavior). The

relatively high item-to-subscale correlations may have reflected the small sample size and the lack of variance in severity of head injury (the majority had perfect CNA and GCS scores).

The inter-item correlations were quite variable among the 21 CNA items. Using the same criteria as in the previous study with adults (.30 - .70), the numbers of inter-item correlations ranged from 3 out of 20 (item 6 assessing the ability to follow eye movement commands) to 18 out of 20 (items 9 and 11 assessing muscle tone and item 19 assessing the presence of yawning). Item one (assessing response to verbal stimulation) positively correlated with 5 out of 20 items, while items 16 and 20 (assessing general voluntary body movement and verbalization) positively correlated with 6 out of 20 items. The remaining 15 items positively correlated with 7 out of 17 other CNA items.

The majority of inter-item correlations not meeting this criteria was due to items having correlations >.70. This again is most likely due to a small sample size with inadequate variations in severity of head injury. One other possibility is that the same explanation for high alpha coefficients for the CNA, the neurologic system being complex and highly integrated, may be true for the

high inter-item correlations. There may be a areas of the neurological system assessed repeatedly when trying to examine specific components of the level of consciousness.

The CNA, in this sample, demonstrated a high degree of internal consistency relative to the severity of head trauma. In the severe head trauma group (GCS = 3 - 8) the CNA alpha coefficient was .87. In the moderate head trauma group (GCS = 9 - 12) the CNA alpha coefficient was .94. The mildly head injured group's (GCS = 13 - 15) CNA alpha coefficient was .92.

The CNA also exhibited a high degree of internal consistency relative to subject's ages. The standardized alpha for the CNA in the 3 - 8 year age group was .98 and .97 in the 9 - 15 year age group.

The CNA demonstrated a high degree of interrater reliability. Cohen's Kappa values for each CNA item ranged from .74 (item 2 assessing eye movement in response to verbal stimulation) to 1.00. Possible Kappa values range from -1.00 - 1.00. Waltz, Strickland, and Lenz (1984) quote an acceptable level as .75. Item 2 (assessing eye movement in response to verbal stimulation) was the only item that did not meet this criteria. This is probably related to the subjectivity in selecting this item's appropriate responses. Some subjects did not

exhibit any of the available responses. This forced the assessor to select the most appropriate response, increasing subjectivity. Twelve of the CNA items had Kappa values = 1.00.

The high Kappa values for many of the CNA items may have been related to high numbers of children in the sample who presented with normal neurological examinations making response selections easier. One argument for the high Kappa values is that both raters are experienced neuroscience nurses (practicing as Clinical Nurse Specialists), although one rater was initially unfamiliar with the CNA while the other rater was proficient in its use.

Validity

Concurrent validity of the CNA was demonstrated by it's highly positive correlation with the GCS ($r = .93$, $p = .000$). The CNA also had a positive correlation with the GCS in relation to severity of head trauma and ages of the subjects. The severe head trauma group (GCS = 3 - 8) had a correlation of $r = .74$ ($p = .000$), the moderate head trauma group (GCS = 9 - 12) a correlation of $r = .57$ ($p = .017$), and the mild head trauma group (GCS = 13 - 15) a correlation of $r = .67$ ($p = .000$). The sub-group correlation values are lower than the overall CNA

correlation because of the smaller sample size of each sub-group. The 3 - 8 age group correlation was .99 ($p = .000$) and the 9 - 15 age group .89 ($p = .000$).

Factor analysis of the CNA in this study demonstrated similar findings when compared with the previous testing in the adult population. The CNA items loaded onto 3 factors. The Response to Verbal Stimulation subscale items (1 and 2) each met the criterion for factor loading onto Factor 1 ($\geq .50$) but did not meet the criteria interval specified to retain them on that factor ($\geq .20$ difference between loadings) (Burns & Grove, 1987). Items 4 and 6 in the Response to Tactile Stimulation subscale (assessing eye movement in response to touch and ability to follow eye movement commands) had identical findings.

Factor 1 did included two of the Response to Tactile Stimulation subscale items (3 and 5) and all of the Chewing, Yawning, and Verbalization subscale. These items reflect an "overall level of consciousness index" (Crosby & Parsons, 1989) by assessing various motor movements in response to a variety of stimuli (verbal, tactile, pain, and commands) and by evaluating an individual's subjective behavior. In the prior study with adults, chewing and yawning loaded solely into one factor.

Factor 2 comprised the items assessing muscle

resistance (items 10 and 12) and the entire Assessment of Body and Extremity Position/Movement subscale. These items reflect levels of consciousness related to motor movement that is spontaneous and not as a result of any stimulation by the assessor. In the prior study with adults, factor 2 consisted of the entire Assessment of Muscle Tone and Resistance subscale.

Items 9 and 11 loaded on factor 3. Each assesses muscle tone of the extremities. Items 10 and 12 assessing muscle resistance loaded onto this factor in the adult population study. The findings between this study and the previous one may have been more similar if this study had a larger and more diverse severity of injury sample.

It is surprising that the items assessing muscle tone and resistance did not load onto a single factor but may be related to the fact that they had the lowest item-to-total scale and item-to-subscale correlations. It is also interesting to note that of the items which did not load onto one factor, three out of four assessed eye movement in response to some type of stimulation. This may be due to subjectivity in interpretation of the responses since two of these items also had lower Kappa values.

Construct validity of the CNA was somewhat supported by the results of the factor analysis. Factor 1 "overall

index of the level of consciousness" combined three subscales which measured cognitive and affective domains of consciousness -- the content component of consciousness. Items 3 and 5 assess responses to touch and pain. Patients with increased levels of consciousness receive higher point values for responses because they require cognitive functioning to discriminate between light, sharp, and dull sensations. In patients with decreased levels of consciousness, items 3 and 5 assess the arousal component of consciousness, since motor movement in "reaction" to a stimulus does not require high levels of cognitive functioning. The population in this study had a high percentage of subjects with perfect CNA and GCS scores. Items 3 and 5 were probably measuring the content component of consciousness more than arousal in this group. It would be interesting to see if these items would load onto factor 2 given a more severely head injured population. Factor 2 items reflect the arousal component of consciousness by measuring body and extremity movement that is spontaneous in origin as opposed to a reaction to a stimulus. These responses require less cognitive effort on the part of the individual and probably assesses their wakeful state.

Limitations

There were several limitations associated with this study. First, the sample size was too small to allow for complete confidence in the results of reliability and validity testing of the Clinical Neurologic Assessment Tool. A larger sample would have assured a reduction in parameter bias and allowed testing based on sub-sample categorization. The small and skewed sample also restricted the generalizability of the findings to the pediatric head trauma population.

The sample was also unevenly distributed in terms of severity of head trauma. The majority of subjects in this study had sustained only mild head trauma. Although this is an accurate reflection of the actual occurrences of head trauma in this age group (Milhorat, 1978), it was a limiting factor in the study.

Another limiting factor in this study may have been utilizing the same subjects for multiple assessments, including the interrater reliability assessments. Optimally, having more diverse types of injuries would allow greater generalizability of the findings.

Other possible limiting factors that may have altered the outcomes of this study included extraneous variables affecting the subject's neurological status. These

included increased body temperature, secondary infections, and medications (especially Morphine and Dilantin) which may have affected how the subjects scored on the CNA.

Since the investigator had sole responsibility of the assessment and calculations of scores, investigator bias and/or error may have also been a possibility.

Recommendations

Recommendations for this study are grouped into two categories: recommendations relative to CNA items when used with children and recommendations for future research.

Recommendations Relative to CNA Items

Items on the CNA tool with specific instructions (i.e. item 1) on how to conduct cues to obtain responses are very helpful. Such instructions would ensure conformity relative to the manner or type of stimuli used, resulting in more consistent testing of patients. An opening paragraph stating specific instructions for use of the entire CNA instrument would prove beneficial for first time users.

For example, some patients who are difficult to arouse become less lethargic as the CNA assessment progresses. It is tempting for the assessor to return to

previous items assessed and increase point values based on the patient's neurologic responses elicited towards the end of the assessment (when the patient seemed less lethargic).

Directions for when and how to assess muscle tone would also be helpful. Most nurses are unfamiliar or uncertain in assessing muscle tone. For example, some difficulty arose in selection of a response when patients would be lethargic and have flaccid extremities at rest (demonstrating lack of muscle tone) but would become aroused by some stimulus during the assessment and very easily responded with a normal motor response (demonstrating good muscle tone). It made selection of responses to items 9 and 11 difficult and inconsistent.

When selecting a response for item 2 (eye movement in response to verbal stimulation), some patients already had their eyes open with purposeful blinking prior to the assessment procedure. When given verbal stimulation, the patient's response did not change. There was a tendency to select response #4 (opens eyes, fluttering and blinking) although this is not an accurate reflection of the patient's actual response to verbal stimulation since that response was present prior to stimulation.

The first response (unable to communicate - this does

not mean because of tracheostomy) in item 21 (assessing orientation) can be misleading to assessors also. Some patients were quite able to communicate verbally but were unable to be evaluated in terms of orientation. None of the responses were accurate reflections of the true response. Disoriented was selected as the appropriate response for these patients when perhaps a response of "able to communicate but unable to elicit orientation level" would be a more accurate reflection of those patients who cannot keep their attention on the question long enough to respond appropriately.

Item eight assessed patients' subjective behavior. There was one behavior that was seen in children and was not one of the offered responses. Some children with head trauma were difficult to maintain in a wakeful state for longer than a few seconds. Even though they may have followed some commands it was not felt that they were "willfully cooperative" or "willfully uncooperative". These children were eventually cooperative but with a great amount of stimulation from the assessor and/or family members. Perhaps a response of cooperative with increased stimulation would be an option in the future.

It was critical to remember to ask parents about any previous neurologic deficits that the child may have had

prior to the head injury. There were a few children who had previous cranial nerve palsies not related to the head trauma. Instructions should be given to ask about previous neurological deficits and deleting those items from the total score.

Interestingly, three of the responses to item 7 which assesses response to following commands by squeezing the assessor's hand, were not selected in any of the 78 assessments completed by the raters. Responses not selected included delayed but slow squeeze, slow squeeze, and brisk squeeze. Although these responses were quite subjective, subjects in this study either gripped and released to command or did not grip at all. Kappa value for item 7 was 1.00. Perhaps a larger sample size would have elicited those responses.

It is important to remember that children are often afraid of health care personnel and tend to be less cooperative during the initial contact. It was helpful to spend time talking to the children and parents prior to conducting the assessment to allay apprehensions.

Some of the CNA items had to be adapted for assessing children. It was helpful to use age appropriate toys to elicit required responses. For example, item six (ability to move eyes to command) was best elicited by using a

small stuffed animal as the cue rather than the assessor's finger. Toys were also used to assess item seven. Instead of asking the child to squeeze the assessor's hand, they were more likely to pick up a toy to command until they become more familiar with the assessor. Prior to assessing items that required the assessor to touch the child, it was helpful to demonstrate the procedure on a doll.

Item 13 also needed to be adapted for children in this study (assessment of position in bed). Many children, especially toddlers and pre-school aged children, sleep in skewed alignments normally. Information from parents regarding the child's normal sleeping configurations were also beneficial to prevent underscoring.

The raters also noticed that many children demonstrated sucking movements with their mouths and not chewing movements. Perhaps incorporating this response into item 18 would be helpful since even a sucking reflex can be a better neurologic sign than no response at all.

Item 21 (assessing orientation) was a challenge for the three to eight year old age group. Depending on age and developmental status, some children know the date or day of the week. Other children do not and may require

different types of questions to assess orientation. Questions about recent holidays may be helpful in assessing time. Questions regarding the patient's home address, city, or phone number may be helpful in assessing orientation to place. Other questions which assisted in the orientation assessment included naming other siblings in the family or pets.

Recommendations for Future Studies

Recommendations for future studies include a larger sample of children with more even distributions in severity of head trauma so that further reliability and validity testing could be completed. Discriminant analysis of the pediatric head trauma population would allow an estimation of the predictive validity of the CNA instrument as well.

Other studies involving the CNA should include other sample populations such as patients with stroke (embolic, thrombotic, or hemorrhagic). Also a multiple facility study would allow more generalizability of the findings.

Lastly, further interrater reliability between assessors less familiar with the CNA instrument, and with less experience in neuroscience nursing, may be helpful to further modify the tool for direct clinical applicability.

Conclusions

In this limited study, the CNA has been found to be a reliable and valid instrument in assessing the neurologic status of children with head trauma. The CNA is easy to use and provides a rapid method for the evaluation of subtle changes in the level of consciousness. Simple adaptations on how to elicit responses from children allow the CNA to be used without difficulty in the very young child.

Internal consistency of the CNA will prove to be a challenge in future studies. Cronbach's alpha may never be an accurate means of estimating reliability of the CNA due to the nervous system's complexity and highly integrated structure. Interrater reliability will most likely be the best method of assessing reliability of the CNA.

Implications for Nursing

Head trauma remains a major health care problem in the United States today. It has been reported (Cooper, 1987) that physiological damage to the central nervous system occurs immediately at the time of impact resulting in changes in the level of consciousness of an individual. Much of the neurologic damage that subsequently occurs is the result of secondary responses of the central nervous system to injury (i.e. increased intracranial pressure,

loss of cerebral autoregulation, cerebral edema, etc.) (Cooper, 1987; Kissoon, Dreyer, & Walis, 1990). This is the area that health care providers can make a critical difference in eventual neurologic outcomes of head trauma victims.

The key to treatment of these secondary responses to injury lie in the early detection of subtle changes in the neurologic status of head trauma patients. It is most often the responsibility of nurses to detect these subtle changes so that prompt nursing and medical interventions can be initiated.

The CNA has the sensitivity to detect these subtle changes in the levels of consciousness of head trauma victims. The CNA has clinical applicability to neuroscience nurses practicing in a wide range of settings. After sufficient instrument testing has been completed, it is hoped that the CNA will be used by nurses in clinical practice.

Summary

The CNA was found to be a reliable and valid instrument in assessing the neurologic status of children who had sustained head trauma. The internal consistency of the CNA was estimated at .98 using Cronbach's alpha. It was determined that the high alpha value was a result

of assessing a complex and highly integrated structure: the human body and its associated nervous system structure. The complex integration of cognitive, sensory, and motor systems prevents assessment of each of these components separately. This results in an overlap in components being assessed in order to adequately assess the entire level of conscousness of an individual.

The CNA demonstrated a high degree of interrater reliability. Only one item's Kappa value (item 2) did not meet the minimum established criterion. Twelve of the CNA items had Kappa values of 1.00 (100% agreement).

Concurrent validity of the CNA was established by its highly significant correlation to the GCS. The CNA continued to demonstrate significant positive correlation with the GCS when the subjects were divided by severity of head trauma and grouped by age.

Construct validity was assessed using exploratory factor analysis. Similar but not identical results were obtained when compared to the the previous study involving adult head trauma victims (Crosby & Parsons, 1989). Three factors continued to emerge although there were some differences in where specific items loaded.

The major limitations of this study involved the smaller than optimal sample size and the lack of diversity

in the severity of head trauma within the population. A larger sample size, which may require a multi-center study, would be optimal to obtain both the quantity of subjects and diversity of injury.

The CNA was found to be easy to use, quickly administered, and valuable in assessing subtle changes in the level of consciousness. It has clinical utility in the head trauma population (both adult and children) and possibly in other types of neurological disorders as well.

APPENDIX A

CLINICAL NEUROLOGIC ASSESSMENT TOOL

CLINICAL NEUROLOGIC ASSESSMENT*

I. Assessment of patient's response following verbal stimulation

Assessor will say, "Hello, [patient's nickname or first name]. This is [assessor's name]. How are you?"

1. Response to verbal stimulation

    1. No response
    2. Minimally aroused/slight movement
    3. Becomes agitated/startles
    4. Attempts to orient toward verbal stimulation
    5. Orients toward verbal stimulation/demonstrates signs of recognition

2. Eye movement in response to verbal stimulation

    1. No response
    2. Slight movement of eyelids/eyes
    3. Opens eyes sluggishly
    4. Opens eyes, lids fluttering and blinking
    5. Opens eyes briskly, purposeful blinking

II. Assessment of patient's response to tactile stimulation

Firmly grasp left or right arm and shake.

3. Body response to touch

    1. No response
    2. Startles or becomes agitated/demonstrates posturing
    3. Slight movement
    4. Movement away from source
    5. Movement toward source
    6. Movement toward source/attempts to grasp assessor

7. Able to discriminate areas of light touch

4. Eye movement in response to touch

1. No response
2. Slight movement of eyelids/eyes
3. Opens eyes sluggishly
4. Opens eyes, lids fluttering and blinking
5. Opens eyes briskly, purposeful blinking

5. Response to painful stimulation

1. No response
2. Startles or becomes agitated/demonstrates posturing
3. Sluggish/delayed motor response
4. Moves away from source of pain
5. Localizes to pain source
6. Purposeful avoidance of pain/grimace
7. Able to discriminate sharp from dull stimulation.

III. Assessment of patient's ability to follow commands

6. Request patient to follow movement of finger with eyes: "[Patient's name], follow my finger."

1. No response
2. Opens eyes
3. Follows < 30-degree arc
4. Follows > 30-degree arc < 90-degree arc
5. Follows 180-degree arc

7. Response to command to squeeze and release assessor's hand. Record best score, right hand versus left hand.

1. No response
2. Delayed but slow squeeze
3. Slow squeeze
4. Brisk squeeze
5. Squeeze and release

8. Demonstrates subjective behavior

    1. None
    2. Willful uncooperative activity
    3. Willing but unable to cooperate
    4. Willful cooperative activity

IV. Assessment of patient's muscle tone and resistance

9. Muscle tone of biceps. Record best score, right arm versus left arm.

    1. Flaccid
    2. Rigid
    3. Tense
    4. Normal

10. Resistance associated with flexion/extension of arms. Record best score, right versus left.

    1. Flaccid
    2. Rigid
    3. Tense
    4. Normal

11. Muscle tone of quadriceps. Record best score, right leg versus left leg.

    1. Flaccid
    2. Rigid
    3. Tense
    4. Normal

12. Resistance associated with flexion/extension of legs. Record best score, right versus left.

    1. Flaccid/no resistance
    2. Inability to flex/fixed
    3. Flexion/rigid (clasp-knife)
    4. Flexion/nonpurposeful resistance
    5. Flexion normal

V. Assessment of patient's body and extremity position/movement

13. Body position in bed

1. Motionless/remains stationary
2. Position secondary to posturing
3. Skewed/nonaligned
4. Relaxed/purposeful/sleeplike

14. Arm activity

1. Motionless/flaccid
2. Both extended and internally rotated (decerebrate)
3. One arm extended and one arm flexed (decorticate/decerebrate)
4. Both decorticate
5. Semiflexed/appears tense
6. Normal/flexed

15. Leg activity

1. Motionless/flaccid
2. Both extended (decerebrate)
3. Semiflexed/appears tense
4. Normal/flexed

16. General voluntary body movement

1. No voluntary movement or posturing
2. Slight movement
3. Restlessness, rolling and turning
4. Aroused/nonpurposeful movement
5. Purposeful movement

17. Position of eyelids. Record best score.

1. Half open
2. Closed/no movement
3. Closed with oscillation of eyes
4. Closed with blinking/fluttering
5. Tightly closed/purposeful
6. Open and blinking/fluttering

VI. Assessment of patient's chewing, yawning, verbalization

18. Chewing

1. Absent
2. Nonpurposeful
3. Grinds teeth
4. Normal/purposeful

19. Yawning

1. Absent
2. Present

If chewing and yawning are not observed, consult with person caring for patient. If no one has observed chewing or yawning, mark absent

20. Verbalization

1. Unconscious/no sound
2. Moaning and or babbling
3. Conscious/no attempts at speech
4. Single-word answers/nodding or shaking head
5. Spontaneous communication to self or others
6. Meaningful communication yet word retrieval problems
7. Meaningful communication (written, verbal, and/or gestures)

21. Orientation

1. Unable to communicate (This does not mean because of tracheostomy)
2. Disoriented
3. Oriented to time, place, situation (reason for hospitalization) (if incorrect responses, patient should be classified disoriented)

*Reference. Crosby L. & Parsons, L. C. (1989). Clinical neurologic assessment tool: Development and testing of an instrument to index neurologic status. Heart & Lung, 18, 121-129.

APPENDIX B

GLASGOW COMA SCALE

GLASGOW COMA SCALE *

Best eye opening response	
Spontaneously	4
To speech	3
To pain	2
No response	1
Best motor response	
Obeys verbal commands	6
Localizes to pain	5
Withdraws to pain	4
Abnormal flexion	3
Abnormal extension	2
No response	1
Best verbal response	
Oriented	5
Confused	4
Inappropriate words	3
Incomprehensible sounds	2
No response	1

*Teasdale, G. & Jennett, B. (1974). Assessment of coma and impaired consciousness - A practical scale. Lancet, 14, 81 - 84.

APPENDIX C

DATA COLLECTION FORM

CLINICAL NEUROLOGIC ASSESSMENT TOOL

Date:_____ MR#:_____ ID#:_____ Age:_____

Sex: M F Date of Injury:_____ Days Since Injury:_____

Mechanism of Injury: MVA____ Fall____ Assault____ Bicycle____

Other_____

Type of Injury: Acc/Dec____ Compression____ Other_____

Site of Impact: R Frontal____ L Frontal_____

R Temporal____ L Temporal____

R Parietal____ L Parietal____

R Occipital____ L Occipital____

R Basilar____ L Basilar____

Initial GCS: E____ M____ V____ Present GCS: E____ M____ V____

ETOH: _____ Rater: _____

CNA Observation # _____

Scoring

Maximum = 101

Minus number of points lost from items not observable: _____

Denominator: _____

Recorded CNA Points (Numerator): _____

Numerator/Denominator: _____/_____

Percent: _____

APPENDIX D

HUMAN SUBJECTS APPROVAL

Human Subject Committee

THE UNIVERSITY OF
ARIZONA
HEALTH SCIENCES CENTER

1690 N. Warren (Bldg. 526B)
Tucson, Arizona 85724
(602) 626-6721 or 626-7575

21 March 1990

Stephanie M. Gillespie, R.N.
c/o Leanna J. Crosby, D.N.Sc., R.N.
College of Nursing
Arizona Health Sciences Center

RE: HSC #A90.43 RELIABILITY AND VALIDITY OF THE CLINICAL NEUROLOGICAL ASSESSMENT (CNA) TOOL IN CHILDREN WITH HEAD TRAUMA

Dear Ms. Gillespie:

We received your above referenced project. The procedures to be followed in this study pose no more than minimal risk to participating subjects. Regulations issued by the U.S. Department of Health and Human Services [45 CFR Part 46.110(b)] authorize approval of this type project through the expedited review procedures, with the condition(s) that subjects' anonymity be maintained. Although full Committee review is not required, a brief summary of the project procedures is submitted to the Committee for their endorsement and/or comment, if any, after administrative approval is granted. This project is approved for one year effective 21 March 1990.

The Human Subjects Committee (Institutional Review Board) of the University of Arizona has a current assurance of compliance, number M-1233, which is on file with the Department of Health and Human Services and covers this activity.

Approval is granted with the understanding that no changes or additions will be made in study personnel, to the procedures followed or to the consent form(s) used (copies of which we have on file) without the knowledge and approval of the Human Subjects Committee and your College or Departmental Review Committee. Any research related physical or psychological harm to any subject must also be reported to each committee.

A university policy requires that all signed subject consent forms be kept in a permanent file in an area designated for that purpose by the Department Head or comparable authority. This will assure their accessibility in the event that university officials require the information and the principal investigator is unavailable for some reason.

Sincerely yours,

Milan Novak, M.D., Ph.D.
Chairman
Human Subjects Committee

MN/ms

cc: Departmental/College Review Committee

Tucson Medical Center
Team • Technology • Tradition

April 3, 1990

Stephanie Gillespie RN
Tucson Medical Center
5301 E. Grant Rd
Tucson, Arizona 85712

Re: Reliability and Validity Assessment of the Clinical Neurological Assessment (CNA) Tool in Children with Head Trauma

Dear Ms. Gillespie:

This is to advise you that the above referenced research study was approved by the Human Research Committee on April 3, 1990 pending receipt of changes on the consent form. Having received these changes as requested, you may start your data collection.

It is understood that no changes will be made in your study without the knowledge and approval of the Human Research Committee. Please be aware that a copy of the consent form must be placed in the patient's medical record.

Review has been set at six months. A copy of the Guidelines for Continuing Review and our membership roster are enclosed. As part of our quality assurance program a new requirement has been set forth by the Human Research Committee. We request that you submit a list of enrollees in your study with your six month Research Activity Status Report. We will be doing periodic audits of the medical record.

Should you have any questions, please contact me at extension 5332 or Chris Arslanian, Research Associate at extension 5512.

Sincerely,

Ronald Spark, MD, Chairman
TMC Human Research Committee

RPS:cla
Encl:

University Medical Center

1501 North Campbell Avenue
Tucson, Arizona 85724
Nursing Administration

April 24, 1990

Stephanie Gillespie, RN, BS
1150 North El Dorado Place #143
Tucson, AZ 85715

Dear Stephanie:

Your request to conduct your research entitled, "Validity and Reliability of the Clinical Neurological Assessment Tool in Children with Head Trauma," has been approved by the Department of Nursing Research. The clinical unit for which you are approved is 3 East with Jill Schneden as your designated contact person. Please contact her to make plans for data collection, arrange for staff education, as appropriate and answer any questions about your proposed plan to collect data.

We look forward to having you report your results and provide us with an abstract of your findings. Please notify me when you have completed your research.

Sincerely,

Carolyn Murdaugh, RN, PhD, FAAN
Director of Nursing Research

CM:bjh

cc: J. Schneden
M. Enriquez

APPENDIX E

CONSENT FORMS

THE UNIVERSITY OF ARIZONA COLLEGE OF NURSING

SUBJECT'S CONSENT

RESEARCH: Reliability and Validity of the Clinical Neurological Assessment (CNA) Tool in Children with Head Trauma

I AM BEING ASKED TO READ THE FOLLOWING MATERIAL TO ENSURE THAT I AM INFORMED OF THE NATURE OF THIS RESEARCH STUDY AND OF HOW MY CHILD WILL PARTICIPATE IN IT, IF I CONSENT TO DO SO. SIGNING THIS FORM WILL INDICATE THAT I HAVE BEEN INFORMED AND THAT I GIVE MY CONSENT. FEDERAL REGULATIONS REQUIRE WRITTEN INFORMED CONSENT PRIOR TO PARTICIPATION IN THIS RESEARCH STUDY SO THAT I CAN KNOW THE NATURE AND THE RISKS OF MY CHILD'S PARTICIPATION AND CAN DECIDE TO PARTICIPATE OR NOT PARTICIPATE IN A FREE AND INFORMED MANNER.

Stephanie Gillespie, R.N. has asked me/my child to take part in a research project that is designed to test the accuracy of the Clinical Neurological Assessment tool, which is designed to measure changes in how concsious a person is once they have hit their head. I/my child has been selected because he/she has hit his/her head and is between the ages of 3-15 years.

If I/my child is to participate in this study, the following will procedure will occur:

after reviewing my child's chart, an assessment will be performed which includes observations of responses when the investigator touches and speaks to my child, how well my child can follow simple commands such as squeezing the investigator's hand, the ability of my child to talk, his/her body position, and evidence of yawning or chewing. A commonly used assessment tool, the Glasgow Coma Scale, will also be used which observes eye opening, movement of the arms and legs, and talking.

The assessment takes approximately 10 - 15 minutes to complete and will be conducted in the emergency room or on the hospital unit where I/my child is admitted. I understand that the assessment may be repeated on another day, and that the assessment will be conducted during periods which will not interfere with nursing/medical care.

I understand that I/my child is free to question the investigator about any aspect of the study.

I understand there are no known physical discomforts or risks involved in the study. All information will remain strictly confidential to be used only for study purposes. The information may be utilized by other authorized researchers and may be published, although confidentiality of the participants in the study will be maintained. The FDA and the Human Research Committee may also need to review my child's chart. There is no cost to us for this project nor will we be paid for

participating. I also understand that my/my child's participation in this research has no direct benefit but may assist in providing a more precise means of following the neurologic status of patients who will sustain head trauma in the future.

BEFORE GIVING MY CONSENT BY SIGNING THIS FORM, THE METHODS, INCONVENIENCES, RISKS, AND BENEFITS HAVE BEEN EXPLAINED TO ME AND MY QUESTIONS HAVE BEEN ANSWERED. I UNDERSTAND THAT I MAY ASK QUESTIONS AT ANY TIME AND THAT I AM FREE TO WITHDRAW FROM THE PROJECT AT ANY TIME WITHOUT CAUSING BAD FEELINGS OR AFFECTING MY MEDICAL CARE. MY PARTICIPATION IN THIS PROJECT MAY BE ENDED BY THE INVESTIGATOR OR BY THE SPONSOR FOR REASONS THAT WOULD BE EXPLAINED. NEW INFORMATION DEVELOPED DURING THE COURSE OF THIS STUDY WHICH MAY AFFECT MY WILLINGNESS TO CONTINUE IN THIS RESEARCH PROJECT WILL BE GIVEN TO ME AS IT BECOMES AVAILABLE. I UNDERSTAND THAT THIS CONSENT FORM WILL BE FILED IN AN AREA DESIGNATED BY THE HUMAN RESEARCH COMMITTEE WITH ACCESS RESTRICTED TO THE PRINCIPAL INVESTIGATOR, STEPHANIE M. GILLESPIE, OR AUTHORIZED REPRESENTATIVE OF THE NURSING DEPARTMENT. I UNDERSTAND THAT I DO NOT GIVE UP ANY OF MY LEGAL RIGHTS BY SIGNING THIS FORM. A COPY OF THIS SIGNED CONSENT FORM WILL BE GIVEN TO ME.

PARENT OR GUARDIAN'S SIGNATURE _____ DATE _____

CHILD'S SIGNATURE (If 7 years or older) _____ DATE _____

WITNESS _____ DATE _____

INVESIGATOR'S AFFIDAVIT

I HAVE CAREFULLY EXPLAINED TO THE SUBJECT THE NATURE OF THE ABOVE PROJECT. I HEREBY CERTIFY THAT TO THE BEST OF MY KNOWLEDGE THE PERSON WHO IS SIGNING THIS CONSENT FORM UNDERSTANDS CLEARLY THE NATURE, DEMANDS, BENEFITS, AND RISKS INVOLVED IN HIS/HER PARTICIPATION AND HIS/HER SIGNATURE IS LEGALLY VALID. A MEDICAL PROBLEM OR LANGUAGE OR EDUCATIONAL BARRIER HAS NOT PRECLUDED THIS UNDERSTANDING.

SIGNATURE OF INVESTIGATOR _____ DATE _____

CHILD'S PRINTED NAME AND MR# _____

Tucson Medical Center
Consent Form

THE UNIVERSITY OF ARIZONA COLLEGE OF NURSING

SUBJECT'S CONSENT

RESEARCH: Reliability and Validity of the Clinical Neurological Assessment (CNA) Tool in Children with Head Trauma

I AM BEING ASKED TO READ THE FOLLOWING MATERIAL TO ENSURE THAT I AM INFORMED OF THE NATURE OF THIS RESEARCH STUDY AND OF HOW MY CHILD WILL PARTICIPATE IN IT, IF I CONSENT TO DO SO. SIGNING THIS FORM WILL INDICATE THAT I HAVE BEEN INFORMED AND THAT I GIVE MY CONSENT. FEDERAL REGULATIONS REQUIRE WRITTEN INFORMED CONSENT PRIOR TO PARTICIPATION IN THIS RESEARCH STUDY SO THAT I CAN KNOW THE NATURE AND THE RISKS OF MY CHILD'S PARTICIPATION AND CAN DECIDE TO PARTICIPATE OR NOT PARTICIPATE IN A FREE AND INFORMED MANNER.

Stephanie Gillespie, R.N. has asked me/my child to take part in a research project that is designed to test the accuracy of the Clinical Neurological Assessment tool, which is designed to measure changes in how concsious a person is once they have hit their head. I/my child has been selected because he/she has hit his/her head and is between the ages of 5-15 years.

If I/my child is to participate in this study, the following will procedure will occur:

- an assessment will be performed which includes observations of responses when the investigator touches and speaks to my child, how well my child can follow simple commands such as squeezing the investigator's hand, the ability of my child to talk, his/her body position, and evidence of yawning or chewing. A commonly used assessment tool, the Glasgow Coma Scale, will also be used which observes eye opening, movement of the arms and legs, and talking.

The assessment takes approximately 10 - 15 minutes to complete and will be conducted in the emergency room or on the hospital unit where I/my child is admitted. I understand that the assessment may be repeated on another day, and that the assessment will be conducted during periods which will not interfere with nursing/medical care.

I understand that I/my child is free to question the investigator about any aspect of the study.

I understand there are no known physical discomforts or risks involved in the study. All information will remain strictly confidential to be used only for study purposes. The information may be utilized by other authorized researchers and may be published, although confidentiality of the participants in the study will be maintained. There is no cost to us for this project nor will we be paid for participating. I also understand that my/my child's participation in this research has no direct benefit but may assist in providing a more precise means of

following the neurologic status of patients who will sustain head trauma in the future.

BEFORE GIVING MY CONSENT BY SIGNING THIS FORM, THE METHODS, INCONVENIENCES, RISKS, AND BENEFITS HAVE BEEN EXPLAINED TO ME AND MY QUESTIONS HAVE BEEN ANSWERED. I UNDERSTAND THAT I MAY ASK QUESTIONS AT ANY TIME AND THAT I AM FREE TO WITHDRAW FROM THE PROJECT AT ANY TIME WITHOUT CAUSING BAD FEELINGS OR AFFECTING MY MEDICAL CARE. MY PARTICIPATION IN THIS PROJECT MAY BE ENDED BY THE INVESTIGATOR OR BY THE SPONSOR FOR REASONS THAT WOULD BE EXPLAINED. NEW INFORMATION DEVELOPED DURING THE COURSE OF THIS STUDY WHICH MAY AFFECT MY WILLINGNESS TO CONTINUE IN THIS RESEARCH PROJECT WILL BE GIVEN TO ME AS IT BECOMES AVAILABLE. I UNDERSTAND THAT THIS CONSENT FORM WILL BE FILED IN AN AREA DESIGNATED BY THE HUMAN SUBJECTS COMMITTEE WITH ACCESS RESTRICTED TO THE PRINCIPAL INVESTIGATOR, STEPHANIE M. GILLESPIE, OR AUTHORIZED REPRESENTATIVE OF THE NURSING DEPARTMENT. I UNDERSTAND THAT I DO NOT GIVE UP ANY OF MY LEGAL RIGHTS BY SIGNING THIS FORM. A COPY OF THIS SIGNED CONSENT FORM WILL BE GIVEN TO ME.

PARENT OR GUARDIAN'S SIGNATURE _____ DATE _____

CHILD'S SIGNATURE (If 7 years or older) _____ DATE _____

WITNESS _____ DATE _____

INVESIGATOR'S AFFIDAVIT

I HAVE CAREFULLY EXPLAINED TO THE SUBJECT THE NATURE OF THE ABOVE PROJECT. I HEREBY CERTIFY THAT TO THE BEST OF MY KNOWLEDGE THE PERSON WHO IS SIGNING THIS CONSENT FORM UNDERSTANDS CLEARLY THE NATURE, DEMANDS, BENEFITS, AND RISKS INVOLVED IN HIS/HER PARTICIPATION AND HIS/HER SIGNATURE IS LEGALLY VALID. A MEDICAL PROBLEM OR LANGUAGE OR EDUCATIONAL BARRIER HAS NOT PRECLUDED THIS UNDERSTANDING.

SIGNATURE OF INVESTIGATOR _____ DATE _____

University Medical Center
Consent Form

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