

## Study Protocol Outline

Title: Newborn Cranial Somatic Dysfunction – An Observational Study

Investigators: Erica Waddington, DO, Karen Snider, DO, Michael Lockwood, DO

### 1) SPECIFIC AIMS

#### a) STUDY OBJECTIVES

- i) The purpose of this study is to quantify the presence of somatic dysfunction in the newborn. We will assess any relationships between the identified somatic dysfunction and the mother's and newborn's medical history.

#### b) HYPOTHESIS

- i) The major hypotheses to be tested during this research project as follows:  
Newborns commonly have somatic dysfunction which can be palpated between 6 and 72 hours of age.

#### c) INTENDED ACCOMPLISHMENTS OF THE RESEARCH PROJECT

- i) This research project intends to demonstrate that newborns have somatic dysfunction. We will also observe whether the dysfunction are correlated with the mother's and newborn's medical history.

### 2) BACKGROUND AND SIGNIFICANCE

Osteopathic physicians have been interested in the area of newborn somatic dysfunction since the writings of A.T. Still. In 1966 Dr. Viola Frymann published a paper on the presence of somatic dysfunction in 1,250 infants. In this paper she outlined anatomic and physiologic considerations of cranial and sacral somatic dysfunction within the context of newborn symptomatology<sup>1</sup>. In 1993 Dr. Jane Carreiro evaluated 1600 newborns for cranial somatic dysfunction. Her research identified a “period of re-organization” in a newborn where there is no palpable cranial strain pattern<sup>2</sup>. Following these papers, there have been no publications investigating the presence of somatic dysfunctions in newborns.

### 3) PRELIMINARY STUDIES

None

### 4) RESEARCH DESIGN AND METHODS

- a) EXPERIMENTAL DESIGN: Observational study
- b) SUBJECT SELECTION CRITERIA

- i) INCLUSION CRITERIA: Infants born at Northeast Regional Medical Center that is greater than 6 but less than 72 hours old.
  - ii) EXCLUSION CRITERIA: Exclusion criteria include birth outside NRMC, critically ill infants, open spina bifida, cleft lip and cleft palate. Additionally, children who are wards of the state will also be excluded.
  - iii) SUBJECT RECRUITMENT AND SAMPLE SIZE JUSTIFICATION: Subjects will be recruited by the newborn nursing staff or the physician caring for either the newborn or the mother in the hospital.
  - iv) GROUPS: All newborns are in the observational study group.
- c) VARIABLES:

100 newborns will be assessed for somatic dysfunction of the head, cervical, lumbar, and sacral areas, these findings will be compared to the findings of a standard newborn physical exam and the newborn and maternal history. The findings to be collected and compared are as follows:

Physical Examination of head –

- Circumference in cm
- Degree of molding – mild, moderate, severe
- Presence/absence of overriding/separation of sutures
- Size of fontanelles– small, normal, large
- Presence of abrasions, edema, or contusions
- Caput succedaneum
- Cephalohematoma
- Presence of facial paralysis
- Symmetry of the eyes, mouth and nares.
- Occiput: condylar compression of right, left, bilateral
- Sphenobasilar strain pattern: flexion, extension, torsion, side-bending rotation, vertical/lateral strain, compression
- Temporal bone restriction: right, left, bilateral
- Cranial quadrate motion restriction. Each quadrant will be given a score using the following parameters: 0 = no restriction, 1 = 1 restriction, 2 = 2 restrictions, 3 = 3 or more restrictions. The motion in each quadrant will be a sum of all the movements of those bones in that quadrant.
  - right frontal
  - left frontal
  - left occipital
  - right occipital

Lumbar spine – restricted motion of lumbar segments

Examination of the sacrum for asymmetry and restricted motion of sacral segments

- S1 – asymmetry and motion restriction
- Sacral base anterior – right, left, bilateral
- Sacral base posterior – right, left, bilateral
- Posterior sacral base is diagnosed by relative posterior positioning of sacral base and resistance to anterior pressure
- S2 – motion restriction - – right, left, bilateral
- S3 – motion restriction - – right, left, bilateral

Review of Medical Record: After the physical exam the infants' prenatal history will be obtained from the maternal history, prenatal record, and delivery record. These records will be reviewed for maternal age, parity, gravity, anesthesia during labor, and estimated gestational age. Birth history and initial newborn assessments will be reviewed for labor augmentation (if any), duration of labor, length of 2<sup>nd</sup> stage of labor, presence of instrumental delivery (vacuum extraction, forceps delivery)(if any), multiple birth (if any), presentation at delivery (vertex – what position (LOA, ROA, etc), breech, transverse, compound presentation).

From the initial newborn assessment the following information will be recorded:

- Weight in kg, length in cm
- Degree of molding – mild, moderate, and severe
- Presence of overriding/separation of sutures
- Presence of abrasions, edema, or contusions
  - Caput succedaneum
  - Cephalohematoma

4) PROJECTED TIMELINE: The study will take place from August 1, 2011 through July 31, 2012.

5) HUMAN SUBJECTS

a) PROTECTION OF HUMAN SUBJECTS

- i) Human Subject Involvement And Characteristics: Newborns who are greater than 6 but less than 72 hours old. We will also be reviewing the maternal and newborn medical record.
- ii) Sources of Material: Hospital charts
- iii) Recruitment and Informed Consent: Patients will be recruited via advertising, nurse recruitment, Obstetrician recruitment, Pediatrician recruitment and Family Medicine Physician recruitment. Informed consent will be obtained from a parent for the palpatory portion of the newborn exam along with the review of the

newborn record. Informed consent will be obtained from the mother for review of her medical record.

- iv) Potential Risks: There are no physical, social, economic or psychological risks identified. The legal risk identified is leakage of personal health information.
- v) Protection Against Risks: We will keep the health information obtained under lock and key in the OMM Department at ATSU-KCOM.
- vi) Risks Versus Benefits And Importance Of Knowledge To Be Gained: This study would benefit the field of Osteopathic Medicine by further defining the incidence of somatic dysfunction found in the newborn and correlating these findings with their medical history. The information gathered from the maternal record may identify factors prenatal and during the birth process that lead to the presence or absence of somatic dysfunction in the newborn.

#### 6) LITERATURE CITED

1. Frymann V. Relation of Disturbances of Craniosacral Mechanism to Symptomatology of the Newborn: Study of 1,250 Infants. *J Am Osteopath Assoc.* 1966; 65: 1059-1075.
2. Carreiro J. Labor, delivery and birth. In: Carreiro, J. *An Osteopathic Approach to Children*, 2<sup>nd</sup> ed. Edinburgh: Churchill Livingstone Elsevier, 2009: 131-145.