The Utilization of Ultrasound to Diagnose Pediatric Elbow Fractures:

Evaluation of Cost Savings, Radiation Exposure, and Patient Satisfaction

Principal Investigator: Dr. Jason Malone
Last Updated: March 26, 2025

RESEARCH PLAN

I. SPECIFIC AIMS

1. **To evaluate whether the use of PoCUS for elbow trauma evaluation results in less radiation exposure, less cost of treatment and shorter length of stay in Emergency Room (ER) than use of radiography.** We will use point-of-care ultrasonography (PoCUS) to screen for isolated elbow fractures presented to the ER. We will compare cost of treatment both for patients and health care system and length of stay in both the groups.
2. **To evaluate whether the use PoCUS alleviates the discomfort to pediatric patients and increases satisfaction of the families as compared to the use of radiography.** Family satisfaction survey and patient pain survey will act as direct measures of family satisfaction. We will use length of stay and cost of treatment as indirect measures of satisfaction. We will compare amount of comfort and satisfaction with and without the use of PoCUS to evaluate the overall patient comfortability and patient satisfaction.

Hypothesis: We hypothesize that the use of PoCUS will reduce time of emergency department length of stay, radiation exposure, pain or discomfort and cost, and will increase patient's and family satisfaction.

II. BACKGROUND AND SIGNIFICANCE

Elbow injuries are one of the most common pediatric injuries presented to the ER, and it accounts for about 15% of fractures in pediatric patients [1]. Although elbow radiographs including standard anteroposterior and lateral views are routinely used for diagnosis of elbow fractures, there are some difficulties in detecting pediatric elbow fractures due to non-ossifying epiphysis and often non-exact two plane radiographs taken in uncooperative children [2-8].

In patients with inadequate diagnosis due to difficulty in interpretation of radiographs, there is a need for other diagnostic modalities such as computer tomographic (CT) scan. Although CT scans are rarely used to diagnose an elbow fracture, these are used more to better define a fraction that is hard to evaluate with plain radiographs alone such as a fracture that involves the joint in multiple locations. X-ray radiation from the effective dose to obtain standard elbow 3-4 views has exposure of 0.001 mSv [9].

There are growing evidence of the use of PoCUS in diagnosing pediatric fractures [6-8, 10-13]. Ultrasonography (US) is a radiation-free diagnostic modality with sensitivity comparable to that of radiographs and CT scans [12-16]. It is a real-time, bedside assessment tool which is easily accessible, fast, and reliable, that could be performed immediately [8, 10-15, 17]. US can be performed by ER physicians accurately and reliably with limited, focused training [6, 18]. PoCUS not only could detect an elevated posterior fat pad as an indirect sign of intracapsular fractures, but it could also detect cortical irregularities and disruptions which directly indicate fractures [6-8]. In fact, PoCUS is even more sensitive than radiography in detecting an elevated posterior fat pad [6, 19, 20]. Any intra-articular/capsular fracture could lead to lipohaemarthrosis – a collection of blood and lipid inside the joint and in the posterior fat pad – which can be easily identified with PoCUS [6, 15].

Nemours Clinical Research Review Committee (CRRC)
807 Children's Way
Jacksonville, FL 32207
Phone: 407-650-7157 Fax: 904-697-3948

Previous studies of PoCUS on elbow joint injuries have demonstrated high sensitivities of 97–100% and negative predictive values of 0.95–1 for diagnosis of elbow fractures in children [6, 7, 13].

To our knowledge, limited evaluation has been performed regarding, its economic value [8], its reduced radiation feature [13], and its simplicity and quickness in fracture diagnosis [21]. Unfortunately, to our knowledge there is no evaluation performed on patient satisfaction and ease of discomfort after PoCUS use. The purpose of this study is to thoroughly investigate the cost savings, the radiation reduction, the pain reduction and patient satisfaction in using the PoCUS for screening pediatric elbow fractures.

III. RESEARCH DESIGN AND METHODS INCLUDING STATISTICAL ANALYSIS

This is a prospective interventional study. Our patient cohort will be pediatric patients who were treated at Nemours Children's Hospital Florida, ER with elbow trauma and pain. We will include patients aged 0 upto 18 years with isolated elbow pain after trauma. We will exclude patients with polytrauma (more than one injury), deformity of the arm including the elbow, pain in any other location than the elbow including other parts of the same limb (wrist, forearm, shoulder, hand) or other limbs, puckering of the skin, obvious fracture, open wound/suspected open fracture, pain and swelling without trauma, concerns for tumor or infection, suspected nursemaid's elbow. We will include up to 225 patients and collect primary variable (Ultrasound measurement of elbow posterior fat pad) and secondary variables such as patient's age, sex, type of trauma, x-ray type obtained at ED visit, X-ray findings at ED visit, x-ray findings at 1 week follow up, missed diagnosis from x-ray or ultrasound, change of plan at follow up, patient's length of stay in the ED, family satisfaction survey, patient pain survey, and the amount of radiation exposure for each radiograph. These variables will help answer the aims of study.

We will divide patients into two groups randomized: **Group A**: 100 patients will be treated with the current standard of care (**Chart 1**) along with obtaining consent by research assistant, radiographs of elbow joint at ER/Orthopaedic provider, pain survey from elbow x-ray and satisfaction with care survey, and collection of secondary variables. **Group B**: 125 patients will undergo PoCUS evaluation (**Chart 2**). Patients who present with elbow pain will be identified in the ED by the triage nurse, treating nurse, or ED provider as possible study participants. Dr. Malone, Dr. Patel, or the research

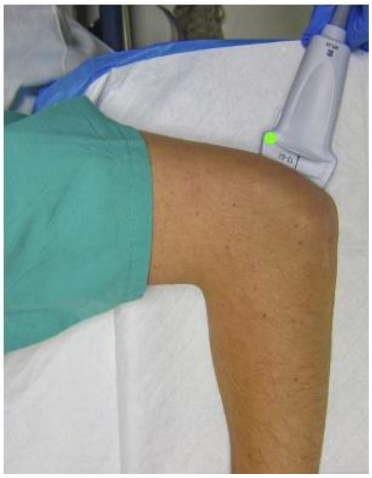

Figure 1. Elbow positioning for PoCUS evaluation

Nemours Clinical Research Review Committee (CRRC)
807 Children's Way
Jacksonville, FL 32207
Phone: 407-650-7157 Fax: 904-697-3948

assistant will approach the potential participants for enrollment into the study. They will explain the study to the potential participants, and answer any of their questions or doubts. If the potential participants agree to participate and give their consents (assents), the consents will be signed by the parents. Children and adolescent assents will be taken after the parental permission. We expect about 80% of patients approached agree to participate in the study.

Randomization plan:
We will create 225 research packets. The packets will be labeled 1 to 225. The packets will be in a blank envelope except for the label. The packet will contain a paper stating "Ultrasound" or "X-ray". The patient will then be enrolled into that group. The consent will then be placed into the envelope and given to Dr Malone, Dr Patel or the research assistant. These signed consents will be scanned documented in a password protected Nemours computer. The patient's name will be added to the patient list and given the assigned number for HIPPA protection. The original consent will be stored in Dr Malone's office in a locked filing cabinet. The two groups are of different sizes as we expect about 25% cross over on the ultrasound group to the x-ray group. Loosing 25 patients from the ultrasound group will still allow 100 patients in the ultrasound group. The power of the study will still be strong enough to show a significant difference between the two groups.

Ultrasound will be obtained by ER provider (see attached ultrasound technique). Positive Ultrasound will get standard elbow 4-view radiographs. For positive radiographs (x-rays), ER provider will obtain Orthopaedic consult. Patients with negative radiographs and resolved pain will be discharged home

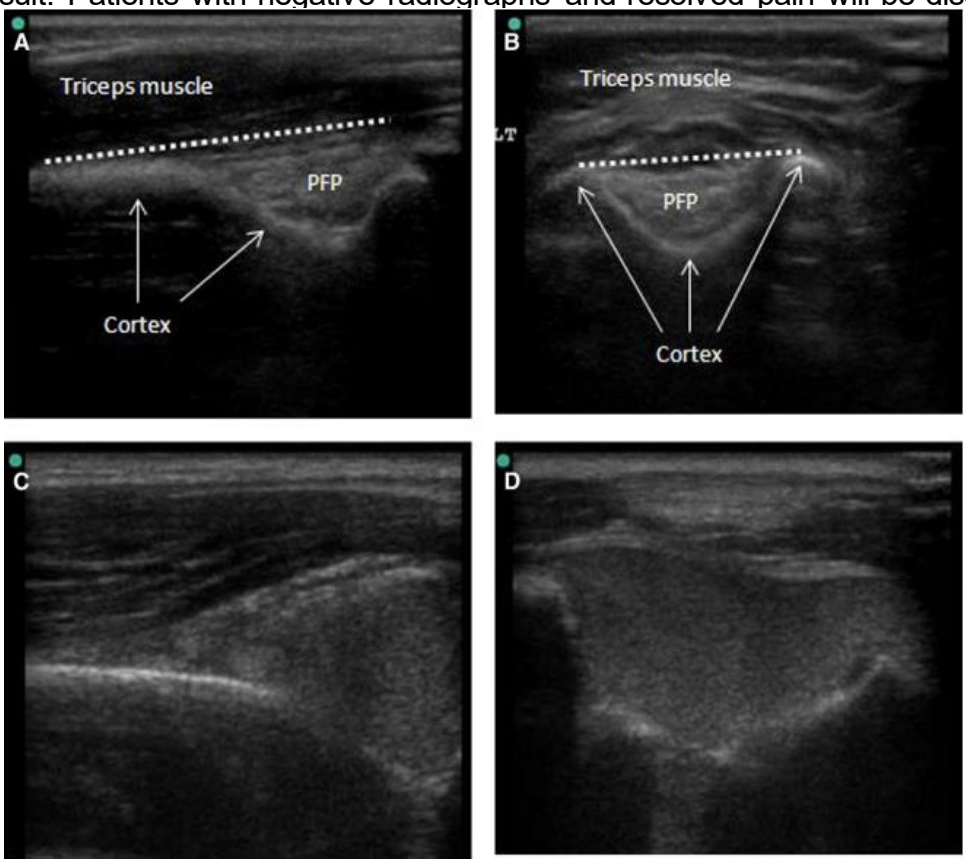

Figure 2. Measurement of posterior fat pad

Nemours Clinical Research Review Committee (CRRC)
807 Children's Way
Jacksonville, FL 32207
Phone: 407-650-7157 Fax: 904-697-3948

without further treatment. They will be contacted in one (1) week from injury by the research assistant to evaluate for continued pain. Patients with continued pain at follow up call will be instructed to follow up with orthopaedics at Nemours. If there is no pain one week after, the participation in the study will be completed and the participants will not be contacted further. The research assistant will continue to follow the patient until a diagnosis is obtained or pain is fully resolved. Patients with a negative Ultrasound but continued pain will be placed into posterior long arm cast. They will have the option to have x-rays in the ED department. They will then follow up with Orthopaedic clinic in one (1) week. Standard 4-view radiographs will be obtained in Orthopaedic clinic at one (1) week follow up to evaluate for missed fracture which will be treated by Orthopaedic provider per Orthopaedic protocol. For ease of understanding of the workflow see Chart 1 and 2. For safety and comfortability, each patient in **Group B** will also be given an option of doing x-ray in the initial diagnosis step.

For PoCUS evaluation, a Butterfly iQ+ ultrasound system (Butterfly Network, Inc. Burlington, MA) will be used and focused ultrasonography will be performed by the pediatric emergency physician, Dr. Amit Patel, who has thorough training to perform PoCUS. With the patient's elbow flexed to 90 degrees, the gel on the ultrasonographic probe will be placed over the posterior aspect of the distal humerus to obtain images, with the probe in contact with the gel but not the underlying skin (**Figure 1**). Both longitudinal and transverse views of the elbow will be obtained and still pictures and video clips in each orientation will be recorded along with measurements of elbow posterior fat pad (**Figure 2**). Ultrasonographic imaging of the contralateral normal, uninjured side will be performed as needed for comparison.

Data collection and statistical analysis:

Data entry will be accomplished by using Microsoft Excel 2003 (Microsoft, Redmond, Washington). To prevent data loss or data corruption, we will save data as a new file with a new date when new data is entered.

Various data points will be collected as described below:

1. Radiation exposure to a 3-4 view elbow x-ray is about 0.001 mSv. This estimate is well described in the article by Mettler and et al. and is widely cited [9]. We will be comparing the radiation exposure to Group A versus Group B. Group A will have standard radiographs. All patients in group A will be exposed to 0.001 mSV. Group B will be evaluated by PoCUS. If no fracture or signs of fracture are identified, they will have no exposure to x-rays. If a fracture is identified with PoCUS, they will have routine elbow radiographs. This subgroup of Group B will have x-rays to evaluate the fracture. We hypothesize that most patients in Group B will not need x-rays thus no exposing patients to radiation. Currently all patients in the ED with elbow pain have elbow x-rays taken and are exposed to radiation. Please see the current workflow (**Chart 1**) along with the research proposal workflow (**Chart 2**) to see that x-rays will be eliminated in the ED visit. The current workflow for patients with elbow pain but negative x-rays is for the patient to follow up in the orthopaedic department in one (1) week for repeat x-rays. There is about a 1-2% false negative rate for x-rays. This workflow will continue for negative PoCUS in patients with continued elbow pain. The mean radiation dose between the two groups will be compared using the T-test.

Nemours Clinical Research Review Committee (CRRC)
807 Children's Way
Jacksonville, FL 32207
Phone: 407-650-7157 Fax: 904-697-3948

2. Cost of PoCUS: There will be no charge for the PoCUS exam. The PoCUS is a medical tool such as an otoscope, blood pressure cuff, reflex hammer, or stethoscope. They are used

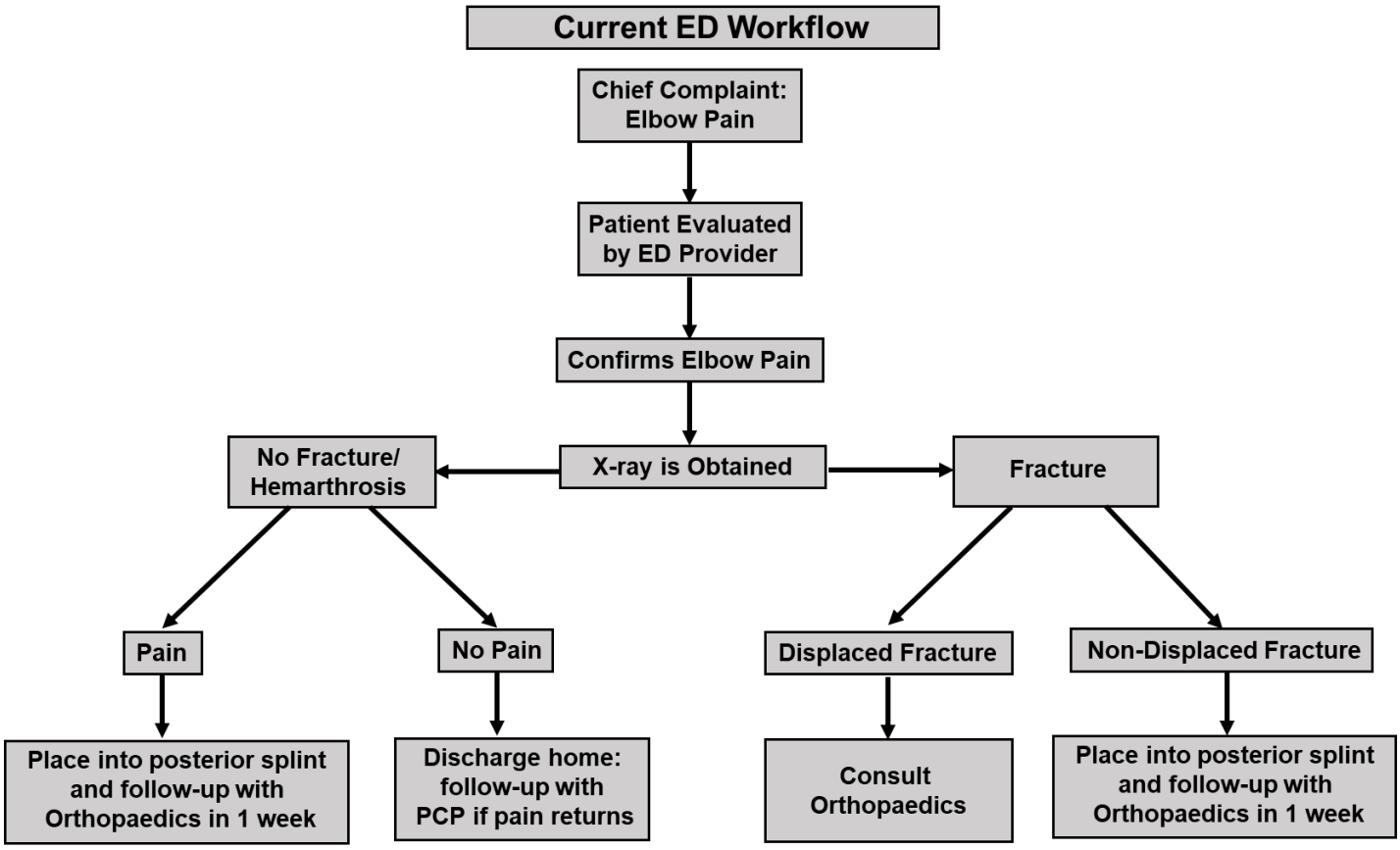

Chart 1: Workflow of Standard of Care in Emergency Department

during the physical exam to help diagnoses medical problems but are not billed to the patient. Eliminating x-rays in the emergency department should save families $300.

3. Cost of treatment: The total cost of treatment will be based from hospital charges. The cost will be based off of the cash charge for the 3-4 view x-rays of the elbow. This information is already available online. It would be impossible to base from reimbursement as each insurance provider reimburses at a different rate. The mean cost of radiographs between the two groups will be compared using the T-test.

4. The length of stay: The length of stay in ED is calculated and recorded in EPIC. The time starts when the patient is registered in the ED. All patients are registered and triaged when they enter the ED lobby. The time in ED in Epic is then stopped when the patient is discharged by the nurse. This data is readily available through epic. The mean length of stay in minutes will be compared between the two groups with T-test.

Nemours Clinical Research Review Committee (CRRC)
807 Children's Way
Jacksonville, FL 32207
Phone: 407-650-7157 Fax: 904-697-3948

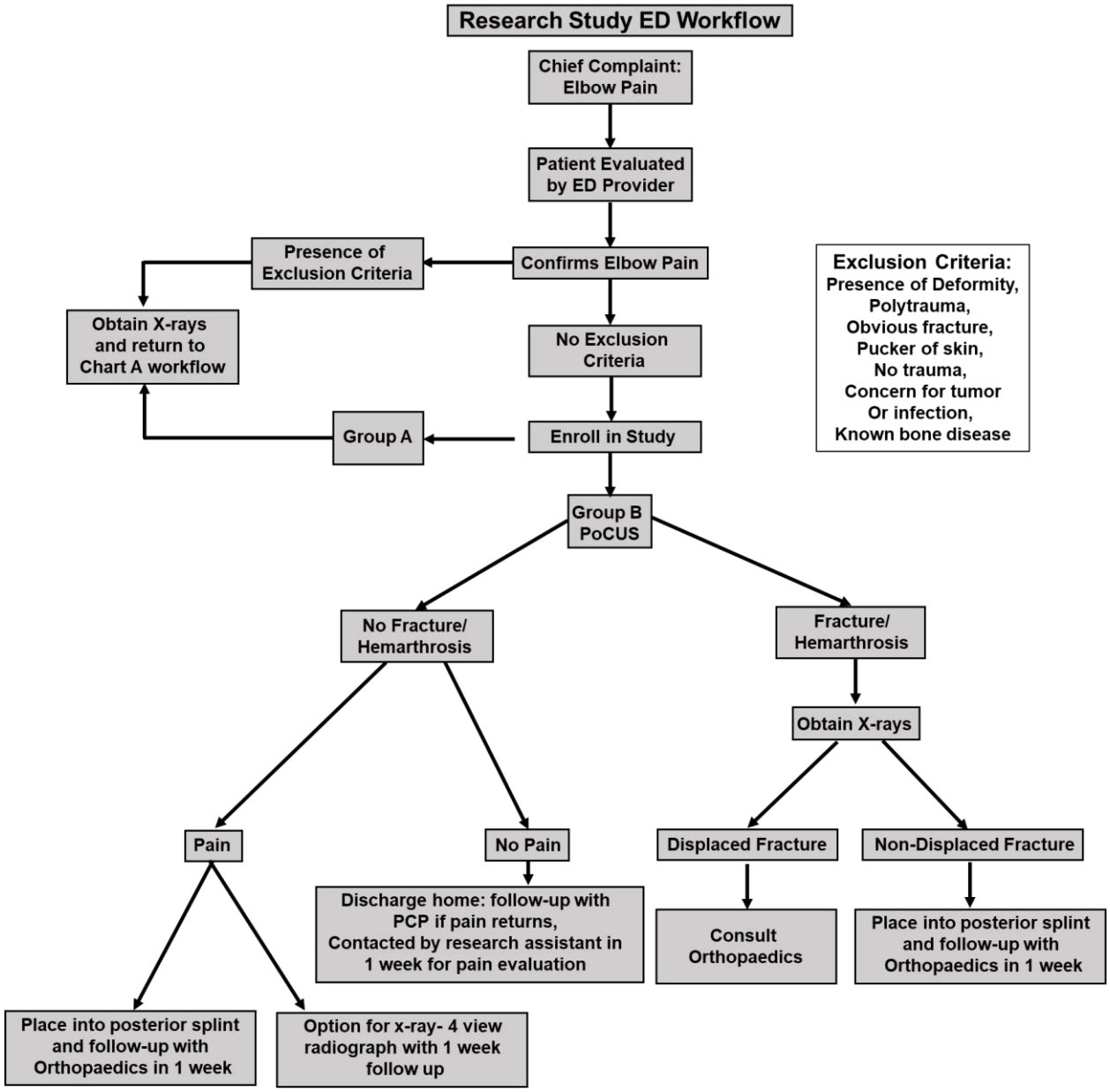

Chart 2: Workflow of Research arm in Emergency Department

5. The patient satisfaction scores: These will be collected by the research assistant using the Emergency Department Consumer Assessment of Healthcare Providers and Systems Survey (ED CAHPS Survey) Version 1.0. The survey will be scored based on the recommended guidelines from CAHPS. Please see the attached scoring guidelines for further information. The mean score will be compared between the two groups with the T-Test.

6. Patient pain scores: These scores for patients younger than 3 years will be collected by using The FLACC score (for face, legs, activity, cry, consolability). The pain scores will be collected using the Wong-Baker FACES Pain Rating Scale for patient ages equal to and greater than 3 years old. The mean score between the two groups will be compared with the T test.

Nemours Clinical Research Review Committee (CRRC)
807 Children's Way
Jacksonville, FL 32207
Phone: 407-650-7157 Fax: 904-697-3948

We will use the biostatistics services that Mayo clinic generously provide to Nemours. The biostatisticians have provided descriptive statistics plan for categorical data and mean, standard deviation and T scores for continuous variables:
Continuous variables will be summarized with the sample median and interquartile range (or sample mean and standard deviation), while categorical and ordinal variables will be reported with the number and percentage. Unadjusted comparisons of patient characteristics between the X-ray and US groups will be made using a two-sample t-test (normally distributed continuous variables), Wilcoxon rank sum test (ordinal and non-normal continuous variables), and for categorical variables either a chi-squared or Fisher's exact test will be used. Patient outcome variables will be compared between the two study groups using unadjusted and multivariable regression models that are appropriate for the nature of the outcome of interest. Normally distributed continuous outcomes will be compared between the two intervention groups using linear regression models. Binary outcomes will be compared between the two intervention groups using logistic regression models. Multivariable regression models will be adjusted for any potential confounding baseline variable. P-values less than 0.05 will be considered as statistically significant. Statistical analyses will be performed using R Statistical Software (version 4.2.2; R Foundation for Statistical Computing, Vienna, Austria).
No identifiers will be shared with our Mayo biostatistician.
In case of potential difficulties and challenges, we will use the strategies mentioned below.

1. Unavailability of ER physician: In case of unavailability of Dr.Patel, he will personally train other ER physicians, orthopaedic PAs, ER fellows, ER residents or Orthopaedic residents to perform elbow US and evaluate their competency by going through the images with them prior to his leave [22, 23]. The article by Larrivee et al. shows residents can learn PoCUS in a half day training environment and maintain the new skills and knowledge for at least 6 months [24]. Alternatively, we will utilize Sports Medicine providers at NCH to perform elbow US.
2. In a case where PoCUS stops functioning, or breaks, a second PoCUS will be available as a backup, as in the beginning of the study two PoCUS systems will be purchased.

IV. FACILITIES REQUIRED/PHYSICAL LOCATION OF STUDY *(Specify the facilities to be used for the conduct of the proposed research and extent of availability to the project. List the most important equipment items required for this project, noting the location and availability of each)*

Facilities/Physical location of Study: **Emergency Department, Nemours Children's Hospital, Orlando, Florida**

Equipment to be used for imaging: **Point-of-Care ultrasound machine (Butterfly iQ+ Lightning (human)**

V. REFERENCES

1. Crowther, M., *Elbow pain in pediatrics.* Curr Rev Musculoskelet Med, 2009. **2**(2): p. 83-7.
2. Kraus, R., L.D. Berthold, and L. von Laer, *[Efficient imaging of elbow injuries in children and adolescents].* Klin Padiatr, 2007. **219**(5): p. 282-7.
3. Skaggs, D. and J. Pershad, *Pediatric elbow trauma.* Pediatr Emerg Care, 1997. **13**(6): p. 425-34.
4. Fick, D.S. and T.A. Lyons, *Interpreting elbow radiographs in children.* Am Fam Physician, 1997. **55**(4): p. 1278-82.

5. Bachman D, S.S., *Musculoskeletal trauma*. Textbook of pediatric emergency medicine, ed. L.S. Fleisher GR. 2010: Lippincott Williams & Wilkins.
6. Rabiner, J.E., et al., *Accuracy of point-of-care ultrasonography for diagnosis of elbow fractures in children.* Ann Emerg Med, 2013. **61**(1): p. 9-17.
7. Eckert, K., et al., *Accuracy of the sonographic fat pad sign for primary screening of pediatric elbow fractures: a preliminary study.* J Med Ultrason (2001), 2014. **41**(4): p. 473-80.
8. Burnier, M., et al., *Diagnostic value of ultrasonography in elbow trauma in children: Prospective study of 34 cases.* Orthop Traumatol Surg Res, 2016. **102**(7): p. 839-843.
9. Mettler, F.A., et al., *Effective Doses in Radiology and Diagnostic Nuclear Medicine: A Catalog.* Radiology, 2008. **248**(1): p. 254-263.
10. Lee, S.H. and S.J. Yun, *Diagnostic Performance of Ultrasonography for Detection of Pediatric Elbow Fracture: A Meta-analysis.* Ann Emerg Med, 2019. **74**(4): p. 493-502.
11. Avcı, M., et al., *The comparison of bedside point-of-care ultrasound and computed tomography in elbow injuries.* Am J Emerg Med, 2016. **34**(11): p. 2186-2190.
12. Tsou, P.Y., et al., *Diagnostic accuracy of ultrasound for upper extremity fractures in children: A systematic review and meta-analysis.* Am J Emerg Med, 2021. **44**: p. 383-394.
13. Tokarski, J., J.R. Avner, and J.E. Rabiner, *Reduction of Radiography with Point-of-Care Elbow Ultrasonography for Elbow Trauma in Children.* J Pediatr, 2018. **198**: p. 214-219.e2.
14. Weinberg, E.R., M.G. Tunik, and J.W. Tsung, *Accuracy of clinician-performed point-of-care ultrasound for the diagnosis of fractures in children and young adults.* Injury, 2010. **41**(8): p. 862-8.
15. Zuazo, I., et al., *Acute elbow trauma in children: role of ultrasonography.* Pediatr Radiol, 2008. **38**(9): p. 982-8.
16. Azizkhani, R., Z. Hosseini Yazdi, and F. Heydari, *Diagnostic accuracy of ultrasonography for diagnosis of elbow fractures in children.* European Journal of Trauma and Emergency Surgery, 2022. **48**(5): p. 3777-3784.
17. Heydari, F., et al., *The use of ultrasonography for the confirmation of pulled elbow treatment.* Journal of Emergency Practice and Trauma, 2018. **4**(1): p. 24-28.
18. Patel, D.D., S.M. Blumberg, and E.F. Crain, *The utility of bedside ultrasonography in identifying fractures and guiding fracture reduction in children.* Pediatr Emerg Care, 2009. **25**(4): p. 221-25.
19. Tsung, J.W. and M. Blaivas, *Rapid screening for the posterior fat pad sign in suspected pediatric elbow fractures using point-of-care ultrasound: a "FAST exam" for the traumatized elbow.* Critical Ultrasound Journal, 2010. **1**(3): p. 111-116.
20. Chaar-Alvarez, F.M., et al., *Bedside ultrasound diagnosis of nonangulated distal forearm fractures in the pediatric emergency department.* Pediatr Emerg Care, 2011. **27**(11): p. 1027-32.
21. Varga, M., et al., *Standardized sonographic examination of pediatric elbow injuries is an effective screening method and improves diagnostic efficiency.* Injury, 2021. **52 Suppl 1**: p. S25-s30.
22. Mackenzie, D.C., et al., *Carotid Flow Time Test Performance for the Detection of Dehydration in Children With Diarrhea.* J Ultrasound Med, 2018. **37**(6): p. 1397-1402.
23. Modi, P., et al., *Accuracy of Inferior Vena Cava Ultrasound for Predicting Dehydration in Children with Acute Diarrhea in Resource-Limited Settings.* PLoS One, 2016. **11**(1): p. e0146859.
24. Larrivée, S., et al., *Orthopaedic residents demonstrate retention of point of care ultrasound knowledge after a brief educational session: a quasi experimental study.* BMC Medical Education, 2019. **19**(1): p. 474.

VI. TIMELINE FOR COMPLETION

April 1st, 2023 – March 31st, 2025

Nemours Clinical Research Review Committee (CRRC)
807 Children's Way
Jacksonville, FL 32207
Phone: 407-650-7157 Fax: 904-697-3948

1. Building redcaps project/survey will take less than one (1) month.
2. Our estimate of enrollment is based on the number of treated patients each year in our hospital. Our data shows that for only supracondylar fracture of humerus underwent some type of surgical treatment in recent years were about 100 patients. This number for radial neck facture underwent surgical treatment was about 20. Because elbow fractures in pediatric concludes several other fractures such as lateral and medial condyle fractures and olecranon fractures, we are going to have enough patients to enrolled in the study in 18-month time.
3. For upto 100 patients, we will provide the current standard care and obtain consent. Then patients will undergo an elbow radiograph and finally we will collect pain survey from the radiograph and satisfaction with the care survey. This will be finished in first 8 month of the study.
4. For upto 125 patients, we will do PoCUS evaluation. Positive Ultrasound will get standard elbow 4-view radiographs. For positive radiographs (x-rays), ER provider will obtain Orthopaedic consult. For negative radiographs and resolved pain, patients will be discharged home without further treatment. They will be contacted in one (1) week from injury by the research assistant to evaluate for continued pain. Patients with continued pain at follow up call will be instructed to follow up with orthopaedics at Nemours. If there is no pain one week after, the participation in the study will be completed and the participants will not be contacted further. All participants will complete steps 1-4in 7 months.
5. Data will be entered in redcap after completion of each study.
6. Statistical analysis should take 1 month with professional statistical assistance.
7. We will have one (1) month to prepare and submit a paper to the Journal of Osteopathic Medicine (JOM).