DNP Portfolio Executive Summary

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"A portfolio is a compilation of accomplishments accrued by the student during learning activities and experiences and represents evidence of clinical competence." (Smolowitz & Honig, 2008)

As I read through the fifteen components of my portfolio, I first notice that I have a stack of paper two and a half inches high and it represents all of the written work I have done in 24 months. Presently, I work with special needs children in a hospital setting. The portfolio reflects my assessment of the need for improved patient outcomes in this population. I was able to identify this need early in the program. This was a valuable piece of information that drove my clinical research and residency.

The first component is the CV, which is a chronological list of my accomplishments, easy to read and reflects my advances in the profession, especially the noteworthy completed endeavors since I began the DNP program. Of all the portfolio components I see the most clinical scholarship in the Clinical Inquiry Report and the Results Report. The culmination of my research efforts, the evolution of my writing skills, and the evidence of my new found knowledge of statistical analysis are demonstrated in this body of work. The Policy Paper was written from a neophyte political change agent viewpoint, but if I were to write the same paper at the end of the DNP program I can visualize fine-tuning it to reflect the specific patient population I work with now. That same perspective applies to the Ethics paper; the difference being the ethical issue was in reference to a patient with special needs. The Organizational Change paper and the Independent Case Report are the two papers I hope my audience will recognize as very early attempts at scholarly writing that afford the reader the opportunity for comparison to the much improved, better organized and scholarly case reports written in the second year.

The beginning of the second summer term was a turning point. I felt with the majority of the coursework finished, the clinical aspect of the doctoral preparation would begin in earnest. In my practice I began to see subtle changes in my critical thinking, looking at the population of patients as a whole in a larger sense than just the inpatient or outpatient visit encounter. At that time, I also became a member of a national group of Pediatric Orthopedic Practitioners and found a network of colleagues across the United States who practice in this specialty. I also attended the first DNP conference in Memphis, Tennessee further widening my ability to influence practice across the United States through networking.

As my education towards the DNP degree has progressed, my practice in Pediatric orthopedics and bone tumors has become more evidence based, having learned to research and look for the existing gold standards to improve our patient outcomes. I have organized 2 new quality improvement projects, one to improve the accuracy of the documentation of History and Physical examinations and second to develop a Same-Day surgery clinic to increase efficiency, decrease costs, and improve patient satisfaction. I regularly attend journal clubs and participate in reviewing articles, critiquing them for level of evidence and clinical relevance. Most recently, because of my clinical residency, I have been added as a co-principle investigator in an international study looking at a new device to treat early onset scoliosis.

Earning the DNP degree is an accomplishment of clinical scholarship. I thank you all for leading me on this journey.

Smolowitz, J. & Honig, J. (2008). DNP portfolio: The scholarly project for the doctor of nursing practice. *Clinical Scholars Review, 1*(1), 18-22.

Running head: CLINICAL INQUIRY PROJECT

# A Nutrition Assessment of Children with Neuromuscular Impairments Undergoing Spinal Fusion and Instrumentation and Frequencies of Postoperative Infections

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## Description and Significance of the Clinical Problem

The quarterly infection control report, issued from the Quality Improvement Department in the institution where the clinical inquiry will be carried out, identified an increase in the infection rate after spine fusion surgery in the neuromuscular scoliosis population. The nutritionist and one of the spine surgeons noted anecdotally that most of those same patients were nutritionally depleted at the time of surgery, using weight as the assessing parameter. The identified patients' weights were at or below the fifth percentile. The question was raised that perhaps these patients needed a preoperative nutritional assessment and intervention to better prepare them for spine fusion and instrumentation surgery to prevent postoperative wound infections.

Not only is the issue of infection rates among spinal fusion patients a problem of best outcomes for the patients in question, but also recently, Medicaid has announced there will no longer be financial reimbursement for treatment for hospital acquired infections (Centers for Medicaid and Medicare Services, 2007). The financial impact of this change warrants all institutions to examine their surgical infection rates and make changes accordingly. Although our hospital does not charge for services, those who do will suffer a significant loss of revenue as post-operative surgical infections incur costs estimated at $67,000 (Murphy et al., 2007).

Additionally, the problem of infections in children undergoing surgery for scoliosis is also a problem for the parents. Parents of children with neuromuscular disorders are challenged with health care decisions throughout the lifetime of their children. The decision to have spine fusion surgery is a difficult one. However, studies of parents' and caregivers' satisfaction postoperatively have demonstrated significant rates of satisfaction with improved comfort in

sitting, increased ease of positioning and increased out of bed time (Tsirikos, Chang, Dabney, & Miller, 2004). The incidence and risk of postoperative infection is explained to the parents during the consent process for surgery, but family members do not realize the enormity of a major wound infection.

Children with neuromuscular scoliosis who undergo surgical release and spinal fusion for scoliosis curve correction have a higher risk of postoperative complications. Research has shown that the risk of complications is higher when nutritional deficiencies are present in the preoperative period (Sponseller, et al, 2000). Heys, Walker, Smith, and Erimen (1999) conducted a meta-analysis which demonstrated a significant decrease in infectious complications and decrease in length of hospital stay in adult patients who received postoperative nutritional supplementation with key nutrients compared to patients who did not (Heys et al., 1999). Results of studies in the adult population undergoing spine fusion surgery have shown, using logistic regression analysis, that preoperative nutritional status was a significant predictor of deep wound infections (Klein et al., 1996).

Data have not been consistently been collected on the preoperative nutritional profile of the pediatric patients seen at a pediatric orthopedic institution. The intended outcome is to have more nutritionally sound patients ready for major surgery. Literature demonstrates patients who are in a nutritionally depleted state have more post-operative complications (Mohamad et al., 2007) while patients with a better nutritional profile will have fewer post-operative problems (Szoke et al., 1999).

## Research Questions

Two questions are being asked in this clinical inquiry project.

1. What is the current nutritional preoperative profile of neuromuscular scoliosis patients undergoing spinal fusion and instrumentation surgery? and

2. What are the current postoperative rates of wound infection, pneumonia, and length of stay in the same population?

## Background

The focus of the clinical inquiry is children undergoing surgery for neuromuscular scoliosis. Unlike idiopathic scoliosis, both neuropathic and myopathic neural pathways are involved in neuromuscular scoliosis. Neuropathic conditions include both upper motor neuron diseases (e.g. cerebral palsy, spinal cord trauma, tumors, and spinal muscular atrophy) and lower motor neuron diseases (e.g. polio). Spina bifida patients have a combination of both neural pathway problems. Myopathic causes include muscular dystrophy and arthrogryposis. The common factor in all causes is the inability to provide support to the spinal column or an imbalance of the muscular control of the spine (Lonstein, 2002).

The diagnosis of a neuromuscular disorder is concomitant with cardiopulmonary, gastrointestinal, and neurological manifestations as well as the skeletal manifestation of scoliosis (Wenger & Rang, 1993). As disease progression occurs, the potential postoperative complications in the adult and pediatric populations associated with these manifestations also increases (Benson, Thomson, Smith, & Banta, 1998). Murphy, Firth, Jorgensen, and Young (2007) found statistically significant longer lengths of hospital stay with increased incidences of pneumonia, respiratory failure, urinary tract infections and wound infections in children and adults with neuromuscular disorders (Murphy et al., 2007).

Neuromuscular scoliosis from both causes is rapidly progressive and occurs at an early age (Murphy & Such-Neibar, 2003). This type of scoliosis is present in 90% of sacral level spina bifida patients, 60% to 75% of children with cerebral palsy with spastic quadriplegia, and nearly all children with Duchene muscular dystrophy (Murphy, Firth, Jorgensen, & Young, 2006). Motor functioning levels for children with these conditions are rated by a Gross Motor Function Classification System (GMFCS). GMFCS levels are rated 1 to 5 with 5 being with most affected. Grade V is defined as "Physical impairment restricts voluntary control of movement and the ability to maintain antigravity head and trunk postures. All areas of motor function are limited. Children have no means of independent mobility and are transported" (Graham, 2005, p.128).

## Rationale for the Study by the Doctor of Nursing Practice

The Doctor of Nursing Practice (DNP) is an integral member of the multidisciplinary team. A multidisciplinary team approach to clinical evaluation, both preoperative and postoperative, is the gold standard for this high risk, vulnerable population. Pruijs, van Tol, van Kersteren, and van Nieuwenhuizen, (2000) described the European Alliance of Muscular Dystrophy Associations' "Utrecht" approach as a team of the rehabilitation physician, physical therapists, nurses, orthopaedic surgeon, and physiatrist collaborating in the best interest of the patient. It is appropriate for the DNP to be a member of the team to study factors that could lead to improved postoperative outcomes.

## Conceptual Framework

In order to lessen the gap between research and practice, the advanced practice nurse leader must demonstrate that care is based on best evidence, drawing on clinical research and literature. A conceptual framework may be developed from a theory or created to describe the

relationship between concepts that are related to the outcomes of interest (Brathwaite, 2003). The use of a conceptual framework is necessary to guide the design and conduct of a research study and explain the effectiveness of an intervention (Brathwaite, 2000). The practical value of using a conceptual framework for this inquiry is the direction it provides in the design, the selection of data to be collected, and the methodology to be used.

*Conceptual Framework*

The care of the child with neuromuscular scoliosis must be approached from a holistic view as not only skeletal problems are being addressed when surgery occurs. These children have multiple fragile systems, which are affected by the stress of a 4 to 12 hour long surgery. They require intensive care nursing for the first 24 hours including fluid resuscitation and blood product administration. Respiratory status is unstable and must be monitored carefully. As they recover and return to their baseline, return of gastrointestinal function is often problematic. Constipation preoperatively also affects return to normal gastrointestinal function postoperatively. Nutritional status and tissue healing is compromised in the non-ambulatory child and is the most important factor in the prevention of wound infections in this population. The risk of infection is always increased with the addition of spinal instrumentation in spite of using less irritating titanium hardware. These variables are discussed for the framework of this inquiry.

*Discussion of Conceptual Framework Variables*

The key elements of the problem include respiratory compromise, wound infection, constipation and malnutrition. Each is defined here but the literature is explained in greater detail in the Review of Literature section which follows.

*Respiratory Compromise.* The range of pulmonary status in patients with neuromuscular disorders preoperatively varies widely. Current research has shown that spinal column growth is directly related to lung growth (Canavese et al., 2007). While this newest information is not directly related to this clinical inquiry, the implications for future practice will change dramatically in the area of pulmonary assessment and functional outcome measurement based on these new findings. Neuromuscular disorders result in respiratory problems due to different types of pathophysiology depending on the diagnosis. For example, in Duchene's muscular dystrophy, muscle tissue becomes fibrous and loses the capacity for stretching, thereby affecting respiratory function, putting those patients at higher risk for pulmonary problems postoperatively (Salter, 1999). In cerebral palsy and spastic quadriplegia, immobility affects respiratory function and the outcome for those patients is also a higher risk for pulmonary problems after surgery (Wenger & Rang, 1993). Postoperative atelectasis is common in this population and pneumonia occurs more frequently (Tredwell, 2001).

*Chronic Constipation.* Gastrointestinal integrity is compromised in children with neuromuscular disorders as in all wheelchair dependent, immobile patients. Gastrointestinal integrity in this population can be defined as alterations in bowel function related to immobility and spasticity. In the spina bifida population, lack of innervation equates with no control over bowel and bladder control. Chronic constipation is a common lifelong problem for these children. In a recent epidemiological survey of nutritional and gastrointestinal problems in children with cerebral palsy, constipation, defined as bowel movements less frequently than once in every 3 days, was reported in 98 of 377 (26%) of children (Elawad, 2001). Children with cerebral palsy exhibit diffuse gastrointestinal clinical manifestations, mostly due to disorders of gastrointestinal motility (Del Giudice et al., 2001).

*Wound Infection*. Spinal fusion and instrumentation surgery involves an average length incision of 16 inches, which produces a considerable dead space when closing the wound. Drains are usually needed and increase the potential for infection if left in place for more than 24 hours. In addition, immobile children (i.e., GMFCS level 4 and 5) do not heal as well as persons who are mobile.

*Measures of Malnutrition.* Total serum hepatic protein, albumin, and prealbumin levels have historically been linked in clinical practice to nutritional status (Mandelbaum, Tolo, McAfee, & Burest, 1988). Measurement of the serum total protein evaluates protein nutritional status and diseases, which alter protein metabolism. Albumin is the primary constituent of human plasma protein. Albumin measures the body's protein reserves. Prealbumin is a marker for protein synthesis, the earliest marker for adequate protein intake (Jacobs, deMott, & Oxley, 2004). As early as 1988, Mandelbaum et al., published a landmark study of nutritional status and immunological incompetency and its significant correlation to increased postoperative complications (Mandelbaum, et al., 1988). Using the criteria for nutritional (decreased albumin levels) and immunological incompetency (decreased lymphocyte count), the study showed that 84% of the patients became malnourished during the hospitalization. Total lymphocyte count of less than 2000/$mm^3$/serum and albumin less than 3.5g/100ml had significantly more postoperative complications (Mandelbaum, et al., 1988).

Literature regarding the inflammatory process and its effects on hepatic protein metabolism have continued to prove the previous reports suggesting that nutritional status and protein intake are the significant correlates with serum hepatic protein levels (Fuhrman, 2004). Fuhrman goes on to explain the state of stress-induced hypoalbuminemia and how those levels can be quickly depleted in trauma or acute illness. (Fuhrman, 2004). Her synthesis of the

literature revealed significant correlations between hypoalbuminemia and morbidity and mortality, increased length of stay, and increased costs of hospitalization (Fuhrman, 2004). "…the degree of injury or illness can impact appetite, gastrointestinal motility, and hemodynamic stability, which in turn, can negatively effect the patient's nutritional status" (Fuhrman, 2004, p. 1259). Fuhrman concludes that these patients need the most aggressive nutritional monitoring to decrease postoperative complications (Fuhrman, 2004).

The effects of nutrition and wound healing have continued to support those previously well-documented studies in the orthopedic surgery literature (Smith, 1987). The American Academy of Physicians published this statement in 2002:

> Determining the level of prealbumin, a hepatic protein, is a sensitive and cost-effective method of assessing the severity of illness resulting from malnutrition in patients who are critically ill or have a chronic disease. Prealbumin levels have been shown to correlate with patient outcomes and are an accurate predictor of patient recovery. In high-risk patients, prealbumin levels determined twice weekly during hospitalization can alert the physician to declining nutritional status, improve patient outcome, and shorten hospitalization in an increasingly cost-conscious economy (Beck, 2002, p.1575).

Jevsevar (1993) retrospectively reviewed records of 44 patients, ages 12 to 32 years, with cerebral palsy and spastic quadriplegia who underwent spinal surgery for scoliosis. The group of 24 patients with total serum albumins greater than 3.5mg% and a total lymphocyte count of $1500mm/^3$ had lower infection rates, less intubation time and a shorter length of stay (Jevsevar, 1993).

# Review of the Literature: Surgical and Nutritional Outcomes

## *General Surgery Outcomes*

Meakins (1998) published a review of the history and progression of the phenomena of surgical infection from 1972-1997. He noted that in 1972 infectious morbidity in colon surgery was 25 to 60%, compared with 3 to 5% contaminated cases in 1997. While this comparison is made in patients having colon surgery, where bowel tissue was compromised, the percentages show marked improvements in infectious morbidity. Improved surgical technique, better pain management, early patient mobilization, and improved understanding of the biology and management of the surgical patient have affected all surgical outcomes over the past 25 years (Meakins, 1998).

Pulmonary complications of general surgery in one study of 175 patients ages 2-37 years, with a mean of 14 years of age, were reported to be 19.4%, accounting for 46.9% of all complications (Mohammed et al, 2007). Prolonged atelectasis and pneumonia were the reported highest complications (Mohammed et al, 2007). Of the 45 pulmonary complications, 22 occurred in patients who had a seizure disorder and were on medications for seizure control (Mohammed et al., 2007).

## *Scoliosis Surgery Outcomes*

Cardiac and pulmonary functions are also affected by the major blood loss in spine fusion surgery. A review of the literature revealed the neuromuscular scoliosis population is at high risk for severe blood loss, up to 200% of total volume with concomitant coagulation problems in the immediate postoperative period (Pruijs, 2000 & Salter, 1999). Mohammed et al. (2007) reported

a blood loss range of 4.82 to 207ml/kg of blood loss, with the higher loss associated with combined anterior muscular release and posterior instrumentation surgical technique.

Researchers studying infection rates in neuromuscular scoliosis spine fusion patients reported rates of 9.3% to 20% (Kretzler and Renshaw, 1991; Transfeldt, Lonstein, Winter, Bradford, Moe, and Mayfield, 1993). More recently, studies show infection rates in these patients ranging from 4% to 14%. The decrease is attributed to prophylactic antibiotic use and better instrumentation techniques (Szoke, Lipton, Miller, and Dabney, 1998). Wound infections are serious complications of spine fusion, necessitating readmission to the hospital, numerous wound irrigation debridement surgical interventions, prolonged hospital admissions and long term intravenous antibiotics via a central intravenous catheter (Labbe et al., 1999).

*Malnutrition and Surgical Outcomes*

Nutrition is important in all surgical cases, but in the child with cerebral palsy or muscular dystrophy attention to the nutritional status is paramount. The literature demonstrates that the highest risk factor for postoperative complications, regardless of the neuromuscular diagnosis, is the preoperative presence or postoperative occurrence of malnutrition (Campanozzi et al., 2007; Chmell, 1996; Craig & Schwartz, 2006; Smith et al., 1987; Snyderman et al., 1999; & Szoke, 1998). The concept has been generalized in oncology patients, specifically with musculoskeletal sarcomas (Chmell & Schwartz, 1996) and oncological head and neck surgery (Snyderman et al., 1999). The presence of malnutrition in the postoperative patient over time has been correlated with increased length of hospital stay, increased risk of complications, and increased use of hospital resources (Fuhrman, Charney & Mueller, 2004). If the child is

nutritionally compromised before surgery, his or her nutritional needs postoperatively will be proportionally increased.

Malnutrition in any population can be categorized in two ways. Marasmus, protein-calorie malnutrition, and kwashiorkor, general protein malnutrition, have both been shown to affect wound healing (Jevsevar & Karlin, 1993). Immune deficiencies, measured by total lymphocyte count, have also been correlated with malnutrition and increased postoperative complication in children undergoing spine fusion surgery (Mandelbaum, et al., 1988) as described earlier. The total lymphocyte count is calculated by taking the absolute white blood cell count and multiplying that by the lymphocyte percentage count.

Markers of malnutrition for children also include height and weight. Recently the measurement of body mass index has been added to assess underweight or overweight in children (Center for Disease Control, 2008). Height, weight and BMI are primarily markers of adequate caloric intake although fluids also affect weight significantly. Measurement of weight in the postoperative period is an inadequate marker for nutritional status because of the fluid balance changes from surgery, blood loss and replacement fluids, and the inability of the patient to eat postoperatively (Smith, 1987).

In addition, the measurement of hemoglobin is an indicator of iron deficiency, a different nutritional status problem. Numerous studies have shown that growth and malnutrition are directly related to hemoglobin levels (Martin et al., 1996; Nathan et al., 1998, & Eden et al, 1997). Malnutrition has been studied as it relates to iron metabolism (Agarwal, Mehta, Mhaiskar, Kumta, & Shah, 1981). Two groups of children with iron deficiency anemia were studied. Forty-five children with protein energy malnutrition were compared with fifteen children without

malnutrition. The results demonstrated that only giving iron supplements to hypoproteinemic children was inadequate treatment. Increased dietary protein was an integral part of treatment in this population (Agarwal, et al., 1981).

Constipation is a significant problem in children with neuromuscular disorders and has been linked to malnutrition from inadequate fiber and fluid intake. Inadequate dietary fiber and fluid intake, lack of erect posture, poor muscle tone together with prolonged immobility without exercise, and no urge to defecate contribute to constipation in children with developmental delays (Chong, 2001). Children with muscular dystrophies have similar lifestyle sedentary causes. The weak abdominal musculature and smooth muscle myopathy in this population further increases problems with gastrointestinal motility (Chong, 2001). One group in the Netherlands is researching recurrent pneumonias in children with cerebral palsy, hypothesizing that risk factors of dysphasia, respiratory function and constipation contributed to the rate of pneumonia (Veuglers et al., 2005). Gastroesophageal reflux and chronic constipation has been significantly correlated with general malnutrition in the cerebral palsy population in many studies (Campanozzi et al, 2005; Chong, 2001; Craig, 2006, & Veuglers, 2005) as well as a possible factor in pneumonias, it needs to be considered as a possible factor related to malnutrition and postoperative outcomes.

## Methods

Two questions are being asked in this clinical inquiry project.

1. What is the current nutritional preoperative profile of neuromuscular scoliosis patients undergoing spinal fusion and instrumentation surgery? and

2. What are the current postoperative rates of wound infection, pneumonia, and length of stay in the same population?

*Design*

In this study, a cross sectional descriptive design will be used to evaluate the preoperative nutritional profile of children with neuromuscular scoliosis prior to undergoing spinal fusion and instrumentation surgery. The same design will also be used to determine the current rates of wound infection and pneumonia and length of stay in the same population. Observations and descriptions will be gathered from record review data. There are no treatments or interventions in this descriptive study. A single group will be evaluated so there will be no separate groups or randomization.

*Setting*

The data will be collected from records at the local pediatric orthopedic hospital. The institution is a one-of-a-kind health care system dedicated to improving the lives of children by providing pediatric specialty care, innovative research and teaching programs. The hospital is one of 22 national hospitals that provide care for children with orthopaedic conditions, burns, spinal cord injuries, and cleft lip and palate, in a family-centered environment at no charge. The hospitals have been leaders in pediatric orthopaedic care since 1922. Innovative research is conducted to provide answers to complex medical difficulties affecting children and contribute to the overall body of medical knowledge for the care and treatment for a wide range of pediatric and adult conditions worldwide. By maintaining relationships with more than 60 medical teaching facilities worldwide, the system fosters an academic environment committed to providing high-quality medical care to all patients.

Organizational readiness for change (ORC) is described by Lehman as it relates to the transfer of evidence based research to the treatment interventions by the counselors in substance abuse treatment centers (Lehman, Greener, & Simpson, 2002). In the past, the hospital lacked all of the factors they describe that an organization must have in place to succeed – motivational readiness, institutional resources, positive staff attributes, and an organizational climate that facilitates group cohesion and cooperation. A change in administration and leadership has begun to move the culture to a place with a renewed sense of purpose and a higher level of accountability.

The DNP clinical residency will be carried out in the local pediatric orthopedic hospital as well as the data collection for the clinical inquiry project. Prior to beginning this inquiry project, we will meet with the Director of Nursing Services and the Medical Chief of Staff to review the proposal. A mentor has also been identified and agreed to participate in the project. Outpatient, inpatient and admission nursing staff will be apprised of the clinical inquiry and all of the stakeholders will be updated on the study's progress.

*Sample*

The population of interest is children with the diagnosis of neuromuscular scoliosis who have been scheduled for posterior spinal fusion and instrumentation surgery at the Shrine Hospital for Children – Portland, Oregon. On average, two spine fusion surgeries are performed weekly on children with neuromuscular scoliosis. The convenience sample will consist of boys or girls 12 to 18 years of age who are classified as Gross Motor Function Classification System (GMFCS) level IV and V. No exclusion criteria are identified for this population. Feasibility and

the issue of bias in non-probability sampling are not of consideration because all records of children having the surgery that meet the two inclusion criteria will be included.

Recruitment and retention for the study is not an issue of concern. It is expected that 2 to 4 neuromuscular scoliosis patients will have spine fusion and instrumentation weekly over the study timeframe of approximately 20 weeks. This should yield a sample size of at least 30 records for review, which meets the Central Limit Theorem requirement. Records are selected by reviewing the weekly surgical schedule, which is on the institution's computer hard drive for all employees to access. This information is password protected by the institution. This electronic database of selected record information will be maintained on a computer secured by a firewall and server.

*Variables*

Preoperative Postoperative (day of discharge)

| Variable | Measure | | Variable | Measure |
|---|---|---|---|---|
| *Gender* | Record review | | *Length of stay* | Record review |
| *Age* | Record review | | *Infection Outcome* | Record review |
| *GMFCS* | Record review | | *Pneumonia Outcome* | Record review |
| *Weight* | Record review | | | |
| *Arm span* | Record review | | | |
| *BMI* | Record review | | | |
| *Constipation Status* | Record review | | | |
| *Prealbumin* | Biophysical | | | |
| *Total protein* | Biophysical | | | |

| | | | | |
|---|---|---|---|---|
| *Albumin* | Biophysical | | | |
| *White blood cell* | Biophysical | | | |
| *Lymphocyte* | Biophysical | | | |
| *Hemoglobin* | Biophysical | | | |

*Data Collection and Management*

Biophysical measures and record reviews are to be used for data collection. Patients who meet the inclusion criteria are identified from the weekly surgical schedule. Paper charts are accessed at the preadmission clinic visit. Since November 2000 an electronic record has been utilized and those records will also be accessed for demographic data collection.

The preoperative profile of height, weight, and BMI data are to be collected at the preadmission physical examination in the outpatient clinic setting. Since these children do not stand, the standard method for measuring height in a non-ambulator is to measure the arm span. This measurement is recorded as height.

Ideally all of these measures would be collected by one person, but in this clinical area there are 3 medical assistants who will be measuring height and weight of the patients. The data will be collected from the admission vital sign flow-sheet in the electronic record or the height/weight chart in the paper record. The measurement tools used in the institution, the manometer for height and digital floor scale for weight, are calibrated monthly per manufacturer's recommendation. The electronic program used to calculate the Body Mass Index is the Med Calc computer program on a Palm based operating system device. That system is updated annually and "these functions include all the standard routines normally accessed by including "math.h" on other systems, including trigonometry (with inverse and hyperbolic),

logarithms, exponentiation, and miscellaneous helper functions" (download 9/23/08) http://www.radiks.net/%7Erhuebner/mathlib.html

SPSS statistical software (17.0) will be used to analyze the data. The analysis of this data will be presented as distributions, using the three measures of central tendency - the mode, the median and the mean allowing for accurate portrayal of the data. Accuracy should increase generalizability within this very specific population. There are no costs, revenues or budget needs associated with this program evaluation.

*Height/Weight/BMI*

The physical measurements are reported as percentiles. The National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion publishes Height and Weight Charts for Boys (Appendix A) and Girls (Appendix B) (downloaded 09/24/08) at http://www.cdc.gov/growthcharts

The height, weight, and BMI charts are used as a standard measurement in pediatrics and data are recorded over time at each clinic visit. This data is used in general pediatric primary care and specialized pediatric care delivery to calculate medication dosage, nutritional needs and overall measure of general well being compared over time. The terms percentile and percentile rank are used in descriptive statistics as well as in the reporting of scores from normal referenced tests. A percentile is the value of a variable below which a certain percent of observations fall. So the 50th percentile is the value (or score) below which 50% of the observations may be found.

*Constipation Status*

The nursing admission assessment includes a gastrointestinal component and includes questions about bowel movement patterns. Constipation is a chronic problem in the population

and data will be gathered on presence of the condition. This information will be collected for baseline information.

*Laboratory Measures*

Measurements of laboratory results are biophysical measures. The measurements for this program are nutritional markers that have been shown to be predictors of healing and rates of wound infection. Numerous laboratories are used by the patients in the study and all are inspected and approved by the Clinical Laboratory Improvements Amendments (CLIA). Normal reference results ranges are set by each independent laboratory and are reported with all results.

The prealbumin level measurement is reported as normal or abnormal instead of an actual number because of the difference in reference range varies widely. One laboratory's machinery may be set to reference the normal level from 20-80 and another laboratory may use 180-240 as their normal. The data would not be representative or meaningful if the real values were analyzed. Therefore this variable will be reported normal and below normal.

The variables of total protein, albumin, and prealbumin will be recorded as measures of nutritional status. The reference ranges for normal of these values is available from all of the laboratories so the actual numbers will be compared to normal reference ranges using descriptive statistics of means, modes and standard deviations. The laboratory testing involved, the sample, and the method of measurement are in the attached appendix (Appendix C).

The complete blood count is comprised of a white blood cell count, the differential of that count, the red blood cell count, hemoglobin, hematocrit and platelet count. The white blood cell count and the leukocyte percentage will be recorded as measures of nutritional status. The leukocyte count is determined by multiplying the white blood cell count by the percentage of

leukocytes in the differential. A lower than normal level of leukocytosis has been shown to be a predictor of incidence of postoperative wound infection. This standard normal has been set at greater than 2000mm3. Hemoglobin is a measure of iron deficiency anemia, which is an indicator of malnutrition. These laboratory tests will be analyzed using actual numbers using descriptive statistics of means, modes and standard deviations. The laboratory testing involved, the sample, and the method of measurement are in the attached appendix (Appendix C).

The data collected in this study will be used as any descriptive statistical data is intended, to determine the need for change in intervention. Frequency distributions bring order to the data. The responses to the categorical variables, lab results, and BMI, and length of stay, infection, and pneumonia outcomes will be counted and presented in bar graphs. The continuous variables of height will be reported in centimeters, weight will be reported in kilograms, and BMI will be reported in percentile.

*Human Subject Protections*

A Clinical Information Tool will be used for all data collection recording (Appendix D). This paper record will be stored in a locked file behind locked doors. Demographic data will be analyzed with descriptive statistics, measuring means, mode and standard deviation. No unique identifiers will be used in this program evaluation. Health Insurance Portability and Accountability Act (HIPAA) rules will be followed and the information in the record review is protected under the general admission HIPAA “opt out” form which is signed by the legal guardian at the time of admission to the hospital. The information gathered from this record review will not be of public record.

Study Timeline

| | | | |
|---|---|---|---|
| 09/29/08 - 10/31/08Committee approval IRB review & approval | 11/15/08 – 03/31/09Data Collection Analyze data Analyze findings | 04/01/09 – 05/04/09Data collection ends 04/01/09 Final CI Report and submit to Portfolio by 05/04/09 | May 18-21, 2009 Oral defense |

## Summary

Practice improvement is the hallmark for nursing science. Clinical and translational nursing research, such as this clinical inquiry project, combines clinical scholarship and clinical research to improve practice. Policy changes with the advent of universal health care and changes in reimbursement from insurance carriers and federal programs are factors that have spurned us toward new ideas in practice to improve safety and improve outcomes. We can reduce infections, shorten length of stay without harm and provide customer service that is customer driven with the patient as a partner. Clinical practice improvement projects must also be implemented and published in order to further the actual practice in the clinical setting. Davidoff (2005) has proposed a thorough and logical set of guidelines that the DNP scholar may build upon (Davidoff & Batalden, 2005). These guidelines support us in publishing the clinical practice improvements we undertake.

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Collective Evidence Table

| Synopsis | | Findings | | Clinical Applicability | |
|---|---|---|---|---|---|
| Citation | Clinical Question | Design | Credibility | Significance | Applicability |
| 1. Benson et al 1998 | Morbidity post op data, variables studied are pneumonia, constipation and wound infection | Retrospective review, 50 pts, all from one center, similar w/respect to age, gender, curve and diagnosis | High reliability | Level IV, no statistical sig but clinical sig is high | Relevant for my inquiry and clinically relevant to my practice with NMS pts |
| 2. Buchowski et al 2006 | Retrospective review of patients | 10 patients, sample similar w/respect age, gender, curve<br>Need increase sample size | High validity but low sample size | Level IV<br>Statistical significance<br>Not clinical | Not relevant for my inquiry but clinically relevant to my practice |
| 3. Bulman et al 1996 | Comparison study of 2 surgical techniques in spine fusion | Comparative,30 pts<br>Similar w/respect age, gender, curve, pelvic obliquity, No change needed | No validity issue high reliability but low number of patients | Level III<br>High statistical & clinical significance | Applies to CP population in my institution and can be applied to my inquiry |
| 4. Campanozzi et al 2007 | Assess relationship between nutrition and GI problems and motor function in CP pts | 21 patients, nutritional assessment, nutritional and pharmacologic intervention and re-assessment | Low sample size, high validity though | Level III<br>High statistical & clinical significance | Relevant for my inquiry and clinically relevant to my practice, generalizable to pediatrics |

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|---|---|---|---|---|---|
| 5. Canavese et al 2007 | If spine growth is retarded, does lung growth also stop? Bench research on lung growth when spine growth is retarded | Animal research | Primary research | High statistical & clinical significance | Highly relevant to future practice even though bench animal research |
| 6. Castle et al 2007 | Experience and impact of chronic pain in CP adolescents | Qualitative | Low sample size, convenienc e sampling | Level V<br><br>High clinical significance | Relevant to clinical practice |
| 7. Chmell et al 1995 | Analysis of factors affecting wound healing | Retrospective review for a 62 month period | Time related, not number of patients, one care provider's patients, high validity but may have bias | Level IV<br><br>High clinical significance | Relevant for my inquiry and clinically relevant to my practice |
| 8. Comstock et al 1998 | Caregiver and patient satisfaction after spinal fusion | Nonrandomize d, descriptive,79 patients, Spastic CP, total body involvement, No change needed | Quantitativ e data showed adequate validity but qualitative was not measured – no scale of satisfaction | Level IV<br><br>High statistical & clinical significance | Applies to CP population in my institution and can be applied to my inquiry |
| 9. Craig et al 1998 | Outcomes measurements of pts with gastrostomy tubes after surgery | Prospective controlled trial, pre and post assess msrmnt, sim pt population | High validity, specificity & reliability | Level II<br><br>High clinical significance | HIGHLY relevant for my inquiry and clinically relevant to my practice |

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|---|---|---|---|---|---|
| 10. Fletcher et al 2007 | Meta-analysis of all RCTs & EBP articles RT preop interventions to prevent infection | Evidence review<br><br>Would not change anything | High rigor & validity excellent analysis & reliability & applicability | Level I<br><br>Excellent clinical sig | Information is HIGHLY significant to my inquiry |
| 11. Hadden et al 2002 | Validate global and observation methods for evaluating pain in children with CP | Qualitative, similar to pt population | High reliability across raters and measures | Level IV<br><br>High clinical significance | relevant for my inquiry and clinically relevant to my practice |
| 12. Heys et al 1999 | Meta-analysis of 11 randomized clinical trials comparing nutritional support intervention | Evidence review | Excellent analysis and review | Level I<br><br>High clinical significance | Information is HIGHLY significant to my inquiry |
| 13. Klein et al 1996 | 3 part study looking at preop nutrition status at 3 points in time preop and post op | Retrospective review of data<br><br>Logistic regression analysis | Excellent analysis and review | Level IV<br><br>High clinical significance | Information is HIGHLY significant to my inquiry |
| 14. Kretzler et al 1991 | Retrospective review of wound infections | Data collection and review | Older data | Level V<br><br>High clinical significance | relevant for my inquiry and clinically relevant to my practice |
| 15. Labbe et al 1999 | Determine rates of surgical site infection & identify risk factors | Active prospective surveillance and case control study retrospectively | High reliability | Level IV<br><br>High clinical significance | relevant for my inquiry and clinically relevant to my practice |

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|---|---|---|---|---|---|
| 16. Manelli et al 1998 | Define range of standard values of lab tests for nutritional markers in burn pts | Retrospective review | Correlational study, low sample size, population differences | Level IV<br>Clinical significance | relevant for my inquiry from a lab test perspective |
| 17. McKearnan et al 2004 | Review of descriptive and qualitative studies | Analysis of articles | Ambiguous terminology but statistical analysis was significant | Level V, Need better data with higher level evidence | Information is sig to my inquiry |
| 18. Mohammed et al 2007 | Retrospective review of patients, variables GI, CV and infection postop | 175 patients<br>Sample similar w/respect age, gender, curve | Good measurement significant influence on practice | Level IV<br>Clinical and statistical significance | Information is HIGHLY significant to my inquiry |
| 19. Murphy et al 2006 | Retrospective comparison of IAS and NMS for risk factors | Data review from a multicenter database | High reliability and validity | Level IV<br>High clinical significance | relevant for my inquiry and clinically relevant to my practice |
| 20. Parrish 2006 | Review of descriptive and qualitative studies | Analysis of articles | Review of articles<br>No rigor | Level V<br>Need better data with higher level evidence | Information is sig to my inquiry |
| 21. Patel et al 2007 | Retrospective review of patients with CP and NMS | Sample of patients from one MD over a 36 month period of time (332 pts)<br>No change | Excellent satisfaction #s but + bias c/o 1 surgeon | Level IV<br>Clinical but not statistical significance | Interesting but maybe not as significant as I thought |

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|---|---|---|---|---|---|
| 22. Snyderman et al 1999 | Is periop nutritional support superior to standard formula in prevention of postop infection? | Prospective, randomized double blind adult study | High reliability, validity and credibility but not generalizable to pediatrics | Level I<br><br>High clinical significance | HIGHLY relevant for my inquiry and clinically relevant to my practice but nor pediatrics |
| 23. Sponseller et al, 2000 | Identify risk for infection, identify organism of infection in NMS pts after spine fusion surgery | Retrospective case control data collection | Large sample size, similar to population under study | Level IV<br><br>High clinical significance | Relevant to the clinical inquiry |
| 24. Szoke et al, 1998 | Retrospective chart review of wound infection rates after spine fusion | Descriptive data collection | High validity and reliability | Level IV<br><br>High clinical significance | Relevant for my inquiry and clinically relevant to my practice |
| 25. Tranzfeldt et al, 1985 | Retrospective chart review of spinal wound infections | Descriptive data collection | Reliable but old data | Level IV<br><br>Clinical significance | Older data but still relevant to the inquiry |
| 26. Tsrikos et al 2004 | Delineate parent and caregiver satisfaction after spinal fusion in CP spastic quad patients | 288 consecutive patients<br><br>190 families participated<br><br>No change | 2 tailed t test, no bias, good interrelator reliability | Level IV<br><br>Clinical significance | Important information for my inquiry |
| 27. Veughlers et al , 2005 | Contribution of risk factor on pneumonia occurrence in post op CP | Nested case controlled design with 18 month followup | Reliable and valid measures | Level IV<br><br>Sample size was not adequate for statistical | Relevant for my inquiry, clinically relevant to practice |

| | | | | | |
|---|---|---|---|---|---|
| | patients | | | sig, not clinically significant | |
| 28. Wimmer et al 2005 | Comparison study of 2 surgical techniques in spine fusion | Retrospective comparative,52 pts, Neuromuscular scoliosis pts similar | As above but added qualitative data for pt satisfaction | Level III<br><br>Clinical significance but not statistical | Patient satisfaction information is sig to my inquiry |

Running head: RESULTS REPORT

# Clinical Inquiry Results Report:

# A Nutrition Assessment of Children with Neuromuscular Impairments Undergoing Spinal Fusion and Instrumentation and Frequencies of Postoperative Infections

Janie Huff-Slankard

Doctor of Nursing Practice Candidate

Oregon Health and Science University

## Introduction

Children with neuromuscular scoliosis who undergo surgical release and spinal fusion for scoliosis curve correction have a higher risk of postoperative complications. Research has shown that the risk of complications is higher when nutritional deficiencies are present in the preoperative period (Sponseller, et al, 2000). Heys, Walker, Smith, and Erimen (1999) conducted a meta-analysis that demonstrated a significant decrease in infectious complications and decrease in length of hospital stay in adult patients who received postoperative nutritional supplementation with key nutrients compared to patients who did not.

The quarterly infection control report, issued in August 2006, from the Quality Improvement Department in the institution where the clinical inquiry was carried out, identified an increase in the infection rate after spine fusion surgery in the neuromuscular scoliosis population. The nutritionist and one of the spine surgeons had noted anecdotally that most of those same patients were nutritionally depleted at the time of surgery, using weight as the assessing parameter. The identified patients' weights were at or below the fifth percentile. The question was raised that perhaps these patients needed a preoperative nutritional assessment and intervention to better prepare them for spine fusion and instrumentation surgery and prevent postoperative wound infections.

Not only is the issue of infection rates among spinal fusion patients a problem of best outcomes for the patients in question, Medicaid announced in 2007 there would no longer be financial reimbursement for treatment for hospital-acquired infections (Centers for Medicaid and Medicare Services, 2007). The financial impact of this change warrants all institutions to examine their surgical infection rates and make changes accordingly.

Although the hospital where this study was conducted does not charge for services, those who do will suffer a significant loss of revenue as postoperative surgical infections incur costs estimated at $67,000 per patient incident (Murphy, Firth, Jorgensen, & Young, 2007). The hospital is financially affected, however, since the operating costs are paid for by donations and funds from the endowment. Those funds could be used to provide services elsewhere if the infection rate is lowered.

Data have not been consistently collected on the preoperative nutritional profile of the pediatric patients seen at this pediatric orthopedic institution. The intended outcome of assessing nutritional status preoperatively is to have a more nutritionally sound patient ready for major surgery. Literature demonstrates patients who are in a nutritionally depleted state have more postoperative complications (Mohamad et al., 2007) while patients with a better nutritional profile will have fewer postoperative problems (Szoke, Lipton, Miller, & Dabney, 1999).

Two questions were asked in this clinical inquiry project:

1. What is the current nutritional preoperative profile of neuromuscular scoliosis patients undergoing spinal fusion and instrumentation surgery? and

2. What are the current postoperative rates of wound infection, pneumonia, and length of stay in the same population?

## Methodology

Descriptive statistical measurements provided a preoperative nutritional profile of the average male and female patients undergoing spinal fusion and instrumentation surgery. Frequency measurements and independent *t* tests were used to search for a relationship between nutritional markers and postoperative infection.

Fifty patient charts were retrospectively analyzed for this study. The data on every fifth chart were recorded twice to ensure accuracy of data collection. The following descriptive variables were analyzed: gender, age, Gross Motor Functioning Classification System (GMFCS) level, height, weight, BMI, white blood cell count, lymphocyte count, hemoglobin, prealbumin, albumin, total protein, length of stay, incidence of postoperative pneumonia, and incidence of postoperative wound infection. Normal laboratory value reference ranges are listed in the respective tables.

The researcher used the Current Procedural Terminology (CPT) coding system to facilitate patient selection and provide specific criteria for inclusion. All patients were selected based on CPT codes 22804 and 22844, spinal fusion with multilevel posterior instrumentation. No unique identifiers were used in this program evaluation. There were no additional financial factors influencing the project. There were no costs to the institution or the researcher for the data collection.

Health Insurance Portability and Accountability Act (HIPAA) rules were followed and the information in the record review was protected under the general admission HIPAA “opt out” form that was signed by the legal guardian at the time of admission to the hospital. The information gathered from this record review was not of public record.

Data collection for this protocol met the requirements for exemption for Institutional Review Board (IRB) review and approval in accordance with 45CFR46.101(b). The requirement to obtain HIPAA authorization was waived as the use or disclosure of the personal health information inferred no more than minimal risk to the

privacy of individuals (see Appendix A).

The IRB process was the most cumbersome piece of the data collection for this clinical inquiry. The submission and approval process is entirely online and while a paper system has limitations, so does the computerized version. A short, steep learning curve was difficult but eventually all required documentation was signed and the proposal was approved. This delay in data collection time did not adversely affect the sample or skew the results in any way.

## Results

### *Patient Characteristics Variables Results*

The mean age for males was 16 years (16 ± 2, n=24) and 14 years (14 ± 2, n=26) for females. One hundred percent of the males were GMFCS level 5 and 88% of the females were level 5. Mean height for males was 156.5cm (156.5 ± 13.2, n=24) and 139.5cm (139.5 ± 12.5) for females. Mean weight for males was 45.5kg (45.5 ± 13.1, n=24) and 36.5kg (36.5 ± 14.1, n=26) for females. Male mean body mass index (BMI) plotted at the 18.5 percentile (18.5 ± 4.2, n=24) and female mean BMI at the 18.3 percentile (18.3 ± 4.6) (see Table 1). Both are less than normal. The mean, median, and mode statistics for BMI are found in Table 2. The median value is more representative of this population. The BMI standard growth charts are found in Appendices B and C.

### *Laboratory Results*

The results of preoperative laboratory markers of nutritional status were collected from the 50 charts. Serum nutritional measurements of white blood cell count (WBC), hemoglobin (Hgb), albumin, total protein, prealbumin and leukocyte levels were collected.

The mean WBC for males was 10.6 K/cc mm (10.6 ± 4.1, n=24) and 14 K/cc mm (4 ± 2.2, n=26) for females. The mean hemoglobin level for males was 12.8 g/dL (12.8 ± 2.3, n=24) and for females was12.7 g/dL (12.7 ± 2.1, n=26). Mean albumin for males was 3.6 g/dL (3.6± 0.7, n=24) and for females was 3.9 g/dL (3.9 ± 0.5, n=26). Mean total protein for males was 7.4 g/dL (7.4 ± 0.9, n=24) and for females was 7.2 g/dL (7.2 ± 0.7, n=26) (see Table 3).

Lower than normal prealbumin levels were present in 62.5% of males and 61.5% of females (see Table 4). These values are reported in percentages because the samples were drawn at different labs and each laboratory used a standard reference range. A low leukocyte count was present in 45.8% of males and 46.2% of females (see Table 5).

*Outcomes Results*

The entire data set, 100% of the patients, had documentation of chronic constipation in the preoperative nursing assessment. Two incidences (4%) of postoperative pneumonia occurred, one aspiration and one related to atelectasis. Seven postoperative infections (14%) were noted (see Table 6).

Tables 7 through 12 document comparisons of normal and low levels of markers of nutritional status split by incidence of infection. Low prealbumin levels were present in 67.4% of non-infected patients and 28.6% of infected. Total protein was normal in 93% and 71.4% of non-infected and infected patients respectively, as was albumin with percentages at 81.4% and 57.1%. Hemoglobin levels were normal in 67.4% of non-infected patients and 85.7% infected patients. Leukocyte counts were normal in 53.5% of non-infected patients and 57.1% of infected patients. BMI was normal in 39.5% of non-infected patients and 100% of the infected.

## Discussion

The patient characteristics data were split for analysis by gender only because the natural split was close to 50%. No differences were seen when the data was split by gender. The mean ages of both genders mimicked national statistics as did gender distribution (Graham, 2005). Height, weight and BMI are primarily markers of adequate caloric intake. The literature demonstrates that the highest risk factor for postoperative complications is the preoperative presence or postoperative occurrence of malnutrition (Campanozzi et al., 2007; Chmell, 1996; Craig & Schwartz, 2006; Smith, 1987; Snyderman et al., 1999; & Szoke, 1998). Recently the measurement of body mass index has been added to assess underweight or overweight children (Centers for Disease Control, 2008).

Mean height of both genders was far less than the 5$^{th}$ percentile and mean weight was also less than the 5$^{th}$ percentile, as documented on the CDC standard growth charts (Appendix D and E). Thus these children were small compared to children with a neuromuscular disorder.

In this sample of patients, although the mean measurement of BMI was at the 12$^{th}$ percentile for males and females, the median BMI for both genders was at just above the 5$^{th}$ percentile; lower than normal, as predicted. Mean, median, and mode measurements more accurately reflect the population data. By BMI, these patients are classified as needing increased caloric intake to achieve adequate body height and weight. As in the pre-study anecdotal data, the weight of all of the patients with postoperative wound infections was less than the 5$^{th}$ percentile for weight but the statistics in this study did not reflect significance in independent *t* testing.

Laboratory results included levels of white blood cell count, hemoglobin, serum albumin, and total protein. These four variables were at the low end of normal for both groups. These variables did not result in any predictors for infection but, again, the sample size was small and needs more research.

Prealbumin levels were lower than normal (62.5% for males and 61.5% for females) as anticipated and as compared to the literature (Beck & Rosenthal, 2002). Leukocyte count was below normal at 45.8% for males and 46.2% for females. Again there was no difference when compared by gender.

Literature demonstrates that the incidence of chronic constipation in this population is quite high (Benson, Thomson, Smith, & Banta, 1998; Elawad & Sullivan, 2001). The results in this project were the same, with 100% of the patient caregivers reporting chronic bowel problems. This evidence impacts future practice for the DNP in preoperative planning, addressing bowel status earlier in time, before the surgery, to decrease postoperative bowel problems such as postoperative ileus.

Research has shown that the risk of complications is higher when nutritional deficiencies are present in the preoperative period (Sponseller, et al, 2000). When the frequency of low prealbumin was calculated, 71% of the infected patients had normal prealbumin levels and only 32% of the non-infected patients had normal levels. This may be attributed to disproportionate numbers, but the results do not indicate that a low prealbumin is a marker to predict an increased rate in postoperative infection rates.

The data in this clinical inquiry recorded a 14% postoperative wound infection rate. The results of the descriptive data suggested significance when comparing percentages, but the independent *t* tests did not result in statistical significance. The

amount of statistical power is low with such a disproportionate comparison as only six of the 50 patients (8.4%) were readmitted for surgical wound infections within three months of the original surgery. This finding, however, suggests the need for further research using a longer timeframe and a larger sample for data collection. Further research is also needed for investigation and identification of other preoperative factors that may predict the incidence of postoperative infection in the neuromuscular scoliosis patient population. Since this clinical inquiry began, new research has been published indicating promising data using preoperative C-reactive protein levels to predict infection postoperatively, another possibility for further research in this area.

Acknowledgement

I would like to express my appreciation and gratitude to my clinical mentor, Charles d'Amato, M.D. Without his guidance, incredible wealth of knowledge and genuine willingness to mentor and teach new professionals, this project would not have been as interesting or as fulfilling. I would also like to thank my committee chair, Dr. Maggie Shaw and my committee member, Dr. Cathie Burns for their patience, support, and wealth of knowledge that has helped me in this journey to a clinical doctorate degree.

# Executive Summary

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The addition of the clinical doctorate in advanced practice education provides clinical leaders and experts the opportunity to be recognized at the highest level of the profession. On a global and local level, the clinical inquiry project, as well as the clinical residency program, affords the DNP student the opportunity to implement practice improvements and translate research into practice. The project culminates in the DNP's reflection of expertise and self-evaluation of the educational process.

The process began with the identification of a relevant clinical question. The challenge for the DNP student was the initial articulation of the problem. This step required a more thoughtful and cognitively challenging process not previously experienced at the Masters level of education.

Evidence based care is the gold standard for practice improvements as well as outcome measurements. To that end, data must first be collected on the specific population. Anecdotal evidence was in place concerning postoperative wound infections after spine surgery and the correlation of malnutrition, evidenced by weight less than the $5^{th}$ percentile, but no actual data were available.

The data in this clinical inquiry demonstrated a 14% postoperative wound infection rate. The results of the descriptive data suggested significance when comparing percentages, but the independent *t* tests did not result in statistical significance. This can be explained by the fact that there is not a lot of power with such a disproportionate

comparison. Six of the 50 patients (12%) were readmitted for surgical wound infections within three months of the original surgery. This finding implicates the need for further research using a longer timeframe for data collection. The findings of the variables indicate the need for further research into investigation and identification of preoperative factors that may predict the incidence of postoperative infection in the neuromuscular scoliosis patient. Since this clinical inquiry began, new research has been published indicating promising data using preoperative and postoperative C-reactive protein levels to predict infection postoperatively, another possibility for further research in this area.

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# Application & Certification for Waiver or Alteration of the HIPAA Authorization requirement

*Version 1.0*

Research Integrity Office
Mail code L106-RI
Portland, Oregon 97239-3098
Phone: 503-494-7887
Fax: 503-494-5081

eIRB Number: 4846

| | |
|---|---|
| Researcher Name: | Margaret Shaw |
| Study Title: | Program Evaluation of Children Undergoing Spinal Fusion |

**Purpose of Waiver or Alteration of HIPAA Authorization**

1. **PARTIAL WAIVER:**
   - A. Waiver is requested to disclose PHI from one covered entity to another for the purposes of contacting and recruiting individuals into the study. — A. ☐
   - OR
   - B. Waiver is requested to collect PHI over the phone, fax, internet or e-mail from study participants. — B. ☐
   - OR
   - C. Waiver is requested to use PHI for research purposes for individuals who are unable to provide authorization and no LAR is available. — C. ☐
   - OR
   - D. Waiver is requested for any other use and disclosure for ONLY part of the research project as described below**. — D. ☐ **Must fill out section below

   NOTE: In cases of a partial waiver, the researcher must obtain HIPAA Authorization from eligible subjects for any use or disclosure of PHI beyond what's approved under the partial waiver.

2. **FULL WAIVER:** Waiver is requested for complete access, use, and creation of records containing Protected Health Information, but only as described in the IRB approved application. — ☒

3. **ALTERATION OF AUTHORIZATION:** Permission is requested to remove some, but not all, of the required elements of an Authorization***. When requesting an alteration, a copy of the proposed altered authorization form must be submitted for review. — ☐

   NOTE: Alterations are often needed in sham or placebo studies when identification of a required HIPAA element would affect the results of the study.

| | |
|---|---|
| **IF APPLICABLE: Description of Partial Waiver from Part 1.D. above | |
| Description of Protected Health Information | demographic, biophysical measurements, constipation status, length of hospital stay, infection and pneumonia outcomes |

**Will the PHI for this study include any of the following elements (check all that apply)?**

- ☒ Patient/Subject Names
- ☐ Age information for those over 89
- ☐ Geographic subdivisions smaller than a State, with first 3 zip digit exceptions.
- ☐ Telephone numbers
- ☐ Fax numbers
- ☐ Electronic mail addresses
- ☐ Social Security Numbers
- ☐ Medical record numbers
- ☐ Account numbers
- ☐ Certificate/license numbers
- ☐ Dates (except year)
- ☐ Device identifiers and serial numbers
- ☐ Vehicle identifiers and serial numbers, including license plate numbers
- ☐ Web Universal Resource Locators (URLs)
- ☐ Internet Protocol (IP) address numbers
- ☐ Biometric identifiers, including finger and voice prints
- ☐ Full face photographic images and any comparable images
- ☐ Health plan beneficiary numbers
- ☐ Results of a genetic test
- ☐ None of the above

| | YES | NO | If yes, what PHI will be shared and how will it be identified? |
|---|---|---|---|
| Will you be sharing PHI with anyone outside of OHSU? | ☐ | ☒ | |

| | |
|---|---|
| Describe the reasons that the research could not practicably be conducted without obtaining a waiver for access to the PHI. | Research is retrospective and descriptive-only. |

| | |
|---|---|
| Describe the plan to protect the identifiers from improper use and/or disclosure. Include how data will be stored and/or coded. | A coded identifier will be used (J. Jones - #1). The key to the code where patients are identified will be kept on a laptop computer in a password protected file and on a password protected backup disc |
| Describe your plan for maintenance of the identifiers after the research project has ended | ☐ De-identifying data<br>☒ Destroying Data<br>☐ Maintaining identifiable data for storage in a research repository for the conduct of future research. |

***Authorization Required Elements (for question #3):

- A description of the PHI to be used or disclosed, identifying the information in a specific and meaningful manner.
- The names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure.
- The names or other specific identification of the person or persons (or class of persons) to whom the covered entity may make the requested use or disclosure.
- A description of each purpose of the requested use or disclosure.
- Authorization expiration date or expiration event that relates to the individual or to the purpose of the use or disclosure ("end of the research study" or "none" are permissible for research, including for the creation and maintenance of a research database or repository).
- Signature of the individual and date. If the individual's legally authorized representative signs the Authorization, a description of the representative's authority to act for the individual must also be provided.

## Important Notice to Researchers

If you access Protected Health Information (PHI) from an OHSU Medicine facility under a waiver of HIPAA Authorization, you are required to comply with the OHSU policy for ***accounting of disclosures of PHI.***

If the results of a genetic test (as defined in ORS192.531) are obtained as part of this research under a partial or complete waiver, requirements for notification and opt out must be met as described in the OHSU Policy for Accessing Tissue Specimens or Information at OHSU for Anonymous or Coded Genetic Research. The plan for compliance with this policy should be outlined in the protocol if applicable.

## ORIO OFFICE USE ONLY

| | | | |
|---|---|---|---|
| IRB Name: | OHSU IRB | Review Type: | Full IRB Review ☐<br>Expedited Review ☒ |
| IRB Registration Number: | 00000469, 00000470, 00000471, 00003277 | Does the IRB approve the request for a Waiver or alteration of HIPAA Authorization? | YES ☒ NO ☐ |
| Date of IRB Approval: | 1/26/2009 | Date of Signature: | 1-28-2009 |
| Signature of IRB Chair OR designated IRB member | | Printed Name: | Susan Bankowski |

**OHRP Regulatory Justification for Waiver (45 CFR 164.512(i)(2)(ii))**

*The IRB, Chair or Designated reviewer certifies that all of the following criteria have been satisfied to grant a Waiver or Alteration of HIPAA Authorization.*

(A) Use or disclosure of PHI involves **no more than a minimal risk** to the privacy of individuals based on, at least, the presence of the following elements:
  (1) Adequate plan to **protect** the identifiers from improper use and disclosure.
  (2) Adequate plan to **destroy** the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
  Adequate **written assurances that the PHI will not be reused or disclosed to any other person or entity, except as** required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

(B) The research could **not practicably be conducted without the waiver or alteration.**

(C) The research could **not practicably be conducted without access to and use of the PHI.**

## 2 to 20 years: Boys
## Body mass index-for-age percentiles

NAME _____

RECORD # _____

| Date | Age | Weight | Stature | BMI* | Comments |
|---|---|---|---|---|---|
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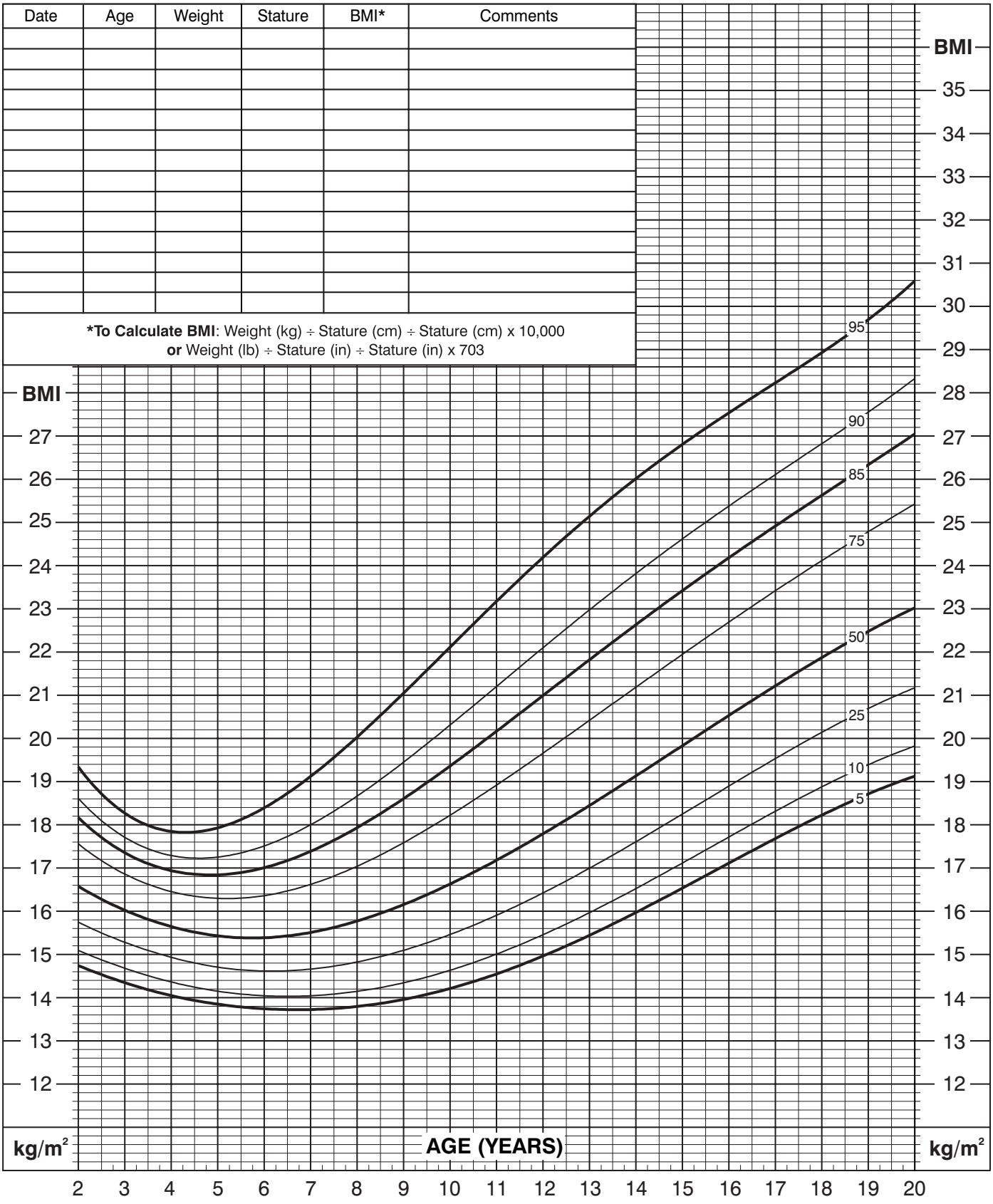
***To Calculate BMI**: Weight (kg) ÷ Stature (cm) ÷ Stature (cm) x 10,000
**or** Weight (lb) ÷ Stature (in) ÷ Stature (in) x 703




Published May 30, 2000 (modified 10/16/00).
SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).
**http://www.cdc.gov/growthcharts**

CDC
SAFER • HEALTHIER • PEOPLE™

## 2 to 20 years: Girls
## Body mass index-for-age percentiles

NAME _____

RECORD # _____

| Date | Age | Weight | Stature | BMI* | Comments |
|---|---|---|---|---|---|
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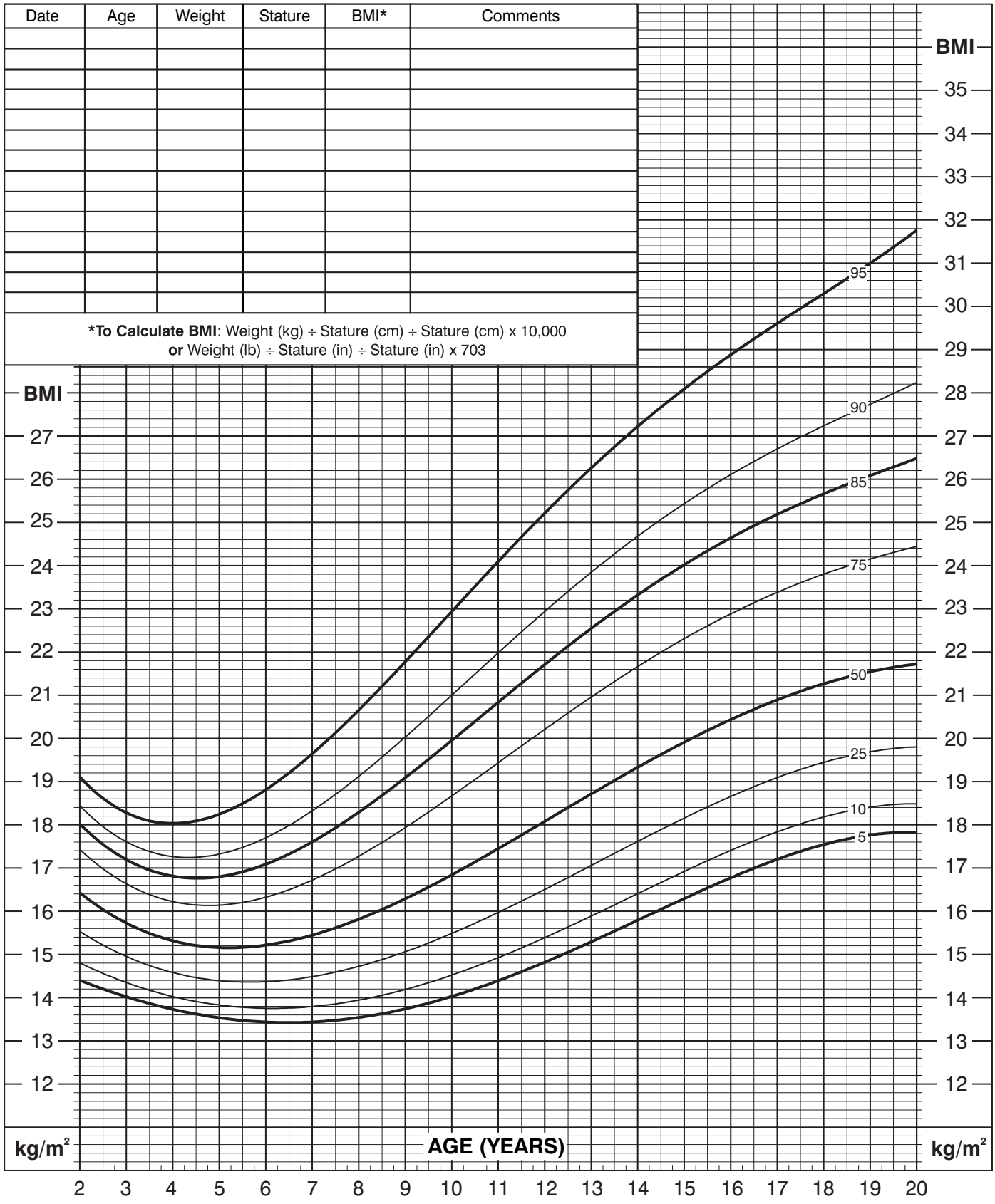
***To Calculate BMI**: Weight (kg) ÷ Stature (cm) ÷ Stature (cm) x 10,000
**or** Weight (lb) ÷ Stature (in) ÷ Stature (in) x 703

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**http://www.cdc.gov/growthcharts**

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## 2 to 20 years: Boys
## Stature-for-age and Weight-for-age percentiles

NAME _____

RECORD # _____

Mother's Stature _____ Father's Stature _____

| Date | Age | Weight | Stature | BMI* |
|---|---|---|---|---|
| | | | | |
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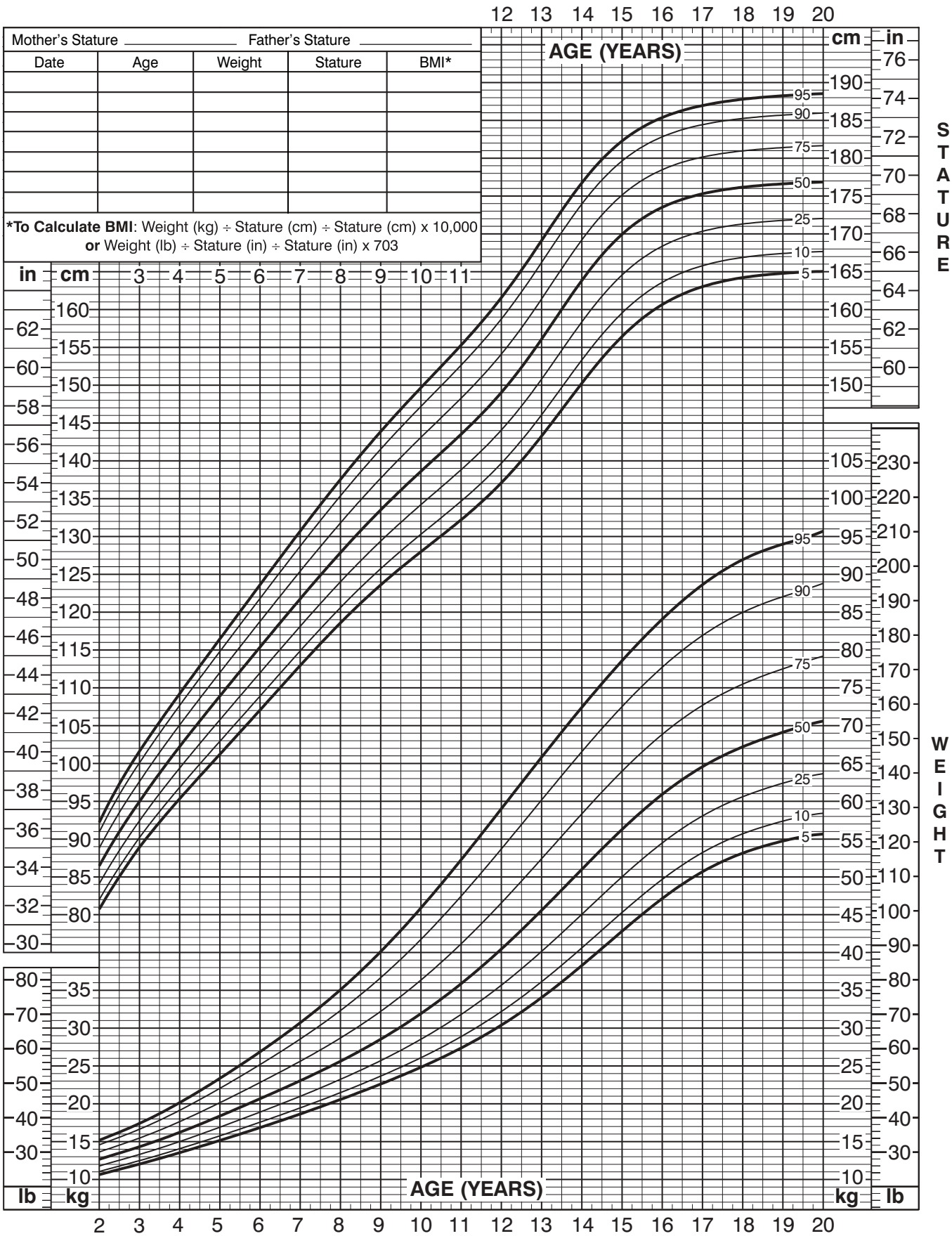
***To Calculate BMI**: Weight (kg) ÷ Stature (cm) ÷ Stature (cm) x 10,000
**or** Weight (lb) ÷ Stature (in) ÷ Stature (in) x 703




Published May 30, 2000 (modified 11/21/00).
SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).
**http://www.cdc.gov/growthcharts**

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## 2 to 20 years: Girls
## Stature-for-age and Weight-for-age percentiles

NAME _____

RECORD # _____

Mother's Stature _____ Father's Stature _____

| Date | Age | Weight | Stature | BMI* |
|---|---|---|---|---|
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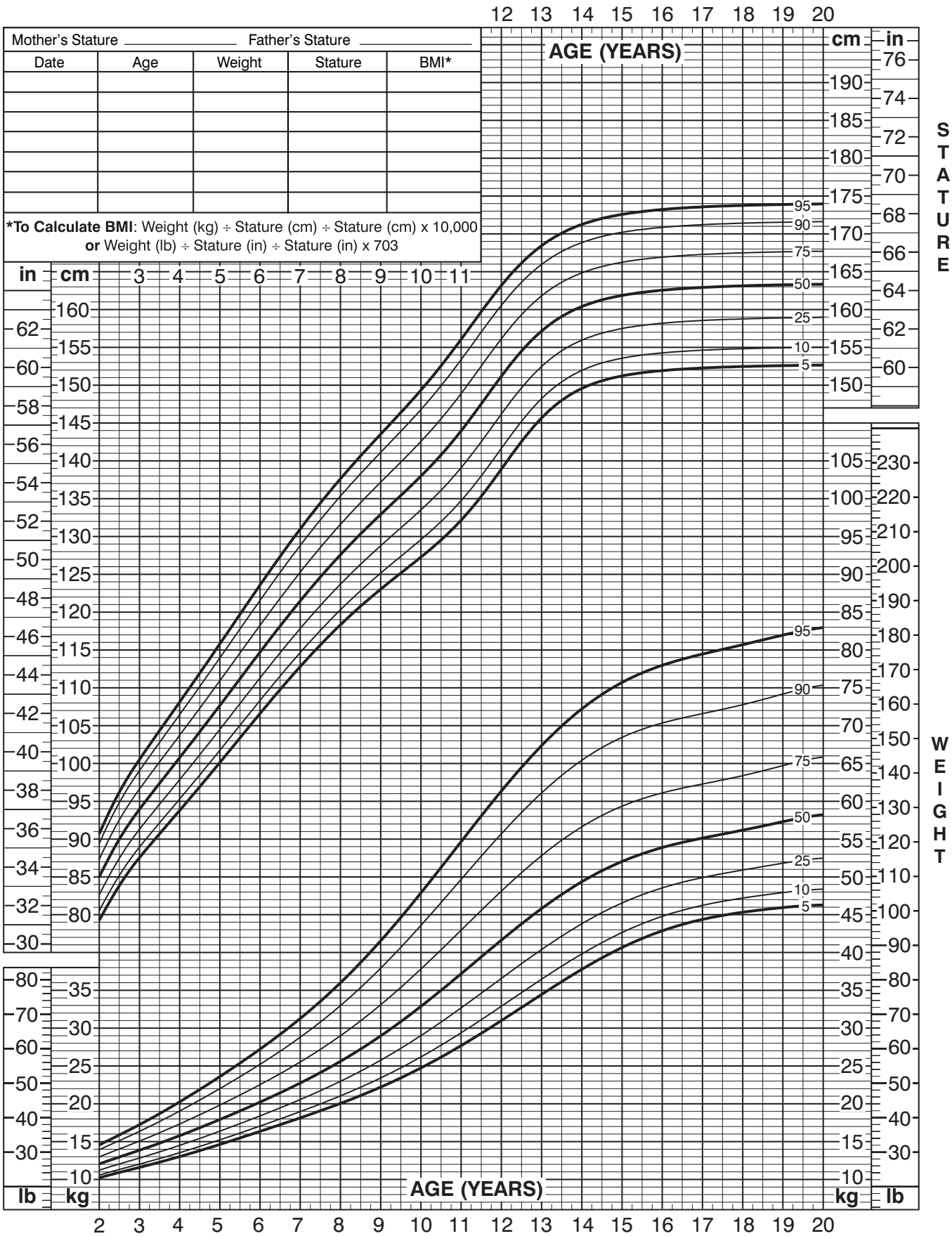
***To Calculate BMI**: Weight (kg) ÷ Stature (cm) ÷ Stature (cm) x 10,000
**or** Weight (lb) ÷ Stature (in) ÷ Stature (in) x 703




Published May 30, 2000 (modified 11/21/00).

SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).
**http://www.cdc.gov/growthcharts**

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Measures Result Report
Laboratory Testing Analysis

| Test | Specimen | Method | Measurement |
|---|---|---|---|
| Total Protein | Serum | Bromcresol green, bromcresol purple, protein electrophoresis, turbimetry, or nephelometry | Grams per deciliter |
| Albumin | Serum | Bromcresol green, bromcresol purple, protein electrophoresis, turbimetry, or nephelometry | Grams per deciliter |
| Prealbumin | Serum | Bromcresol green, bromcresol purple, protein electrophoresis, turbimetry, or nephelometry | Grams per deciliter |
| White blood cell | Whole blood | High capacity multichanel measuring system | K/cc mm |
| Leukocyte count | Whole blood | High capacity multichanel measuring system | Millimeters cubed |
| Hemoglobin | Whole blood | High capacity multichanel systyem | Grams per deciliter |

(Jacobs, DeMott, & Oxley, 2004)

Table 1

*Mean and Standard Deviations Patient Characteristics*

Variable

| Gender | Age (yrs) | | GMFCS | | Ht (cm) | | Wt (kg) | | BMI(%tile) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | Mean | SD | Mean | SD | Mean | SD |
| Male n=24 | 16 | 2.1 | 5 | 0 | 156.5 | 13.2 | 45.5 | 13.1 | 18.46 | 4.2 |
| Female n=26 | 14 | 2.2 | 4.88 | 0.3 | 139.5 | 12.5 | 36.5 | 14.1 | 18.3 | 4.6 |

Normal Values

16 yr Male at 50$^{th}$ percentile Ht =174cm Wt = 60kg BMI =20.6%tile

14 yr Female at 50$^{th}$ percentile Ht = 160cm Wt = 48kg BMI = 19.2%til

Table 2

*BMI - Mean Median and Mode*

| | BMI | | |
|---|---|---|---|
| Gender | | | |
| | Mean | Median | Mode |
| Male n=24 | 18.5 | 17.5 | 10.86[a] |
| Female n=26 | 18.3 | 16.9 | 10.51[a] |

a. Multiple modes exist. The smallest value is shown

Normal Values

16 yr Male BMI at 50$^{th}$ percentile = 20.6 percentile

14yr Female BMI at 50$^{th}$ percentile = 19.2 percentile

Table 3

*Mean and Standard Deviations for WBC, Hgb, S Albumin and Total Protein*

| | Variable | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | WBC | | Hgb | | S Albumin | | Total Protein | |
| | N = 4.9-15.5K/cumm | | >12g/dL | | >3.2g/dL | | >6.4g/dL | |
| Gender | | | | | | | | |
| | Mean | SD | Mean | SD | Mean | SD | Mean | SD |
| Male n=24 | 10.6 | 4.1 | 12.8 | 2.3 | 3.6 | 0.7 | 7.4 | 0.9 |
| Female n=26 | 14 | 2.2 | 12.7 | 2.0 | 3.9 | 0.5 | 7.2 | 0.7 |

Table 4

*Prealbumin Low or Normal Frequencies*

| | Frequency | Percent |
|---|---|---|
| Gender | | |
| Male | | |
| Low | 15 | 62.5 |
| Normal | 9 | 37.5 |
| Total | 24 | 100.0 |
| Female | | |
| Low | 16 | 61.5 |
| Normal | 10 | 38.5 |
| Total | 26 | 100.0 |

Low was defined as lower than the normal reference range value assigned by the laboratory performing the test.

Table 5

*Leukocyte count Low or Normal Frequencies*

| | Frequency | Percent |
|---|---|---|
| Gender | | |
| Male | | |
| (mean = 2463) | | |
| Low | 11 | 45.8 |
| Normal | 13 | 54.2 |
| Total | 24 | 100.0 |
| Female | | |
| (mean = 2550) | | |
| Low | 12 | 46.2 |
| Normal | 14 | 53.8 |
| Total | 26 | 100.0 |

Low value <2000$mm^3$

Normal value >2000$mm^3$

Table 6

*Outcome Frequencies*

Length of Stay

| Gender | Mean | SD |
|---|---|---|
| Male n=24 | 7.29 | 3.2 |
| Female n=26 | 7.19 | 2.7 |

Constipation

| Gender | Frequency | Percent |
|---|---|---|
| Male n=24 | 24 | 100.0 |
| Female n=26 | 26 | 100.0 |

Incidence of Infection

| | Frequency | Percent |
|---|---|---|
| None | 43 | 86 |
| Infection | 7 | 14 |

Table 7

*Comparison of Normal and Low Prealbumin levels split by incidence of infection*

| | Normal | Low | Total |
|---|---|---|---|
| No infection | 14<br>(32.6%) | 29<br>(67.4%) | 43<br>(100%) |
| Infection | 5<br>(71.4%) | 2<br>28.6%) | 7<br>(100%) |

Normal values are not assigned secondary to different laboratory reference ranges.

Table 8

*Comparison of Normal and Low Total Protein levels split by incidence of infection*

| | Normal (>6.4g/dL) | Low | Total |
|---|---|---|---|
| No infection | 40 (93%) | 3 (7%) | 43 (100%) |
| Infection | 5 (71.4%) | 2 (28.6%) | 7 (100%) |

Table 9

*Comparison of Normal and Low Albumin levels split by incidence of infection*

| | Normal (>3.2g/dL) | Low | Total |
|---|---|---|---|
| No infection | 35 (81.4%) | 8 (18.6%) | 43 (100%) |
| Infection | 4 (57.1%) | 3 (42.9%) | 7 (100%) |

Table 10

*Comparison of Normal and Low Hemoglobin levels split by incidence of infection*

| | Normal (>12g/dL) | Low | Total |
|---|---|---|---|
| No infection | 29 (67.4%) | 14 (32.6%) | 43 (100%) |
| Infection | 6 (85.7%) | 1 (14.3%) | 7 (100%) |

Table 11

*Comparison of Normal and Low Leukocyte count split by incidence of infection*

| | Normal (>2000mm$^3$) | Low | Total |
|---|---|---|---|
| No infection | 23 (53.5%) | 20 (46.5%) | 43 (100%) |
| Infection | 4 (57.1%) | 3 (42.9%) | 7 (100%) |

Table 12

*Comparison of Normal and Low BMI split by incidence of infection*

| | Normal (19.2 – 20.6%tile) | Low | Total |
|---|---|---|---|
| No infection | 17 (39.5%) | 26 (60.5%) | 43 (100%) |
| Infection | 7 (100%) | 0 | 7 (100%) |

OREGON HEALTH & SCIENCE UNIVERSITY

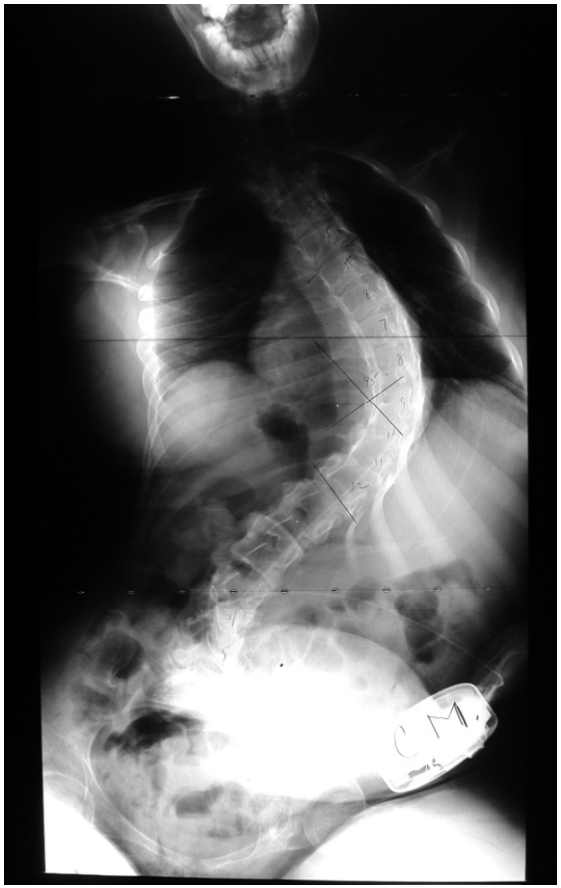
OHSU

# A Preoperative Nutritional Assessment of Neuromuscular Spine Fusion Patients and Frequencies of Postoperative Infection

Janie Huff-Slankard MS, CPNP

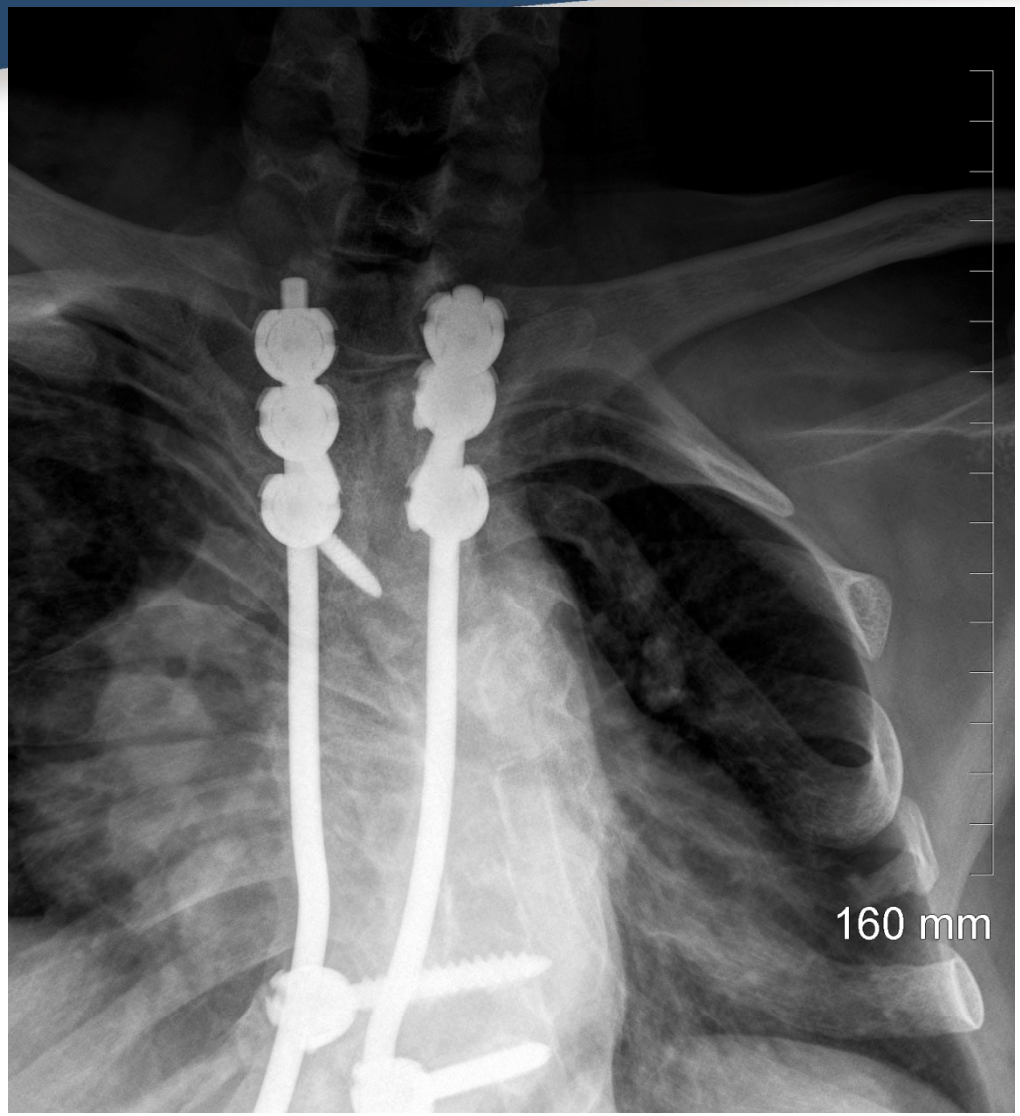
Doctor of Nursing Practice candidate

# Significance





OREGON HEALTH & SCIENCE UNIVERSITY

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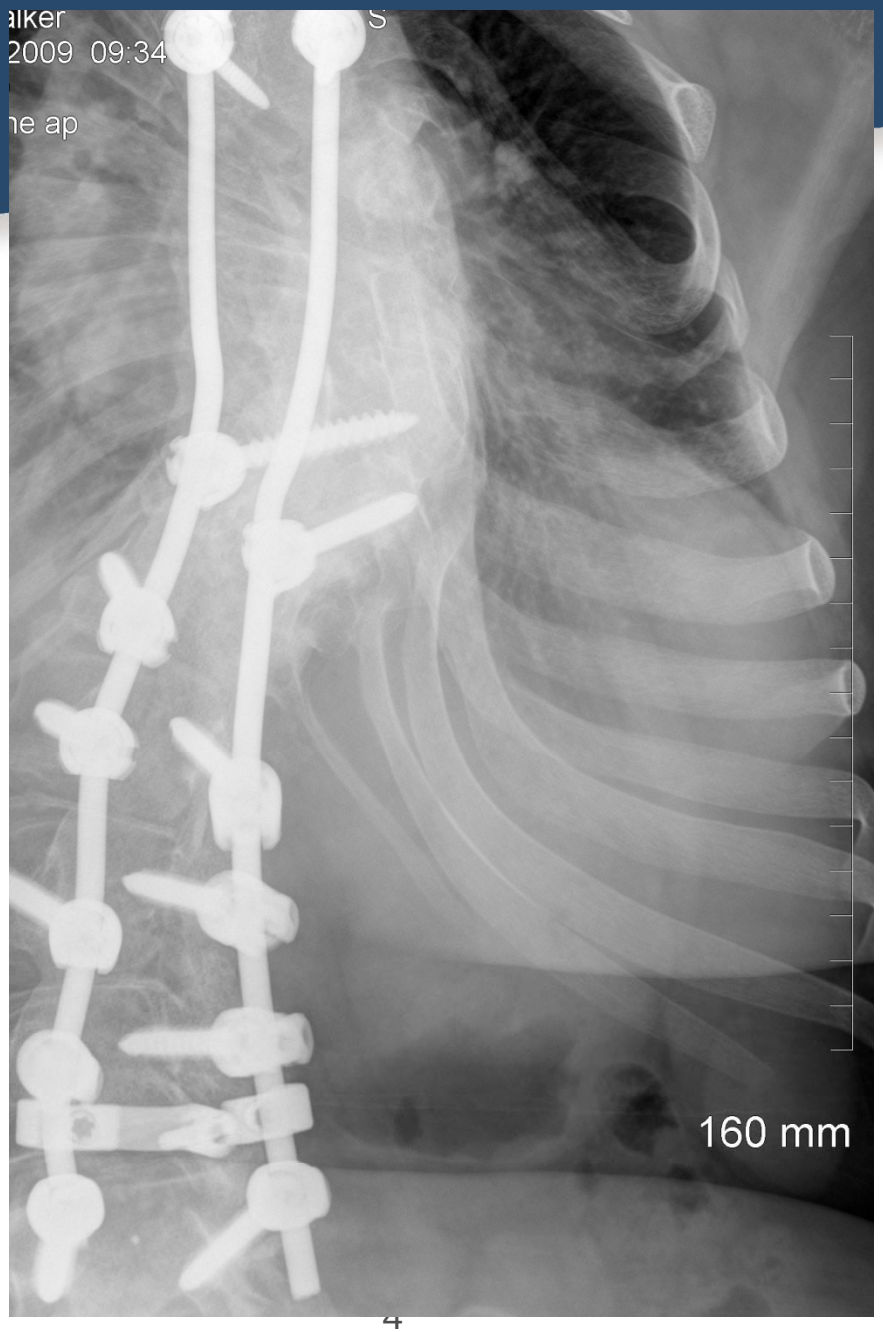




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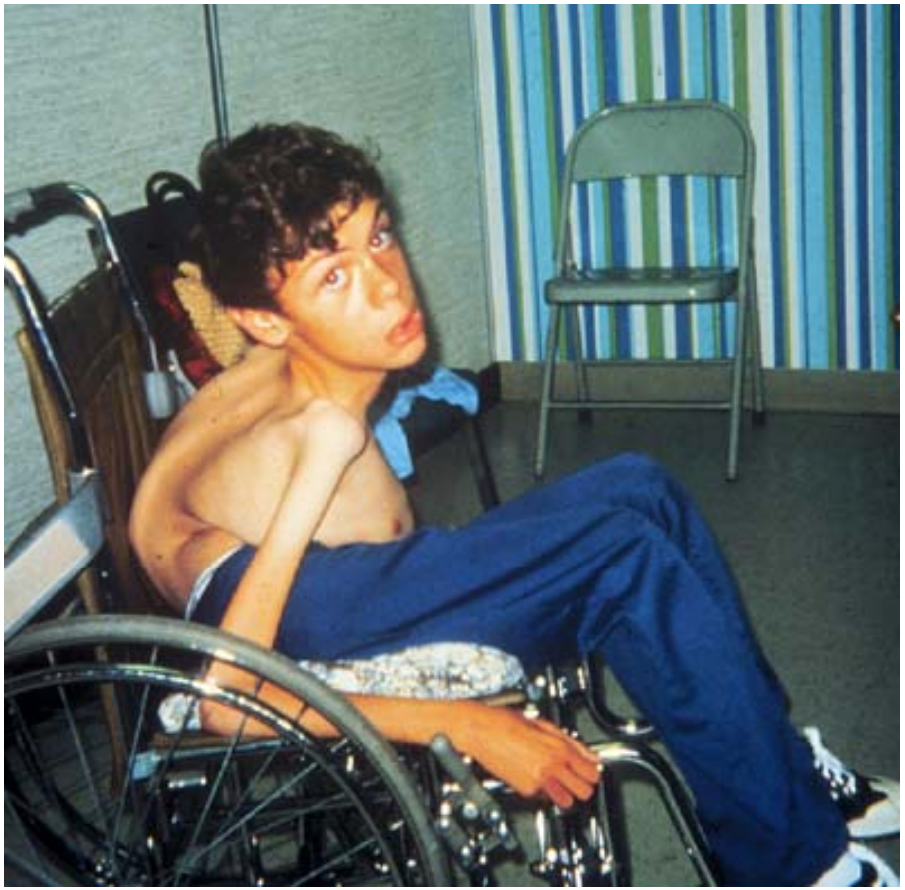

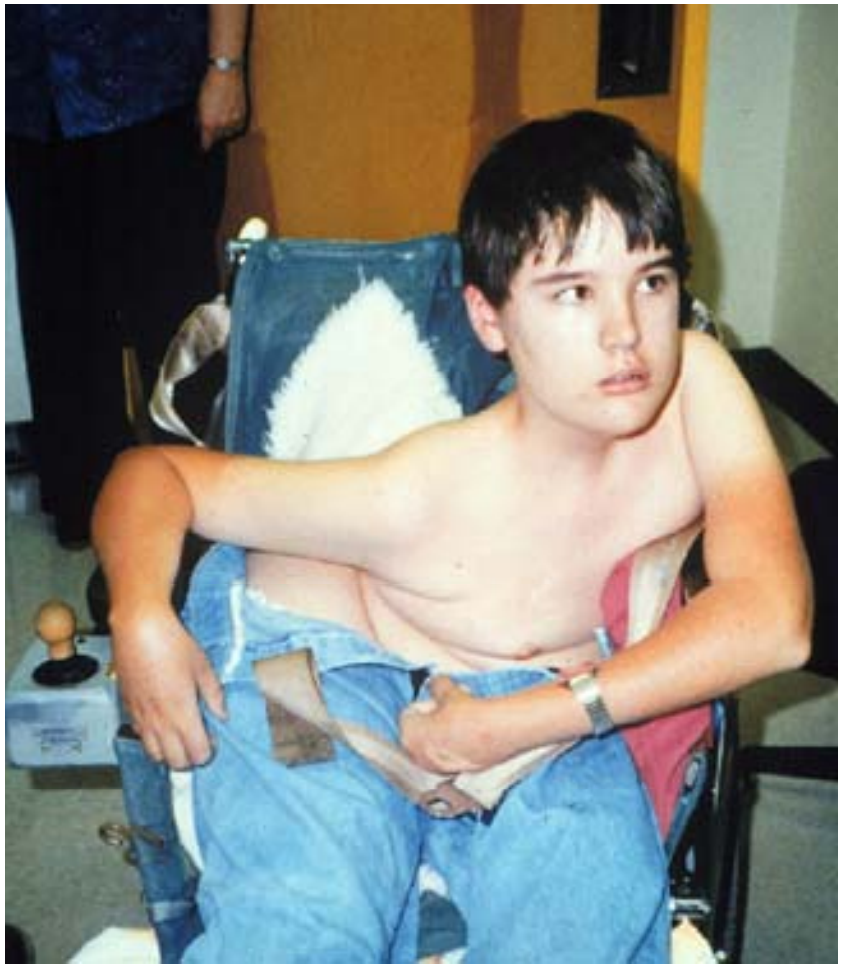

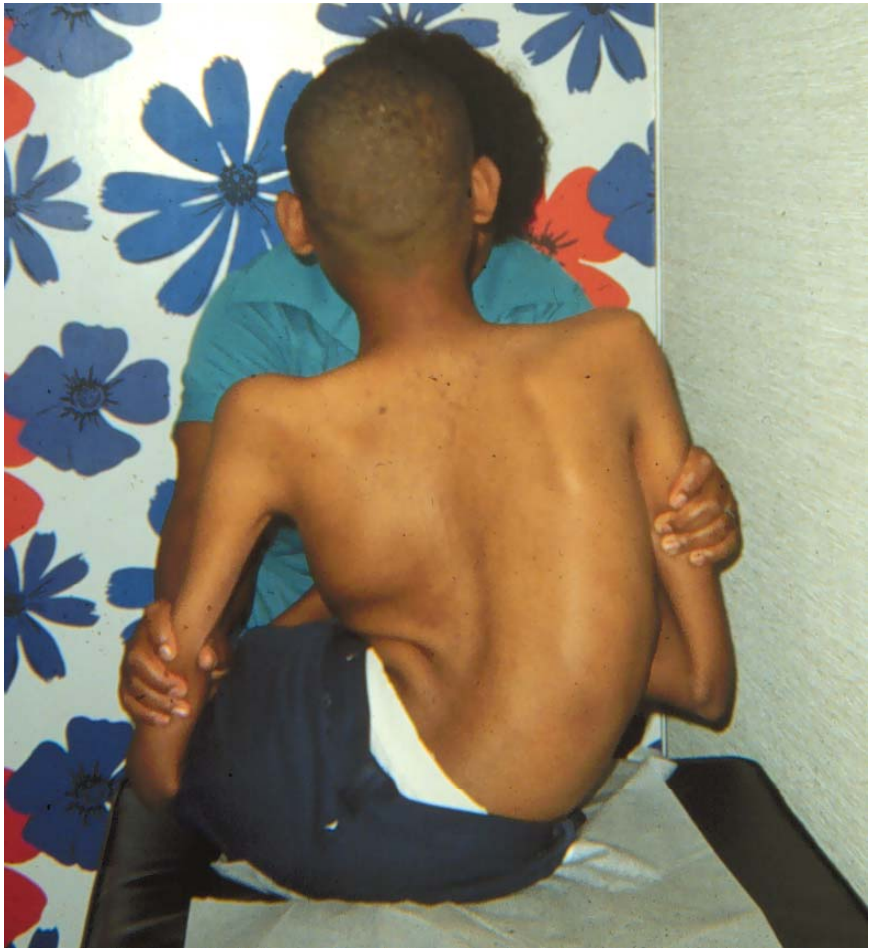

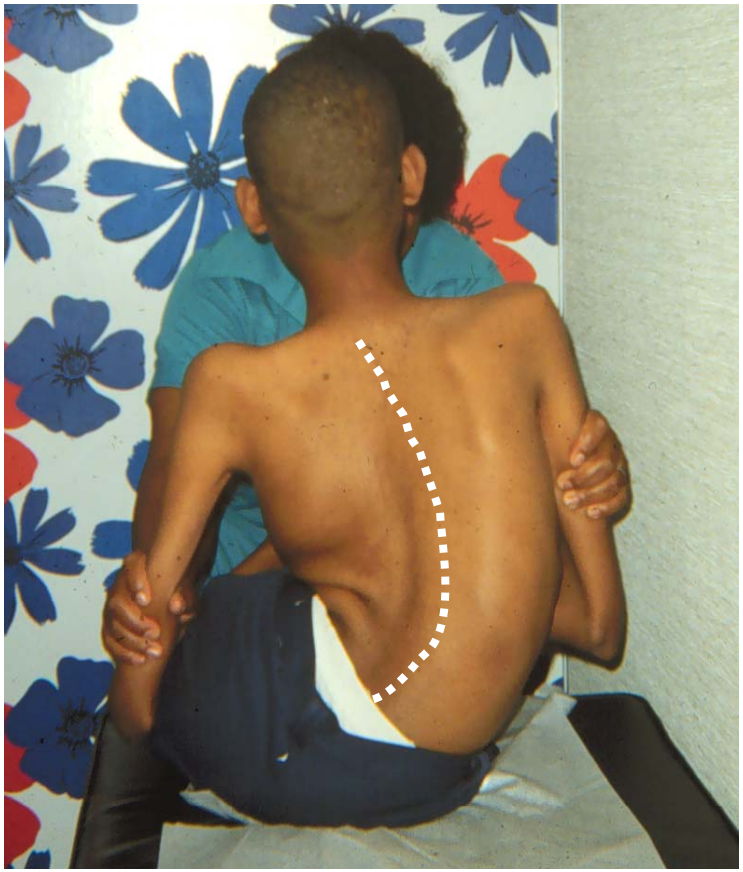

# Background

- Infection Control Quarterly report
- Anecdotal evidence
- No data had been gathered

# Clinical Inquiry Questions

1. What is the current nutritional preoperative profile of neuromuscular scoliosis patients undergoing spinal fusion and instrumentation surgery?
2. What are the current postoperative rates of wound infection, pneumonia, and length of stay in the same population?

# Review of the Literature

1. Evidence supporting nutritionally sound patients and better healing outcomes
2. Evidence supporting laboratory nutritional markers can predict patients at risk for infection
3. Evidence supporting high risk of postoperative infections in this population

# Design

1. Cross sectional descriptive design
2. Observations and descriptions gathered from chart review
3. No treatments or interventions
4. Evaluation of a single group

# Setting

1. Records from a pediatric orthopedic hospital

# Sample

1. Boys or girls
2. Ages 12 to 18 years
3. GMFCS level IV or V
4. CPT codes 22804 and 22844, spinal fusion with multilevel posterior instrumentation

# Variables

| Variable | Measure | | Outcome | Measure |
|---|---|---|---|---|
| *Gender* | Record review | | *Length of stay* | Record review |
| *Age* | Record review | | *Infection Outcome* | Record review |
| *GMFCS* | Record review | | *Pneumonia Outcome* | Record review |
| *Weight* | Record review | | | |
| *Arm span* | Record review | | | |
| *BMI* | Record review | | | |
| *Constipation Status* | Record review | | | |
| *Prealbumin* | Biophysical | | | |
| *Total protein* | Biophysical | | | |
| *Albumin* | Biophysical | | | |
| *White blood cell* | Biophysical | | | |
| *Lymphocyte* | Biophysical | | | |
| *Hemoglobin* | Biophysical | | | |

# Analysis

1. Descriptive statistics
2. Chi square
3. Independent *t* tests

# Results

1. What is the current nutritional preoperative profile of neuromuscular scoliosis patients undergoing spinal fusion and instrumentation surgery?

# Results - Variables

- Age
- GMFCS
- Arm span
- Constipation Status
- Total protein
- WBC
- Hemoglobin
- Gender
- Weight
- BMI
- Prealbumin
- Albumin
- Lymphocyte count

# Results

| Constipation | | |
|---|---|---|
| | Frequency | Percent |
| Gender | | |
| Male n=24 | 24 | 100 |
| Female n=26 | 26 | 100 |

# Results - Outcomes

1. What are the current postoperative rates of wound infection, pneumonia, and length of stay in the same population?

# Results

| Incidence of Infection | | |
|---|---|---|
| | Frequency | Percent |
| Infection | 7 | 14% |
| No Infection | 43 | 86% |

# Results

| Pneumonia | | |
|---|---|---|
| | Frequency | Percent |
| Gender | | |
| Male n=24 | 1 | 0.04% |
| Female n=26 | 0 | 0% |

# Results

| Length of Stay | | |
|---|---|---|
| | Mean | SD |
| Gender | | |
| Male n=24 | 7.29 | 3.2 |
| Female n=26 | 7.19 | 2.7 |

# Variables Split by Incidence of Infection

1. BMI
2. Leukocyte count
3. Hemoglobin
4. Albumin
5. Total Protein
6. Prealbumin

# Results Normal & Low Prealbumin levels

| | Normal | Low | Total |
|---|---|---|---|
| No infection | 14 (32.6%) | 29 (67.4%) | 43 (100%) |
| Infection | 5 (71.4%) | 2 (28.6%) | 7 (100%) |

# Results Normal and Low Total Protein levels

| | Normal (>6.4g/dL) | Low | Total |
|---|---|---|---|
| No infection | 40 (93%) | 3 (7%) | 43 (100%) |
| Infection | 5 (71.4%) | 2 (28.6%) | 7 (100%) |

# Results Normal and Low Albumin levels

| | Normal (>3.2g/dL) | Low | Total |
|---|---|---|---|
| No Infection | 35 (81.4%) | 8 (18.6%) | 43 (100%) |
| Infection | 4 (57.1%) | 3 (42.9%) | 7 (100%) |

# Results of Normal and Low Hemoglobin

| | Normal (>12g/dL) | Low | Total |
|---|---|---|---|
| No Infection | 29 (67.4%) | 14 (32.6%) | 43 (100%) |
| Infection | 6 (85.7%) | 1 (14.3%) | 7 (100%) |

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# Results of Normal and Low Leukocyte count

| | Normal ($>2000 mm^3$) | Low | Total |
|---|---|---|---|
| No Infection | 23 (53.5%) | 20 (46.5%) | 43 (100%) |
| Infection | 4 (57.1%) | 3 (42.9%) | 7 (100%) |

# Results of Normal and Low BMI

| | Normal (19.2-20.6%tile) | Low | Total |
|---|---|---|---|
| No Infection | 17 (39.5%) | 26 (60.5%) | 43 (100%) |
| Infection | 7 (100%) | 0 | 7 (100%) |

# Discussion

1. Mean weight was less than the 5th percentile - these children are smaller
2. Infected patients had lower BMI (less than 5th percentile)
3. WBC, Hgb Albumin & TP low end of normal
4. Low prealbumin levels (60%) in all patients
5. Low leukocyte count (40%) in all patients
6. 100% constipation incidence



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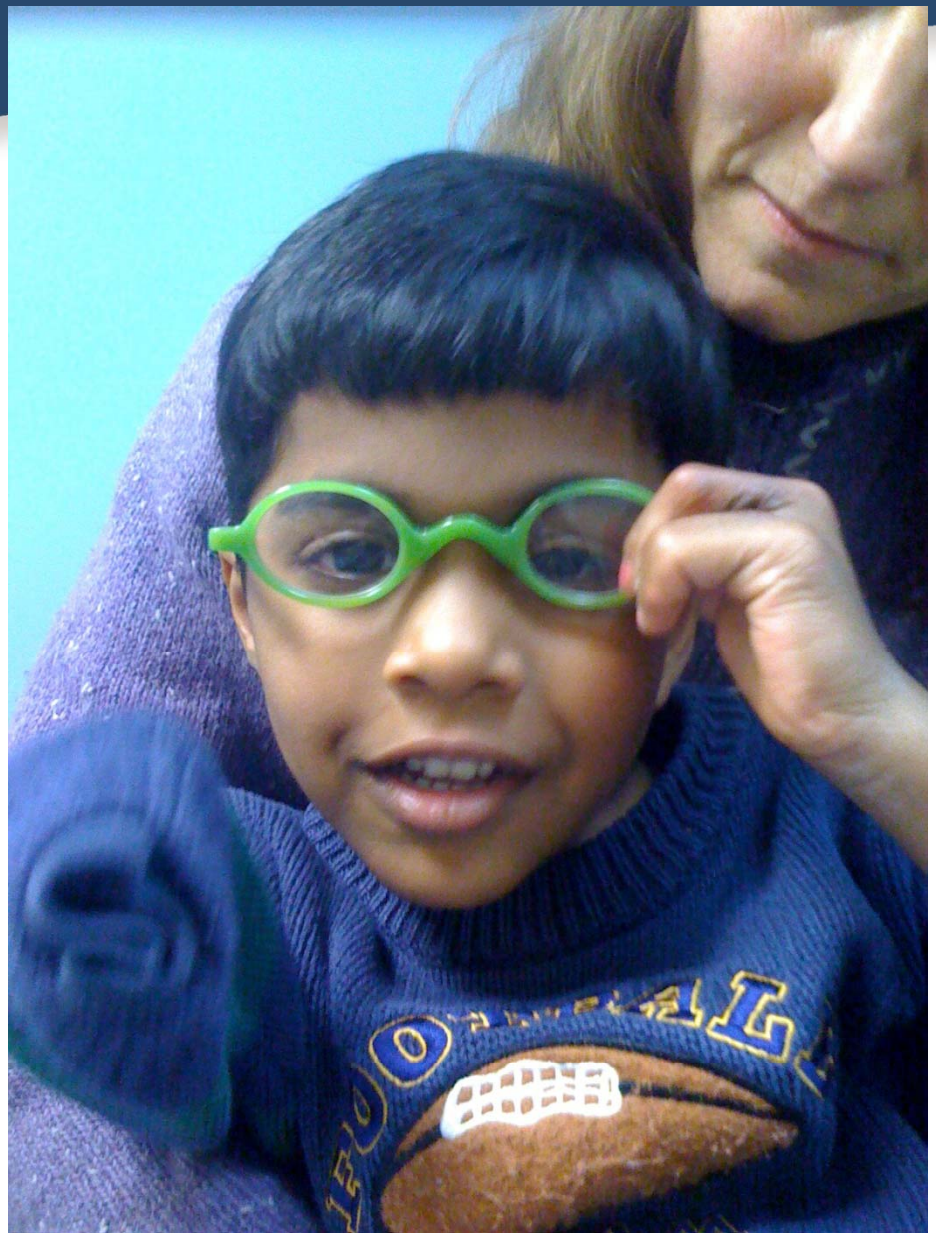

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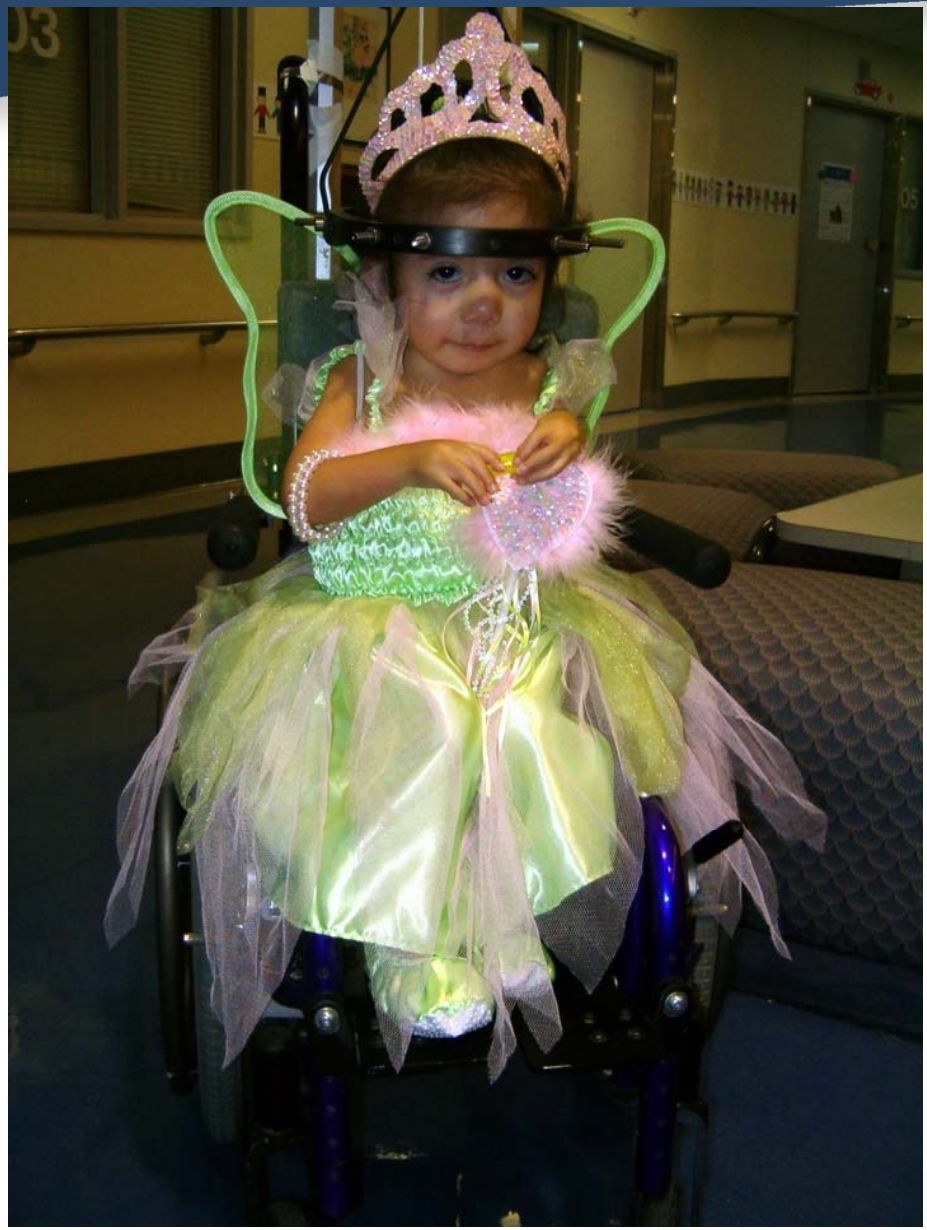
Cinderella
or
Tinkerbell?



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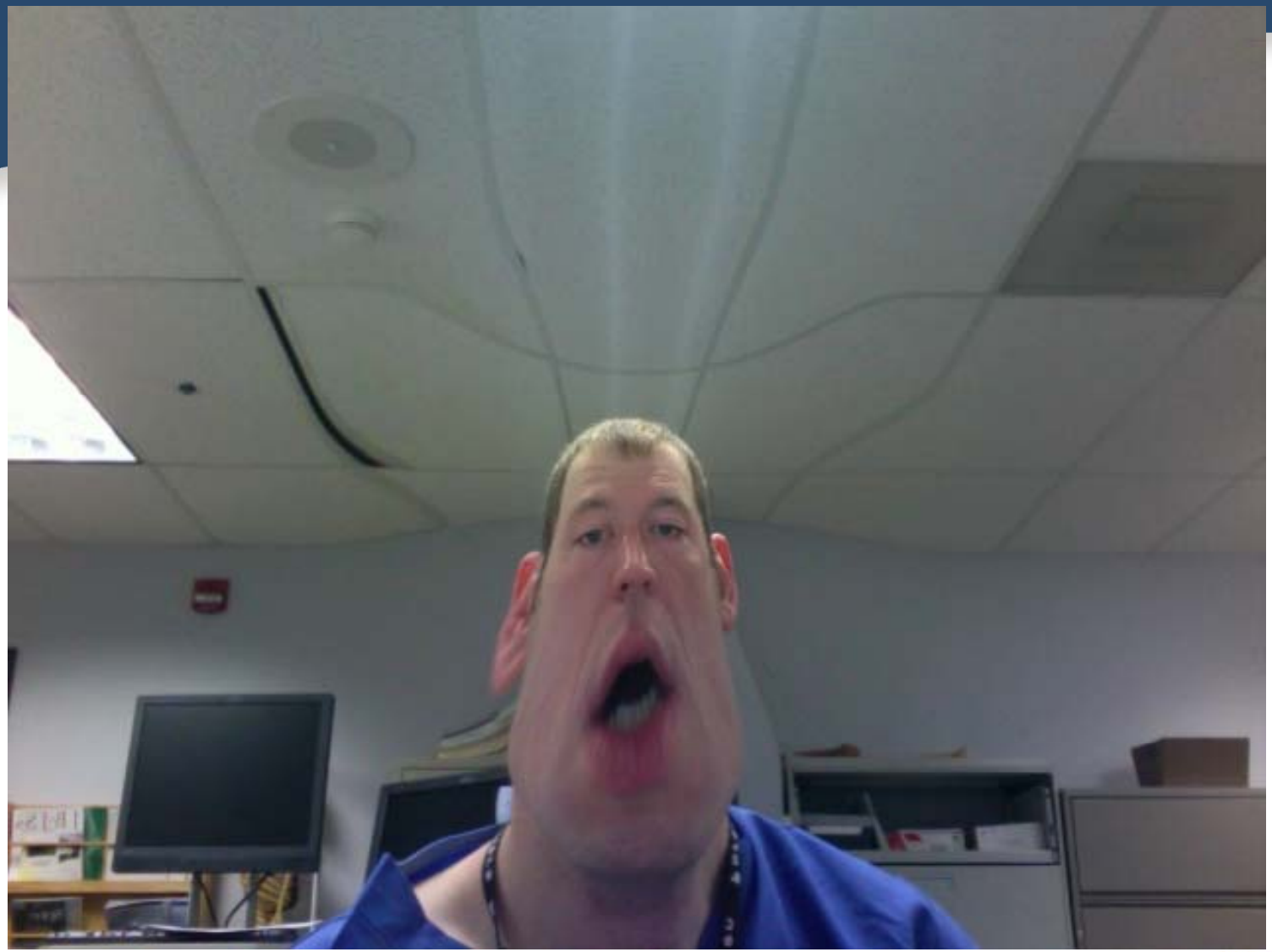
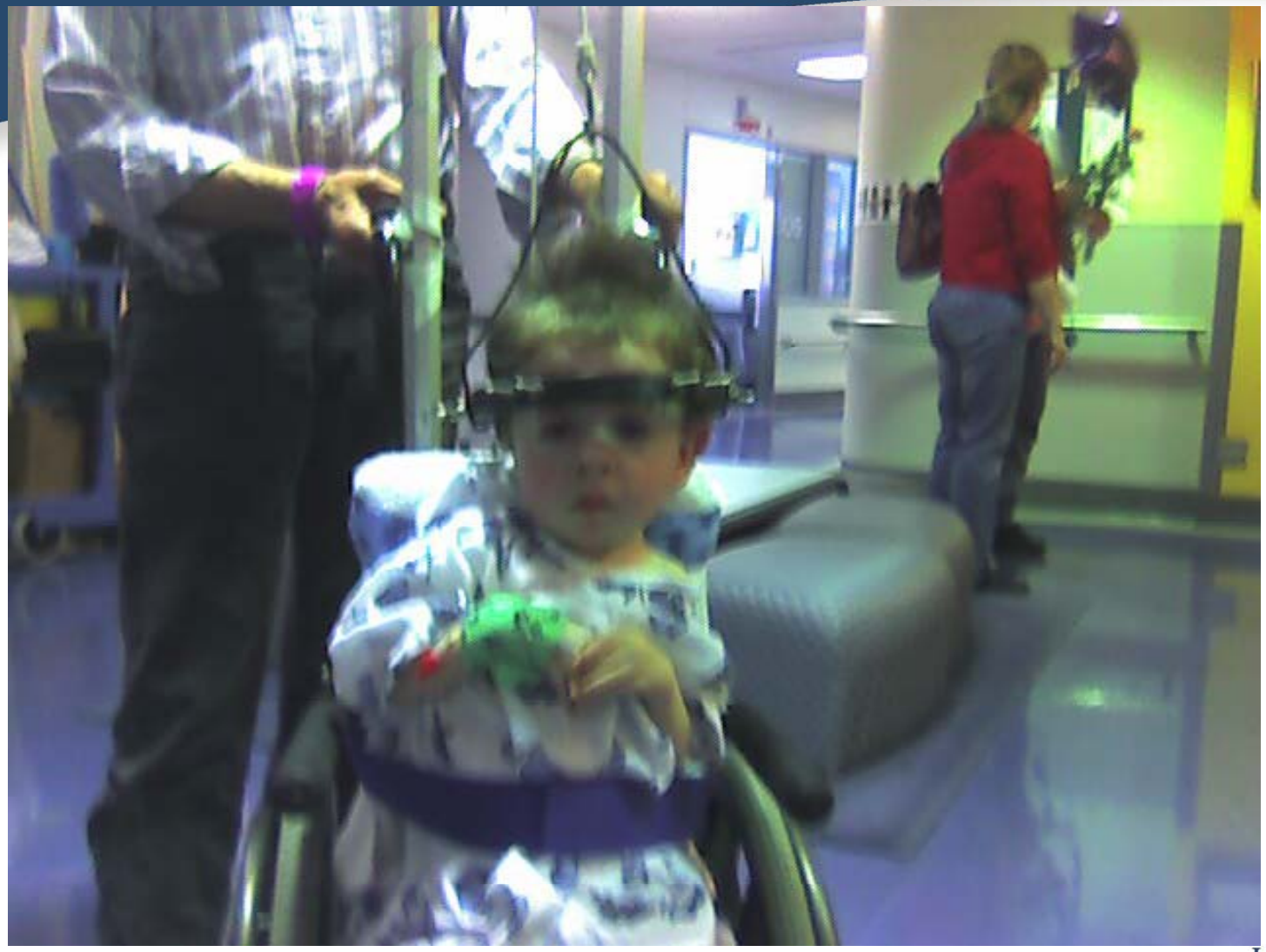
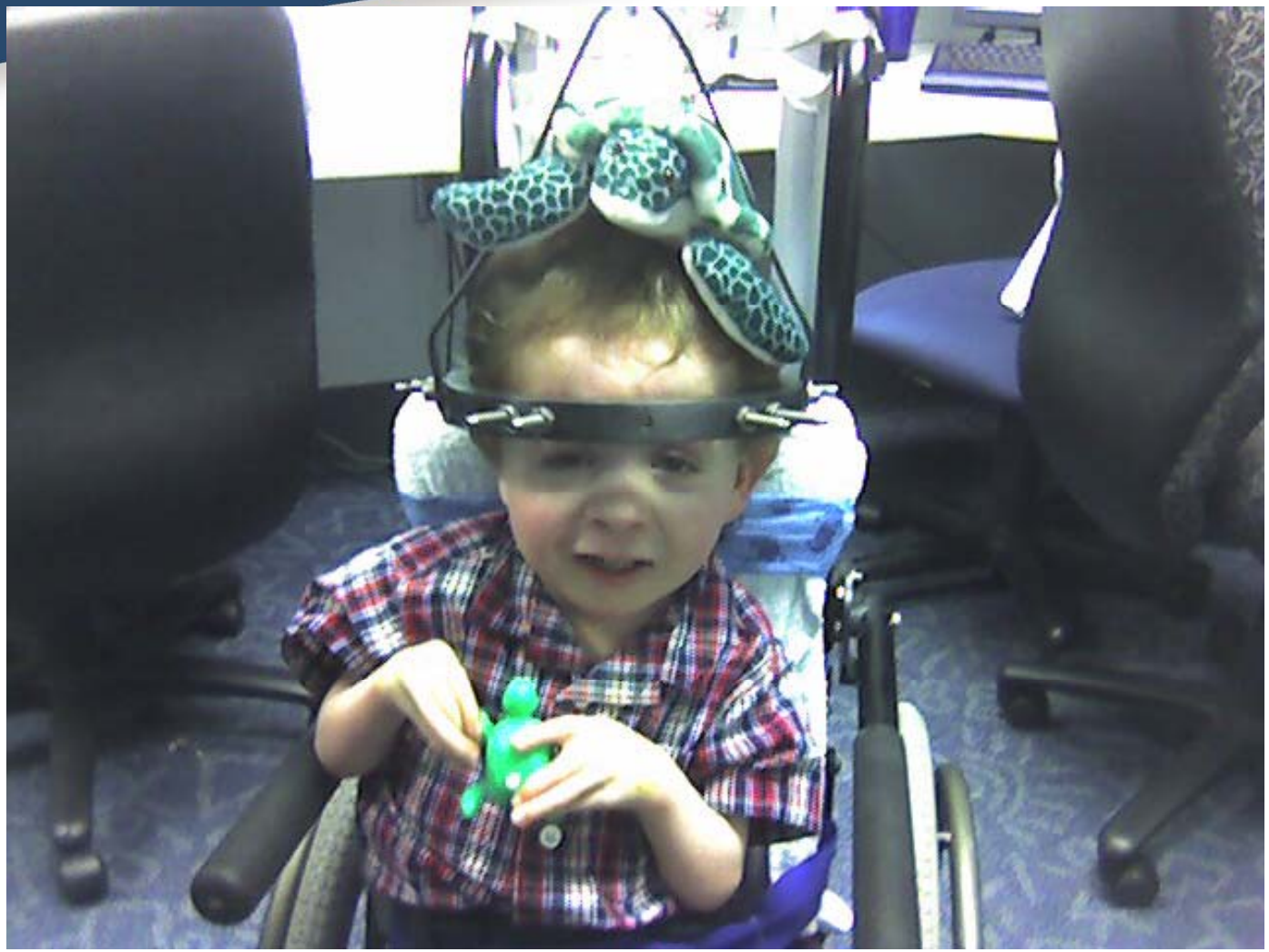
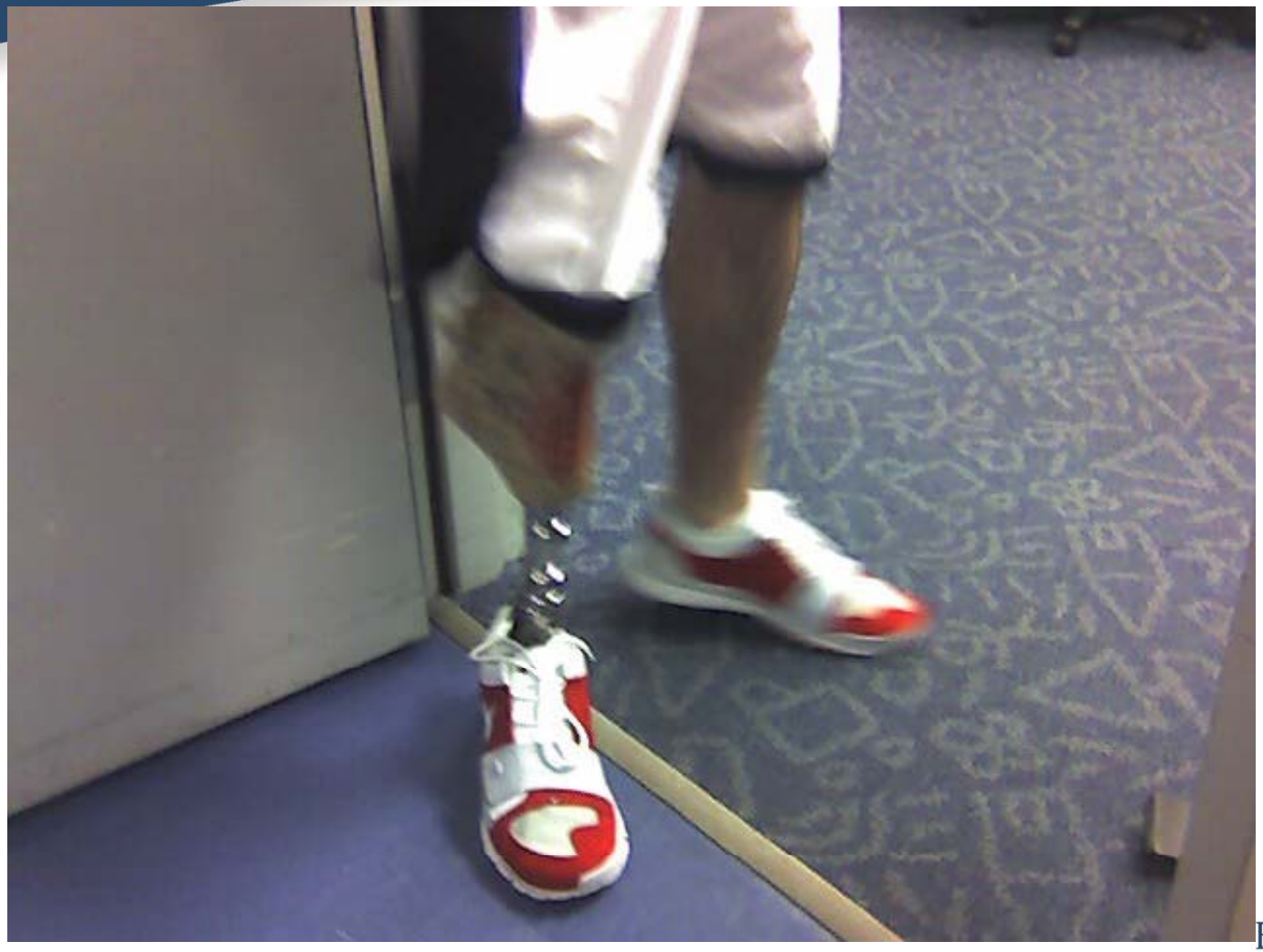
Spiderman or Superman

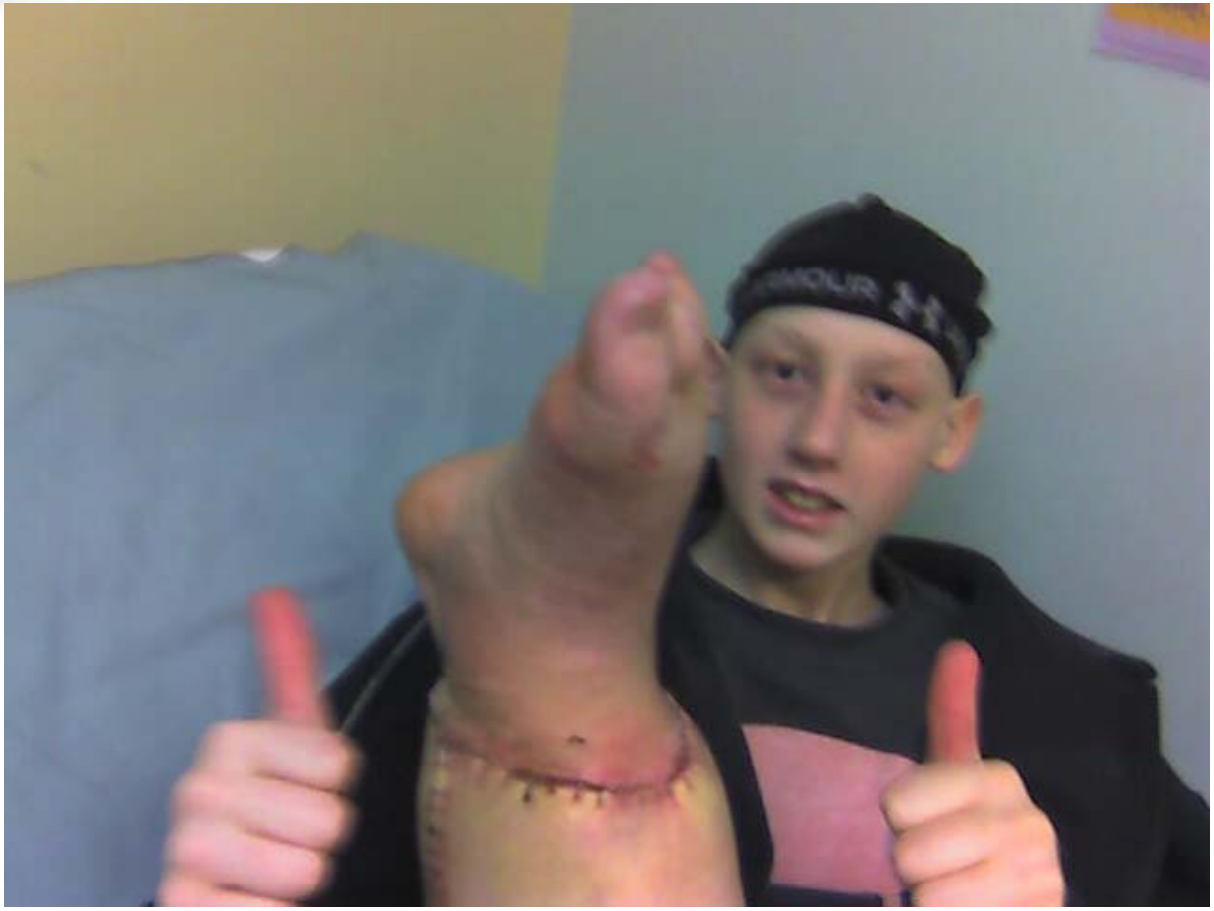


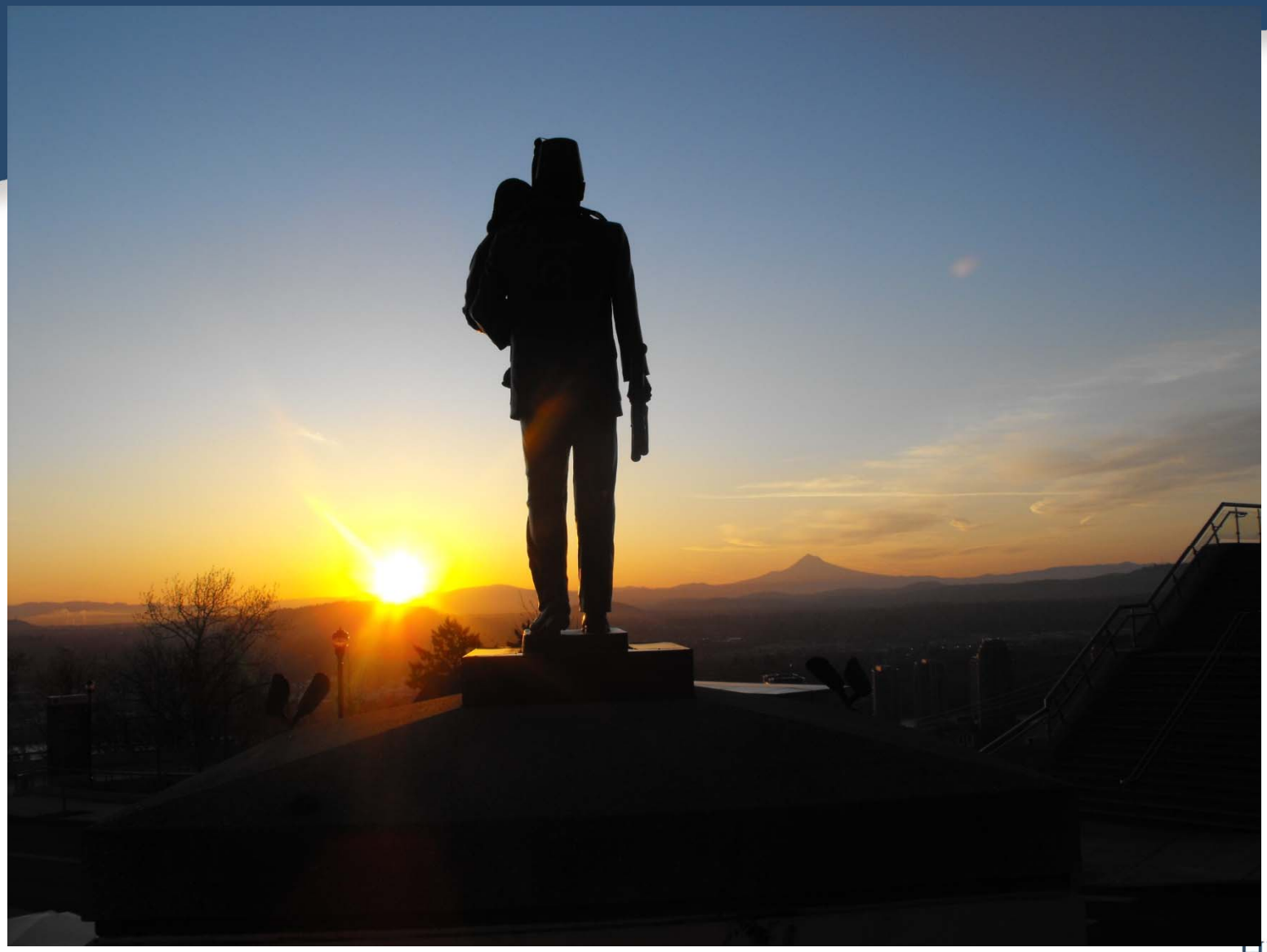





TRAVIS







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## 2 to 20 years: Boys
## Stature-for-age and Weight-for-age percentiles

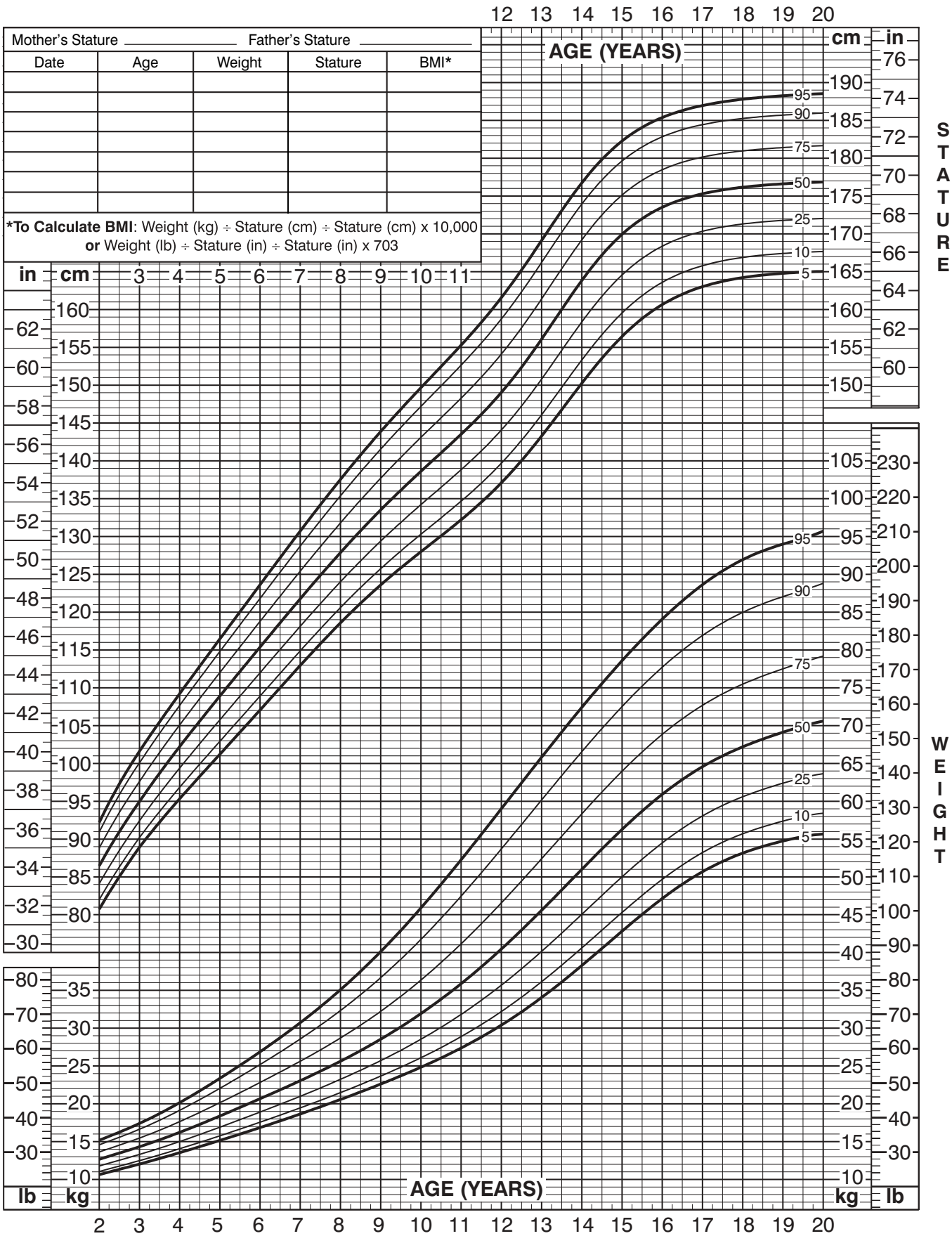
NAME _____

RECORD # _____

Mother's Stature _____ Father's Stature _____

| Date | Age | Weight | Stature | BMI* |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

***To Calculate BMI**: Weight (kg) ÷ Stature (cm) ÷ Stature (cm) x 10,000
**or** Weight (lb) ÷ Stature (in) ÷ Stature (in) x 703




Published May 30, 2000 (modified 11/21/00).
SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).
**http://www.cdc.gov/growthcharts**

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## 2 to 20 years: Girls
## Stature-for-age and Weight-for-age percentiles

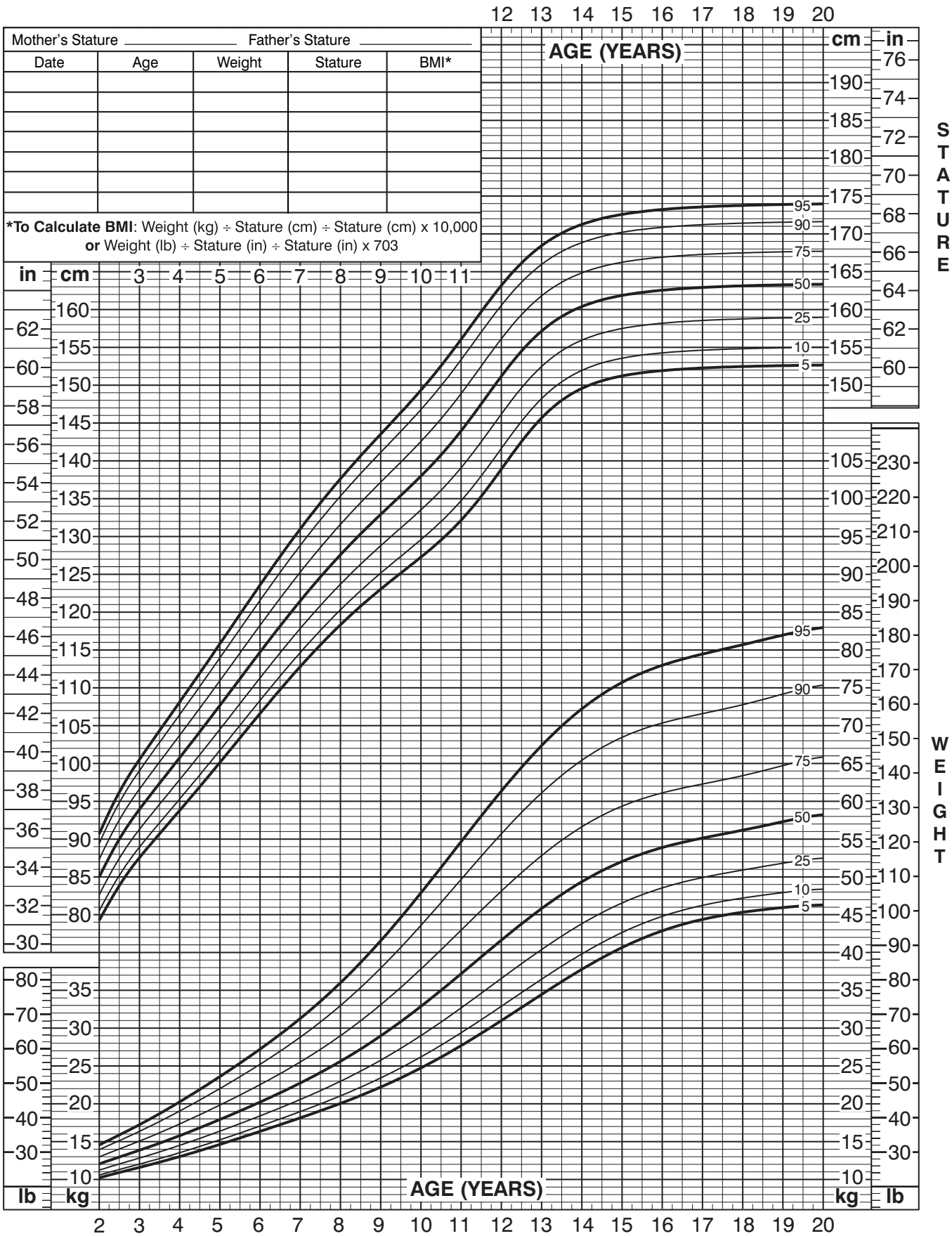
NAME _____

RECORD # _____

Mother's Stature _____ Father's Stature _____

| Date | Age | Weight | Stature | BMI* |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

***To Calculate BMI**: Weight (kg) ÷ Stature (cm) ÷ Stature (cm) x 10,000
**or** Weight (lb) ÷ Stature (in) ÷ Stature (in) x 703




Published May 30, 2000 (modified 11/21/00).

SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).
**http://www.cdc.gov/growthcharts**

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Appendix C
Laboratory Testing Analysis

| Test | Specimen | Method | Measurement |
|---|---|---|---|
| Total Protein | Serum | Bromcresol green, bromcresol purple, protein electrophoresis, turbimetry, or nephelometry | Grams per deciliter |
| Albumin | Serum | Bromcresol green, bromcresol purple, protein electrophoresis, turbimetry, or nephelometry | Grams per deciliter |
| Prealbumin | Serum | Bromcresol green, bromcresol purple, protein electrophoresis, turbimetry, or nephelometry | Grams per deciliter |
| White blood cell | Whole blood | High capacity multichanel measuring system | Percent |
| Leukocyte count | Whole blood | High capacity multichanel measuring system | Millimeters cubed |
| Hemoglobin | Whole blood | High capacity multichanel systyem | Grams per deciliter |

(Jacobs, DeMott, & Oxley, 2004)

Appendix D

Clinical Information Data Tool

# _____

Age _____

Sex _____

GMFCS _____

Ht _____

Wt _____

BMI _____

WBC _____

Lymph_____

Hgb_____

Prealb _____

ALB _____

TP _____

LOS_____

Running head: UNIVERSAL HEALTH CARE COVERAGE

# Universal Health Care Coverage

Janie Huff-Slankard

Oregon Health and Science University

## Context

Over the past 53 years, no significant advancements toward a universal health care system have been made, despite attempts by numerous government commissions on health care. The most recent proposal was the Clinton health care plan, which was defeated before the commission was even convened (Blankenau, 2001). Canada, which offers a universal health care system, spends 4,411 dollars per person on health care annually (Canadian, 2005) while the United States (U.S.) spends 6,700 dollars per person (National, 2007).

Despite spending more per capita on health care than any other country, an average of 6700 dollars per person, approximately 19 percent of adults were unable to receive needed medical services in 2005 because they could not afford them (National, 2007). Up to 14 percent of the population did not receive needed prescription drugs for the same reason (National, 2007). The Centers for Disease Control (CDC) also reports that uninsured and impoverished patients are more likely to be unable to afford needed services (National, 2007). Those under 65 years of age with no health insurance coverage varied between 16-17 percent from 1999 to 2005 (National, 2007). The U.S. poverty rate continues to rise; it was 11.3 percent in 2000 and 12.6 percent in 2005 (DeNavas-Walt, 2006).

The U.S. population rose to 296 million in 2005. Life expectancy at birth for the total population was 77.8 years in 2004, a record high, while the infant mortality rate fell to 6.8 infant deaths per 1,000 live births (National, 2007). Standard measures of health status utilized globally and historically suggest a relatively unhealthy nation (Starfield, 2000). In one study of 13 nations the U.S. ranked 12$^{th}$ of 16 health measurements (Starfield, 2000). Starfield (2000) also reports

that five of the top seven ranking nations have a strong primary care infrastructure, lacking in our nation.

The social context of universal health care, or socialized medicine as it was previously called, began when Medicare was introduced in the 1950's (Brief, 2007). The populations most at risk for lacking coverage are the low and moderate income families, small firm and low wage workers, non-standard workers, young adults, minorities, unemployed, and people with disabilities in the two year waiting period for Medicaid (Collins, 2007). Navarro (1995) disagreed with the view that since Congress represents the people of the U.S. and the 103rd Congress did not enact health care reform, the people do not want health care reform. Instead, his opinion is that the voice of the people of the U.S. is not being heard by the political representatives and 74 percent of the people believe Congress does not represent them (Navarro, 1995).

The political structure of the U.S. is democratic and largely bi-partisan. The Presidential office is currently held by a Republican and the Congress in the last year changed power from Republican to Democratic. The year 2008 is an election year and the political climate is certainly ripe for change as the Republican Party has been in power for the past eight years and historically the change over to the alternate party happens in this time frame.

An important contextual factor in the U.S. affecting the economy is the active involvement in defense programs. The U.S. is currently involved in Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and homeland defense. These military programs have a significant impact on the country's financial state and economic stability.

## Problem

Health care insurance coverage is the most important determinant of access to healthcare (Collins, 2007). Universal health care coverage is the only answer to the health care crisis in the U.S. (Collins, 2007; Emanuel & Fuchs, 2006; Gruber, 2006). Emanuel and Fuchs (2006) have written a policy for Universal Healthcare Vouchers (UHV) based on the benefit package in place for Federal government employees. This paper will analyze their policy using the Collins method of analysis. Emanuel and Fuchs (2007) make the argument for designing a completely new system of health care coverage, not reforming the current, non-functioning system. The systems in place currently fit for some but only the poorest of the poor and promote a class system of access to health care (Emanuel & Fuchs, 2007; Navarro, 1995).

## Evidence

The evidence supports that uninsured working-age Americans are more likely to be sicker and die sooner (Coleman, 2002). It is also shown that this population receives too little medical care, receives it too late and receives poorer care when they are admitted to acute care hospitals (Coleman, 2002). A review of the literature also demonstrates the gap between public and employer based coverage is widening (Collins, 2007). Michael Moore's recent documentary film, *Sicko*, demonstrates how this country, based on a tenet that we are a government for the people, is failing to prevent the preventable in health care (Summers, 2007). Health care horror stories are criticized for their drama, but there is an element of ethics and social responsibility imbedded in the issue of universal health care (Hacker, 2007; Navarro, 1995).

Collins (2007) estimates the number of uninsured rose to 47 million in 2006 and estimates that 16 million adults were inadequately insured. Access to health care is directly related to health insurance coverage. Statistics bear out that people without insurance are more likely to die prematurely, suffer more loss in productivity in the workplace, which affect earnings, and have different life experiences than those with insurance. “It is critical on moral and economic grounds that the nation move affirmatively to guarantee affordable, comprehensive and continuous health insurance for everyone.” (Collins, 2007, p. 40). The Current Population Survey (CPS) of 2005 showed 21 percent of uninsured are below 18 years of age and 63 percent are under age 34 (CPS, 2005). The correlation is thought to be related to age and income as younger people have lower incomes. A critical point in time for young adults who have been on federally funded programs, Medicare and SCHIP, is the 19th birthday. At that point in time, federal funding ends unless they qualify for Medicaid as an adult (Collins, 2007). Twenty two percent of disabled young adults who work are uninsured, compared to 10 percent of disabled children 11 to 18 years of age (Fishman, 2001).

Not surprising are the statistics published by the Current Population Survey (CPS) (2005) that demonstrate the majority of uninsured individuals are working people or the children of those who work. Reasons range from employers not offering coverage to the fact that the coverage for dependents offered was too expensive for the wages paid. Another interesting fact in the CPS data was the number of uninsured individuals was ever changing; people would have insurance for three or four months of the year and then none for the remainder. Fifty one percent had no insurance for the entire year. Intermittent insurance coverage means that those individuals faced at least one month of time when they were vulnerable to a catastrophic event or medical

emergency for which they would have pay for out of pocket or the hospital would write off in bad debt (CPS, 2005).

Fifty five percent of today's health care insurance is employer-based (Fuchs, 2005). When the employer-based system began in the 1940's, the U.S. economy was highly driven by the labor market and big business monopolies such as American Telephone and Telegraph AT&T (Barer, Marmor, & Morrison, 1995). Increases in insurance rates were recouped by increasing costs of services to customers. With the destruction of monopolies, the cost now shifts to the employee. Today, Wal-Mart is the largest private employer and they maintain a high volume of part-time workers who are not eligible for insurance benefits (Fuchs, 2005). Although employers are required to offer benefits through the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), the cost of the premiums, averaging more than $12,000 a year for a family plan, is prohibitive for the majority of the unemployed (Collins, 2007).

Another group of individuals who are at a higher risk of being uninsured are minorities (Doty & Holmgren, 2006). Data shows 62 percent of Hispanics and 33 percent of African Americans compared to 20 percent of Whites were uninsured for some part of the year in 2005 (Doty & Holmgren, 2006).

The disabled population waiting to be enrolled in Medicaid is a staggering 1.7 million (Collins, 2007). Statistics from Collins, et al. (2007) show that 15 percent of those, 255,000, are uninsured. In one study of disabled people ages 50 to 64, 41 percent of them reported they were uninsured just prior to entering Medicare.

## Policy Options

Alternatives to the policy of Universal Healthcare Vouchers as proposed by Emanuel and Fuchs (2005) involve reforming current systems in place. Reform proposals can be categorized into three groups: (1) incremental reforms, (2) individual mandates and (3) single-payer plans (Emanuel, 2007). Incremental reform makes no changes; current programs' coverage is expanded. Individual mandates require everyone to buy insurance. Single-payer plans leave a fee for service plan in place.

The Economic and Social Research Institute (ESRI), supported by the Robert Wood Johnson Foundation, published Covering America: Real Remedies for the Uninsured in 2001 in an effort to raise awareness related to health care system reform and to assist policy makers with making evidence based decisions. Forty plus proposals were selected were reviewed by the ESRI and ten were chosen for publication. The papers were not chosen to spark interest and debate, but merely to provide information for policy makers (Covering America, 2001). The ten papers are categorized into the three groups as proposed by Emanuel and Fuchs for analysis, incremental reforms, individual mandates and single-payer plans.

### *Incremental Reforms*

Three of the ten proposals are incremental reforms, which build on the existing high cost federal programs in place today. This first group proposes expansion of Medicaid and State Children's Health Insurance Program (SCHIP) and extending eligibility for coverage without cost-sharing or premiums for people whose income is below 150 percent of federal poverty level (FPL). SCHIP eligibility would be extended to people at 150 to 200 percent below FPL but with

a maximum of 5 percent of income in cost sharing and premium fees. Those with incomes greater than 200 percent of FPL could buy coverage based on a sliding-scale fee system. They also advocate for a tax credit for low-wage employers in order for them to provide insurance for their employees (Feder, Levitt, O'Brien, & Rowland, 2001).

Another incremental plan extends SCHIP and Medicare by providing federal incentives to states to expand their coverage to anyone with incomes at or below 250 percent of FPL and those with high cost health care needs regardless of income. States would have the option not to participate (Holahan, Nichols, & Blumberg, 2001).

Medicare Plus would replace Medicaid and SCHIP in this reformation plan. Employers could offer and enroll employees in Medicare Plus or enroll them in an equitable plan from another source by paying a "modest" payroll contribution. Modest is not specified. Employees also have the option of accepting Medicare Plus or choosing an alternative insurance minus a penalty. A state financial incentive would be offered to states that enrolled non-workers in Medicare Plus. People who are not working and not enrolled by the state could buy the plan with premiums based on income (Hacker, 2001).

*Individual Mandates*

Half of the proposals in the ESRI report propose individual mandates as the best evidenced reform proposal. This plan achieves near universal coverage through tax credits that replace current tax exclusions. If your employer sponsors coverage then employees are mandated to participate in that plan. If employers do not offer insurance, the employee's tax credit is to be used to purchase coverage from other plans. Groups like labor unions and even churches could

offer insurance plans for purchase (Butler, 2001). Employers would be the clearinghouses for payroll deductions of the credits, even if they are not supplying the coverage. An incentive for states is built into the system whereby they can receive federal grants for programs that the state runs to make coverage affordable for low income employees (Butler, 2001).

A right to health insurance is the tenet upon which Kronick and Rice build their reform (Kronick & Rice, 2001). “Health insurance would be a social insurance program, not a means-tested program” (Kronick & Rice, 2004). Each state would develop its own plan and would get federal monies if they assured that all residents were covered in a basic plan. The plan would be paid for by employer and employee taxes supplemented by federal and state revenues and possibly people who want to purchase a more substantial added benefit program. They also added quality improvement monitoring but no details are provided for the process to accomplish this piece of the proposal (Kronick & Rice, 2001).

Pauly’s (2001) approach to reform is a gentle, easy entry into universal coverage that starts with reducing the number of uninsured. Households with incomes above the median would stay with the current system and lower middle-income households would receive tax credits or coupons that would equal the cost of the premium. Very low income households would be insured without any premiums charged (Pauly, 2001).

Insurance exchanges and tax credits would make premiums affordable for nearly all people with this plan. A U.S. Insurance Exchange would offer at least two plans per geographic region (Singer, Garber, & Enthoven, 2001).

Low and middle-income families would receive tax credits if they purchase through a pool. Low-income persons would be enrolled in an individual state default plan (Singer, et al., 2001).

The last proposal mandates coverage for all and penalties are charged for every month one is not insured. Refundable tax credits varying by income will fund the plan. Aggregate purchasing agreements, (i.e. pools) and centralization of the administration of the plan are two other highlights (Wicks, Meyer, & Silow-Carroll, 2001).

*Single-payer Plans*

Only two of the proposals advocate for single-payer plans. This plan is named Medical Security System (MSS) and covers all persons less than 65 years of age. A basic package would be paid for by the employer. The insurance system would be reorganized into health insurance exchanges based on geographic area that would standardize the benefits package. Employers and employees could participate in other plans if the plan was equal to the MSS. Medicaid and SCHIP would be eliminated and a payroll tax would be added for the additional financing (Weil, 2001).

Gruber (2001) restructures the insurance system by having state based insurance pools to purchase from. Federal subsidies would fund persons below 300 percent of FPL and those with higher incomes would pay 10 percent or less of their income. Money would be redirected by phasing out Medicaid and SCHIP, but keeping disability and over 65 programs. Insurers would be paid on a risk-adjusted basis (Gruber, 2001).

The current role of government, insurance and politics must be eliminated to reduce interference. “Universal coverage is essential to a high performance health system” argues the Commonwealth Fund Commission on a High Performance Health System (Collins, Schoen, Davis, Gauthier, & Schoenbaum, 2007). Universal care is an equalizing force. Advocacy of universal health care coverage by health care providers is needed in order to align with the patients rather than the profiteers and become politically active (Altom & Churchill, 2007).

The analysis of the reform packages revealed the fact that none of the reforms change the players, therefore, the struggle for dollars and power will continue unless a more comprehensive reform such as Universal Healthcare Vouchers is implemented.

## Project the Outcomes

Reform proposals have the potential to impact health care for all but maintain systems that are not functioning efficiently or effectively (Gruber, 2006). The general approach in incremental reform expands services such as covering people at age 55 under Medicare, offering SCHIP to all children and giving tax credits to buy insurance for those not enrolled in a federal or state program (Pauly, 2001). Managed competition and health savings accounts are two other examples of incremental reform proposals, both of which are based on dollars saved by the individual (Fuchs & Emanuel, 2005). In one combined report of 10 reform proposals, 5 would phase out Medicaid and SCHIP but all would continue with Medicare (Covering America: Real Remedies for Covering the Uninsured, 2001).

Emanuel and Fuchs (2007) label individual mandates as a fill in the gap approach. The state of Massachusetts enacted legislation that includes fill in the gaps along with requiring large

pools of insurance companies to select from and subsidies (Gruber, 2006). Their mandate that all persons must purchase health insurance is compared to state regulations around auto insurance in order to license your vehicle (Gruber, 2006). Gruber (2006) goes on to say "Health insurance reform that does not incorporate private health insurance seems unlikely in our lifetime, and maybe even in God's." (p. 14). Critics of the Massachusetts plan declare that this reform package is merely a political stepping off point to get a candidate into the White House (Woolhandler & Himmelstein, 2006). Another negative effect of mandates is the minimum wage workers' loss of employment because employers cannot pass on the costs of insurance by reducing wages (Fuchs, 2005).

The single payer plan of reform models itself more after the reform in Canada. The U.S. government lost $188.5 billion in 2004 just from losses in tax policies for health insurance (Sheils and Haught, 2008). This is just one of the pools of deficit dollars that would be eliminated by universal coverage. It is also estimated that Medicare will use all taxes collected under current law in just over 50 years (Federal Hospital, 2007).

## Evaluation

Standard criteria to evaluate the projected outcomes are relevance, progress, efficiency, effectiveness and impact (Collins, 2004). All of the options are relevant to the problem of providing health care to the citizens of the United States. Navarro (1995) outlined many reasons why although the citizens of the United States want universal health care, the political climate and contextual features of the times are in actuality the driving forces behind our inability to enact a system.

Significant costs to the people of the United States are inherent in all of the packages. Economic factors, insurance companies, drug manufacturers, big money makers and building blocks in the economy stand to lose profit margins, face employee cutbacks and will suffer with all universal health care, possibly more so with the UHV system because it so radically changes the scenario of health care coverage (Emanuel & Fuchs, 2005). Even Emanuel and Fuchs (2005) recognize this factor by stating that a major social change may have to happen before such a radical change can take place. They reference Hurricane Katrina, which many predicted would force the country into universal health care in order to care for the thousands of people affected by the disaster (Emanuel & Fuchs, 2005). Acceleration in the war in the Middle East or another terrorist attack on the U.S. are predicted to be possible catalysts for change in the current health care crisis (Emanuel & Fuchs, 2005).

When evaluating progress of an intervention it is useful to look at the results comparison (Collins, 2005). The newest data on two health care reforms in the U.S. enacted in the states of Massachusetts and Maine demonstrate much higher costs than originally predicted (Optimistic Patriot, 2008; Sack, 2007). Socialized medicine in the United Kingdom recently has experienced budget deficits related to pay for performance (Epstein, 2006). In an effort to improve quality, incentives were offered to physicians tied to a point system involving 146 quality criteria and a substantial number of physicians saw a dramatic increase in their reimbursements (Epstein, 2006).

In order to evaluate the efficiency and impact of universal health care, examining the results of the Canadian health insurance system is one option since none of the U.S. plans have been in place for a sufficient amount of time to evaluate. The U.S. ranks 38$^{th}$ in the nation in the World

Health Organization's ranking of best health care systems (Starfield, 2000). Canada ranks 30th and ranks lower in African-American infant mortality rates compared to U.S. (Crowley, 2004).

## Weigh the Outcomes

In order to weigh the outcomes, the alternatives must first be converted to outcomes (Collins, 2005). Two of the alternatives to the UHV policy, individual mandates and single-payer plans, will be discussed in order to weigh the outcomes.

The Dirigo Health Reform Act, a comprehensive reform package, was written by Governor Baldacci of Maine and signed into law in June of 2003. One of the plans goals was to provide all citizens in the state of Maine with access to health care by 2009. This reform package utilizes individual mandates and Medicaid eligibility expansion to help expand coverage for low and moderate income families. As of September 2006 less than 10 percent of previously uninsured residents were enrolled in either of the initiatives. Currently, DirigoChoice, the subsidized health care plan is not accepting new members (www.**dirigo**health.**maine**.gov/dhlp01.html ).

In April of 2006 Massachusetts enacted legislation that has been heralded as the closest to universal health care coverage than anywhere else in the U.S. (Gruber, 2006). This system is a blend of single-payer and individual mandates. Three components, an insurance pool, subsidies and an individual mandate, must be in place in order for the system to succeed (Gruber, 2006). The New York Times reported in November 2007 that while 200,000 people have enrolled in the program, at least that many have not (Sack, 2007). The New England Republican reported in January of this year the budget for the plan, predicted to cost $1.8 billion is expected to exceed

that figure by $150 to $400 million and over the next decade will cost $2 to 4 billion more than budgeted (Optimistic Patriot, 2008).

The proposed policy of Universal Healthcare Vouchers is not an incremental reform nor a single-payer plan nor an individual mandate. All citizens would receive a voucher that would give them the right to enroll in an insurance plan with a standard set of benefits. (Emanuel & Fuchs, 2005).

Federal Employees Health Benefits (FEHB) is the standard benefit plan proposed by the voucher system. The package includes coverage for preventative screenings, brand name and generic drugs, dental care, home and office visits, physical and occupational therapy, and mental health inpatient and outpatient services. Individuals choose their own health care provider and no referrals to specialists are required (FEHB, 2007).

## Recommendation

This policy analysis reviewed the proposed Universal Healthcare Voucher system written by Emanuel and Fuchs from the National Institute of Health. The United States is the only industrialized nation that does not offer universal health care to its citizens despite spending more per capita on health care than any other country (National, 2007).

The evidence is clear in support of implementation of health care coverage for all. The analysis of the alternatives to the UHV system revealed gaps in coverage would continue if alternative systems were chosen. Only the universal health care voucher system addresses the problem of health care for all. A voucher allows enrollment in an insurance plan with a standard

set of benefits. Each of the reform packages continue to leave a disproportionate number of Americans without access to health care benefits.

The UHV system spends U.S. dollars more wisely and more efficiently (Emanuel, 2007). A drop in the health care expenditure of the Gross National Product is projected with this system (Emanuel, 2007). As employers will not be spending dollars on employee health care, it is hoped that wages and benefits will be raised, an economic benefit to end a recession (Emanuel, 2007).

In addition, cost and quality are better addressed with the UHV proposal. Currently the Centers for Medicaid and Medicare have been charged with addressing quality in the form of non-payment for certain conditions, mandated by the Deficit Reduction Act of 2005 (CMS, 2006). The voucher system utilizes an independent board to review quality and is not under the umbrella of the U.S. government (Fuchs, 2005).

Universal health care coverage is a dominant political issue for the candidates in the upcoming 2008 Presidential election. Each candidate has given the public pieces of what their reform would look like but not in any great detail. The timing for introduction and implementation of a Universal Healthcare Vouchers system is now.

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Running head: ETHICAL DILEMMA

# Ethical Dilemma Case Analysis

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## Case Presentation

CW is an eighteen year-old young adult with the diagnosis of cerebral palsy and spastic quadriplegia. He was born at twenty-eight weeks gestation and mechanically ventilated for eighteen days. He was on supplemental oxygen for the first 60 days of his life. He has never achieved motor or cognitive developmental milestones of childhood and is classified a Gross Motor Function Classification System (GMFCS) level 5. GMFCS levels are rated 1 to 5 with 5 being with most affected. “Physical impairment restricts voluntary control of movement and the ability to maintain antigravity head and trunk postures. All areas of motor function are limited. Children have no means of independent mobility and are transported” (Graham, 2005, p. 128). He is fed via a gastrostomy tube, diapered for toiletry, and responds only to painful stimuli. His height is at the 50$^{th}$ percentile and weight at the 95$^{th}$ percentile with a Body Mass Index (BMI) of 41. He has not been tested for Type II diabetes but he does have a family history of diabetes. His race is Hispanic and he has acanthosis nigricans, two significant risk factors for Type II diabetes. CW spends the majority of his day in his wheelchair in the living room of his parents’ home. His parents are in their 60’s and have no other children. His mother has always been his main caregiver. He has recently required the use of continuous positive end pressure mask (CPAP) at night for sleep apnea. CW’s life expectancy is difficult to estimate but with his history of respiratory compromise and the recent need for CPAP at night to maintain his airway, the chances of him suffering a respiratory arrest are increased.

As with the majority of children with severe CP, he has the diagnosis of severe scoliosis with a right thoracolumbar curve of 90 degrees, which has increased over the

past six months. Figure 1 is a digital representation of a 90 degree thoracolumbar spinal curve. His pelvis is not level and he sits in his wheelchair bearing weight on the left hip. He has had numerous decubitus ulcer exacerbations at the area of the left trochanter, but is currently without any skin breakdown. His biological mother, the main caregiver, is experiencing more and more difficulty in positioning, diapering, and transporting CW secondary to the severe C-shape of his spine.

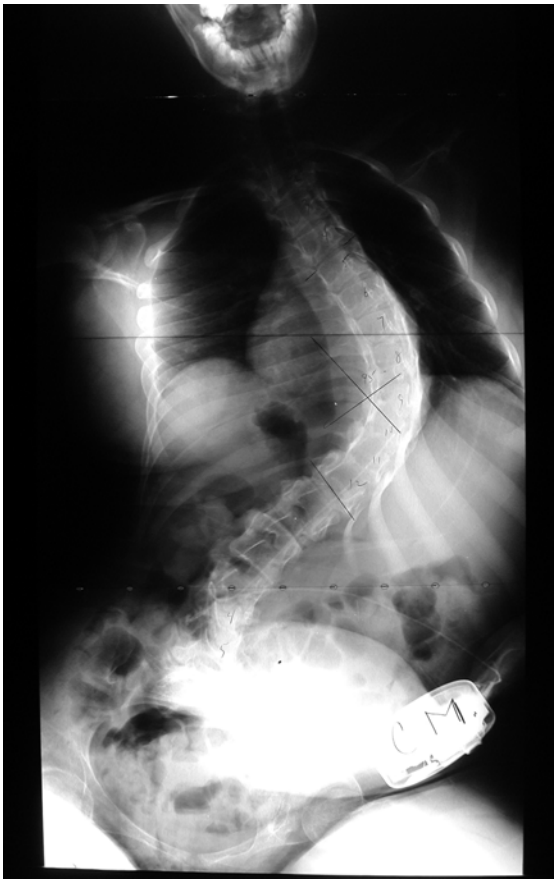

*Figure 1.* Radiograph of a 90 degree spinal thoracolumbar curve.

He is classified as a Tanner stage 5 male, Risser 5, which indicates skeletal maturity and he is likely to have no further spinal column growth (Wenger & Rang, 1993). The likelihood of his scoliosis worsening is difficult to assess as curves do not usually

progress after skeletal maturity but that cannot be guaranteed because neuromuscular scoliosis differs in that the spasticity of the muscles continues to exert forces on the spinal column and rotational curvature continues on the coronal plane while the sagittal curvature may remain constant (Salter, 1998).

CW and his parents present today in the Spine/Scoliosis clinic for ongoing evaluation of his neuromuscular scoliosis. His family would like to proceed with spinal fusion surgery. The ethical dilemma is should CW, a high risk, vulnerable patient, be offered this elective surgery.

## Medical Indications

CW has an appointment in the outpatient Spine and Scoliosis clinic for evaluation of progressive neuromuscular scoliosis. The chief complaint is the family's difficulty in caring for him and progressively decreasing lung function primarily because of the pulmonary compromise secondary to the worsening scoliosis. His medical history includes neuromuscular scoliosis, spastic quadriplegia secondary to cerebral palsy, gastroesophogeal reflux, numerous decubitus ulcers, morbid obesity (BMI of 41), numerous episodes of aspiration pneumonia early in his life and most recently, sleep apnea. Past surgical history is contributory for gastrostomy placement with Nissen fundoplication, and bilateral adductor tenotomies, hamstring lengthenings, psoas tenotomies and gastrocnemius releases for contractures of the lower extremities. Currently he is in general good health with no recent illness or fever.

While CW has numerous medical issues, the majority are being treated and managed without complications. However, CW's right thoracolumbar scoliosis measures 90 degrees and is increasing. Cardiopulmonary dysfunction is known to be more

prevalent in children with curves greater than 70 degrees (Wenger & Rang, 1993). For every 10 degrees of curvature there is an estimated loss of 4% of forced vital capacity of lung function (FVC) (Skaggs & Flynn, 2006). In addition, studies have shown a significant probability of postoperative complication related to increased BMI and morbid obesity as well as Type II diabetes (Mohamad et al., 2007).

Neuromuscular scoliosis is a chronic and progressive condition, which can be corrected with spinal fusion, via posterior and/or anterior approach and muscular release, and instrumentation. The goal is to level the pelvis, so that there is equal pressure on the hips and sitting is comfortable. Performing activities of daily living for CW, showering, diapering, transporting, will be easier for the caregivers. The success of the surgical correction is quite high, greater than 95%; with the overall complication rate in one study was 33.1%. Other studies have reported complication rates between 24% and 75% (Mohamad et al., 2007).

## Patient Preferences

CW is 18 years old but is cognitively at an infant level. He is nonverbal, cortically blind and responds to tactile stimulation only. He cries out without respect to stimulus and caregivers have not been able to ascertain his wishes through verbal communication or sign language. This constitutes of evidence of incapacity. The parents are the appropriate surrogates for their child. Their decision-making is appropriate. They have been vigilant parents, keeping medical appointments and providing CW with emotional and physical support throughout his life.

## Quality of Life

While there are medical indications for CW to have this surgery, it remains an elective procedure. The surgery will not improve his lung function or his sleep apnea. His demise will, more than likely, be from a respiratory event. Deficits from the surgery could include irreversible or long-standing neuropathic pain or reflexive sympathetic disorder. Mental and social deficits are not relevant in CW's case. The quality of life issues are more relative to the caregivers and family members as caring for CW will be less burdensome and the family's perception is that he will be more comfortable. He will have less skin breakdown and the more upright position of his trunk could possibly benefit his oral airway, but not lung function.

## Contextual Features

CW is a GMFCS level 5 patient. He has global delays that necessitate total care 24 hours per day, 7 days a week, and 365 days per year and will continue until his death, which is expected in his early 20's according to statistics for severe cerebral palsy patients with spastic quadriplegia. Financial and economic issues are not of concern, as our institution does not bill for services. The family is Hispanic, whose cultural beliefs include doing everything to preserve life at any cost. They are of the Roman Catholic faith and CW was baptized in the Catholic Church. There is no clinical research or conflict of interest in this case.

## Case Analysis and Recommendations

CW's family has his best interests in mind. Jonsen (2006) describes two issues relating to surrogacy and ethical issues. If there are conflicts between the provider and the parents, the relevance and weight of parental preferences should be determined.

Secondly, if the child is old enough, he or she can express his or her own wishes (Jonsen, Siegler, & Winslade, 2006). In this case, CW is of diminished capacity and cannot speak for himself and there are no provider/family conflicts.

The predominant ethical issue in this case is the principle of proportionate care. Much of the discussion around proportionate care is in relation to life-sustaining treatment and withdrawal or withholding of treatment but it is applicable in CW's case. "…the correct test of the ethical obligation is the estimate of its expected benefit over its attendant burdens" (Jonsen et al., 2006). This also applies to the care provider's reasoning and decision making when recommending or offering the surgery to this patient population.

Few studies have been done that assess parents' or caregivers' satisfaction after spinal fusion. One such study reported 95.8% of parents and 84.3% of caregivers would recommend surgery and the benefits clearly outweighed the risks (Tsirikos, Chang, Dabney, & Miller, 2004).

Therefore it is recommended that posterior approach spinal fusion and instrumentation be offered for CW along with detailed and thorough informed consent with benefits and risks clearly stated.

## Ethical Essay

The questions asked by principalism, applying the four basic principles of biomedical ethics, respect for autonomy, beneficence, non-malficence and justice, developed by Beauchamp and Childress in the 1970's have been appropriately answered in this decision to proceed with the surgery (Beauchamp & Childress, 2001). The action does not impose on CW's family or CW's autonomy and the family has expressed

consent. CW and his family will benefit from this elective surgery. There are risks to this elective surgery but no harm is intended and risks have been minimized and will be averted to the best of everyone's ability. The decision to proceed with surgery is equitable for all who are involved.

Paternalism is one of the confounding factors when dealing with a pediatric population in healthcare and ethical issues. Beauchamp and Childress define paternalism as "the intentional overriding of one person's known preferences or actions by another person, where the person who overrides justifies the action by the goal of benefiting or avoiding harm to the person whose preferences or actions are overridden" (Beauchamp & Childress, 2001). The concept of benefit and burden is based in paternalism and is not always necessarily an inappropriate path to follow.

Paternalism and autonomy are at odds with each other in the ethical realm. As the movement towards respect for autonomy and choice has shifted in the Western culture, the concept of paternalism has taken on a more negative connotation. It infers factors of incompetence, inability to make correct choices, and the assumption that one person "knows what is best" for another.

The informed consent process is one of the ways in which the paternalistic influence can be diminished and autonomy is preserved. The consent process is, more often than not, treated with a cursory, short conversation with little time for reflection and no real time to make a decision. The concept of "shared decision making" is under much scrutiny, being as it is a misnomer of sorts. A decision is a decision, the information is shared but the decision is in the hands of the client. "The goal should be to make it (decision making) difficult; to make sure that patients understand that every decision is

influenced by uncertainty and risk. The ideal is not to reduce decisional conflict, but to maximize it" (McNutt, 2004, p.2518).

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Running head: ORGANIZATIONAL CHANGE

# Case Study of Organizational Change

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## Introduction

This case study will review an organizational change effort initiated in the fall of 2004 in our institution. The diagnosis of neuromuscular scoliosis encompasses patients with cerebral palsy, muscular dystrophies and spina bifida (Salter, 1999). These patients require total care, are non-ambulatory and nonverbal. The majorities are fed via gastrostomy tube. The Infection Control report, issued from the Quality Improvement department, identified an increase in the infection rate after spine fusion surgery in this population during a routine quarterly reporting period. The nutritionist and one of the spine surgeons noted anecdotally that those same patients were nutritionally deplete at the time of surgery, using weight as the assessing parameter. The identified patients' weight was at or below the fifth percentile.

A change in practice was initiated. The protocol for change in practice in the institution begins at the Medical Executive Committee level. All neuromuscular patients would have lab tests done at least 6 weeks prior to the expected surgical date. If the results revealed a low pre-albumin and total protein, a dietary plan would be made, increased calories and protein in their diet would be initiated and labs would be repeated before surgery. No decision was made whether or not the surgery would be postponed if the lab results had not improved. The change was not evidence based, although there is literature that demonstrates patients who are in a nutritionally deplete status have more post-operative complications (Mohamad et al., 2007).

The change in practice affected medical staff, nursing staff, dietary staff and families. No roles were identified and no one took responsibility for follow-up of these patients. The practice change had not identified how the lab results would be reviewed, who would review them, or

how the results would be documented. At the time of the preoperative history and physical, performed the day before surgery, the majority of the patients do not have laboratory results in the chart.

Infection rates in surgical patients have been tracked on a local and national level for many years by quality improvement indicators (Kanayama, Hashimoto, Shigenobu, Oha, & Togawa, 2007). Most recently, Medicaid has announced there will no longer be financial reimbursement for treatment for hospital-acquired infections (CMS, 2006). The financial impact of this change warrants all institutions to examine their surgical infection rates and make changes accordingly. Although our hospital does not charge for services, those who do will suffer a significant loss of revenue as post-operative surgical infections incur costs estimated at $67,000 (Murphy, 2006).

Spine fusion patients, particularly neuromuscular patients, have a 30% increased rate of post-operative infection (Mohamad et al., 2007). Other co-morbidities of cerebral palsy and spastic quadriplegia are significant risk factors to be taken into consideration when offering this high-risk surgery to these patients and families (Fletcher, Sofianos, Berkes, & Obremskey, 2007). Seizure disorders requiring medications that impair platelet function increase the risk of peri-operative and post-operative bleeding (Fletcher, et al., 2007). Fletcher (2007) also reports osteopenia and brittle bone disease in a non-ambulatory patient delay healing and fusion in the spine (Fletcher et al., 2007).

The intended outcome of the change process was to have a more nutritionally sound patient ready for major surgery by assessing their nutritional status preoperatively and intervening if needed. Literature demonstrates that a better prepared patient will have less post-

operative problems (Lipton, Miller, Dabney, Altiok, & Bachrach, 1999). Unfortunately the actual outcome is an unchanged infection rate measured by the Infection Control reports for the three quarters after the change was introduced. By chart review, 15% of the patients at high risk for infection, those identified at less than fifth percentile for weight, had a nutritional assessment performed.

## Analysis

Bronfenbrenner's ecological environmental framework for understanding human development was adapted to the study of organizations, specifically, providing a framework to map the various organizational systems that comprise a given environment (Bronfenbrenner, 1979). "The ecological environment is conceived as a set of nested structures, each inside the next…" (Bronfenbrenner, 1979). There are two models, global and inside the global is the organizational model. For this case study in the first "nest" of the global model, the central core is the neuromuscular scoliosis patient, surrounded by the micro system, which is made up of the immediate and extended family, respite caregivers, school teachers, physical and occupational therapists, primary care provider and the office staff, the orthopedic surgeon and staff, neighbors, and the religious community. The next structure is the mesosystem, comprised of the urban housing setting in which they live, county healthcare clinic, the pediatric orthopedic hospital, Trimet transportation, parents' work environment, after school daycare, and the public school system. Surrounding that nest is the exosystem made up of the Masons, the Joint Commission, Centers for Disease Control, Spine Research Society, and the Pediatric Orthopedic Society of North America. Finally the macrosytem is the larger population of special needs children in society and Americans with disabilities.

Within the mesosystem of the global model is a smaller nest of the organizational model. The first layer looking at the outside of the model is the macrosytem consisting of the Shriners hospital and the second layer, the exosystem, made up of the mission statement, job descriptions and roles, policies, quality improvement, board of directors, and financial department. The micro system level contains the registered nurses and dieticians, physical and occupational therapists, social workers and orthotists. Finally the internal system is the licensed independent practitioner that orders the laboratory tests.

Root cause analysis (RCA) is a tool that many organizations, including the one I am involved with, use to investigate sentinel events that could have or have impacted patient safety or quality of care. Not only the what and how of the circumstances of the occurrence are identified but the why is explained so that corrective measures can be put in place to effect change at the organizational level so that quality is improved.

The ideal RCA involves an interdisciplinary group, in my case representatives from the medical staff, registered dieticians, financial services, care coordination planners and outpatient clinic staff are stakeholders who adequately represent the systems that are involved in the ordering and/or collection of lab specimens.

The what and how pieces of the problem have been identified so the “Five Whys” is the most appropriate technique to identify the core of the problem. This system of analysis also breaks down the myth of “one root cause” as you continue to ask why of each piece of the problem until there are no further answers. Some of the answers are listed here. Medical staff did not order the tests consistently. Why? One surgeon did not believe the nutritional status was a determining cause of infection. Outpatient staff did not know who to send lab reports to when

they were seen on the fax machine. Why? Their manager had not review the change in policy with her staff when the change was introduced. Financial services did not know who to question about why the labs were ordered and therefore did not know to bill insurance if applicable. Why? When changes in practice are made, the chain of communication includes the management team and they were not informed. Family education about the importance of adequate nutrition and how it affects surgical outcome was not taken into account. Why? The care coordinators who provide the education for families simply forgot.

Organizational readiness for change (ORC) was described by Lehman as it relates to the transfer of evidence based research to the treatment interventions by the counselors in substance abuse treatment centers (Lehman, Greener, & Simpson, 2002). Our organization lacked all of the factors they describe that the organization must have in place to succeed – motivational readiness, institutional resources, positive staff attributes, and an organizational climate that facilitates group cohesion and cooperation.

Within the mesosystem are the inputs and outputs that contributed to the root cause. Analyzing this RCA, there are several systems-level issues that contribute to the failure of the change effort. At a systems level, the dissemination of information in the institution, at the medical staff, outpatient staff and management staff level, is inadequate. Even though the change effort is clearly documented in meeting minutes, no formal plan to implement the change was put in place. While the leader of the change was highly motivated, all of the staff members did not share that passion for the change in practice. Staff members whose workload would change were not motivated to add an extra duty to their existing heavy workload. Family members were not educated; no one explained why their child needed increased calories preoperatively. Financial considerations were not researched, who would pay for the laboratory tests, the extra tube

feedings and supplies for these children. None of the necessary steps for successful change were in place for this effort to succeed.

Interviews with stakeholders in this change effort provided valuable insight into the case study and problem. Financial questions, philosophical issues, and cultural aspects of the institution came to light during the interviews and made a large contribution in the analysis.

## Conclusions

"Efficacious interventions are fundamental to improving service delivery, but they are useless without being adopted and giving attention to their implementation in the field."(Simpson & Flynn, 2007, p. 111). Of the readings, Simpson's article best describes why the change in this organization failed. Evidence based practice research supports the fact that nutritionally sound persons heal significantly better, with less complications postoperatively, than nutritionally deplete persons, but moving the research into practice within the institution was haphazardly implemented.

Given the environment of the institution, knowing the stakeholders, and the systems in place, from the evidence in the literature a stage based approach to making the change seems the most feasible and likely successful strategy. Simpson's model illustrates a change in a drug treatment therapy, but it translates easily into any setting. Training, adoption and implementation are the steps of the process. Figure 1 illustrates the model that Texas Christian University used in a counselor therapy change.

In order for this change to succeed, we have identified a core group of people to perform a root cause analysis of the problem. The core group has representatives from all of the departments who are stakeholders in this change effort, unlike the original effort. At present we

have used a fishbone diagram and utilized the 5-whys system of analysis. We have identified the need for a central tracking system of laboratory results, a calendar for follow-up calls or office visits, follow-up communication with primary care providers and creating family education tools. Short term and long term goals are in the planning stages as the group is working on the timeline for implementation of the change effort. These additional components, together with increased communication and resources will contribute to the success of this endeavor.

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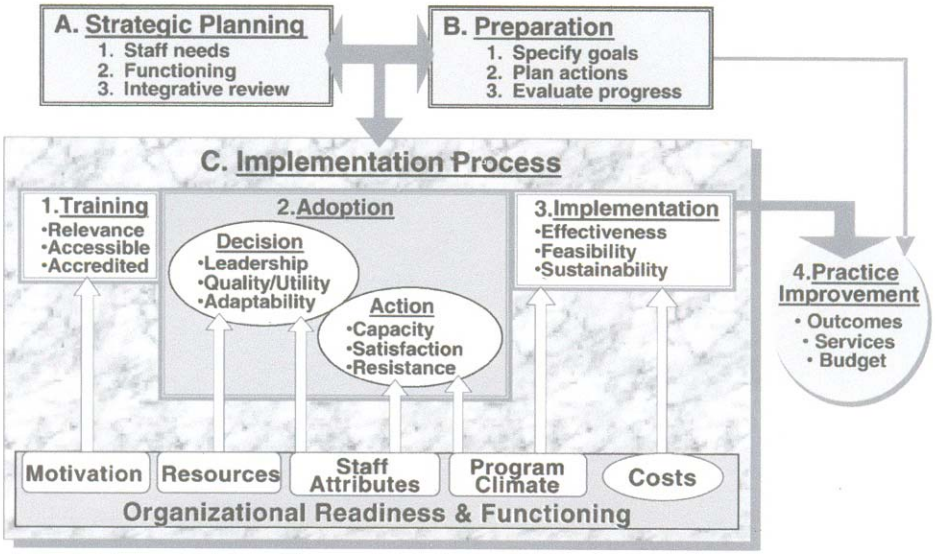


Fig. 1. TCU Program Change Model for planning and implementing innovations for treatment improvement.

Figure 1 – TCU Program Change Model

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Running head: INDEPENDENT CASE REPORT

# Independent Case Report

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## Introduction

As a clinical leader, the Doctor of Nursing Practice (DNP) is the change agent who has the skill, knowledge and resources to assess, plan, and execute inquiry that will improve patient outcomes. Improvement of practice and patient outcomes through application of research findings is a major component of the DNP's practice. The clinical significance of this inquiry is to demonstrate that a focused preoperative assessment and intervention can have implications for reducing postoperative complications in a high risk population.

## The Clinical Problem

The focus of the clinical inquiry is neuromuscular scoliosis, of which there are two causes – neuropathic and myopathic. Neuropathic involves upper motor neuron diseases including cerebral palsy, spinal cord trauma and tumors, and spinal muscular atrophy. Lower motor neuron problems are seen in polio patients. Spina bifida patients have a combination of both neural pathway problems. Myopathic causes include muscular dystrophy and arthrogryposis. The common factor in both is the inability to provide support to the spinal column or an imbalance of the muscular control of the spine (Lonstein, 2002).

Neuromuscular scoliosis is rapidly progressive, occurs at an early age and is associated with chronic and systemic conditions such as cerebral palsy and muscular dystrophies (Murphy & Such-Neibar, 2003). This type of scoliosis is present in 90% of sacral level spina bifida patients, 60% to 75% of children with cerebral palsy with spastic quadriplegia, and nearly all children with Duchene muscular dystrophy (Murphy, Firth, Jorgensen & Young, 2006).

Children with neuromuscular scoliosis who undergo surgical release and spinal fusion for scoliosis curve correction have a higher risk of postoperative complications when nutritional

deficiencies are present in the preoperative period (Sponseller, et al., 2000). Heys (1999) conducted a meta-analysis which demonstrated a significant decrease in infectious complications and decrease in length of hospital stay in adult patients who received postoperative nutritional supplementation with key nutrients compared to patients who did not (Heys, Walker, Smith, & Erimen, 1999). Nutritional status had no significant effect on postoperative pneumonia occurrence or death however (Heys, 1999). Results of studies in the adult population undergoing spine fusion surgery have shown through logistic regression analysis that preoperative nutritional status was an extremely significant predictor of deep wound infections (Klein, et al., 1996).

The diagnosis of a neuromuscular disorder is concomitant with cardiopulmonary, gastrointestinal and neurological manifestations as well as the skeletal manifestation of scoliosis (Wenger & Rang, 1993). As these systems are affected by the underlying disorder, the potential postoperative complications in the adult and pediatric populations associated with these manifestations are also increased (Benson, Thomson, Smith, & Banta, 1998). Murphy's study (2006) revealed statistical significance in longer length of hospital stay, increased incidence of pneumonia, respiratory failure, urinary tract infections and wound infections in the neuromuscular disordered patients (Murphy, Firth, Jorgensen & Young, 2006).

Parents of children with neuromuscular disorders are challenged with health care decisions throughout the lifetime of their child. The decision to have spine fusion surgery is difficult for all parents. However, studies of parents and caregivers satisfaction postoperatively have demonstrated significant rates of satisfaction (Tsirikos, Chang, Dabney, & Miller 2004 ).

The purpose of this practice improvement project is to assess the health status of the preoperative neuromuscular scoliosis patient in two contexts in order to affect the outcomes

postoperatively in pulmonary health, gastrointestinal integrity and nutritional status. In this high risk, vulnerable population, will a preoperative intervention lead to better outcomes postoperatively? Do nutritionally sound patients, as evidenced by normal weight for age and normal BMI for age, have lower infection rates than nutritionally deplete patients? Does preoperative bowel assessment and constipation management affect the rate of postoperative ileus?

The inquiry will also collect data to assess the effectiveness of a rigorous postoperative pulmonary toilet regimen on the rate of postoperative pneumonia. Does this intervention decrease the rate of postoperative pneumonia and respiratory compromise in a compromised population?

Baseline retrospective data is currently being collected on comorbidities of neuromuscular patients having undergone spinal fusion surgery. The data will be available by the time this clinical inquiry is to begin the fall of 2008.

## Conceptual Framework

In order to lessen the gap between research and practice, the advanced practice nurse leader must demonstrate that care is based on best evidence drawing on clinical research and literature. A conceptual framework may be developed from a theory or created to describe the relationship between concepts that are related to the outcomes of interest (Brathwaite, 2000). Analysis of a conceptual framework is necessary to guide the design and conduct of a research study and explain the effectiveness of an intervention (Brathwaite, 2000). The practical value of using a conceptual framework for this inquiry is the direction it provides in the design, the

selection of data to be collected and methodology. Figure 1 illustrates the conceptual framework that will be utilized for this clinical inquiry.

Neuromuscular disorders involve muscle innervations at different levels of physiology depending on the diagnosis. For example, in Duchene's muscular dystrophy, muscle tissue becomes fibrous and loses the capacity for stretching, thereby affecting respiratory function, putting those patients at higher risk for pulmonary problems postoperatively (Salter, 1999). In cerebral palsy and spastic quadriplegia, immobility affects respiratory function and the outcome for those patients is also a higher risk for pulmonary problems after surgery (Wenger & Rang, 1993). The range of pulmonary status in patients with neuromuscular disorders varies widely. Current research has shown that spinal column growth is directly related to lung growth (Canavese, et al., 2007). While this newest information is not directly related to this clinical inquiry, the implications for future practice will change dramatically in the area of pulmonary assessment and functional outcome measurement based on these new findings. What preoperative assessment should be done to assess pulmonary function? Is past medical history indicative of postoperative outcome? Does a rigorous postoperative pulmonary toilet regimen decrease the rate of postoperative pneumonia?

Gastrointestinal integrity is compromised in this population as in all wheelchair dependent, immobile patients. Gastrointestinal integrity in this population can be defined as alterations in bowel function related to immobility and spasticity. In the spina bifida population, lack of innervation equates with no bowel and bladder function. For these patients, does preoperative bowel assessment and constipation management affect the rate of postoperative ileus and translate into shorter hospital stay? Identified high risk patients will be followed more

closely with data collection at 3 points in time postoperatively to better manage postoperative gastrointestinal problems.

## Review of the Literature

Nutrition is important in all surgical cases but in the child with cerebral palsy or muscular dystrophy attention to the nutritional status is paramount. The literature demonstrates the highest risk factor for postoperative complications in all of these patients, regardless of the neuromuscular diagnosis, is nutritional status (Bahn, 2006; Campanozzi, et al., 2007; Chmell, 1996; Craig, 2006; Smith, 1987; Snyderman, 1999; Szoke, 1998). The status of nutrition is inversely related to the incidence of postoperative wound infection. Do nutritionally sound patients, as evidenced by normal weight for age and normal BMI for age, have lower infection rates than nutritionally depleted patients? How will this be measured? If an intervention is put in place, will there be a decrease in the postoperative wound infection rate? This clinical inquiry will involve an intervention, a preoperative history and physical performed by the DNP student, a nutritional needs assessment and laboratory values to measure nutritional markers. If the patient meets criteria for nutritional instability, a supplemental feeding plan will be initiated 6 weeks prior to the surgery date to increase protein, carbohydrate and fat intake. The current rate of 6% postoperative would infection rate is expected to decrease to 2%.

The effects of nutrition and wound healing have been well documented in the orthopedic surgery literature (Smith, 1987). The concept has been generalized in oncology patients, specifically with musculoskeletal sarcomas (Chmell & Schwartz, 1996) and oncological head and neck surgery (Snyderman et al., 1999). Meakins (1998) published a review of the history and progression of the phenomena of surgical infection from 1972-1997. He reminds us that in 1972

infectious morbidities in colon surgery were 25 to 60%, compared with 3 to 5% of contaminated cases in 1997 (Meakins, 1998). While this comparison is made to patients having colon surgery, where bowel was compromised, the percentages show marked improvements in infectious morbidity. Improved surgical technique, better pain management and early patient mobilization, and improved understanding of the biology and management of the surgical patient have affected all surgical outcomes over the past 25 years (Meakins, 1998).

A multidisciplinary approach to clinical evaluation, both preoperative and postoperative, is the gold standard for this high risk, vulnerable population. Pruijs (2000) described the European Alliance of Muscular Dystrophy Associations' "Utrecht" approach as a team of the rehabilitation physician, physical therapists, nursing, orthopedic surgeon, and physiatrist collaborating in the best interest of the patient (Pruijs, Tol, Kesteren, & van Nieuwenhuizen, 2000). Pulmonary and cardiac function must be assessed preoperatively because of the high surgical demands on these systems in all patients. Pulmonary complications in one study of 175 patients were reported to be 19.4%, accounting for 46.9% of all complications (Mohammed, et al., 2007). Prolonged atelectasis and pneumonia were the reported highest complications (Mohammed et al., 2007). Of the 45 pulmonary complications, 22 occurred in patients who had a seizure disorder and were on medications for seizure control (Mohammed et al., 2007).

A review of the literature revealed this population is at high risk for severe blood loss, up to 200% of total volume with concomitant coagulation problems in the immediate postoperative period (Salter, 1999 & Pruijs, 2000). Mohammed (2007) reported a blood loss range of 4.82 to 207ml/kg of blood loss, with the higher loss associated with combined anterior muscular release and posterior instrumentation surgical technique (Mohammed et al., 2007).

Early studies of infection rates in neuromuscular scoliosis spine fusion patients reported rates of 9.3% to 20% (Kretzler and Renshaw, 1991; Transfeldt, et al. 1985; Tresdwell, 1993). More recently, studies show infection rates in these patients ranging from 4% to 14%. The decrease is attributed to prophylactic antibiotic use and better instrumentation techniques (Szoke et al., 1998). Wound infections are a serious complication of spine fusion, necessitating readmission to the hospital, numerous wound irrigation debridement surgical interventions, prolonged hospital admissions and long term intravenous antibiotics via a central intravenous catheter (Labbe, et al., 1999).

The presence of malnutrition in the postoperative patient over time has been correlated with increased length of hospital stay, increased risk of complications, and increased use of hospital resources (Fuhrman, Charney & Mueller, 2004). However, the definition of malnutrition is not clear. How can this be measured? The majority of research in nutritional status and postoperative healing has been in the orthopedic surgery arena. A high correlation between malnourishment and morbidity is well documented (Smith, 1987). Measurement of weight in the postoperative period is an inadequate marker for nutritional status because of the fluid balance changes from surgery, blood loss and replacement fluids, and the inability of the patient to eat postoperatively (Smith, 1987).

In the past, total protein, serum albumin and prealbumin levels were thought to be nutritional markers but in fact, recent studies have revealed no correlation to nutritional status (Banh, 2006). There have been studies in burn patients that showed low albumin and prealbumin levels and high C-reactive protein levels were indicators of infection and low levels of all three markers were indicators of poor nutrition (Manelli, et al., 1998).

Inadequate dietary fiber and fluid intake, lack of erect posture, poor muscle tone together with prolonged immobility without exercise, and no urge to defecate contribute to constipation in children with developmental delays (Chong, 2001). Children with muscular dystrophies have similar lifestyle sedentary causes and adding the weak abdominal musculature and smooth muscle myopathy in this population further increases problems with gastrointestinal motility (Chong, 2001). One group in the Netherlands is researching recurrent pneumonias in children with cerebral palsy, hypothesizing that risk factors of dysphasia, respiratory function and constipation contributed to the rate of pneumonia (Veuglers et al., 2005). Gastroesophageal reflux and chronic constipation has been significantly correlated with malnutrition in the cerebral palsy population in many studies (Campanozzi et al., 2005; Chong, 2001; Veuglers, 2005; Craig, 2006).

The quarterly Infection Control report, issued from the Quality Improvement department, identified an increase in the infection rate after spine fusion surgery in the neuromuscular scoliosis population in our institution. The nutritionist and one of the spine surgeons noted anecdotally that those same patients were nutritionally deplete at the time of surgery, using weight as the assessing parameter. The identified patients' weight was at or below the fifth percentile.

A change in practice was  initiated. All neuromuscular patients would have lab tests done at least 6 weeks prior to the expected surgical date. If the results revealed a low pre-albumin and total protein, a dietary plan would be made. Increased calories and protein in their diet would be initiated and labs would be repeated before surgery. No decision was made whether or not the surgery would be postponed if the lab results had not improved. The change was not evidence

based, although there is literature that demonstrates patients who are in a nutritionally deplete status have more post-operative complications (Mohamad et al., 2007).

The intended outcome of the change process was to have a more nutritionally sound patient ready for major surgery by assessing their nutritional status. Literature demonstrates that a better prepared patient will have less post-operative problems (Szoke, Miller, Dabney, Altiok, & Bachrach, 1999). Unfortunately the actual outcome is an unchanged infection rate measured by the Infection Control reports for the three quarters after the change was introduced. By chart review, only 15% of the patients at high risk for infection, those identified at less than fifth percentile for weight, had a nutritional assessment performed.

Infection rates in surgical patients have been tracked on a local and national level for many years by quality improvement indicators (Kanayama, Hashimoto, Shigenobu, Oha, & Togawa, 2007). Most recently, Medicaid has announced there will no longer be any reimbursement for treatment for hospital acquired infections (CMS, 2007). The financial impact of this change warrants all institutions to examine their surgical infection rates and make changes accordingly. Although our hospital does not currently charge for services, those who do will suffer a significant loss of revenue as post-operative surgical infections incur costs estimated at $67,000 (Murphy, 2006).

## Summary

Practice improvement is the hallmark for nursing science. Clinical and translational nursing research, such as this clinical inquiry project, will combine clinical scholarship and clinical research to improve practice. Policy changes with the advent of universal health care and changes in reimbursement from insurance carriers and federal programs are factors that have

spurned us toward new ideas in practice to improve safety and improve outcomes. We can reduce infections, shorten length of stay without harm and provide customer service that is customer driven with the patient as a partner. It can be done and the DNP is the leader of the new nurse in the field.

In the area of neuromuscular scoliosis, especially in the pediatric population, there is a paucity of clinical nursing research. This clinical inquiry will not be a randomized, double-blinded study and will not have a high level of evidence-based significance attached. However, the outcomes, if proven significant, will change nursing practice in this population and will be generalizable to a significant number of patients with neuromuscular disorders.

Clinical practice improvement changes, such as this proposal, must also be implemented and published in order to further the actual practice in the clinical setting. Davidoff (2005) has proposed a thorough and logical set of guidelines that the DNP scholar may build upon (Davidoff & Batalden, 2005). These guidelines will support us in publishing the clinical practice improvements we undertake. Taking that next step is the challenge.

Figure 1. Conceptual Framework - Improving Outcomes through a Targeted Preoperative Assessment

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Neuromuscular scoliosis patients with identified risk factors

- Respiratory compromise
- Chronic constipation and/or gastrointestinal compromise
- Nutritionally compromised
- Nonverbal
- Ages 12-20 years
- Male and female
- GMFCS Level 5

Based on History and Physical performed by DNP student at 6 weeks (minimum) preoperative planned spine fusion surgery

Focused assessment includes:

- Height
- Weight
- Body Mass Index
- Nutritional assessment
- Caloric needs
- Laboratory data
- Pulmonary history
- Gastrointestinal history

- Wound infection rate measured at postop day 14

- Pneumonia rate measured at postop day 3

- Postoperative ileus rate measured at postop day 5

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Collective Evidence Table

| Synopsis | | Findings | | Clinical Applicability | |
|---|---|---|---|---|---|
| Citation | Clinical Question | Design | Credibility | Significance | Applicability |
| 1. Benson et al. 1998 | Morbidity post op data, variables studied are pneumonia, constipation and wound infection | Retrospective review, 50 pts, all from one center, similar w/respect to age, gender, curve and diagnosis | High reliability | Level IV, no statistical sig but clinical sig is high | Relevant for my inquiry and clinically relevant to my practice with NMS pts |
| 2. Buchowski et al. 2006 | Retrospective review of patients | 10 patients, sample similar w/respect age, gender, curve<br><br>Need increase sample size | High validity but low sample size | Level IV<br><br>Statistical significance<br><br>Not clinical | Not relevant for my inquiry but clinically relevant to my practice |
| 3. Bulman et al. 1996 | Comparison study of 2 surgical techniques in spine fusion | Comparative,30 pts<br><br>Similar w/respect age, gender, curve, pelvic obliquity<br><br>No change needed | No validity issue high reliability but low number of patients | Level III<br><br>High statistical & clinical significance | Applies to CP population in my institution and can be applied to my inquiry |

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| 4. Campanozzi et al. 2007 | Assess relationship between nutrition and GI problems and motor function in CP pts | 21 patients, nutritional assessment, nutritional and pharmacologic intervention and re-assessment | Low sample size, high validity though | Level III<br><br>High statistical & clinical significance | Relevant for my inquiry and clinically relevant to my practice, generalizable to pediatrics |
| 5. Canavese et al. 2007 | If spine growth is retarded, does lung growth also stop? Bench research on lung growth when spine growth is retarded | Animal research | Primary research | High statistical & clinical significance | Highly relevant to future practice even though bench animal research |
| 6. Castle et al. 2007 | Experience and impact of chronic pain in CP adolescents | Qualitative | Low sample size, convenience sampling | Level V<br><br>High clinical significance | Relevant to clinical practice |
| 7. Chmell et al. 1995 | Analysis of factors affecting wound healing | Retrospective review for a 62 month period | Time related, not number of patients, one care provider's patients, high validity but may have bias | Level IV<br><br>High clinical significance | Relevant for my inquiry and clinically relevant to my practice |
| 8. Comstock et al. 1998 | Caregiver and patient satisfaction after spinal fusion | Nonrandomized, descriptive,79 patients, Spastic CP, total body involvement, No change | Quantitative data showed adequate validity but qualitative was not measured – no | Level IV<br><br>High statistical & clinical | Applies to CP population in my institution and can be applied to my |

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| | | needed | scale of satisfaction | significance | inquiry |
| 9. Craig et al. 1998 | Outcomes measurements of pts with gastrostomy tubes after surgery | Prospective controlled trial, pre and post assessment measurement, similar pt population | High validity, specificity & reliability | Level II<br>High clinical significance | HIGHLY relevant for my inquiry and clinically relevant to my practice |
| 10. Fletcher et al. 2007 | Meta-analysis of all RCTs & EBP articles RT preop interventions to prevent infection | Evidence review<br>Would not change anything | High rigor & validity excellent analysis & reliability & applicability | Level I<br>Excellent clinical sig | Information is HIGHLY significant to my inquiry |
| 11. Hadden et al. 2002 | Validate global and observation methods for evaluating pain in children with CP | Qualitative, similar to pt population | High reliability across raters and measures | Level IV<br>High clinical significance | relevant for my inquiry and clinically relevant to my practice |
| 12. Heys et al. 1999 | Meta-analysis of 11 randomized clinical trials comparing nutritional support intervention | Evidence review | Excellent analysis and review | Level I<br>High clinical significance | Information is HIGHLY significant to my inquiry |
| 13. Klein et al. 1996 | 3 part study looking at preop nutrition status at 3 points in time preop and post op | Retrospective review of data<br>Logistic regression analysis | Excellent analysis and review | Level IV<br>High clinical significance | Information is HIGHLY significant to my inquiry |

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| 14. Kretzler et al. 1991 | Retrospective review of wound infections | Data collection and review | Older data | Level V<br>High clinical significance | relevant for my inquiry and clinically relevant to my practice |
| 15. Labbe et al. 1999 | Determine rates of surgical site infection & identify risk factors | Active prospective surveillance and case control study retrospectively | High reliability | Level IV<br>High clinical significance | relevant for my inquiry and clinically relevant to my practice |
| 16. Manelli et al. 1998 | Define range of standard values of lab tests for nutritional markers in burn pts | Retrospective review | Correlational study, low sample size, population differences | Level IV<br>Clinical significance | relevant for my inquiry from a lab test perspective |
| 17. McKearnan et al. 2004 | Review of descriptive and qualitative studies | Analysis of articles | Ambiguous terminology but statistical analysis was significant | Level V, Need better data with higher level evidence | Information is sig to my inquiry |
| 18. Mohammed et al. 2007 | Retrospective review of patients, variables GI, CV and infection postop | 175 patients<br>Sample similar w/respect age, gender, curve | Good measurement significant influence on practice | Level IV<br>Clinical and statistical significance | Information is HIGHLY significant to my inquiry |
| 19. Murphy et al. 2006 | Retrospective comparison of | Data review from a | High reliability | Level IV | relevant for my inquiry and |

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| | IAS and NMS for risk factors | multicenter database | and validity | High clinical significance | clinically relevant to my practice |
| 20. Parrish 2006 | Review of descriptive and qualitative studies | Analysis of articles | Review of articles<br><br>No rigor | Level V<br><br>Need better data with higher level evidence | Information is sig to my inquiry |
| 21. Patel et al. 2007 | Retrospective review of patients with CP and NMS | Sample of patients from one MD over a 36 month period of time (332 pts)<br><br>No change | Excellent satisfaction #s but + bias c/o 1 surgeon | Level IV<br><br>Clinical but not statistical significance | Interesting but maybe not as significant as I thought |
| 22. Snyderman et al. 1999 | Is periop nutritional support superior to standard formula in prevention of postop infection? | Prospective, randomized double blind adult study | High reliability, validity and credibility but not generalizable to pediatrics | Level I<br><br>High clinical significance | HIGHLY relevant for my inquiry and clinically relevant to my practice but nor pediatrics |
| 23. Sponseller et al., 2000 | Identify risk for infection, identify organism of infection in NMS pts after spine fusion surgery | Retrospective case control data collection | Large sample size, similar to population under study | Level IV<br><br>High clinical significance | Relevant to the clinical inquiry |
| 24. Szoke et al., 1998 | Retrospective chart review of wound infection rates after spine | Descriptive data collection | High validity and reliability | Level IV<br><br>High clinical significance | Relevant for my inquiry and clinically relevant to my practice |

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| | fusion | | | | |
| 25. Tranzfeldt et al., 1985 | Retrospective chart review of spinal wound infections | Descriptive data collection | Reliable but old data | Level IV<br>Clinical significance | Older data but still relevant to the inquiry |
| 26. Tsrikos et al. 2004 | Delineate parent and caregiver satisfaction after spinal fusion in CP spastic quad patients | 288 consecutive patients<br>190 families participated<br>No change | 2 tailed t test, no bias, good interrelator reliability | Level IV<br>Clinical significance | Important information for my inquiry |
| 27. Veughlers et al. , 2005 | Contribution of risk factor on pneumonia occurrence in post op CP patients | Nested case controlled design with 18 month followup | Reliable and valid measures | Level IV<br>Sample size was not adequate for statistical sig, not clinically significant | Relevant for my inquiry, clinically relevant to practice |
| 28. Wimmer et al. 2005 | Comparison study of 2 surgical techniques in spine fusion | Retrospective comparative,52 pts, Neuromuscular scoliosis pts similar | As above but added qualitative data for pt satisfaction | Level III<br>Clinical significance but not statistical | Patient satisfaction information is sig to my inquiry |

Running head: CHILDREN WITH SPECIAL HEALTH CARE NEEDS

# Health Disparity Case Report: Children with Special Health Care Needs

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## Introduction

Disparities in healthcare are commonly thought of as issues in relation to race, ethnicity and gender, when in reality there are many more reasons for the current marginalized state of healthcare. Lack of insurance coverage can lead to postponement of medical care and lack of prescription drug usage. Literacy and linguistic barriers create disparities as well as a lack of diverse healthcare providers. Children with special health care needs (CSHCN) have many healthcare providers who, because of their independence from one another, experience breakdowns in communication, causing inefficiencies and duplication of services. This case report will review the concept of the medical home and how this care delivery system has the potential to improve outcomes and decrease disparities for the CSHCN population.

## Description of the Problem

As cited by McPherson (1998), the Federal Maternal and Child Health Bureau's Division of Services for Children with Special Health Care Needs defined the CSHCN as:

> "Children with special health care needs are those who have or are at increased risk for a chronic physical, developmental, behavioral or emotional condition and who also require health and related services of a type or amount beyond that required by children generally" (p. 138).

This population is disparate because chronically ill children differ in three major ways from adults with disabilities. First, children are dependents of adults and are dependent on that adult's income and socioeconomic status. Secondly, depending on the timing of the disability or illness trajectory, the impact will be directly related to the child's growth

and development milestones at the time of the insult. Finally, most disabilities in children can be low-incidence conditions that happen rarely in the adult population (Kastner, 2004).

Strickland et al. (2004) reported 12.8% of children under the age of 18 years, or approximately 9.4 million children, could be classified as CSHCN in 2001. The group interviewed and surveyed 38,866 families of CSHCN over a 3-year period beginning in 1999. For this survey, five criteria were used to operationalize the medical home concept. Using the American Academy of Pediatrics (AAP) policy statement as a guide, the essential components of the model are the presence of a usual source of care, the accessibility of a personal doctor or nurse, referrals for specialty care are efficient and easy to access, coordination of care is of paramount importance, and family-centered care is the contextual framework for care (Strickland et al., 2004).

The National Survey of Children with Special Health Care Needs identified that the household prevalence of CSHCN is 20% and statistically is more prevalent in boys than girls, 15% and 10.5% respectively. The results also revealed the fact that CSHCN prevalence increases as children age, which also supports earlier data that suggests the same occurrence. Prevalence was not shown to vary between income groups but did vary by race and ethnicity, with Native American/Alaskan Native and Mixed Race Children with the highest prevalence (Maternal and Child Health Bureau, 2008).

The term medical home was formally defined in 1967 by the AAP in the Standards of Child Health Care, written by the Council on Pediatric Practice (COPP) (Sia, Tonniges, Osterhus, & Taba, 2004). Although the phrase has been used for over 40 years, the definition “should be for families and child health care professionals:

accessible, continuous, comprehensive, family-centered, coordinated, compassionate, and culturally effective" is just as applicable today as then (Tonniges, Palfrey, & Mitchell, 2004, p.1472).

## Case Study

The following case study is an example of a teenager with cerebral palsy, spastic quadriplegia and a seizure disorder. The chronicity and complexity of his conditions make him an ideal candidate whose needs would best be served by the care provider model of a medical home.

This teen is now 14 years old, born at twenty-eight weeks gestation and mechanically ventilated for 18 days. He was on supplemental oxygen for the first 60 days of his life. He has never achieved motor or cognitive developmental milestones of childhood and is classified a Gross Motor Function Classification System (GMFCS) level 5, level 5 being the most significantly impaired. "Physical impairment restricts voluntary control of movement and the ability to maintain antigravity head and trunk postures. All areas of motor function are limited. Children have no means of independent mobility and are transported." (Graham, 2005, p.128). He is fed via a gastrostomy tube, diapered for toiletry, and responds only to painful stimuli. He had his first seizure at two years of age and has been treated with many different drug regimens, none of which have completely controlled the seizure activity. Currently, he has one to three seizures per week, more when he is tired and has not slept well.

He sees a local pediatrician for his acute care needs and well child examinations. He is seen at the Shriners Hospital in the tone management clinic for spasticity issues related to his cerebral palsy, in the spine clinic for scoliosis and in the orthopedic clinic

for hip subluxation and flexion contractures of the hips, knees, wrists and elbows. He is seen at the tertiary care hospital gastroenterology clinic for feeding and nutritional issues and at the neurology clinic for seizure management. Yearly brain computerized tomography scans are done to assess for hydrocephalus, every 6 month spinal films to assess scoliosis progression, pelvic films every 6 months for hip assessments, and every 3 month laboratory tests to monitor seizure medication levels.

The standard of care for follow-up assessments in all of the disciplines is met with the above interventions. Because the spasticity and tone of the changes rapidly and frequently, per the recommendations by the American Academy for Cerebral Palsy and Developmental Medicine (AACPDM) and community practice standards, the tone of cerebral palsy patients, GMFCS level 5, should be made at a minimum of every 6 months in order to evaluate need for medication or physical therapy changes in management (E. S. del Rosario, FNP-C, personal communication, November 14, 2008). Pharmacotherapy of seizure disorders is complex, multilevel management, which at minimum standard should be co-managed with a neurologist and a primary care provider (Child Neurology Society, 2008). Pediatric orthopedic standards, set by the Pediatric Orthopedic Society of North America (POSNA), recommend a minimum radiological evaluation of the cerebral palsy patient with subluxated hips every six months, as the tone and spasticity forces migrate the femoral head out of the acetabulum and surgery may required if the hip becomes dislocated (POSNA, 2008). The Spine Research Society and evidence-based literature document that changes in the spine occur more frequently in the growing child and a twice-yearly spinal assessment should be performed (Salter, 1999).

Of all of the disciplines that see this patient, no one clinic or healthcare provider is designated as his medical home. Opportunities and challenges exist in the identification and maintenance of a medical home for CSHCN.

## Intervention/Change Strategies and Implications for Nursing and Potential Impact

The first formal education and training of pediatricians in the medical home model was begun with a grant from the Maternal and Child Health Bureau (MCHB) awarded to the state of Hawaii in 1989 (Moore & Tonniges, 2004). This training program was developed through the collaborative efforts of the AAP, MCHB, Family Voices, the National Association of Children's Hospitals and Related Institutions, and Shriners Hospitals for Children (Sia, et al., 2004). Moore and Tonniges (2004) articulate 5 lessons learned from the implementation of the training program. First, they identified that physicians who are interested in caring for this population must be found and recruited. Residency programs, such as the ones offered by the Shriners Hospitals, promote interest in the field and must be supported by the educational institutions. Families are the second important piece of the program that is essential to success, both in planning and facilitating. The third integral piece is the team members, physical therapists, DNP prepared nurses, mental health professionals, education representatives and the myriad of support service entities that are involved in providing care for CSHCN. No one discipline works in isolation. Process and community are the final areas, which impact the success of the program. The level of commitment of the team members correlates highly with the positive outcomes of the program.

This model of care can be initiated, facilitated and/or managed by the DNP. In each of the five criteria, operationalized by the MCHB, the DNP has the training and education to improve the outcomes in each area (Strickland, et al., 2004).

*Usual Source of Care*

Primary care training has traditionally been the foundation for the advanced practice nurse education. With DNP graduate's advanced education this role is expanded to include evidence-based research in preventive care, continuity of care and improved well child services. Having this background enhances the resources available to the CSHCN's family's awareness of the need for continuity and importance of the medical home.

*Personal Doctor or Nurse*

Continuity of care is contingent on having a personal care provider with whom the family and patient have a relationship. Trust fosters the consistent relationship, which fosters continuity furthering better outcomes (Strickland, et al., 2004).

*Referrals for Specialty Care*

This aspect of the medical home model must be co-managed with access to healthcare and insurance. The literature supports that the identification with a person as the medical home is supported by more evidence than identification with a place as it relates to client benefits of effectiveness, costs, and reducing disparities (Starfield and Shi, 2004). The efforts of the DNP graduate in health policy and legislative change can propel the United States into the universal healthcare coverage the CSHCN should receive.

*Coordinated Care*

The coordinated treatment plan between the many specialties involved with the CSHCN requires a leader with a background in multidisciplinary management. The DNP is adequately prepared in the doctoral program to be that person, with a basic background education in health policy and organizational systems analysis.

*Family Centered Care*

Long-standing studies have shown parents' improved perception of the partnership and relationship with their healthcare provider when a family centered approach is the premise for all family interaction (King, King, & Rosenbaum, 1996). The doctorally prepared advanced practice nurse working in a pediatric setting will have a strong foundation in family centered philosophy and the importance of maintaining this evidence-based skill in order to ensure a respectful and rewarding experience for the family and practitioner.

## Summary

In order to decrease disparity in this fragile population of children, the DNP is challenged to create a common understanding of health care needs, delivery and systems analyses. National surveys demonstrate the need to continue to attempt to reduce disparities by expanding federal, state, and community efforts that support the medical home model (Strickland, et al., 2004). Disparities can be eliminated with access to insurance but it is not known whether having insurance equates with the guarantee of having a medical home (Starfield & Shi, 2004), but the DNP's role in changing health policy to support universal coverage may improve our health statistics.

Six pediatric practices in Boston, Massachusetts recently collaborated to provide medical homes for the CSHCN population in the area, beginning the Pediatric Alliance for Coordinated Care (PACC). Palfrey (2004) surveyed 150 CSHCN families at a baseline and 2-year follow-up for experience assessments. The results revealed a significant decrease in parents missed work time and decreased hospitalizations (Palfrey et al., 2004).

Palfrey (2004) concludes with:

> "It is feasible to field medical homes for CSHCN. The work ahead is to do this in the most effective and efficacious manner and to determine ways to ensure that the gains made can be sustained for the children and families and for the PCPs who care for them" (p. 1515).

The potential for outcomes improvement for this population and decrease in disparities is an achievable goal for the DNP.

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Running head: SECONDHAND SMOKE EXPOSURE

# Secondhand Smoke Exposure: An Environmental Health Risk

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## Introduction

Children who are exposed to secondhand smoke (SHS) are at risk for adverse health outcomes. This preventable environmental health risk is of particular concern in children who are medically fragile. As a Pediatric Nurse Practitioner working with medically fragile children in a not for profit institution, I see many children whose parents are unaware of the extent that secondhand smoke can negatively impact the health of their children. As with many other environmental health risks, research has implicated SHS in major causes of morbidity and mortality (Tyc, Hovell, & Winickoff, 2008). The habit of tobacco smoking has been transformed from a socially acceptable habit to a political debate issue in the past twenty years.

The majority of the children I care for are nonverbal and have global cognitive and physical handicaps. Their voice is heard through the advocacy of their parents and family, their healthcare providers, friends, community and society. Advocacy for children and family and patient education are integral components of the advanced practice role. The purpose of this case study is to review implications for patient and family education around secondhand smoke exposure and how this role is best managed by the Doctor of Nursing Practice (DNP) and the Pediatric Nurse Practitioner (PNP).

## Description of the Problem

Although laws prohibiting smoking in public places and in the workplace have decreased the exposure to SHS for adults, the primary source of this exposure for children is in the home. Joad (2000) reported statistically significant increases in the early development of asthma in children who are exposed to SHS (Joad, 2000). The 2005 United States Surgeon General's Report reported that SHS exposure is a cause of disease and premature death in women and

children (US DHHS, 2006). An earlier public health reports revealed that worldwide over 40% of men smoke tobacco compared to 12% of women (Jha & Chaloupka, 1999). Data from the Morbidity and Mortality Weekly Report (MMWR) in July 2008, showed SHS exposure at home declined from 21% from 1988-1994 to 10% in 1999-2004, but among children the decline was less (CDC, 2008). In a survey organized by the World Health Organization (WHO) from 1999 to 2005, 44% of youths in the world were exposed to tobacco smoke at home (GTSS, 2006). Households with inside smokers had a median air nicotine concentration level 17 times higher than nonsmoker households in a study of 31 countries (Wipfli et al., 2008). Medically at-risk children are at a higher risk to extensive residential exposure because children with chronic medical conditions spend a significant time indoors secondary to the disease condition (Tyc et al., 2008).

The United States Surgeon General's report on the health consequences of SHS showed a causal relationship between SHS and disease and premature death in children and adults who do not smoke and between parental smoking and reactive airway disease in school age children (USDHHS, 2006). Demographic studies have shown that families in lower socioeconomic groups have higher tobacco smoking rates (Tyc et al., 2008). As with the previous studies on air levels of nicotine, more disturbing are the studies of actual nicotine levels measured in hair and blood samples of children exposed to SHS. In one study of cotinine levels (the blood measurement of nicotine) the percentage of nonsmokers with detectable levels was found to be inversely associated with family income; the smaller decline in blood levels over time, as exposure decreased, was seen in the lower income group (CDC, 2008). The data on the ill effects of SHS are undisputed and easily reproducible (CDC, 2008; Joad, 2000; Tyc et al., 2008; USDHHS, 2006).

## Case Study

This case study involves an eighteen year-old young adult with the diagnosis of cerebral palsy and spastic quadriplegia. He is seen in our institution for scoliosis and other orthopedic issues related to the diagnosis of cerebral palsy and spastic quadriplegia. He has never achieved motor or cognitive developmental milestones of childhood and is classified a Gross Motor Function Classification System (GMFCS) level 5. GMFCS levels are rated 1 to 5 with 5 being with most affected. “Physical impairment restricts voluntary control of movement and the ability to maintain antigravity head and trunk postures. All areas of motor function are limited. Children have no means of independent mobility and are transported” (Graham, 2005, p.128). He is totally dependent on a caregiver for all activities of daily living.

He is fed via a gastrostomy tube, diapered for toiletry, and responds only to painful stimuli. The teenager spends the majority of his day in his wheelchair in the living room of his parents’ home. He has recently required initiation of the use of continuous positive end pressure (CPAP) mask at night for treatment of sleep apnea. The life expectancy of a patient with this diagnosis is difficult to estimate but with his history of respiratory compromise and the recent need for CPAP at night to maintain his airway, the chances of him suffering a respiratory arrest are increased.

This family is Hispanic, described as “traditional” by the Spanish interpreter who works with the family. His father makes all decisions for the family, accompanies the patient and his mother to all medical appointments, and assists in caring for his son on a daily basis. They are of Roman Catholic faith. It is the family’s wish that all efforts at life support be offered if he should need resuscitation.

His father and mother are his main caregivers and the father smokes up to one package of cigarettes per day. He smokes inside the home, in the same room as his wheelchair bound son.

This family is considered to be living at below the poverty level, with an income of less than $12,000 per year. The family's income is supplemented with Social Security disability benefits and the patient will be cared for by our orthopedic institution until he is 21 years old without any cost to the family or child.

In this case study, the client is unable to remove himself from the smoke and avoid exposure. He spends his entire day with his father, essentially inhaling the same amount of tobacco smoke as his father. SHS has been linked to increased risk of rhinitis, rhinoconjuctivitis, asthma, wheeze and nocturnal cough (Zuraimi, Tham, Chew, Ooi, & David, 2008), all of which constitute potential harmful risks to this teenager.

## Intervention/Change Strategies

The use of tobacco and the subsequent exposure to the secondhand smoke, directly from the burning ash and also from the exhaled smoke, is a multi-level problem. In this case study, the ethnicity of the family, Hispanic, is a dominating factor in determining strategies to reduce SHS exposure of the patient inside his home. In the Hispanic culture, the family relationships are traditionally headed by the father or oldest male (dePaula, Lagana, & Gonzalez-Ramirez, 1998). However, other cultural factors should be taken into consideration. While the traditional mother is deferential to the father in public, she is held in high esteem within the family at home and has power in the decision-making when it comes to the children and their care (dePaula et al., 1998). In this case, the boy's mother does not express her concerns about SHS when her husband is present, but through the interpreter, it is revealed that she has been trying to persuade her

husband to smoke outside. All interaction with non-English speaking families is interpreted through medically prepared interpreter services. All written information has been translated into the needed language. Statistical information on the decreased levels of nicotine in children whose family member changed from smoking inside the home to outside may be given to mom to help her in the campaign to change her husband's behavior. One study of smoking parents showed that brief interventions addressing effects of SHS on their children enhanced the chances of quitting (Mills et al., 2008).

From an ethical perspective, an analysis from the nonmalfecience point of view can be made. Nonmalfecience, to do no harm, is paramount in exposing children to secondhand smoke. While ethical principles are generally applied to healthcare professionals, from personal experience, using an ethical perspective in teaching often is motivating.

## Implications for Nursing and Potential Impact

On the national level the Center for Disease Control (CDC) has most recently updated the *Best Practices for Comprehensive Tobacco Control Programs – 2007*, originally published in 1999 (CDC, 2007). The report is published in an effort to decrease the number of smokers by 5 million in 5 years, thereby reducing lung cancer to a rare disease (CDC, 2007). The report also addresses the tobacco-related disparities within populations and the need to identify and reduce the disparities in order to eliminate SHS (CDC, 2007). The DNP advanced practice role encompasses change efforts at the organizational, community, state and national level. Supporting lobbying efforts for change in tobacco laws and increasing community awareness of deleterious effects of SHS are in the DNP's scope of practice. At the state level, identification of lobbying efforts currently in place, finding stakeholders who are involved in anti-smoking

movements and supporting efforts to reduce the number of smokers is an attainable professional goal.

At the national level, the National Institutes of Health recently funded a 3-day working conference, “Tobacco Control Strategies for Medically At-Risk-Youth”, that resulted in the publication of four papers, which emphasize that translating research into practice requires the collaboration of all parties - care providers, families and patients (Bloche, Haverkos, & Jobe, 2008). Nursing, and specifically the advanced practice nurse, is the ideal coordinator in this transition.

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Running head: FEVER OF UNKNOWN ORIGIN

# Case Study:
# Fever of Unknown Origin Following Spinal Cord Injury

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## Introduction

DNP competencies will be demonstrated in this case study. The American Association of Colleges of Nursing (AACN) published the Essentials of Doctoral Education for Advanced Nursing Practice (American Association of Colleges of Nursing, 2005). There are three competencies addressed by this case: a) providing healthcare services to sick patients in an inpatient setting based on age and emotional development, family history, and risk, b) using principles of epidemiology as a framework for population based and evidenced based care, and c) the ability to develop a differential diagnosis and provide appropriate care including diagnostic testing (Smolowitz & Honig, 2008). This case study is a review of a complex inpatient with fever of unknown origin (FUO), presented to demonstrate clinical competency and diagnostic strategy skills of the Doctor of Nursing Practice (DNP).

## Case Study

CW is a 14 year plus 11-month-old teenage boy with the diagnosis of early onset scoliosis. In the past, scoliosis was categorized by age at diagnosis, with congenital diagnosed at birth, infantile at 0 -3 years, juvenile at 4 - 8 years and adolescent at 10 years and older. More recently term, Fernandes and Weinstein (2007) found the magnitude of the curve at diagnosis to be more predictive of curve progression than age at diagnosis. CW is insured but the institution caring for him is not-for-profit and does not bill for any of its services. The significance of this will be better understood as the case study evolves.

Early onset scoliosis, if left untreated, results in pulmonary hypertension and cor pulmonale (Tolo & Gillespie, 1978; Ferreira & James, 1972; and Mehta, 1972).

However, if early surgical intervention is needed, the risk of resultant junctional kyphoscoliosis is increased to 30% (Fernandes & Weinstein, 2007). Junctional kyphoscoliosis occurs as the un-fused portion of the spine continues to grow. Because spinal growth continues until approximately age 16 years in males (Mehta, 2005), multiple revisions of the original surgical intervention are required. Spinal growth arrest at such an early age with fusion and instrumentation also damages the lungs' ability to grow. Lung growth and pulmonary alveolar growth have been directly related to spinal growth (Canavese, et al., 2007). Surgical correction of kyphoscoliosis also places the client at higher risk for spinal cord injury and death (McMaster, Glasby, Singh, and Cunningham, 2007).

## History of Present Illness

CW was born at 25 weeks gestation to a gravida 1 para 0 28 year old female whose labor progressed despite medical intervention. He required respiratory and fluid resuscitation at birth. Inhaled surfactant was administered at delivery, but CW required mechanical ventilation for 20 days, which left him with the sequelae of bronchopulmonary displasia (BPD). Also noted at birth was the lack of abdominal muscle wall tone, which contributed to the difficulty in stabilizing his respiratory status. He was in the neonatal intensive care unit for the first 3 months of life. The diagnosis of scoliosis was made when CW began to walk at 18 months of age. Despite bracing and minimally invasive interventions, CW required surgical fusion at age four years. He underwent his second anterior muscle release and posterior instrumentation surgery at seven years of age. At age 14 years, CW's pulmonary function had deteriorated, with

functional vital capacity measured at 26% of normal and he had developed junctional kyphosis.

CW was admitted to our pediatric orthopedic hospital, where he was clinically managed by the Pediatric Nurse Practitioner, and DNP student, and the orthopedic surgeon. He was placed in halo traction for 90 days in an effort to maximize muscle stretch and release before having surgery to correct the kyphoscoliosis. During the surgery, CW suffered a spinal cord injury resulting in lower extremity flaccid paralysis. On magnetic resonance imaging, the insult was demonstrated by an infarcted area at the fifth thoracic vertebra, resulting in paraplegia including no bladder or bowel control.

On postoperative day 42 from spinal surgery, CW developed a core temperature elevation to 40 degrees Celsius with rigors. The fever defervesced with anti-pyretic administration and comfort measures. Over the next 72 hours, CW's fever curve continued to show a high spike in the early afternoon with subsequent fall back to normal with medication. His vital signs were normal otherwise, except for slight tachycardia during the fever episodes. All systems of his physical exam were within normal limits. The review of systems did not reveal any contributory information.

## Plan of Care/Diagnostic Strategy

In the outpatient setting, the management of the patient with FUO with this presentation would be close monitoring and ensuring adequate fluid intake (Blosser, Goodman, & Brady, 2004). In a spinal cord injury patient the differential diagnoses for FUO include autonomic hyperthermia, urinary tract infection/pyelonephritis, and heterotopic ossification (Ditunno & Formal, 1994). In the hospitalized patient, nosocomial infections are also included in the differential. CW is a hospitalized patient, a new spinal cord injury

patient, who performs every 4-hour clean, straight urinary catheterization, and is at risk for osteopenia secondary to immobilization. He also has a peripherally inserted central catheter (PICC) for intravenous (IV) access.

The management of this patient requires a more in depth search for the cause of the FUO. The DNP plan of care began with obtaining infectious laboratory markers, complete blood count with differential (CBC), erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP). In addition, liver function tests, including hepatitis titers, and electrolyte assessment were indicated. Urinalysis and urine culture, as well as blood cultures for bacteria and fungus from a peripheral venipuncture and the PICC line were also indicated. Chest radiographs to assess respiratory function were included in the initial work up of FUO.

Utilizing a multidisciplinary approach to acute inpatient medical care, a telephone consult was obtained with the Pediatric Infectious Disease department at the local university medical center. The above plan was reviewed and the team recommended initiation of empiric intravenous antibiotics as this patient was at risk category for hardware seeding of bacteria and life-threatening sepsis (Kanayama, Hashimoto, Shigenobu, & Togawa, 2007). Because of the potential risk of catheter induced infection, the PICC line was discontinued.

The entire battery of diagnostic tests yielded negative results. CW continued to have high fevers, now more frequently than once a day. At least once per 24 hours the fever elevations included shaking chills. Subsequent laboratory tests of CRP and ESR were elevated on day 10 of the fevers, so further imaging tests were indicated. A magnetic resonance image of his spine, computerized tomography of the chest and

abdomen, and echocardiogram were normal. A bone scan ruled out heterotopic ossification and a Doppler vascular examination showed no evidence of deep vein thrombus (DVT).

On day 10 of IV antibiotics, CW's white blood cell count dropped with an absolute neutrophil count of 1200/$mm^3$. One of the broad-spectrum antibiotic coverage side effects is neutropenia. Since the fevers continued despite continuation of IV antibiotics and neutropenia is an untoward side effect with implications, the decision was made to discontinue the empiric coverage.

Further laboratory tests were ordered by the DNP after ongoing consultation with the Infectious Disease department to investigate and broaden the differential diagnosis for nosocomial infections, specifically testing for Epstein-Barr viral (EBV) antigen and cytomegalic viral (CMV) antibodies. Although there were no known usual exposures, CW did receive a blood transfusion 6 weeks prior to the onset of FUO. Rare cases of blood borne transmission of EBV have been reported (American Academy of Pediatrics, 2006). The EBV antibody and antigen resulted positive. CW was diagnosed with infectious mononucleosis. CW continued to have fever for 48 hours and then normalized.

Originally, the post-operative plan was to transfer CW to a spinal cord rehabilitation facility once he had recovered from spinal surgery. Since the transfer was delayed secondary to the FUO, the DNP facilitated weekly multidisciplinary team meetings, outlining weekly goals and defining discharge criteria. Once CW had been afebrile for 72 hours, he was transferred to the spinal cord rehabilitation center. He is currently healthy.

## Epidemiology

EBV is a member of the γ-herpesviruses family and is reported to cause more than 90% of infectious mononucleosis cases (Jenson, 2000). Transmission is generally through contact with saliva from the mouth of an infected person. Airborne and blood borne transmission is rare but has been reported (Centers for Disease Control and Prevention, 2009). The prodromal phase of infectious mononucleosis generally lasts for 1-2 weeks, with most adolescent and young adult patients seeking care for persistent, severe pharyngitis (Jenson, 2000; Centers for Disease Control and Prevention, 2009; & American Academy of Pediatrics, 2006).

In disparate populations and in developing countries, EBV infection is primarily in children less than 4 years of age and children are asymptomatic (Jenson, 2000). The Centers for Disease Control estimate that 95% of adults in the United States have been exposed and infected with the virus (Centers for Disease Control and Prevention, 2009).

## Implications for Nursing Practice and Self Reflection

The DNP role as an inpatient health care provider in this case study was pivotal in the day to day management of care. Along with the medical management, the DNP provides emotional support and counseling to the patient and family. The unexpected outcome, paraplegia, devastated the family and necessitated our finding resources to support them as the grief and loss process began. Daily rounds, actually sitting down with the patient and family members, were essential in caring for CW. Weekly multidisciplinary meetings, including the family and CW, facilitated by the DNP fostered open communication and coordinated care. Understanding principles of grief, loss,

growth and development, and family dynamics was the basis of a supportive and caring relationship that fostered trust and security in a tragic situation.

The clinical picture in this case study was not a classical presentation of Epstein-Barr viral infection. While malaise and unremitting fevers were present, CW had no complaints of sore throat or any signs of lymphadenopathy or splenomegaly. Better understanding of the epidemiology of diseases is also a competency that the DNP builds on with each new scenario. The rare occurrence of transmission of EBV infection was overlooked. The confounding factors of the present postoperative state overshadowed the investigation into the more rare causes of FUO. But, evidence-based approach to diagnosis and care of the complex patient did play a pivotal role in eventually diagnosing this complex case.

Medicaid's newest rulings, announcing there will no longer be financial reimbursement for treatment for nosocomial, hospital acquired, infections warrants clinical expertise in prevention of illness and health maintenance (Centers for Medicaid and Medicare Services, 2007). The total estimated cost of the diagnostic workup for this nosocomial infection was $185,000. While our institution does not charge for services, the costs are paid by the endowment that funds our hospital. Fine-tuning the depth of the diagnostic strategies employed by the DNP until a diagnosis is made is costly. In this case study, if viral titers had been done in the first assay of laboratory testing, the client and hospital would have been saved significant burden. Gaining diagnostic experience as a DNP is an ongoing exercise, one that will continue throughout the professional career. Each new case provides moments of learning and broadens my knowledge base.

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Running head: BONE TUMOR

# Case Study: Osteosarcoma and Van Nes Rotationplasty

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## Introduction

An essential competency for practice at the Doctor of Nursing Practice (DNP) level of practice is the ability to manage and coordinate care for the patient in the acute and sub-acute hospital setting (Smolowitz & Honig, 2008). This case study presents the DNP management of a newly diagnosed patient with osteosarcoma (OS). This case was chosen for two reasons: 1) newly diagnosed patients benefit from a multidisciplinary team approach and 2) coordination of care early in treatment impacts morbidity outcomes (Rougraf, Simon, Kneisl, Greenberg, & Mankin, 1994).

## History of Present Illness

DK is a five year-old boy who presented to his pediatrician with a left lower extremity painful limp. Five abnormal gaits have been identified in children: antalgic, Trendelenberg, spastic, weak muscle origin, and limb length inequality (Flynn & Skaggs, 2006). The origin of the limp may be from the hip, knee, ankle or foot, necessitating assessment and radiographs of all joints of the affected extremity.

Plain films were obtained and a suspicious lesion was noted in the left proximal femur. Further imaging with magnetic resonance imaging (MRI) scan showed a lesion extending from the distal femoral epiphysis to the proximal part of the femur as well as a lesion that extended adjacent to the greater trochanter at the base of the femoral neck. DK also had a soft tissue mass in the posterior knee area involving femoral vessels intermittently associated with the tumor. Figure 1 shows the extent of the tumor. Additional imaging studies revealed no metastatic disease. DK's primary care provider referred the patient and family to the appropriate oncology specialty care service. Family history was negative for cancer or any orthopedic conditions. He was otherwise a well

child, no history of trauma, infection or recent febrile illness. Vaccinations were up to date and he saw a pediatrician for well child care and acute care needs.

Treatment of OS in children in this demographic area is based on clinical trials executed by the Children's Oncology Group (COG), the national clearinghouse for children' cancer treatment. DK was enrolled in a clinical trial that began with 3 months of twice monthly intravenous chemotherapy treatments, attempting to shrink the tumor prior to surgical excision and limb salvage. Preoperative chemotherapy is used as an adjuvant therapy because COG clinical trials have shown that measurements of "tumor kill" at surgery are highly predictive of prognosis (Bacci, Bertoni, Longhi, Ferrari, Forni, et al., 2003: Kaste, Liu, Billups, Daw, Pratt, & Meyer, 2004). DK completed the first stage of chemotherapy treatment and presented at our clinic for a second opinion for surgical options.

En bloc excision of an OS tumor with wide surgical margins is the gold standard treatment of this disease (Longhi, Errani, de Paolis, Mercuri, & Bacci, 2006). Three surgical options were presented to DK and his family. Based on the extent of his tumor, a total hip replacement with allograft bone was one option. The second was an allograft replacement only and the third was a modified Van Nes rotationplasty. The parents chose the Van Nes rotationplasty surgical option and DK's surgery was scheduled. Figure 1 shows the skeletal sketch of tumor involvement and rotationplasty surgical outcome. Figure 2 shows an actual orthopedic surgical outcome.

## Epidemiology

OS is the most common primary bone tumor in children, occurring in six children per million per year and is highly aggressive, with a 10-year disease free survival (DFS)

of 60% (Grimer, 2005; Longhi, et al. 2006). Median peak age at diagnosis is 16 years. The World Health Organization (WHO) initially classified bone tumors based on histology in 1972 (Schajowicz, Ackerman, & Sobin, 1972). The classification was revised in 1993. The guide has provided diagnosticians with a histological base to study bone tumors on a clinical, pathological and epidemiological level. Bone tumors are first classified as benign or malignant. OS is further defined as high or low grade. Low grade has a better prognosis and event free survival (EFS) than high grade (Schajowicz, Sissons, & Sobin, 1995). DSF is further impacted if the patient presents with metastases at diagnosis, decreasing survival to 30% (Longhi, et al., 2006). The primary site of metastasis in OS is to the lung (Grimer, 2005). OS metastasizes very early to the lungs in a large percentage of patients. Many researchers believe that “micro-disease” exists in greater than 90% of newly diagnosed OS patients (Bielack, Kempf-Bielack, & Delling, 2002).

Standard treatment consists of preoperative chemotherapy followed by surgical resection in 90% of pediatric OS patients (Kaste, et al., 2004). Four drugs have been used in clinical trials and have been proven to be effective in OS. Doxorubicin (Doxo), Cisplatin (CDP), Methotrexate (MTX) and Ifosfamide (Ifos) in varying combinations are given before and after surgery (Longhi, et al., 2006). Morbidities associated with these chemotherapeutic agents include cardiotoxicity (Doxo), requiring dose limits and baseline echocardiogram and renal toxicity (MTX and CDP) (Meyers, Schwartz, Krailo et al., 2005).

Surgical options include rotationplasty, allograft, endoprosthesis, vascularized fibular graft and amputation (Grimer, 2005). In the pediatric population, functional

outcome studies, over time, continue to show that limb salvage provides for a more useful functioning limb than amputation (Rougraff, et al.,1994; Hillman, Hoffman, Gosheger, Krankau, & Winkelmann, 1999; Renard, Veth, Schrueder, Van Loon, Koops, & Horn, 2000; Grimer, 2005).

Van Nes rotationplasty for treatment of bone tumors was first performed in Vienna in the 1970's by Kotz (Krajbich, 1990). Before that time the procedure was used for the treatment of proximal femoral focal deficiency (PFFD) and then modified by Krajbich in 1981 for malignant bone tumors (Krajbich, 1990). Krajbich (1990) describes the surgery as limb-sparing in OS patients instead of limb-saving as in the PFFD population, as the leg is benefited by the surgery. This technique involves removal of the affected bone and tumor, the tibia and foot are rotated 180 degrees and reattached to the remaining femur (Longhi, et al., 2006).

DK's tumor involved the proximal femur (see Figure 1) so the tibia was attached to the pelvis with pins. This allowed him forward and backward motion at the hip but limited abduction or adduction at the hip. Even with the limitations in side-to-side hip motion, functionally his outcome was better with this limb-sparing procedure than an endoprosthesis with allograft.

## Case Study/Management of Care

Having completed 12 weeks of chemotherapy, DK was admitted to our hospital the day before limb salvage surgery. He had two episodes of fever and neutropenia related to chemotherapy during that time and required inpatient intravenous antibiotic treatment. Otherwise his pain was manageable with hydrocodone and acetaminophen and he was able to ambulate without crutches.

The bone tumor program team members meet monthly and review all patients on the service and the limb deficiency clinic is held once a month. The surgical plan and chemotherapy plan is reviewed and social issues and/or needs are communicated as well. Prior to the admission, DK and his family met with the members of the bone tumor program: the Pediatric Nurse Practitioner/DNP student (PNP), nursing care coordinator, physical therapist, child life therapist, social worker and orthopedic surgeon.

DK was seen three times in the clinic preoperatively. At each visit the PNP/DNP was able to provide education for the child and family as they were learning more about the disease, treatment and surgery. The DNP and the care coordinator, in conjunction with the oncology team nurse practitioner, were able to coordinate two encounters with children who had previously undergone Van Nes rotationplasty. DK's family expressed how they were more reassured and less anxious about the surgery having met other families who had been through the process. Numerous studies have shown statistical significance in patient satisfaction when previous patients have been introduced to preoperative patients (Harris, Leff, Gitelis, & Simon, 1990; Hillman, Hoffman, Gosheger, Krankau, & Winkelmann, 1999; Rodl, Pohlmann, Gosheger, Lindner, & Winkelmann, 2002; Hopyan, Tan, Graham, & Tarode, 2006). In addition to quality of life outcome measurements, functional outcome studies have demonstrated near normal restoration of gait and function in rotationplasty patients (Rodl, Pohlmann, Gosheger, Lindner, & Winkelmann, 2002; Hopyan, Tan, Graham, & Tarode, 2006).

Surgical time was seven hours, during which time the vascular surgical team assisted with maintaining perfusion of the foot after disarticulation from the leg. DK was placed in a modified half spica splint and transferred to the Pediatric intensive care unit

(PICU). Close, vigilant observation and assessment of the rotated foot is paramount in the immediate postoperative period. Doppler assessment of pulses and venous flow is measured as well as oxygen saturation of the toes. DK spent an uneventful night in the PICU and returned to the acute care area on postoperative day (POD) 1.

Daily ward rounds are made with the PNP/DNP student, orthopedic fellowship MD, orthopedic resident and orthopedic surgeon. Hand-off rounds are utilized to ensure continuity and flow of necessary information between care providers. While the advanced practice education prepares the PNP for primary care and the specialized on the job training fine tunes that education with skills in a specific practice arena, the DNP education expands the knowledge base to include the more multidisciplinary leadership role at the inpatient comprehensive care level. The DNP is responsible for the day to day management of the inpatient children, writing orders in the electronic record, monitoring laboratory and radiology results, and writing progress notes in the electronic medical record. The DNP's office on the nursing unit provides close proximity to inpatients that allows families and staff to utilize the PNP/DNP student as needed for emergencies, spontaneous teaching moments, and general education of staff and families. DK's progress was presented by the PNP/DNP at weekly inpatient multidisciplinary rounds to address any concerns from staff or family.

Postoperatively, DK's pain was managed with epidural Bupivicaine and Fentanyl. The Wong/Baker pain scale was used to assess, plan care and manage pain, which is the nursing standard of care for pain management in our institution. This regimen worked well for DK so no further change in pain management was necessary. He was easily weaned to oral medications by POD#4. As with the majority of patients who receive

narcotics for pain control, bowel care was initiated and constipation avoided. This side effect was reviewed preoperatively with the family and the plan was to use Senna for bowel care and glycerin suppository if needed for constipation lasting greater than 48 hours. DK had no bowel issues while in the hospital.

The rotationplasty surgical site was covered by the spica splint, but the dressing remained dry and intact throughout the admission. The plan was to discharge him to home in the splint and return in 2 weeks for an examination under anesthesia to check the incision and be placed in a regular spica cast that would be left in place for a minimum of 6 weeks.

Pulmonary, cardiovascular, and renal systems were all at normal baseline at the time of discharge. DK was discharged to his home on POD #7. He returned 2 weeks later for the examination under anesthesia and the incision was healing well, without any sign of breakdown or infection. A fiberglass spica cast was placed. The cast remained in place for another six weeks, at which time radiographs demonstrated callous formation with new bone growth and stable fixation. The cast was removed without incident. Emotionally the family and DK were happy to be home and getting the cast off.

Chemotherapy was recommenced and DK completed the treatment course without problems. He began weight bearing and range of motion at postoperative week16 and was doing well with the new prosthesis. He was being seen in the outpatient clinic for physical therapy twice a week and saw the PNP/DNP for fast track office visits if he or the family had any questions. We met twice and the majority of time was spent planning DK’s Make-A-Wish trip to Disneyland in the summer.

On a routine follow-up chest computerized tomography scan (CT) at postoperative week 24, massive pulmonary metastases were noted bilaterally in the lungs and a large tumor was encasing the aorta in two areas. DK died 2 weeks later at home, under hospice care, from respiratory failure.

## Implications for Nursing Practice and Self Reflection

Studies have shown the expanded role of nurse practitioners in Emergency Departments and Intensive Care Units have decreased length of stay and decreased some costs, but there is a low level of evidence of outcome measurements (Kleinpell, Ely, & Grabenkort, 2008; Silvestri & McDaniel-Yakscoe, 2005). In an early study by Rudy, et al., (1998) nurse practitioners and physician assistants in an inpatient setting were measured against medical residents and were found to be more likely to spend more time with families, educate nurses and participate in clinical research than the residents (Kleinpell, et al., 2008).

While our multidisciplinary team provided care for DK and his family with a holistic and comprehensive focus, the orthopedic surgeon, the pediatric oncologist and the DNP were the leaders of the group, meeting informally to bring a cohesive medical plan to the team. All members of the team, with the coordination of the PNP/DNP, were kept informed of changes in the plan of care, goals of therapy and a timeline for outpatient services and outpatient clinic visits. Caring for children at this level increases the responsibility of the PNP/DNP in the management of inpatient children. DK's surgery and postoperative recovery were without complications or adverse events. Knowing both DK and his family were able to look ahead to their future, making plans for a family trip left the staff with a sense of providing a way back to normalcy for this family.

Although there is no certain method of predicting outcome and mortality, DK did fall into a high risk OS classification. The younger the patient, the higher mortality and his tumor was classified as high grade OS. He also presented with a mass located behind the knee, which was highly vascularized. The inpatient care DK received did decrease morbidities associated with surgery, such as postoperative pneumonia, urinary tract infection or wound infection, but the mortality rate for this high-risk group of patients is still in the 70% range (Longhi, et al., 2006).

While our staff did not manage DK's cancer therapy, we were well informed of his progress by being part of a multi-institutional team as well as a multidisciplinary team. Providing medical management and emotional support for the family on a day-to-day basis while DK was in hospital demonstrates the DNP's competency in delivering comprehensive complex care. The family came back to me months after DK's death, which many families do, to thank me for the support and honest communication I provided the family. They felt along with the high quality medical care I delivered, DK also trusted me because I spoke with him on his level and always told him the truth. This expert experience is the level of care the DNP brings to the advance practice role.

DK's untimely and sudden death was difficult for all of us. Reflection on whether or not the team spent enough time with the family concerning the poor prognosis is a venue we continue to question and now add earlier in our assessment of the family and child.

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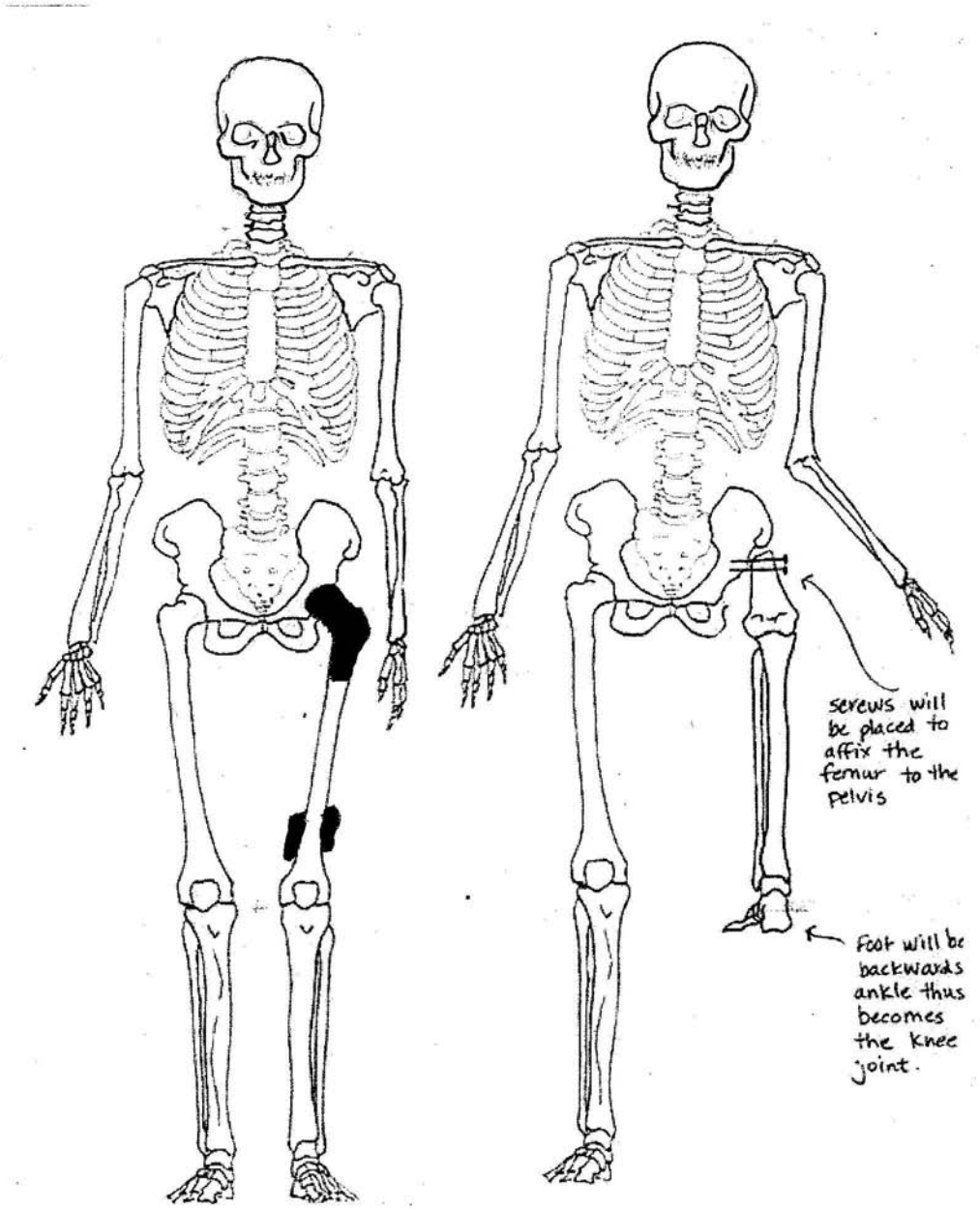


Figure 1 – Osteosarcoma tumor location – left

Van Nes rotationplasty surgical correction - right

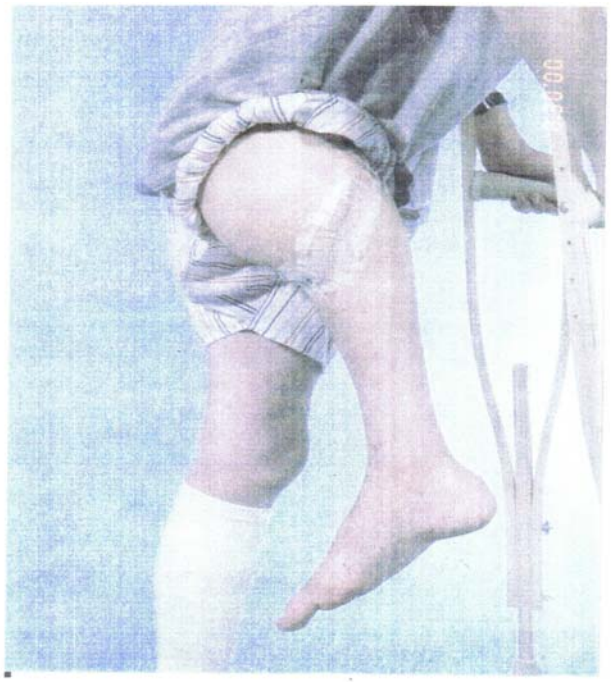

Figure 2 – Side view 6 weeks postoperative Van Nes rotationplasty

Running head: TRANSITIONING MEDICAL CARE

Case Study:

# Transitioning Patients with Special Needs to Adult Healthcare Providers

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## Introduction

Healthcare providers who care for children with special needs, realize and are anxious about the time when they can no longer be cared for by a pediatric practice and will require an adult provider. Transition programs in today's shortage of resources may be suspended for lack of funding, while the need remains. The Doctor of Nursing Practice (DNP) Advanced Practice Nurse (APN) has been educated in managing patients with chronic illnesses and providing seamless continuity of care when the focus of care shifts in service needs or delivery of service. This case study will review how the DNP is competent at that level of population management.

## Case Study History

The Shriners' orthopedic team has cared for KB since he was 18 months of age. He was born at term but required major resuscitation at birth. He was a gestationally large baby whose shoulders were difficult to bring though the birth canal. His initial Apgar scores were 1 and 3. He was mechanically ventilated for 15 days, but surprisingly, once his respiratory issues had resolved he was discharged within 1 week. However, by 9 months of age he had not met the first motor milestone of rolling from back to front. He was evaluated at a Children's Developmental Research Center and diagnosed with spastic cerebral palsy.

Over the course of this young man's life he had six major orthopedic surgeries before he was 18 years old, including rotational osteotomies of both femurs for chronic hip subluxation, tibial and foot surgeries to maintain a plantigrade foot position, and a posterior spinal fusion and instrumentation for neuromuscular scoliosis.

I met KB after his spinal surgery when he 18 years old. Both of his parents were over 65 years in age with multiple medical problems. He lives with his parents and is to complete high school this spring. KB is a power wheelchair ambulator, but has only enough motor control to use a joystick for locomotion. He is cognitively normal with an intelligence quotient (IQ) of 126. He has plans to attend community college. The birth trauma he suffered had been considered medical malpractice and a large settlement was placed in trust for KB's lifetime needs.

He presented to me in the postoperative scoliosis clinic 6 months after spine fusion surgery and we began planning his transition to an adult care provider after identifying a medical home for continuity of care.

## Epidemiology

KB and his family had not discussed the process of transitioning with his health care provider, despite the fact the National Association of Pediatric Nurse Practitioners (NAPNAP) as well as the Adolescent Medical Society recommends beginning discussions on this subject early in the teenage years (Palfrey et al., 2004; Moore & Tonniges, 2004). We began this dialogue at our first clinic visit.

The term "medical home" was formally defined in 1967 by the American Academy of Pediatrics (AAP) in the Standards of Child Health Care, written by the Council on Pediatric Practice (COPP) (Sia, Tonniges, Osterhus, & Taba, 2004). Although the phrase has been used for over 40 years, the definition "the medical home…should be for families and child health care professionals: accessible, continuous, comprehensive, family-centered, coordinated, compassionate, and culturally effective" is just as applicable today as then (Tonniges, Palfrey, & Mitchell, 2004, p.1472).

In 1989 the Surgeon General's report *Growing Up and Getting Medical Care: Youth with Special Health Care Needs* brought the subject to the nation's attention (Koop, 1989). The Individuals with Disabilities Education Act and the Maternal and Child Health Bureau (MCHB) states that all youth with special health needs will have in place by age 14 years a plan by 2010 that outlines how the child will receive the services necessary to make health care, work, and independence transitions (MCHB, 2008).

Numerous surveys have been done around transition planning, implementation and evaluation of programs (Kelly, Kratz, Bielski, & Mann-Rinehart, 2002; Lotstein, McPherson, Strickland, & Newacheck, 2005; Geeenen, Powers, & Sells, 2002). Geenen, Powers and Sells (2002) surveyed 753 parents and 141 health care providers to assess the perceptions of how involved the parents felt the providers were involved and the reverse. They found significant differences in perceptions with health care providers believing they were more involved in transition in 11 of 13 areas of transition than did parents (Geeenen, Powers, & Sells, 2002).

## Case Study Management of Care

Children with special health care needs (CSHCN) have many healthcare providers who, because of their independence from one another, experience breakdowns in communication, causing inefficiencies and duplication of services. As cited by McPherson (1998), the Federal Maternal and Child Health Bureau's Division of Services for Children with Special Health Care Needs defined the CSHCN as:

> "Children with special health care needs are those who have or are at increased risk for a chronic physical, developmental, behavioral or emotional condition and

who also require health and related services of a type or amount beyond that required by children generally" (p. 138).

Although KB had a pediatrician who managed his well child visits in the past, he had not been seen in their office for over a year. The last time he was seen only for an acute illness. A neurologist, neurosurgeon, orthopedic surgeon, physical therapist occupational therapist, physiatrist, and gastroenterologist are addressing his chronic medical issues at this point in time.

The family reported that they had asked their Internal Medicine physician if he was accepting new patients and if he would consider accepting KB as a new patient. He had agreed and I contacted him following the appropriate Health Insurance Portability and Accountability Act (HIPAA) rules and consent process. He was familiar with the medical home model and he agreed to attend our first transition conference.

The transition plan begins with an assessment of complexity of needs. Through literature searches and consulting with transition leaders in the Shriners systems, I chose to use the University of Minnesota's U Special Kids (USK) program's complexity of needs assessment tool (see Table 1) (Kelly, et al., 2002). Based upon this scale assessment tool, KB had 5 of 19 areas of complex needs. While some of KB's needs require multiple providers, he was in a good position to successfully transition from child-centered care to adult-centered care based on my assessment.

Complete record transfer and open communication is an integral piece to a successful transition (Kelly, et al., 2002; Lotstein, et al., 2005; Geeenen, et al., 2002). After the initial postoperative clinic appointment, KB and his family were scheduled into a followup appointment in 4 weeks with myself. In those 4 weeks I made contact with his

new provider, reviewed our chart, and organized records to be copied for the new practice health care provider. I also contacted each of the sub-specialists who managed KB's health care and reviewed the transition to his new medical home with them. All of the providers were in agreement that the new provider would be the appropriate gatekeeper for services and all were willing to continue to care for KB.

Kelly et al., (2002) identified components of transition within the medical home model that guided my plan. The skills and abilities of the adolescent drive the continuum based needs. Her team identified 5 components: 1) Maintain the patient in the home/community. 2) Make critical information accessible and organized. 3) Identify the collaborating team. 4) Coordinate care with providers and family. and 5) Coordinate sub-specialty service. Using the USK model, I was able to identify these components in planning KB's transition.

When I met with KB and his family, we set a date for the comprehensive transition team for the first meeting. The team consisted of KB and his family, myself, the new provider, speech, occupational and physical therapists, the high school guidance counselor, social worker, and the county agency resource ombudsman. I asked each of the team members to send their therapy plans or plan of care to me 2 weeks before the meeting in order to ensure that all of the components of the medical home for an adolescent were in place. With all of their information I completed the needs assessment and finalized the initial transition plan.

The goal of the first team meeting was to have the plan agreed upon by the family and medical members and plan for the last visit at our institution. The goals were met

successfully and KB transitioned from our facility to the new care provider. He is currently in college.

## Implications for Nursing Practice and Self Reflection

The term transition implies a much more complex process than merely transferring care; a process inherent in the philosophy of the medical home model. This case study demonstrated "an intrinsic component of doctoral education that affords the student the opportunity to integrate knowledge amassed during the course of study…" (Smolowitz & Honig, 2008, p. 18).

Performing at this level of practice would not have been possible for me prior to the DNP coursework I have completed in the past 24 months. The building blocks of the program, preparing us for organizational assessment, policy research, and informational technology, built the knowledge base in preparation for the clinical residency that has culminated in my ability to plan and coordinate care for patients like KB. While my primary focus as a Masters prepared PNP in an inpatient setting was managing one sub-specialty of postoperative patients, the DNP has opened my practice to a larger patient population on a program level.

Shriners Hospital has been asked to participate on the national level in educating medical students, fellowship residents, and nurses on the medical home model of care. We are fortunate to have a transition nurse position in our institution that speaks internationally on the model and transition of care for children with special needs. I now have a close working relationship with her and as a DNP I can bring national policy changes to the local level.

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Running head: NEW PATIENT

# Case Study: Evaluating New Patients

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## Introduction

The purpose of case study presentations by the Doctor of Nursing Practice (DNP) student is to demonstrate the competencies outlined by the Council for Advancement of Comprehensive Care (CACC) (Council for the Advancement of Comprehensive Care, 2003, 2006). One of the competencies is to "Provide health promotion, anticipatory guidance, counseling, and disease prevention services to healthy or sick patients in any clinical setting based on age, developmental stage, family history, ethnicity, and individual risk, including genetic profile" (Smolowitz & Hong, 2008, p. 20). This case study will review a patient's first clinic visit in our institution, the history and physical assessment, and plan of care. In an effort to minimize redundancy, I have inserted the demonstrated competencies in the History and Physical section in bold print.

New patients are seen in designated clinics with a 60-minute appointment slot so that a comprehensive, detailed history and physical may be performed. As the healthcare provider, the DNP performs the history and physical and reports the findings to the attending orthopedic physician, who then does a focused orthopedic examination. Physical and occupational therapists (PT and OT), social services, and child life therapists (CLT) also evaluate the patient. The multidisciplinary team meets at the end of the visit, first without the family, and then with the family to review the findings and initiate the plan of care.

## Case Study

The Medical Chief of Staff and the Board of Governors of the hospital review monthly the patient applications for treatment. Once accepted, the patient is scheduled with an appointment and is usually seen within 3 months, earlier if for a more urgent

need. No emergency care is delivered at our institution. The following is the history and physical findings for CDM, a 19 month-old male whose parents are concerned about his bowed legs.

HISTORY

HISTORIAN: Biological mom and dad.

CHIEF COMPLAINT: Bowed legs.

HISTORY OF PRESENT ILLNESS: CDM is a 19-month-old boy whose mom noted at birth that both of his legs were bowed. He has been followed by his local pediatrician and the problem is slightly improved but the parents are worried because of a family history of bowed legs. His activity is not limited by fatigue or pain CDM was referred to our hospital for further evaluation. PAST MEDICAL HISTORY: He has no chronic or general illness conditions.

PAST SURGICAL HISTORY: He has had no surgical interventions.

FAMILY HISTORY: Mother was diagnosed with bowed legs when she was a child. She remembers having to wear braces and special shoes for an undetermined amount of time. No family history of metabolic disorders, orthopedic problems, or genetic diseases involving the musculoskeletal system.

SOCIAL HISTORY: CDM lives with his biological parents and one sibling. He is not passively exposed to tobacco smoke. There are no guns in the home. The family uses seat belts when in the car and CDM travels in a car seat. **(anticipatory guidance)**

BIRTH HISTORY: CDM is the second child born to these parents. Mom reports that she had no problems during her pregnancy. She denies any alcohol, drug, tobacco, or environmental exposures. She went into labor naturally at term and delivered CDM

vaginally after a 12-hour labor. He went home with mom. His birth weight was around 7 pounds.

DEVELOPMENTAL HISTORY: He currently is at the 60th percentile for weight and at the 50th percentile for height. He walked early at 7 1/2 months. He met all other motor and cognitive milestones at the appropriate ages.

ALLERGIES: None.

MEDICATIONS: None.

IMMUNIZATION STATUS: Up to date.

REVIEW OF SYSTEMS: In general he has been in good health with no recent infection, illness, or fever and no recent weight gain or loss. He has a pediatrician of record and has well-child examinations per AAP schedule. A dentist has not seen him. Otherwise, the review of systems did not reveal any contributory information.

PHYSICAL EXAMINATION

GENERAL: He is a well-nourished, well-developed, verbally interactive, and very strong willed 19-month-old in no acute distress. He is cognitively well above his chronological age, writes his name, recognizes numbers up to 10 visually, and his sentences contain more than 5 words.

HEENT: Head is normocephalic and atraumatic. Pupils equal, round, reactive to light and accommodation. Bilateral red reflexes positive. Extraocular movements intact. Tops of both auricles are in line with outer edge of eyebrows. Bilateral tympanic membranes are pearl gray with positive landmarks. Nares are clear. Turbinates are moist and pink. Mouth is pink and moist. Throat is unable to be examined secondary to lack of

cooperation. The teeth I am able to visualize are without caries or plaque. Chin is midline.

NECK: Supple and symmetrical without adenopathy.

CHEST: Lungs clear with equal bilateral breath sounds. No distress or adventitious sounds.

HEART: Normal sinus rhythm, S1 and S2. No murmur appreciated. Pulses are brisk and equal. He is centrally and peripherally well perfused.

ABDOMEN: Soft, non-tender, positive bowel sounds. No hepatosplenomegaly or masses appreciated.

GENITOURINARY: Exam deferred.

SKIN: Well hydrated. No rashes or lesions.

SPINE AND PELVIS: Spine is essentially straight and non-tender without midline deformity. Pelvis and shoulders are level. No hairy tufts or sacral dimpling noted.

NEUROLOGICAL EXAM: No significant pathology noted.

EXTREMITIES: Gait: Heel-toe pattern. Intoeing on the left with a foot progression angle of negative 10 degrees. Normal foot progression angle of positive 5 degrees on the right. Upper extremities have active full range of motion in all joints with 5/5 strength on resistance and intact sensation. Lower extremities have active full range of motion with 5/5 strength on resistance and intact sensation. Deep tendon reflexes are normal at patellae. Feet are pink and warm with brisk capillary refill, equal pedal pulses, and without deformity. Rotational profile: Hips have external rotation of 45 degrees bilaterally and internal rotation of 45 degrees bilaterally. Knees are of equal height. There is tibial bowing noted, but the inner knee-to-knee measurement is less than 6 cm

when the ankles are together. The Galeazzi sign is negative. Ankles have full plantar flexion and dorsiflexion. He has a flexible hindfoot and full talar motion.

X-RAYS: No x-rays done today.

IMPRESSION/DIAGNOSIS:

1. Physiological bowing.
2. Left internal tibial torsion.
3. Advanced cognitive skills

PLAN: Dr. X and I explained physiological bowing to the family and the internal tibial torsion on the left. Mom agreed with observation and will call on an as needed basis. Recommended that parents take pictures of CDM every 3 months to document progression or regression of bowing to help allay family's fears. **(anticipatory guidance)** Reviewed vaccination schedule per American Academy of Pediatrics (AAP) recommendations. **(provide health promotion) (counseling, and disease prevention)** Parents commended for being up to date on immunizations and following well-child examination schedule. Education provided: immunization schedule reviewed, use of fluoride, iron supplements, dental referral at age 3 years per public health standards. **(health maintenance)**

Reviewed need for Fluoride, and iron supplements if needed. **(anticipatory guidance) (counseling, and disease prevention)**

We also spoke about CDM's advanced cognitive skills. Both parents' faces flush as I explain how advanced CDM's speech and cognitive skills appear and they state how proud they are of him. I advised them to speak with his pediatrician about testing and observation. **(anticipatory guidance) (provide health promotion)**

As far as the rest of the team members, PT and OT did not identify any needs and CLT is to facilitate and followup with CDM's pediatrician for cognitive testing.

## Implications for Nursing Practice and Self Reflection

Being trained in Pediatric Primary Care is one of the building blocks that has enabled me to advance to the DNP. Performing new patient physicals in a hospital setting mimics the primary care model with the addition of providing a more focused exam of the musculoskeletal system in our specialty practice. The importance of the DNP role in this setting, particularly a DNP with a PNP Masters, is the pediatric growth and development understanding and expertise. The pediatric orthopedic surgeons are stellar clinical surgeons, but the skill in managing the family needs and coordination of care by the DNP allows our hospital to provide true family-centered care. The DNP role is an integral part of that team.

Mary O'Neal Mundinger, (2009) from Columbia University School of Nursing, succinctly described clinical scholarship as " …one developing clinical scholarship must be a clinician, engaged in thoughtful, deliberate, curious, *reflective* (the word appears again and again) thinking." (p. 4). Reflection on her commentary strengthens my conviction that I made the right choice to obtain the DNP degree. Despite the challenges of the being in the first graduating class, changing advisors mid-year, and the multitude of online learning technical changes, as a DNP I am developing clinical scholarship and am proud of that accomplishment.

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Running head: LEADERSHIP

# Case Report: DNP Leadership

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## Introduction

The Essentials of Doctoral Education published in 2006 by the American Association of Colleges of Nursing (AACN) defines eight foundational essentials, which constitute the Doctor of Nursing Practice (DNP) curriculum (AACN, 2006). Seven of the essentials specifically address the concept of leadership. For this case report on DNP Leadership, the first focus will be on Essential II, Organizational and Systems Leadership for Quality Improvement and Systems Thinking. This essential piece of the curriculum ensures that the DNP student is able to use evidence-based queries to conceptualize new care delivery models.

The AACN also identified competencies that serve in an attempt to define, but not limit, the nursing leader (AACN, 2008). Six essential competencies constitute their framework. Four of the competencies are broad enough to generalize to any leadership style. I have selected four competencies, self-leadership, global-thinking, visioning, and consensus building, for self-reflection and demonstration of my clinical scholarship and leadership as it relates to this case study.

The case study will review a dynamic process currently in the planning stage, opening a Same-Day Surgery program that is feasible in today's economic climate as well as feasible based on the organization's fiscal limitations.

## Background

The practice setting is an inpatient unit of a pediatric orthopedic hospital. The institution is a one-of-a-kind health care system dedicated to improving the lives of children by providing pediatric specialty care, innovative research and teaching programs. The hospital is one of 22 national hospitals that provide care for children with

orthopedic conditions, burns, spinal cord injuries, and cleft lip and palate defects in a family-centered environment. The hospitals have been leaders in pediatric orthopedic care since 1922. Innovative research is conducted to provide answers to complex medical difficulties affecting children and contribute to the overall body of medical knowledge for the care and treatment for a wide range of pediatric and adult conditions worldwide. By maintaining relationships with more than 60 medical teaching facilities worldwide, the system fosters an academic environment committed to providing high-quality medical care to all patients.

The current admission process for all preoperative patients is to be seen the day before surgery. The patients are seen by the DNP or medical resident for the history and physical, an anesthesiologist, a registered nurse for nursing assessment, a social worker for assessment, and physical or occupational therapy depending on surgical procedure and postoperative need. This complex process involves a minimum of a two-hour clinic visit. For the patients who are having a surgical procedure that, in an acute care hospital, would be done in a Same-Day Surgical unit, this process is cumbersome, inefficient and costly.

To assess patient satisfaction within the hospital, the patient satisfaction survey system the hospital employs is the Press Ganey report. A quarterly result in 2008 demonstrated a significantly low satisfaction rating with the admissions process for the same-day surgery patient population. While using outcome measurements to evaluate quality medical care is a valid method for some outcomes, Donabedian (2005) reminds us those outcomes that are not clearly defined, such as patient satisfaction, have limitations and are difficult to measure. He stated, “All these limitations to the use of outcomes as criteria of medical

care are presented not to demonstrate that outcomes are inappropriate indicators of quality but to emphasize that they must be used with discrimination. Outcomes, by and large, remain the ultimate validators of the effectiveness and quality of medical care." (Donabedian, 2005, p. 694).

## Case Study

In an effort to decrease costs, improve efficiency, and increase patient satisfaction, I proposed to the Medical Executive staff to bring together the stakeholders who had an interest in creating a Same-Day Surgery program and to head the research developing that new program for our institution. We have 2 operating suites and 5 orthopedic surgeons. Surgeries are scheduled Monday through Friday, first cases starting at 7AM and last cases beginning at 3PM. The weekly surgical schedule is set 6 weeks in advance. The average number of surgeries is 25 per week with a limited number of same-day surgeries scheduled due to bed availability on the Inpatient Unit.

After performing a cost analysis, balancing operating room time, surgeon and staff salaries, benefits associated with those full time equivalents (FTEs) and maintenance costs, I found that opening a Same-Day Surgery unit could save the hospital close to $300,000 per year. Besides the monetary benefit, the efficiency reports I reviewed from other hospitals that had introduced similar programs revealed increased job satisfaction of a cadre of staff who enjoyed the fast track pace of same-day admission and discharge. The patient and family satisfaction surveys from those hospitals also reported dramatic improvement by the more efficient program.

I identified the stakeholders as the Inpatient Nursing Director, the Surgical Services Director, the Admissions clinic nurses, the Quality Improvement facilitator, and

the Outpatient Nursing Services Director. I also sent a general email to the nursing staff and asked for any volunteers to join the group as I knew a few of the nurses had expressed interest in working in this arena. Two of the director level members had experience in setting up this type of program. Their expertise was important to the group as they had access to policies from other institutions that we were able to rewrite for our hospital.

To develop a process for the group to understand what was currently in place, I felt a flow chart was the best way to begin the project. Numerous studies have been done around this flow diagram system, also known by other names, such as process map, micro map, or symbolic flowchart (Tague, 2004; National Institute for Open Schooling, 2009). Tague (2004) stresses in her instruction manual that the name of the process is not as important as that the team understands the process. Our first meeting reviewed the basic principles of a flow chart and the use of note cards, flip charts and brainstorming. The final flow chart was completed by the third meeting (Appendix A).

Using a democratic leadership style engages the participants and incorporates many perspectives about the issue. Communication is of vital importance in any program development as change is difficult for any group (Tague, 2004). At the first meeting tasks were identified and the group members chose the tasks they felt they could best accomplish. The Inpatient Nursing Director and the Admissions nurses decided they would be able to write criteria for patients who would be eligible for same-day admission. The Surgical Services Director volunteered to network with colleagues in other institutions for policies and procedures concerning program development. I

coordinate the meetings, record minutes, and meet with the Chief Medical Officer on a weekly basis to keep him abreast of the progress of the committee.

## Outcomes

The program is still in the building stages and the process is working well for the group. Conflicts in decision-making have not occurred. The group is small and we make sure there is no triangulating communication that can undermine the goal of opening a new program. We hope to have the program ready to open with the opening of the new addition to the hospital in 2010.

In the past, as a clinical manager, I would classify my style of leadership as democratic or participative. This style allows the team members to contribute in decision-making and also improve their skills. Recently I have read more on executive leadership moving towards the concept of executive teams instead of an individual leader (Kiefer, 1994). This style of leadership is appealing for the same reasons as the democratic style; it promotes team members to learn new skills and motivates team members to perform at a higher level of productivity (Kiefer, (1994).

Since this is the first project I have begun as a DNP student, although my leadership style has not changed, I am able to see differences in how I envision the future of this project based on the coursework in policy and finance. I continue to deal with the members of any team with respect for all ideas, using basic rules of meeting etiquette, and modeling a positive attitude.

## Self Reflection

The case study demonstrated how I used the DNP competency (Essential II) to compliment my democratic leadership style. I identified a new method of providing care

that improves finances for the institution, increases efficiency and utilization of staff, and improves patient and provider satisfaction. I used certain leadership skills to accomplish this change in practice and those skills have been improved by my exposure to the DNP program. This is evidenced by four of the essential competencies for governance leadership, self-leadership, global-thinking, visioning, and consensus building.

*Self-Leadership*

Inherent in the components of this competency are self-confidence, resilience and the ability for introspection. The Same-Day Surgery program is an improvement in practice and as a DNP I am able to assess the organization's readiness for change to improve patient outcomes.

*Global-Thinking*

Leadership at the doctoral level moves the student to think beyond local issues and the DNP becomes competent in applying new perspectives to the role. Being aware of systems issues in the organization on the local level, as well as the effects on the 22 other hospitals in the system, demonstrate global thinking. Creating the Same-Day surgery program was the result of researching national trends and patient satisfaction.

*Visioning*

Visionary leadership is best combined with a democratic style. I was able to communicate to the Medical Executive Committee the need for the new program and how the practice change would benefit their practice by increasing operating room efficiency.

*Consensus-Building*

Bringing together the right people when building a team is of paramount importance in the success of the project. Mastery in consensus building is a learned skill, unfortunately through previous failures. My experience in team building and group process work brought a broad view of how to effect positive change.

## Conclusion

The Clinical Doctorate program provides the Advanced Practice Nurse the opportunity to lead by example and clinical research. As a DNP I have been prepared to strategize, create and hopefully sustain changes in the organization's culture to improve patient outcomes. Our new Same-Day Surgery program is built on the systems leadership skills I have been taught in the DNP program.

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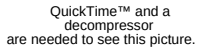
# Appendix A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# Case Study:
# Fever of Unknown Origin Following Spinal Cord Injury

## Introduction

DNP competencies will be demonstrated in this case study. The American Association of Colleges of Nursing (AACN) published the Essentials of Doctoral Education for Advanced Nursing Practice (American Association of Colleges of Nursing, 2005). There are three competencies addressed by this case: a) providing healthcare services to sick patients in an inpatient setting based on age and emotional development, family history, and risk, b) using principles of epidemiology as a framework for population based and evidenced based care, and c) the ability to develop a differential diagnosis and provide appropriate care including diagnostic testing (Smolowitz & Honig, 2008). This case study is a review of a complex inpatient with fever of unknown origin (FUO), presented to demonstrate clinical competency and diagnostic strategy skills of the Doctor of Nursing Practice (DNP).

## Case Study

CW is a 14 year plus 11-month-old teenage boy with the diagnosis of early onset scoliosis. In the past, scoliosis was categorized by age at diagnosis, with congenital diagnosed at birth, infantile at 0 -3 years, juvenile at 4 - 8 years and adolescent at 10 years and older. More recently, Fernandes and Weinstein (2007) found the magnitude of the curve at diagnosis to be more predictive of curve progression than age at diagnosis. CW is insured but the institution caring for him is not-for-profit and does not bill for any of its services. The significance of this will be better understood as the case study evolves.

Early onset scoliosis, if left untreated, results in pulmonary hypertension and cor pulmonale (Tolo & Gillespie, 1978; Ferreira & James, 1972; and Mehta, 1972).

However, if early surgical intervention is needed, the risk of resultant junctional kyphoscoliosis is increased to 30% (Fernandes & Weinstein, 2007). Junctional kyphoscoliosis occurs as the un-fused portion of the spine continues to grow. Because spinal growth continues until approximately age 16 years in males (Mehta, 2005), multiple revisions of the original surgical intervention are required. Spinal growth arrest at such an early age with fusion and instrumentation also damages the lungs' ability to grow. Lung growth and pulmonary alveolar growth have been directly related to spinal growth (Canavese, et al., 2007). Surgical correction of kyphoscoliosis also places the client at higher risk for spinal cord injury and death (McMaster, Glasby, Singh, and Cunningham, 2007).

## History of Present Illness

CW was born preterm at 25 weeks gestation to a 28 year old, gravida 1, para 0, whose labor progressed despite medical intervention. He required respiratory and fluid resuscitation at birth. Inhaled surfactant was administered at delivery, but CW also required mechanical ventilation for 20 days, which left him with the sequelae of bronchopulmonary displasia (BPD). Also noted at birth was the lack of abdominal muscle wall tone, which contributed to the difficulty of stabilizing his respiratory status. He was in the neonatal intensive care unit for the first 3 months of life. The diagnosis of scoliosis was made when CW began to walk at 18 months of age. Despite bracing and minimally invasive interventions, CW required surgical fusion at age four years. He underwent his second anterior muscle release and posterior instrumentation surgery at seven years of age. At age 14 years, CW's pulmonary function had deteriorated, with

functional vital capacity measured at 26% of normal and he had developed junctional kyphosis.

CW was admitted to our pediatric orthopedic hospital, where he was clinically managed by the Pediatric Nurse Practitioner, a DNP student, and the orthopedic surgeon. He was placed in halo traction for 90 days in an effort to maximize muscle stretch and release before having surgery to correct the kyphoscoliosis. During the surgery, CW suffered a spinal cord injury resulting in lower extremity flaccid paralysis. On magnetic resonance imaging, the insult was demonstrated by an infarcted area at the fifth thoracic vertebra, resulting in paraplegia including no bladder or bowel control.

On postoperative day 42 from spinal surgery, CW developed a core temperature elevation to 40 degrees Celsius with rigors. The fever defervesced with anti-pyretic administration and comfort measures. Over the next 72 hours, CW's fever curve continued to show a high spike in the early afternoon with subsequent fall back to normal with medication. His vital signs were otherwise normal, except for slight tachycardia during the fever episodes. All systems of his physical exam were within normal limits. The review of systems did not reveal any contributory information.

## Plan of Care/Diagnostic Strategy

In the outpatient setting, the management of the patient with a fever of unknown origin (FUO) with this presentation would be close monitoring and ensuring adequate fluid intake (Blosser, Goodman, & Brady, 2004). In a spinal cord injury patient the differential diagnoses for FUO include autonomic hyperthermia, urinary tract infection/pyelonephritis, and heterotopic ossification (Ditunno & Formal, 1994). In the hospitalized patient, nosocomial infections are also included in the differential. CW is a

hospitalized patient, a new spinal cord injury patient, who performs every 4-hour clean, straight urinary catheterization, and is at risk for osteopenia secondary to immobilization. He also has a peripherally inserted central catheter (PICC) for intravenous (IV) access.

The management of this patient required a more in depth search for the cause of the FUO. The DNP plan of care began with obtaining infectious laboratory markers, complete blood count with differential (CBC), erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP). In addition, liver function tests, including hepatitis titers, and electrolyte assessment were indicated. Urinalysis and urine culture, as well as blood cultures for bacteria and fungus from a peripheral venipuncture and the PICC line were also indicated. Chest radiographs to assess respiratory function were included in the initial work up of FUO.

Utilizing a multidisciplinary approach to acute inpatient medical care, a telephone consult was obtained with the Pediatric Infectious Disease department at the local university medical center. The above plan was reviewed and the team recommended initiation of empiric intravenous antibiotics as this patient was at risk category for hardware seeding of bacteria and life-threatening sepsis (Kanayama, Hashimoto, Shigenobu, & Togawa, 2007). Because of the potential risk of catheter induced infection, the PICC line was discontinued.

The entire battery of diagnostic tests yielded negative results. CW continued to have high fevers, now more frequently than once a day. At least once per 24 hours the fever elevations included shaking chills. Subsequent laboratory tests of CRP and ESR were elevated on day 10 of the fevers, so further imaging tests were indicated. A magnetic resonance image of his spine, computerized tomography of the chest and

abdomen, and echocardiogram were normal. A bone scan ruled out heterotopic ossification and a Doppler vascular examination showed no evidence of deep vein thrombus (DVT).

On day 10 of IV antibiotics, CW's white blood cell count dropped with an absolute neutrophil count of 1200/$mm^3$. One of the broad-spectrum antibiotic coverage side effects is neutropenia. Since the fevers continued despite continuation of IV antibiotics and neutropenia is an untoward side effect with implications, the decision was made to discontinue the empiric coverage.

Further laboratory tests were ordered by the DNP after ongoing consultation with the Infectious Disease department to investigate and broaden the differential diagnosis for nosocomial infections, specifically testing for Epstein-Barr viral (EBV) antigen and cytomegalic viral (CMV) antibodies. Although there were no known usual exposures, CW did receive a blood transfusion 6 weeks prior to the onset of FUO. Rare cases of blood borne transmission of EBV have been reported (American Academy of Pediatrics, 2006). The EBV antibody and antigen resulted positive. CW was diagnosed with infectious mononucleosis. CW continued to have fever for 48 hours and then normalized.

Originally, the post-operative plan was to transfer CW to a spinal cord rehabilitation facility once he had recovered from spinal surgery. Since the transfer was delayed secondary to the FUO, the DNP facilitated weekly multidisciplinary team meetings, outlining weekly goals and defining discharge criteria. Once CW had been afebrile for 72 hours, he was transferred to the spinal cord rehabilitation center. He is currently healthy.

## Epidemiology

EBV is a member of the γ-herpesviruses family and is reported to cause more than 90% of infectious mononucleosis cases (Jenson, 2000). Transmission is generally through contact with saliva from the mouth of an infected person. Airborne and blood borne transmission is rare but has been reported (Centers for Disease Control and Prevention, 2009). The prodromal phase of infectious mononucleosis generally lasts for 1-2 weeks, with most adolescent and young adult patients seeking care for persistent, severe pharyngitis (Jenson, 2000; Centers for Disease Control and Prevention, 2009; & American Academy of Pediatrics, 2006).

In disparate populations and in developing countries, EBV infection is primarily in children less than 4 years of age and children are asymptomatic (Jenson, 2000). The Centers for Disease Control estimate that 95% of adults in the United States have been exposed and infected with the virus (Centers for Disease Control and Prevention, 2009).

## Implications for Nursing Practice and Self Reflection

The DNP role as an inpatient health care provider in this case study was pivotal in the day to day management of care. Along with the medical management, the DNP provided emotional support and counseling to the patient and family. The unexpected outcome, paraplegia, devastated the family and necessitated our finding resources to support them as the grief and loss process began. Daily rounds, actually sitting down with the patient and family members, were essential in caring for CW. Weekly multidisciplinary meetings, including the family and CW, facilitated by the DNP fostered open communication and coordinated care. Understanding principles of grief, loss,

growth and development, and family dynamics was the basis of a supportive and caring relationship that fostered trust and security in a tragic situation.

The clinical picture in this case study was not a classical presentation of Epstein-Barr viral infection. While malaise and unremitting fevers were present, CW had no complaints of sore throat or any signs of lymphadenopathy or splenomegaly. Better understanding of the epidemiology of diseases is also a competency that the DNP builds on with each new scenario. The rare occurrence of transmission of EBV infection was overlooked. The confounding factors of the present postoperative state overshadowed the investigation into the more rare causes of FUO. But, the evidence-based approach to diagnosis and care of the complex patient did play a pivotal role in eventually diagnosing this complex case.

Medicaid's newest rulings, announcing there will no longer be financial reimbursement for treatment for nosocomial, hospital acquired, infections warrants clinical expertise in prevention of illness and health maintenance (Centers for Medicaid and Medicare Services, 2007). The total estimated cost of the diagnostic workup for this nosocomial infection was $185,000. While our institution does not charge for services, as the costs are paid by the endowment that funds our hospital, this would have had a major impact if CW had been hospitalized in another facility. Fine-tuning the depth of the diagnostic strategies employed by the DNP until a diagnosis is made is costly. In this case study, if viral titers had been done in the first assay of laboratory testing, the client and hospital would have been saved significant burden. Gaining diagnostic experience as a DNP is an ongoing exercise, one that will continue throughout the professional career. Each new case provides moments of learning and broadens my knowledge base.

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# Information for Authors

**Clinical Scholars Review**

*Clinical Scholars Review* is a biannual, peer reviewed publication focused on presenting articles that demonstrate clinical excellence in the application of evidence-based practice of doctoral nursing. Articles submitted for consideration discuss clinical practice and patient care; case studies; practice issues, including management, scope of practice, and reimbursement; ethical dilemmas, legal issues, and business practices; innovative methods of teaching and evaluating advanced practice and profiling the scholarly nature of clinical practice of nursing.

As an innovative feature, students in clinical doctoral (DNP) programs will be asked to contribute original articles as well as serve as part of the review team for student submissions.

The mission of the *Clinical Scholars Review* is to support the advancement of the doctoral practice of nursing.

**Manuscript Preparation and Review:** Manuscripts must be submitted electronically as a Word document and should be double-spaced with one-inch margins and the font set to Times New Roman (12 point). A title page separate from the main manuscript must include the title; the names of all authors (including academic degrees and primary affiliations); the name, mailing address, e-mail address, and telephone of the corresponding author. The manuscript itself should include a title page without author identifiers.

The manuscript should conform to the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication" in matters of style and formatting, including the text, references, tables. (Visit http://www.icmje.org) Digital files for any figure should conform to tiff at 300 ppi or eps. Please include written permission for previously published materials. A brief abstract (no more than 200 words) should accompany the manuscript.

Authors should supply a list of four keywords describing the scientific content of the article and which should be used for indexing in bibliographic databases.

Manuscripts submitted are for the exclusive use of Clinical Scholars Review, and should not have been previously published or be presently under consideration for publication elsewhere.

All submissions must be accompanied by a copy of the following copyright statement:

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**Manuscripts should be submitted via e-mail to the editor at csrj@columbia.edu**

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# Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication

(*Updated October 2008*)

**Publication Ethics: Sponsorship, Authorship, and Accountability**

**International Committee of Medical Journal Editors**

The following information is available to be viewed/printed in Adobe Acrobat pdf format.


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## I. Statement of Purpose

### I. A. About the Uniform Requirements

A small group of editors of general medical journals met informally in Vancouver, British Columbia, in 1978 to establish guidelines for the format of manuscripts submitted to their journals. This group became known as the Vancouver Group. Its requirements for manuscripts, including formats for bibliographic references developed by the National Library of Medicine (NLM), were first pub-

lished in 1979. The Vancouver Group expanded and evolved into the International Committee of Medical Journal Editors (ICMJE), which meets annually. The ICMJE has gradually broadened its concerns to include ethical principles related to publication in biomedical journals.

The ICJME has produced multiple editions of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Over the years, issues have arisen that go beyond manuscript preparation, resulting in the development of a number of Separate Statements on editorial policy. The entire Uniform Requirements document was revised in 1997; sections were updated in May 1999 and May 2000. In May 2001, the ICMJE revised the sections related to potential conflict of interest. In 2003, the committee revised and reorganized the entire document and incorporated the Separate Statements into the text. The committee prepared this revision in 2008.

The total content of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals may be reproduced for educational, not-for-profit purposes without regard for copyright; the committee encourages distribution of the material.

Journals that agree to use the Uniform Requirements are encouraged to state in their instructions to authors that their requirements are in accordance with the Uniform Requirements and to cite this version. Journals that wish to be listed on www.ICMJE.org as a publication that follows the Uniform Requirements should contact the ICMJE secretariat office.

The ICMJE is a small working group of general medical journals, not an open-membership organization. Occasionally, the ICMJE will invite a new member or guest when the committee feels that the journal or organization will provide a new perspective. Open membership organizations for editors and others in biomedical publication include the World Association of Medical Editors www.WAME.org and the Council of Science Editors www.councilofscienceeditors.

### I. B. Potential Users of the Uniform Requirements

The ICMJE created the Uniform Requirements primarily to help authors and editors in their mutual task of creating and distributing accurate, clear, easily accessible reports of biomedical studies. The initial sections address the ethical principles related to the process of evaluating, improving, and publishing manuscripts in biomedical journals and the relationships among editors and authors, peer reviewers, and the media. The latter sections address the more technical aspects of preparing and submitting manuscripts. The ICMJE believes that the entire document is relevant to the concerns of both authors and editors.

The Uniform Requirements can provide many other stakeholders—peer reviewers, publishers, the media, patients and their families, and general readers—with useful insights into the biomedical authoring and editing process.

### I. C. How to Use the Uniform Requirements

The Uniform Requirements state the ethical principles in the conduct and reporting of research and provide recommendations relating to specific elements of editing and writing. These recommendations are based largely on the shared experience of a moderate number of editors and authors, collected over many years, rather than on the results of methodical, planned investigation that aspires to be "evidence-based." Wherever possible, recommendations are accompanied by a rationale that justifies them; as such, the document serves an educational purpose.

Authors will find it helpful to follow the recommendations in this document whenever possible because, as described in the explanations, doing so improves the quality and clarity of reporting in manuscripts submitted to any journal, as well as the ease of editing. At the same time, every journal has editorial requirements uniquely suited to its purposes. Authors therefore need to become familiar with the Instructions to Authors specific to the journal they have chosen for their manuscript—for example, the topics suitable for that journal, and the types of papers that may be submitted (for example, original articles, reviews, or case reports)—and should follow those instructions.

## II. Ethical Considerations in the Conduct and Reporting of Research

### II. A. Authorship and Contributorship

#### *II. A. 1. Byline Authors*

An "author" is generally considered to be someone who has made substantive intellectual contributions to a published study, and biomedical authorship continues to have important academic, social, and financial implications (1). In the past, readers were rarely provided with information about contributions to studies from persons listed as authors and in Acknowledgments (2). Some journals now request and publish information about the contributions of each person named as having participated in a submitted study, at least for original research. Editors are strongly encouraged to develop and implement a contributorship policy, as well as a policy on identifying who is responsible for the integrity of the work as a whole.

While contributorship and guarantorship policies obviously remove much of the ambiguity surrounding contributions, they leave unresolved the question of the quantity and quality of contribution that qualify for authorship. The ICJME has recommended the following criteria for authorship; these criteria are still appropriate for journals that distinguish authors from other contributors.

- Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
- When a large, multicenter group has conducted the

work, the group should identify the individuals who accept direct responsibility for the manuscript (3). These individuals should fully meet the criteria for authorship/contributorship defined above and editors will ask these individuals to complete journal-specific author and conflict-of-interest disclosure forms. When submitting a manuscript authored by a group, the corresponding author should clearly indicate the preferred citation and identify all individual authors as well as the group name. Journals generally list other members of the group in the Acknowledgments. The NLM indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript; it also lists the names of collaborators if they are listed in Acknowledgments.

- Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Some journals now also request that one or more authors, referred to as "guarantors," be identified as the persons who take responsibility for the integrity of the work as a whole, from inception to published article, and publish that information.

Increasingly, authorship of multicenter trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship/contributorship.

The group should jointly make decisions about contributors/authors before submitting the manuscript for publication. The corresponding author/guarantor should be prepared to explain the presence and order of these individuals. It is not the role of editors to make authorship/contributorship decisions or to arbitrate conflicts related to authorship.

#### *II. A. 2. Contributors Listed in Acknowledgments*

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chairperson who provided only general support. Editors should ask corresponding authors to declare whether they had assistance with study design, data collection, data analysis, or manuscript preparation. If such assistance was available, the authors should disclose the identity of the individuals who provided this assistance and the entity that supported it in the published article. Financial and material support should also be acknowledged.

Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship may be listed under such headings as "clinical investigators" or "participating investigators," and their function or contribution should be described—for example, "served as scientific advisors," "critically reviewed the study proposal," "collected data," or "provided and cared for study patients." Because readers may infer their endorsement of the data and conclusions, these persons must give written permission to be acknowledged.

### II. B. Editorship

#### *II. B. 1. The Role of the Editor*

The editor of a journal is the person responsible for its entire content. Owners and editors of medical journals have a common endeavor—publication of a reliable, readable journal produced with due respect for the stated aims of the journal and for costs. Owners and editors, however, have different functions. Owners have the right to appoint and dismiss editors and to make important business decisions in which editors should be involved to the fullest extent possible. Editors must have full authority for determining the editorial content of the journal. The concept of editorial freedom should be resolutely defended by editors even to the extent of their placing their positions at stake. To secure this freedom in practice, the editor should have direct access to the highest level of ownership, not to a delegated manager.

Editors of medical journals should have a contract that clearly states his or her rights and duties, the general terms of the appointment, and the mechanisms for resolving conflict.

An independent editorial advisory board may be useful in helping the editor establish and maintain editorial policy.

#### *II. B. 2. Editorial Freedom*

The ICMJE adopts the World Association of Medical Editors' definition of editorial freedom. According to this definition, editorial freedom, or independence, is the concept that editors-in-chief have full authority over the editorial content of their journal and the timing of publication of that content. Journal owners should not interfere in the evaluation, selection, or editing of individual articles either directly or by creating an environment that strongly influences decisions. Editors should base decisions on the validity of the work and its importance to the journal's readers not on the commercial success of the journal. Editors should be free to express critical but responsible views about all aspects of medicine without fear of retribution, even if these views conflict with the commercial goals of the publisher. Editors and editors' organizations have the obligation to support the concept of editorial freedom and to draw major transgressions of such freedom to the attention of the international medical, academic, and lay communities.

### II. C. Peer Review

Unbiased, independent, critical assessment is an intrinsic part of all scholarly work, including the scientific

process. Peer review is the critical assessment of manuscripts submitted to journals by experts who are not part of the editorial staff. Peer review can therefore be viewed as an important extension of the scientific process. Although its actual value has been little studied and is widely debated (4), peer review helps editors decide which manuscripts are suitable for their journals and helps authors and editors to improve the quality of reporting. A peer-reviewed journal submits most of its published research articles for outside review. The number and kinds of manuscripts sent for review, the number of reviewers, the reviewing procedures, and the use made of the reviewers' opinions may vary. In the interests of transparency, each journal should publicly disclose its policies in its Instructions to Authors.

### II. D. Conflicts of Interest

Public trust in the peer-review process and the credibility of published articles depend in part on how well conflict of interest is handled during writing, peer review, and editorial decision making. Conflict of interest exists when an author (or the author's institution), reviewer, or editor has financial or personal relationships that inappropriately influence (bias) his or her actions (such relationships are also known as dual commitments, competing interests, or competing loyalties). These relationships vary from negligible to great potential for influencing judgment. Not all relationships represent true conflict of interest. On the other hand, the potential for conflict of interest can exist regardless of whether an individual believes that the relationship affects his or her scientific judgment. Financial relationships (such as employment, consultancies, stock ownership, honoraria, and paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself. However, conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion.

All participants in the peer-review and publication process must disclose all relationships that could be viewed as potential conflicts of interest. Disclosure of such relationships is also important in connection with editorials and review articles, because it can be more difficult to detect bias in these types of publications than in reports of original research. Editors may use information disclosed in conflict-of-interest and financial-interest statements as a basis for editorial decisions. Editors should publish this information if they believe it is important in judging the manuscript.

#### *II. D. 1. Potential Conflicts of Interest Related to Individual Authors' Commitments*

When authors submit a manuscript, whether an article or a letter, they are responsible for disclosing all financial and personal relationships that might bias their work. To prevent ambiguity, authors must state explicitly whether potential conflicts do or do not exist. Authors should do so in the manuscript on a conflict-of-interest notification page that follows the title page, providing additional detail, if necessary, in a cover letter that accompanies the manuscript. *(See Section IV. A. 3. Conflict-of-Interest Notification Page)*

Authors should identify Individuals who provide writing or other assistance and disclose the funding source for this assistance.

Investigators must disclose potential conflicts to study participants and should state in the manuscript whether they have done so.

Editors also need to decide whether to publish information disclosed by authors about potential conflicts. If doubt exists, it is best to err on the side of publication.

#### *II. D. 2. Potential Conflicts of Interest Related to Project Support*

Increasingly, individual studies receive funding from commercial firms, private foundations, and government. The conditions of this funding have the potential to bias and otherwise discredit the research.

Scientists have an ethical obligation to submit creditable research results for publication. Moreover, as the persons directly responsible for their work, researchers should not enter into agreements that interfere with their access to the data and their ability to analyze them independently, and to prepare and publish manuscripts. Authors should describe the role of the study sponsor, if any, in study design; collection, analysis, and interpretation of data; writing the report; and the decision to submit the report for publication. If the supporting source had no such involvement, the authors should so state. Biases potentially introduced when sponsors are directly involved in research are analogous to methodological biases. Some journals, therefore, choose to include information in the Methods section about the sponsor's involvement.

Editors may request that authors of a study funded by an agency with a proprietary or financial interest in the outcome sign a statement, such as "I had full access to all of the data in this study and I take complete responsibility for the integrity of the data and the accuracy of the data analysis." Editors should be encouraged to review copies of the protocol and/or contracts associated with project-specific studies before accepting such studies for publication. Editors may choose not to consider an article if a sponsor has asserted control over the authors' right to publish.

#### *II. D. 3. Potential Conflicts of Interest Related to Commitments of Editors, Journal Staff, or Reviewers*

Editors should avoid selecting external peer reviewers with obvious potential conflicts of interest–for example, those who work in the same department or institution as any of the authors. Authors often provide editors with the names of persons they feel should not be asked to review a manuscript because of potential, usually professional, con-

flicts of interest. When possible, authors should be asked to explain or justify their concerns; that information is important to editors in deciding whether to honor such requests.

Reviewers must disclose to editors any conflicts of interest that could bias their opinions of the manuscript, and they should recuse themselves from reviewing specific manuscripts if the potential for bias exists. As in the case of authors, silence on the part of reviewers concerning potential conflicts may mean either that conflicts exist and the reviewer has failed to disclose them or conflicts do not exist. Reviewers must therefore also be asked to state explicitly whether conflicts do or do not exist. Reviewers must not use knowledge of the work, before its publication, to further their own interests.

Editors who make final decisions about manuscripts must have no personal, professional, or financial involvement in any of the issues they might judge. Other members of the editorial staff, if they participate in editorial decisions, must provide editors with a current description of their financial interests (as they might relate to editorial judgments) and recuse themselves from any decisions in which a conflict of interest exists. Editorial staff must not use information gained through working with manuscripts for private gain. Editors should publish regular disclosure statements about potential conflicts of interests related to the commitments of journal staff.

## II. E. Privacy and Confidentiality

### *II. E. 1. Patients and Study Participants*

Patients have a right to privacy that should not be violated without informed consent. Identifying information, including names, initials, or hospital numbers, should not be published in written descriptions, photographs, or pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that an identifiable patient be shown the manuscript to be published. Authors should disclose to these patients whether any potential identifiable material might be available via the Internet as well as in print after publication. Patient consent should be written and archived either with the journal, the authors, or both, as dictated by local regulations or laws. Applicable laws vary from locale to locale, and journals should establish their own policies with legal guidance.

Nonessential identifying details should be omitted. Informed consent should be obtained if there is any doubt that anonymity can be maintained. For example, masking the eye region in photographs of patients is inadequate protection of anonymity. If identifying characteristics are altered to protect anonymity, such as in genetic pedigrees, authors should provide assurance, and editors should so note, that such alterations do not distort scientific meaning.

The requirement for informed consent should be included in the journal's Instructions for Authors. When informed consent has been obtained, it should be indicated in the published article.

### *II. E. 2. Authors and Reviewers*

Manuscripts must be reviewed with due respect for authors' confidentiality. In submitting their manuscripts for review, authors entrust editors with the results of their scientific work and creative effort, on which their reputation and career may depend. Authors' rights may be violated by disclosure of the confidential details during review of their manuscript. Reviewers also have rights to confidentiality, which must be respected by the editor. Confidentiality may have to be breached if dishonesty or fraud is alleged but otherwise must be honored.

Editors must not disclose information about manuscripts (including their receipt, content, status in the reviewing process, criticism by reviewers, or ultimate fate) to anyone other than the authors and reviewers. This includes requests to use the materials for legal proceedings.

Editors must make clear to their reviewers that manuscripts sent for review are privileged communications and are the private property of the authors. Therefore, reviewers and members of the editorial staff must respect the authors' rights by not publicly discussing the authors' work or appropriating their ideas before the manuscript is published. Reviewers must not be allowed to make copies of the manuscript for their files and must be prohibited from sharing it with others, except with the editor's permission. Reviewers should return or destroy copies of manuscripts after submitting reviews. Editors should not keep copies of rejected manuscripts.

Reviewer comments should not be published or otherwise publicized without permission of the reviewer, author, and editor.

Opinions differ on whether reviewers should remain anonymous. Authors should consult the Information for Authors of the journal to which they have chosen to submit a manuscript to determine whether reviews are anonymous. When comments are not signed, the reviewers' identity must not be revealed to the author or anyone else without the reviewers' permission.

Some journals publish reviewers' comments with the manuscript. No such procedure should be adopted without the consent of the authors and reviewers. However, reviewers' comments should be sent to other persons reviewing the same manuscript, which helps reviewers learn from the review process. Reviewers also may be notified of the editor's decision to accept or reject a manuscript.

## II. F. Protection of Human Subjects and Animals in Research

When reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of

1975, as revised in 2000 (5). If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. When reporting experiments on animals, authors should indicate whether the institutional and national guide for the care and use of laboratory animals was followed.

## III. Publishing and Editorial Issues Related to Publication in Biomedical Journals

### III. A. Obligation to Publish Negative Studies

Editors should consider seriously for publication any carefully done study of an important question, relevant to their readers, whether the results for the primary or any additional outcome are statistically significant. Failure to submit or publish findings because of lack of statistical significance is an important cause of publication bias.

### III. B. Corrections, Retractions, and "Expressions of Concern"

Editors must assume initially that authors are reporting work based on honest observations. Nevertheless, two types of difficulty may arise.

First, errors may be noted in published articles that require the publication of a correction or erratum on part of the work. The corrections should appear on a numbered page, be listed in the Table of Contents, include the complete original citation, and link to the original article and vice versa if online. It is conceivable that an error could be so serious as to vitiate the entire body of the work, but this is unlikely and should be addressed by editors and authors on an individual basis. Such an error should not be confused with inadequacies exposed by the emergence of new scientific information in the normal course of research. The latter requires no corrections or withdrawals.

The second type of difficulty is scientific fraud. If substantial doubts arise about the honesty or integrity of work, either submitted or published, it is the editor's responsibility to ensure that the question is appropriately pursued, usually by the authors' sponsoring institution. Ordinarily it is not the responsibility of the editor to conduct a full investigation or to make a determination; that responsibility lies with the institution where the work was done or with the funding agency. The editor should be promptly informed of the final decision, and if a fraudulent paper has been published, the journal must print a retraction. If this method of investigation does not result in a satisfactory conclusion, the editor may choose to conduct his or her own investigation. As an alternative to retraction, the editor may choose to publish an expression of concern about aspects of the conduct or integrity of the work.

The retraction or expression of concern, so labeled, should appear on a numbered page in a prominent section of the print journal as well as in the online version, be listed in the Table of Contents page, and include in its heading the title of the original article. It should not simply be a letter to the editor. Ideally, the first author of the retraction should be the same as that of the article, although under certain circumstances the editor may accept retractions by other responsible persons. The text of the retraction should explain why the article is being retracted and include a complete citation reference to that article.

The validity of previous work by the author of a fraudulent paper cannot be assumed. Editors may ask the author's institution to assure them of the validity of earlier work published in their journals or to retract it. If this is not done, editors may choose to publish an announcement expressing concern that the validity of previously published work is uncertain.

Editors who have questions related to editorial or scientific misconduct may find it useful to consult the excellent flow charts that the Committee on Publication Ethics (COPE) has developed (www.publicationethics.org.uk ). COPE, which was formed in 1997, is a forum in which editors of peer-reviewed journals can discuss issues related to the integrity of the scientific record; it supports and encourages editors to report, catalogue, and instigate investigations into ethical problems in the publication process. COPE's major objective is to provide a sounding board for editors struggling with how best to deal with possible breaches in research and publication ethics.

### III. C. Copyright

Many biomedical journals ask authors to transfer copyright to the journal. However, an increasing number of "open-access" journals do not require transfer of copyright. Editors should make their position on copyright transfer clear to authors and to others who might be interested in using editorial content from their journals. The copyright status of articles in a given journal can vary: Some content cannot be copyrighted (for example, articles written by employees of the U.S. and some other governments in the course of their work); editors may agree to waive copyright on others; and still others may be protected under serial rights (that is, use in publications other than journals, including electronic publications, is permitted).

### III. D. Overlapping Publications

#### *III. D. 1. Duplicate Submission*

Most biomedical journals will not consider manuscripts that are simultaneously being considered by other journals. Among the principal considerations that have led to this policy are: 1) the potential for disagreement when two (or more) journals claim the right to publish a manuscript that has been submitted simultaneously to more than one; and 2) the possibility that two or more journals will unknowingly and unnecessarily undertake the work of peer review, edit the same manuscript, and publish the same article.

However, editors of different journals may decide to

simultaneously or jointly publish an article if they believe that doing so would be in the best interest of public health.

#### *III. D. 2. Redundant Publication*

Redundant (or duplicate) publication is publication of a paper that overlaps substantially with one already published in print or electronic media.

Readers of primary source periodicals, whether print or electronic, deserve to be able to trust that what they are reading is original unless there is a clear statement that the author and editor are intentionally republishing an article. The bases of this position are international copyright laws, ethical conduct, and cost-effective use of resources. Duplicate publication of original research is particularly problematic, since it can result in inadvertent double counting or inappropriate weighting of the results of a single study, which distorts the available evidence.

Most journals do not wish to receive papers on work that has already been reported in large part in a published article or is contained in another paper that has been submitted or accepted for publication elsewhere, in print or in electronic media. This policy does not preclude the journal considering a paper that has been rejected by another journal, or a complete report that follows publication of a preliminary report, such as an abstract or poster displayed at a professional meeting. It also does not prevent journals from considering a paper that has been presented at a scientific meeting but was not published in full or that is being considered for publication in a proceedings or similar format. Brief press reports of scheduled meetings are not usually regarded as breaches of this rule, but they may be if additional data or copies of tables and figures amplify such reports. The ICMJE does not consider results posted in clinical trial registries as previous publication if the results are presented in the same, ICMJE-accepted registry in which initial registration of trial methods occurred and if the results are posted in the form of a brief structured abstract or table. The ICMJE also believes that the results registry should either cite full publications of the results when available or include a statement that indicates that the results have not yet been published in a peer-reviewed journal.

When submitting a paper, the author must always make a complete statement to the editor about all submissions and previous reports (including meeting presentations and posting of results in registries) that might be regarded as redundant or duplicate publication. The author must alert the editor if the manuscript includes subjects about which the authors have published a previous report or have submitted a related report to another publication. Any such report must be referred to and referenced in the new paper. Copies of such material should be included with the submitted manuscript to help the editor decide how to handle the matter.

If redundant or duplicate publication is attempted or occurs without such notification, authors should expect editorial action to be taken. At the least, prompt rejection of the submitted manuscript should be expected. If the editor was not aware of the violations and the article has already been published, then a notice of redundant or duplicate publication will probably be published with or without the author's explanation or approval.

Preliminary reporting to public media, governmental agencies, or manufacturers of scientific information described in a paper or a letter to the editor that has been accepted but not yet published violates the policies of many journals. Such reporting may be warranted when the paper or letter describes major therapeutic advances or public health hazards, such as serious adverse effects of drugs, vaccines, other biological products, or medicinal devices, or reportable diseases. This reporting should not jeopardize publication, but should be discussed with and agreed upon by the editor in advance.

#### *III. D. 3. Acceptable Secondary Publication*

Certain types of articles, such as guidelines produced by governmental agencies and professional organizations, may need to reach the widest possible audience. In such instances, editors sometimes deliberately publish material that is also being published in other journals, with the agreement of the authors and the editors of those journals. Secondary publication for various other reasons, in the same or another language, especially in other countries, is justifiable and can be beneficial provided that the following conditions are met.

1. The authors have received approval from the editors of both journals; the editor concerned with secondary publication must have a photocopy, reprint, or manuscript of the primary version.

2. The priority of the primary publication is respected by a publication interval of at least 1 week (unless specifically negotiated otherwise by both editors).

3. The paper for secondary publication is intended for a different group of readers; an abbreviated version could be sufficient.

4. The secondary version faithfully reflects the data and interpretations of the primary version.

5. The footnote on the title page of the secondary version informs readers, peers, and documenting agencies that the paper has been published in whole or in part and states the primary reference. A suitable footnote might read: "This article is based on a study first reported in the [title of journal, with full reference]."

Permission for such secondary publication should be free of charge.

6. The title of the secondary publication should indicate that it is a secondary publication (complete republication, abridged republication, complete translation, or abridged translation) of a primary publication. Of note, the NLM does not consider translations to be "republica-

tions" and does not cite or index translations when the original article was published in a journal that is indexed in MEDLINE.

7. Editors of journals that simultaneously publish in multiple languages should understand that NLM indexes the primary language version. When the full text of an article appears in more than one language in a journal issue (such as Canadian journals with the article in both English and French), both languages are indicated in the MEDLINE citation (for example, Mercer K. The relentless challenge in health care. Healthc Manage Forum. 2008 Summer;21(2):4-5. English, French. No abstract available. PMID:18795553.)

#### *III. D. 4. Competing Manuscripts Based on the Same Study*

Publication of manuscripts to air the disputes of coinvestigators may waste journal space and confuse readers. On the other hand, if editors knowingly publish a manuscript written by only some of a collaborating team, they could be denying the rest of the team their legitimate coauthorship rights and journal readers access to legitimate differences of opinion about the interpretation of a study.

Two kinds of competing submissions are considered: submissions by coworkers who disagree on the analysis and interpretation of their study, and submissions by coworkers who disagree on what the facts are and which data should be reported.

Setting aside the unresolved question of ownership of the data, the following general observations may help editors and others address such problems.

*III. D. 4. a. Differences in Analysis or Interpretation* If the dispute centers on the analysis or interpretation of data, the authors should submit a manuscript that clearly presents both versions. The difference of opinion should be explained in a cover letter. The normal process of peer and editorial review may help the authors to resolve their disagreement regarding analysis or interpretation.

If the dispute cannot be resolved and the study merits publication, both versions should be published. Options include publishing two papers on the same study, or a single paper with two analyses or interpretations. In such cases, it would be appropriate for the editor to publish a statement outlining the disagreement and the journal's involvement in attempts to resolve it.

*III. D. 4. b. Differences in Reported Methods or Results* If the dispute centers on differing opinions of what was actually done or observed during the study, the journal editor should refuse publication until the disagreement is resolved. Peer review cannot be expected to resolve such problems. If there are allegations of dishonesty or fraud, editors should inform the appropriate authorities; authors should be notified of an editor's intention to report a suspicion of research misconduct.

#### *III. D. 5. Competing Manuscripts Based on the Same Database*

Editors sometimes receive manuscripts from separate research groups that have analyzed the same data set (for example, from a public database). The manuscripts may differ in their analytic methods, conclusions, or both. Each manuscript should be considered separately. If interpretation of the data is very similar, it is reasonable but not mandatory for editors to give preference to the manuscript that was received first. However, editorial consideration of multiple submissions may be justified under these circumstances, and there may even be a good reason to publish more than one manuscript because different analytical approaches may be complementary and equally valid.

### III. E. Correspondence

The corresponding author/guarantor has primary responsibility for correspondence with the journal, but the ICMJE recommends that editors send a copy of any correspondence to all listed authors.

Biomedical journals should provide the readership with a mechanism for submitting comments, questions, or criticisms about published articles, as well as brief reports and commentary unrelated to previously published articles. This probably but not necessarily takes the form of a correspondence section or column. The authors of articles discussed in correspondence should be given an opportunity to respond, preferably in the same issue in which the original correspondence appears. Authors of correspondence should be asked to declare any competing or conflicting interests.

Published correspondence may be edited for length, grammatical correctness, and journal style. Alternatively, editors may choose to publish unedited correspondence, for example in rapid-response sections on the Internet. The journal should declare its editorial practices in this regard. Authors should approve editorial changes that alter the substance or tone of a letter or response. In all instances, editors must make an effort to screen out discourteous, inaccurate, or libelous statements and should not allow ad hominem arguments intended to discredit opinions or findings.

Although editors have the prerogative to reject correspondence that is irrelevant, uninteresting, or lacking cogency, they have a responsibility to allow a range of opinions to be expressed. The correspondence column should not be used merely to promote the journal's or the editors' point of view.

In the interests of fairness and to keep correspondence within manageable proportions, journals may want to set time limits for responding to published material and for debate on a given topic. Journals should also decide whether they would notify authors when correspondence bearing on their published work is going to appear in standard or rapid-response sections. Journals should also set policy with regard to the archiving of unedited correspon-

dence that appears online. These policies should be published both in print and electronic versions of the journal.

### III. F. Supplements, Theme Issues, and Special Series

Supplements are collections of papers that deal with related issues or topics, are published as a separate issue of the journal or as part of a regular issue, and are usually funded by sources other than the journal's publisher. Supplements can serve useful purposes: education, exchange of research information, ease of access to focused content, and improved cooperation between academic and corporate entities. Because funding sources can bias the content of supplements through the choice of topics and viewpoints, journals should consider adopting the following principles. These same principles apply to theme issues or special series that have external funding and/or guest editors.

1. The journal editor must take full responsibility for the policies, practices, and content of supplements, including complete control of the decision to publish all portions of the supplement. Editing by the funding organization should not be permitted.

2. The journal editor must retain the authority to send supplement manuscripts for external peer review and to reject manuscripts submitted for the supplement. These conditions should be made known to authors and external supplement editors before beginning editorial work on the supplement.

3. The journal editor must approve the appointment of any external editor of the supplement and take responsibility for the work of the external editor.

4. The sources of funding for the research, publication, and products of the funding source that are considered in the supplement should be clearly stated and prominently located in the supplement, preferably on each page. Whenever possible, supplements should be funded by more than one sponsor.

5. Advertising in supplements should follow the same policies as those of the rest of the journal.

6. Journal editors must enable readers to distinguish readily between ordinary editorial pages and supplement pages.

7. Journal editors and supplement editors must not accept personal favors or remuneration from sponsors of supplements.

8. Secondary publication in supplements (republication of papers published elsewhere) should be clearly identified by the citation of the original paper. Supplements should avoid redundant or duplicate publication. Supplements should not republish research results, but republication of guidelines or other material in the public interest might be appropriate.

9. The principles of authorship and disclosure of potential conflicts of interest discussed elsewhere in this document should be applied to supplements.

### III. G. Electronic Publishing

Most biomedical journals are now published in electronic as well as print versions, and some are published only in electronic form. Because electronic publishing (which includes the Internet) is the same as publishing in print, in the interests of clarity and consistency the recommendations of this document should be applied to electronically published medical and health information.

The nature of electronic publication requires some special considerations, both within and beyond this document. At a minimum, Web sites should indicate the following: names, appropriate credentials, affiliations, and relevant conflicts of interest of editors, authors, and contributors; documentation and attribution of references and sources for all content; information about copyright; disclosure of site ownership; and disclosure of sponsorship, advertising, and commercial funding.

Linking from one health or medical Internet site to another may be perceived as an implicit recommendation of the quality of the second site. Journals thus should exercise caution in linking to other sites; when users are linking to another site, it may be helpful to provide an explicit statement that they are leaving the journal's site. Links to other sites posted as a result of financial considerations should be clearly indicated as such. All dates of content posting and updating should be indicated. In electronic layout as in print, advertising and promotional messages should not be juxtaposed with editorial content, and commercial content should be clearly identified as such.

Electronic publication is in flux. Editors should develop, make available to authors, and implement policies on issues unique to electronic publishing. These issues include archiving, error correction, version control, choice of the electronic or print version of the journal as the journal of record, and publication of ancillary material.

Under no circumstances should a journal remove an article from its Web site or archive. If a correction or retraction becomes necessary, the explanation must be labeled appropriately and communicated as soon as possible on a citable page in a subsequent issue of the journal.

Preservation of electronic articles in a permanent archive is essential for the historical record. Access to the archive should be immediate and should be controlled by a third party, such as a library, instead of the publisher. Deposition in multiple archives is encouraged.

### III. H. Advertising

Most medical journals carry advertising, which generates income for their publishers, but advertising must not be allowed to influence editorial decisions. Journals should have formal, explicit, written policies for advertising in both print and electronic versions; Web site advertising policy should parallel that for the print version to the extent possible. Editors must have full and final authority for approving advertisements and enforcing advertising policy.

When possible, editors should make use of the judg-

ments of independent bodies for reviewing advertising. Readers should be able to distinguish readily between advertising and editorial material. The juxtaposition of editorial and advertising material on the same products or subjects should be avoided. Interleafing advertising pages within articles interrupts the flow of editorial content and should be discouraged. Advertising should not be sold on the condition that it will appear in the same issue as a particular article.

Journals should not be dominated by advertising, but editors should be careful about publishing advertisements from only one or two advertisers, as readers may perceive that these advertisers have influenced the editor.

Journals should not carry advertisements for products that have proved to be seriously harmful to health—for example, tobacco. Editors should ensure that existing regulatory or industry standards for advertisements specific to their country are enforced, or develop their own standards. The interests of organizations or agencies should not control classified and other nondisplay advertising, except where required by law. Finally, editors should consider all criticisms of advertisements for publication.

### III. I. Medical Journals and the General Media

The public's interest in news of medical research has led the popular media to compete vigorously for information about research. Researchers and institutions sometimes encourage reporting research in the nonmedical media before full publication in a scientific journal by holding a press conference or giving interviews.

The public is entitled to important medical information within a reasonable amount of time, and editors have a responsibility to facilitate the process. Biomedical journals are published primarily for their readers, but the general public has a legitimate interest in their content: An appropriate balance between these considerations should guide the journal's interaction with the media. Doctors in practice need to have reports available in full detail before they can advise their patients about the reports' conclusions. Moreover, media reports of scientific research before the work has been peer reviewed and fully vetted may lead to dissemination of inaccurate or premature conclusions.

An embargo system has been established in some countries to prevent publication of stories in the general media before publication of the original research in the journal. The embargo creates a "level playing field," which most reporters appreciate since it minimizes the pressure on them to publish stories which they have not had time to prepare carefully. Consistency in the timing of public release of biomedical information is also important in minimizing economic chaos, since some articles contain information that has great potential to influence financial markets. On the other hand, the embargo system has been challenged as being self-serving of journals' interests and an impediment to rapid dissemination of scientific information.

Editors may find the following recommendations useful as they seek to establish policies on these issues.

- Editors can foster the orderly transmission of medical information from researchers, through peer-reviewed journals, to the public. This can be accomplished by an agreement with authors that they will not publicize their work while their manuscript is under consideration or awaiting publication and an agreement with the media that they will not release stories before publication of the original research in the journal, in return for which the journal will cooperate with them in preparing accurate stories.
- Editors need to keep in mind that an embargo system works on the honor system; no formal enforcement or policing mechanism exists. The decision of a significant number of media outlets or biomedical journals not to respect the embargo system would lead to its rapid dissolution.
- Very little medical research has such clear and urgently important clinical implications for the public's health that the news must be released before full publication in a journal. However, if such exceptional circumstances occur, the appropriate authorities responsible for public health should decide whether to disseminate information to physicians and the media in advance and should be responsible for this decision. If the author and the appropriate authorities wish to have a manuscript considered by a particular journal, the editor should be consulted before any public release. If editors acknowledge the need for immediate release, they should waive their policies limiting prepublication publicity.
- Policies designed to limit prepublication publicity should not apply to accounts in the media of presentations at scientific meetings or to the abstracts from these meetings (see Redundant Publication). Researchers who present their work at a scientific meeting should feel free to discuss their presentations with reporters, but they should be discouraged from offering more detail about their study than was presented in the talk.
- When an article is soon to be published, editors should help the media prepare accurate reports by providing news releases, answering questions, supplying advance copies of the journal, or referring reporters to the appropriate experts. This assistance should be contingent on the media's cooperation in timing the release of a story to coincide with publication of the article.
- Editors, authors, and the media should apply the above-stated principles to material released early in electronic versions of journals.

### III. J. Obligation to Register Clinical Trials

The ICMJE believes that it is important to foster a comprehensive, publicly available database of clinical trials. The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical interven-

tion and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like.

The ICMJE member journals will require, as a condition of consideration for publication in their journals, registration in a public trials registry. The details of this policy are contained in a series of editorials (see Editorials, under Frequently Asked Questions). The ICMJE encourages editors of other biomedical journals to adopt similar policy.

The ICMJE does not advocate one particular registry, but its member journals will require authors to register their trial in a registry that meets several criteria. The registry must be accessible to the public at no charge. It must be open to all prospective registrants and managed by a not-for-profit organization. There must be a mechanism to ensure the validity of the registration data, and the registry should be electronically searchable. An acceptable registry must include at minimum the data elements listed in Table 1. Trial registration with missing fields or fields that contain uninformative terminology is inadequate.

It is important to note that the ICMJE requires registration of trial methodology but does not require registration of trial results; it recognizes the potential problems that could arise from the posting of research results that have not been subjected to an independent peer-review process. However, the ICMJE understands that the U.S. Food and Drug Administration Amendments Act of 2007 (FDAAA) does require researchers to register results. The ICMJE will not consider to be previous publication results posted in the same primary clinical trial registry as the initial registration if the results are posted in the tabular form dictated by the FDAAA. Researchers should be aware that editors of journals that follow the ICMJE recommendations may consider more detailed description of trial results and results published in registries other than the primary registry (in the case of FDAAA, ClinicalTrials.gov) to be prior publication. The ICMJE anticipates that the climate for results registration will change dramatically over coming years and the ICMJE may need to amend these recommendations as additional agencies institute other mandates related to results registration.

The ICMJE recommends that journals publish the trial registration number at the end of the abstract. The ICMJE also recommends that, whenever a registration number is available, authors list the registration number the first time they use a trial acronym to refer to either the trial they are reporting or to other trials that they mention in the manuscript.

## IV. Manuscript Preparation and Submission

### IV. A. Preparing a Manuscript for Submission to a Biomedical Journal

Editors and reviewers spend many hours reading manuscripts, and therefore appreciate receiving manuscripts that are easy to read and edit. Much of the information in a journal's Instructions to Authors is designed to accomplish that goal in ways that meet each journal's particular editorial needs. The following information provides guidance in preparing manuscripts for any journal.

#### *IV. A. 1. a. General Principles*

The text of observational and experimental articles is usually (but not necessarily) divided into the following sections: Introduction, Methods, Results, and Discussion. This so-called "IMRAD" structure is not an arbitrary publication format but rather a direct reflection of the process of scientific discovery. Long articles may need subheadings within some sections (especially Results and Discussion) to clarify their content. Other types of articles, such as case reports, reviews, and editorials, probably need to be formatted differently.

Electronic formats have created opportunities for adding details or whole sections, layering information, cross-linking or extracting portions of articles, and the like only in the electronic version. Authors need to work closely with editors in developing or using such new publication formats and should submit supplementary electronic material for peer review.

Double spacing all portions of the manuscript— including the title page, abstract, text, acknowledgments, references, individual tables, and legends—and generous margins make it possible for editors and reviewers to edit the text line by line and add comments and queries directly on the paper copy. If manuscripts are submitted electronically, the files should be double-spaced to facilitate printing for reviewing and editing.

Authors should number all of the pages of the manuscript consecutively, beginning with the title page, to facilitate the editorial process.

#### *IV. A. 1. b. Reporting Guidelines for Specific Study Designs*

Research reports frequently omit important information. Reporting guidelines (Table 2) have been developed for a number of study designs that some journals may ask authors to follow. Authors should consult the Information for Authors of the journal they have chosen.

The general requirements listed in the next section relate to reporting essential elements for all study designs. Authors are encouraged also to consult reporting guidelines relevant to their specific research design. For reports of randomized, controlled trials, authors should refer to the CONSORT statement. This guideline provides a set of recommendations comprising a list of items to report and a patient flow diagram.

#### *IV. A .2. Title Page*

The title page should have the following information:

1. Article title. Concise titles are easier to read than long, convoluted ones. Titles that are too short may, however, lack important information, such as study design

(which is particularly important in identifying randomized, controlled trials). Authors should include all information in the title that will make electronic retrieval of the article both sensitive and specific.

2. Authors' names and institutional affiliations. Some journals publish each author's highest academic degree(s), while others do not.

3. The name of the department(s) and institution(s) to which the work should be attributed.

4. Disclaimers, if any.

5. Contact information for corresponding authors. The name, mailing address, telephone and fax numbers, and e-mail address of the author responsible for correspondence about the manuscript (the "corresponding author;" this author may or may not be the "guarantor" for the integrity of the study). The corresponding author should indicate clearly whether his or her e-mail address can be published.

6. The name and address of the author to whom requests for reprints should be addressed or a statement that reprints are not available from the authors.

7. Source(s) of support in the form of grants, equipment, drugs, or all of these.

8. A running head. Some journals request a short running head or footline, usually no more than 40 characters (including letters and spaces) at the foot of the title page. Running heads are published in most journals, but are also sometimes used within the editorial office for filing and locating manuscripts.

9. Word counts. A word count for the text only (excluding abstract, acknowledgments, figure legends, and references) allows editors and reviewers to assess whether the information contained in the paper warrants the amount of space devoted to it, and whether the submitted manuscript fits within the journal's word limits. A separate word count for the Abstract is useful for the same reason.

10. The number of figures and tables. It is difficult for editorial staff and reviewers to determine whether the figures and tables that should have accompanied a manuscript were actually included unless the numbers of figures and tables are noted on the title page.

#### *IV. A. 3. Conflict-of-Interest Notification Page*

To prevent the information on potential conflicts of interest from being overlooked or misplaced, it needs to be part of the manuscript. However, it should also be included on a separate page or pages immediately following the title page. Individual journals may differ in where they include this information, and some journals do not send information on conflicts of interest to reviewers. (See *Section II. D. Conflicts of Interest.*)

#### *IV. A. 4. Abstract*

The abstract (requirements for length and format vary) should follow the title page. It should provide the context or background for the study and should state the study's purpose, basic procedures (selection of study subjects or laboratory animals, observational and analytical methods), main findings (giving specific effect sizes and their statistical significance, if possible), and principal conclusions. It should emphasize new and important aspects of the study or observations. Articles on clinical trials should contain abstracts that include the items that the CONSORT group has identified as essential (www.consort-statement.org/?=1190 ).

Because abstracts are the only substantive portion of the article indexed in many electronic databases, and the only portion many readers read, authors need to be careful that they accurately reflect the content of the article. Unfortunately, the information contained in many abstracts differs from that in the text (6). The format required for structured abstracts differs from journal to journal, and some journals use more than one format; authors need to prepare their abstracts in the format specified by the journal they have chosen.

The ICMJE recommends that journals publish the trial registration number at the end of the abstract. The ICMJE also recommends that, whenever a registration number is available, authors list that number the first time they use a trial acronym to refer to either the trial they are reporting or to other trials that they mention in the manuscript.

#### *IV. A. 5. Introduction*

Provide a context or background for the study (that is, the nature of the problem and its significance). State the specific purpose or research objective of, or hypothesis tested by, the study or observation; the research objective is often more sharply focused when stated as a question. Both the main and secondary objectives should be clear, and any prespecified subgroup analyses should be described. Provide only directly pertinent references, and do not include data or conclusions from the work being reported.

#### *IV. A. 6. Methods*

The Methods section should include only information that was available at the time the plan or protocol for the study was being written; all information obtained during the study belongs in the Results section.

*IV. A. 6. a. Selection and Description of Participants*
Describe your selection of the observational or experimental participants (patients or laboratory animals, including controls) clearly, including eligibility and exclusion criteria and a description of the source population. Because the relevance of such variables as age and sex to the object of research is not always clear, authors should explain their use when they are included in a study report–for example, authors should explain why only participants of certain ages were included or why women were excluded. The guiding principle should be clarity about how and why a study was done in a particular way. When authors use such

variables as race or ethnicity, they should define how they measured these variables and justify their relevance.

*IV. A. 6. b. Technical Information* Identify the methods, apparatus (give the manufacturer's name and address in parentheses), and procedures in sufficient detail to allow others to reproduce the results. Give references to established methods, including statistical methods (see below); provide references and brief descriptions for methods that have been published but are not well-known; describe new or substantially modified methods, give the reasons for using them, and evaluate their limitations. Identify precisely all drugs and chemicals used, including generic name(s), dose(s), and route(s) of administration.

Authors submitting review manuscripts should include a section describing the methods used for locating, selecting, extracting, and synthesizing data. These methods should also be summarized in the abstract.

*IV. A. 6. c. Statistics* Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results. When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Avoid relying solely on statistical hypothesis testing, such as *P* values, which fail to convey important information about effect size. References for the design of the study and statistical methods should be to standard works when possible (with pages stated). Define statistical terms, abbreviations, and most symbols. Specify the computer software used.

*IV. A. 7. Results* Present your results in logical sequence in the text, tables, and illustrations, giving the main or most important findings first. Do not repeat all the data in the tables or illustrations in the text; emphasize or summarize only the most important observations. Extra or supplementary materials and technical detail can be placed in an appendix where they will be accessible but will not interrupt the flow of the text, or they can be published solely in the electronic version of the journal.

When data are summarized in the Results section, give numeric results not only as derivatives (for example, percentages) but also as the absolute numbers from which the derivatives were calculated, and specify the statistical methods used to analyze them. Restrict tables and figures to those needed to explain the argument of the paper and to assess supporting data. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables. Avoid nontechnical uses of technical terms in statistics, such as "random" (which implies a randomizing device), "normal," "significant," "correlations," and "sample."

Where scientifically appropriate, analyses of the data by such variables as age and sex should be included.

#### *IV. A. 8. Discussion*

Emphasize the new and important aspects of the study and the conclusions that follow from them. Do not repeat in detail data or other information given in the Introduction or the Results section. For experimental studies, it is useful to begin the discussion by summarizing briefly the main findings, then explore possible mechanisms or explanations for these findings, compare and contrast the results with other relevant studies, state the limitations of the study, and explore the implications of the findings for future research and for clinical practice.

Link the conclusions with the goals of the study but avoid unqualified statements and conclusions not adequately supported by the data. In particular, avoid making statements on economic benefits and costs unless the manuscript includes the appropriate economic data and analyses. Avoid claiming priority or alluding to work that has not been completed. State new hypotheses when warranted, but label them clearly as such.

#### *IV. A. 9. References*

*IV. A. 9. a. General Considerations Related to References* Although references to review articles can be an efficient way to guide readers to a body of literature, review articles do not always reflect original work accurately. Readers should therefore be provided with direct references to original research sources whenever possible. On the other hand, extensive lists of references to original work on a topic can use excessive space on the printed page. Small numbers of references to key original papers often serve as well as more exhaustive lists, particularly since references can now be added to the electronic version of published papers, and since electronic literature searching allows readers to retrieve published literature efficiently.

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using the following search term, where pt in square brackets stands for publication type: Retracted publication [pt] in PubMed.

*IV. A. 9. b. Reference Style and Format* The Uniform Requirements style for references is based largely on an American National Standards Institute style adapted by the NLM for its databases. Authors should consult NLM's Citing Medicine for information on its recommended formats for a variety of reference types.

References should be numbered consecutively in the order in which they are first mentioned in the text. Identify references in text, tables, and legends by Arabic numerals in parentheses. References cited only in tables or figure legends should be numbered in accordance with the sequence established by the first identification in the text of the particular table or figure. The titles of journals should be abbreviated according to the style used in the list of Journals Indexed for MEDLINE, posted by the NLM on the Library's Web site. Journals vary on whether they ask authors to cite electronic references within parentheses in the text or in numbered references following the text. Authors should consult with the journal to which they plan to submit their work.

#### *IV. A. 10. Tables*

Tables capture information concisely and display it efficiently; they also provide information at any desired level of detail and precision. Including data in tables rather than text frequently makes it possible to reduce the length of the text.

Type or print each table with double spacing on a separate sheet of paper. Number tables consecutively in the order of their first citation in the text and supply a brief title for each. Do not use internal horizontal or vertical lines. Give each column a short or an abbreviated heading. Authors should place explanatory matter in footnotes, not in the heading. Explain all nonstandard abbreviations in footnotes, and use the following symbols, in sequence:

*, †, ‡, §, ||, ¶, **, ††, ‡‡

Identify statistical measures of variations, such as standard deviation and standard error of the mean.

Be sure that each table is cited in the text.

If you use data from another published or unpublished source, obtain permission and acknowledge that source fully.

Additional tables containing backup data too extensive to publish in print may be appropriate for publication in the electronic version of the journal, deposited with an archival service, or made available to readers directly by the authors. An appropriate statement should be added to the text to inform readers that this additional information is available and where it is located. Submit such tables for consideration with the paper so that they will be available to the peer reviewers.

#### *IV. A. 11. Illustrations (Figures)*

Figures should be either professionally drawn and photographed, or submitted as photographic-quality digital prints. In addition to requiring a version of the figures suitable for printing, some journals now ask authors for electronic files of figures in a format (for example, JPEG or GIF) that will produce high-quality images in the Web version of the journal; authors should review the images of such files on a computer screen before submitting them to be sure they meet their own quality standards.

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Photographs of potentially identifiable people must be accompanied by written permission to use the photograph.

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For illustrations in color, ascertain whether the journal requires color negatives, positive transparencies, or color prints. Accompanying drawings marked to indicate the region to be reproduced might be useful to the editor. Some journals publish illustrations in color only if the author pays the additional cost.

Authors should consult the journal about requirements for figures submitted in electronic formats.

#### *IV. A. 12. Legends for Illustrations (Figures)*

Type or print out legends for illustrations using double spacing, starting on a separate page, with Arabic numerals corresponding to the illustrations. When symbols, arrows, numbers, or letters are used to identify parts of the illustrations, identify and explain each one clearly in the legend. Explain the internal scale and identify the method of staining in photomicrographs.

#### *IV. A. 13. Units of Measurement*

Measurements of length, height, weight, and volume should be reported in metric units (meter, kilogram, or liter) or their decimal multiples.

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#### *IV. A. 14. Abbreviations and Symbols*

Use only standard abbreviations; use of nonstandard abbreviations can be confusing to readers. Avoid abbreviations in the title of the manuscript. The spelled-out abbreviation followed by the abbreviation in parenthesis should be used on first mention unless the abbreviation is a standard unit of measurement.

### IV. B. Sending the Manuscript to the Journal

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- The name, address, and telephone number of the corresponding author, who is responsible for communicating with the other authors about revisions and final approval of the proofs, if that information is not included in the manuscript itself.

The letter should give any additional information that may be helpful to the editor, such as the type or format of article in the particular journal that the manuscript represents. If the manuscript has been submitted previously to another journal, it is helpful to include the previous editor's and reviewers' comments with the submitted manuscript, along with the authors' responses to those comments. Editors encourage authors to submit these previous communications. Doing so may expedite the review process.

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Letters of permission to reproduce previously published material, use previously published illustrations, report information about identifiable persons, or to acknowledge people for their contributions must accompany the manuscript.

## V. References

### A. References Cited in This Document

1. Davidoff F, for the CSE Task Force on Authorship. Who's the author? Problems with biomedical authorship, and some possible solutions. Science Editor. 2000; 23:111-9.

2. Yank V, Rennie D. Disclosure of researcher contributions: a study of original research articles in *The Lancet*. Ann Intern Med. 1999;130:661-70.

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4. Godlee F, Jefferson T. Peer Review in Health Sciences. London: BMJ Books; 1999.

5. World Medical Association Declaration of Helsinki. Ethical principles for medical research involving human subjects. JAMA. 2000;284:3043-5.

6. Pitkin RM, Branagan MA, Burmeister LF. Accuracy of data in abstracts of published research articles. JAMA. 1999;281:1110-1.

### B. Other Sources of Information Related to Biomedical Journals

World Association of Medical Editors (WAME)
Council of Science Editors (CSE)
European Association of Science Editors (EASE)
Cochrane Collaboration
Committee on Publication Ethics (COPE)

## VI. About the International Committee of Medical Journal Editors

The ICMJE is a group of general medical journal editors whose participants meet annually and fund their work on the Uniform Requirements for Manuscripts. The ICMJE invites comments on this document and suggestions for agenda items.

## VII. Authors of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals

The ICMJE participating journals and organizations and their representatives who approved the revised Uniform Requirements for Manuscripts in September 2008 include *Annals of Internal Medicine, British Medical Journal, Canadian Medical Association Journal, Croatian Medical Journal, Journal of the American Medical Association, Nederlands Tijdschrift voor Geneeskunde (The Dutch Medical Journal), New England Journal of Medicine, New Zealand Medical Journal, The Lancet, The Medical Journal of Australia, Tidsskrift for Den Norske Lægeforening (The Journal of the Norwegian Medical Association), Ugeskrift for Laeger (Journal of the Danish Medical Association)*, the U.S. NLM, and the World Association of Medical Editors.

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OREGON HEALTH & SCIENCE UNIVERSITY
SCHOOL OF NURSING

# DNP Clinical Inquiry Project Report & DNP Portfolio Approval

Student Name: Janie Huff-Slankard

Degree: Doctor of Nursing Practice

Title of Study:

A Nutrition Assessment of Children with Neuromuscular Impairments Undergoing Spinal Fusion and Instrumentation and Frequencies of Postoperative Infections

APPROVED:

Committee Chair: MAGGIE SHAW, CNM, PHD (name and credentials) Signature: Maggie Shaw, CNM, PhD

Committee Member: Catherine Burns PhD, CPNP (name and credentials) Signature: Catherine Burns PhD CPNP

Committee Member: _____ (name and credentials) Signature: _____

Michael R. Bleich, PhD, RN, MPH, FAAN
Dean, School of Nursing Signature: Michael R. Bleich, PhD, RN

Date: 5/26/09

*Submit completed original form to the Graduate Program office.*

Revised 4/2009