Standard Operating Procedures for CORTICES Registry - NAT Femur Fracture Data Entry

When entering your patient data, you will be asked to enter a new or existing Record ID. Please use your 2-digit Unique Site Number (shown below) for your site's data.

SITE #	SITE	SITE #	SITE
20	Boston Children's	30	Le Bonheur Children's
21	Carolinas Medical Center	31	Lurie Children's
22	Children's Atlanta	32	Nationwide Children's
23	Children's Colorado	33	Rady Children's
24	Children's Dallas	34	Seattle Children's
25	Children's LA USC	35	St. Louis Children's
26	Children's Philadelphia	36	Texas Children's
27	Cincinnati Children's	37	Vanderbilt Children's
28	CS Mott Children's (Michigan)	38	UCSF
29	Gillette Children's		

To generate your REDCap Record IDs, please use the following format (below), where 'S' is the 2-digit site code and 'P' is the 3-digit record ID. The IDs should be sequentially recorded.

$$\underline{S}\,\underline{S} - \underline{P}\,\underline{P}\,\underline{P}$$

2-digit Unique **Site** Number

3-digit Sequential **Patient** ID Number

For example, BCH's first patient would have a REDCap ID of "20-001". BCH's twentieth patient would have a REDCap ID of '20-020'. It is crucial that sites use the correct site ID to avoid duplicate REDCap IDs.

*Note: If you were a site involved with testing this REDCap and inputted training data (**BCH, Cincinnati Children's, CS Mott Children's, Texas Children's**), please review all fields for your test patients as the REDCap was changed. You may keep the same Record ID for the test patient, but the data must be re-validated.

Patient Search

Patients diagnosed with diaphyseal femur fracture between **1/1/2017 and 6/30/2020** who were 36 months old or younger at time of presentation. Listed below are ICD-10 codes that can be used to search for all patients with a diaphyseal femur fracture.

- Please conduct an additional data search with ICD-10 code S72.90XA, S72.91XA, and S72.92XA: Unspecified femur fracture also highlighted below
- Sites will need to manually determine if any diaphyseal femur fractures are present in this query.
- Only add the femur fracture to the REDCap if it is a diaphyseal femur fracture. All other fractures should not be included.

| ICD-10 Codes Search Query		
S72.90XA	Unspecified fracture of unspecified femur, initial encounter for closed fracture	
S72.91XA	Unspecified fracture of unspecified femur, initial encounter for closed fracture	
S72.92XA	Unspecified fracture of unspecified femur, initial encounter for closed fracture	
S72.301A	Unspecified fracture of shaft of right femur, initial encounter for closed fracture	
S72.302A	Unspecified fracture of shaft of left femur, initial encounter for closed fracture	
S72.309A	Unspecified fracture of shaft of unspecified femur, initial encounter for closed fracture	
S72.321A	Displaced transverse fracture of shaft of right femur, initial encounter for closed fracture	
S72.322A	Displaced transverse fracture of shaft of left femur, initial encounter for closed fracture	
S72.323A	Displaced transverse fracture of shaft of unspecified femur, initial encounter for closed fracture	
S72.331A	Displaced oblique fracture of shaft of right femur, initial encounter for closed fracture	
S72.332A	Displaced oblique fracture of shaft of left femur, initial encounter for closed fracture	
S72.333A	Displaced oblique fracture of shaft of unspecified femur, initial encounter for closed fracture	
S72.341A	Displaced spiral fracture of shaft of right femur, initial encounter for closed fracture	
S72.342A	Displaced spiral fracture of shaft of left femur, initial encounter for closed fracture	
S72.343A	Displaced spiral fracture of shaft of unspecified femur, initial encounter for closed fracture	
S72.351A	Displaced comminuted fracture of shaft of right femur, initial encounter for closed fracture	
S72.352A	Displaced comminuted fracture of shaft of left femur, initial encounter for closed fracture	
S72.353A	Displaced comminuted fracture of shaft of unspecified femur, initial encounter for closed fracture	
S72.361A	Displaced segmental fracture of shaft of right femur, initial encounter for closed fracture	
S72.362A	Displaced segmental fracture of shaft of left femur, initial encounter for closed fracture	
S72.363A	Displaced segmental fracture of shaft of unspecified femur, initial encounter for closed fracture	
S72.391A	Other fracture of shaft of right femur, initial encounter for closed fracture	
S72.392A	Other fracture of shaft of left femur, initial encounter for closed fracture	

<u>Study-Specific Definitions</u>

A **positive NAT or non-accidental trauma workup** includes any one of the following:
1. child at least temporarily removed from caregiver
2. ICD code (T74.12 XA)
3. SW/CAP concern for NAT with...
   - referral to government agency or
   - referral for ongoing social work follow-up or
   - supervised or prohibited contact

Non-accidental trauma or NAT may also be referred to as child abuse in the medical record.

Diaphyseal Femur Fracture: please see the below photo for identification of the diaphysis and which fractures should be included
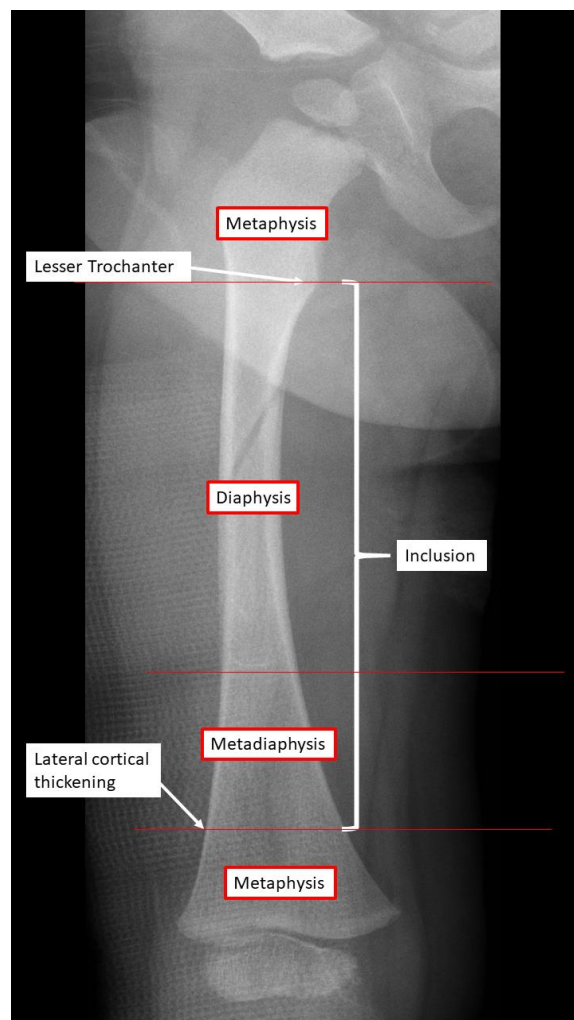
Transverse fracture - fracture line runs perpendicular to the bone axis

Spiral fracture - fracture line that wraps around the bone; there may be two superimposed fracture lines and a fracture corner; see below for an example – red asterisks indicate fracture corners

Oblique fracture - fracture line is at an angle from the transverse plane; single fracture line
Segmental fracture – at least 2 fracture lines isolate a segment of bone
Displaced fracture: "angulation in any plane >10 degrees and/or >2mm cortical displacement on any radiographic view"

Form Completion Technique

All data is to be entered directly into REDCap from the medical records, all femur fractures need to be inputted into REDCap for the timeline even if they are not NAT positive.

When entering data, please follow the rules below:

1. Mark REDCap page status for each form as appropriate:
   a. **Incomplete (RED):** Data not fully entered
   b. **Complete (GREEN):** Data is fully entered

2. Use correct missing codes (no fields/questions should be blank)
   a. **-999** = missing/not recorded
      i. Fields expecting dates (MM/DD/YYYY) will not accept -999. In instances where a date needs to be documented as missing/not recorded, please enter a comment by clicking on the small comment icon at the bottom left corner of the field. Enter -999 and click on 'Comment' to save.

<u>Eligibility - REDCap</u>

The inclusion and exclusion criteria for the study are as follows:

Inclusion:
- Presented with diaphyseal femur fracture between 1/1/2017 and 6/30/2020
- Age 0 to 36 months at date of injury presentation
- Presented at or transferred to a CORTICES-participating institution

Exclusion:
- Diaphyseal femur fracture sustained via a motor vehicle accident or during the delivery/birthing process
- Metaphyseal corner fractures and pathologic fractures as the index fracture
- Known history of osteogenesis imperfecta at time of injury

If any of the inclusion criteria are not met or if any of the exclusion criteria are met, the patient is not eligible for further data collection. Answer "**No**" to the final question on this instrument and do not proceed. Otherwise, answer "**Yes**" and proceed to Data instrument.

<u>Data - REDCap</u>

Demographics

Patient's date of birth
- Enter the patient's date of birth in the MM/DD/YYYY format

Patient's date of presentation to CORTICES institution
- Enter in the MM/DD/YYYY format

Age (months) at date of presentation
- Calculated field – will display the age of the patient at the date of presentation after the date of birth and date of presentation have been entered

Pre-injury ambulatory status
- Indicate whether patient was Not walking independently or Walking independently. If, after reviewing ALL NOTES IN THE CHART, you cannot determine if the child was walking prior to injury, select "Unable to determine from chart review"

Patient Sex
- Indicate whether patient is Male or Female

Race
- Indicate the race of the patient
  - If "Other", please specify in the open text field

Hispanic or Latino
- Indicate if patient is Hispanic or Latino

Insurance type
- Indicate patient's insurance type.

Neighborhood Atlas ADI Score
- Go to https://www.neighborhoodatlas.medicine.wisc.edu/mapping. Enter state and change ADI Score to National Percentiles. Enter patient's full home address and record **NATIONAL** Percentile ADI Score only.
  - If the patient's home address at the time of injury is known (sometimes specified in Discharge Paperwork), use that information. Otherwise, use the location on file for the patient.

Chronic Illness
- Indicate if patient has chronic illness.
  - If "Yes," please mark all that apply
    - If "Other" chronic illness, please specify in the open text field

Developmental disability
- Indicate if patient has developmental disability
  - If "Yes," please mark all that apply
    - If "Other," please specify in the open text field

Injury Characteristics

Known date of injury
- Indicate if date of injury is known
  - If "Yes," enter date of injury in the MM/DD/YYYY format
  - Length of time between injury and presentation is a calculated field that will be displayed if date of birth and date of injury are entered

Number of visits to ED for ANY injury prior to femur fracture presentation
- Indicate number of prior visits to ED for injury. Specify injury type at each visit as needed

Worked up for NAT at prior ED visit?
- Indicate if NAT evaluation occurred at prior ED visit. If the result of the workup was positive for NAT, indicate if follow-up notes are available. If yes, briefly describe the outcome.

Location of presentation for current femur fracture
- Indicate if patient was transferred to CORTICES institution or presented first to a CORTICES institution's Emergency Department or orthopedic clinic

Type of provider the patient was **FIRST** seen by at CORTICES institution
- Indicate provider type. APP is Advanced Practice Provider, which includes nurse practitioners and physician assistants.

Reported mechanism of injury
- Select the reported mechanism of injury using the below criteria

Low energy fall	Fall from less than the height of the person (includes standing falls)
High energy fall	Fall from greater than the height of the person
Conflicting stories	Caregivers' stories don't align with each other and/or conflict with the type of injury presented
Other	Please specify
Unknown to family	
Missing/not recorded	

Fracture type
- Indicate if fracture type is unilateral (impacting only 1 side) or bilateral (impacting both sides)

Unilateral Fracture type (if applicable)
  - Select the fracture type using the below criteria

Transverse	Fracture line runs perpendicular to the bone axis
Spiral	Fracture line wraps around the bone; there may be 2 superimposed fracture lines and a fracture corner
Oblique	Fracture line is at an angle from the transverse plane; single fracture line
Segmental	At least 2 fracture lines isolate a segment of bone
Other	Please specify

Bilateral Fracture type (if applicable)

- o Select the fracture type using the above criteria. If left and right fractures are the same type, please select 1 choice ONLY. If left and right fractures are different types, select the 2 that apply.

Fracture displaced?

- Indicate if the unilateral fracture or any of the bilateral fractures were displaced based on following definition: "angulation in any plane >10 degrees and/or >2mm cortical displacement on any radiographic view"

Treatment modality

- Indicate treatment modality. If applicable, include spica casting location and description. If other, please specify.

Abuse Workup

C0. Was any form of NAT evaluation initiated?

- Indicate if NAT evaluation was initiated, even if it was not completed or no abuse was uncovered. This will look differently across institutions, but it may include a social work consultation, child abuse team consultation and/or additional testing outside of that typical for isolated femur fracture.

If you answered "no" to the previous question, the next question is: Did the provider document consideration of NAT?

- o Indicate if consideration of non-accidental trauma or potential for child abuse was documented in provider notes, regardless of whether an evaluation was initiated.

If you answered "yes" to the previous question, the next question is: Did the provider determine that the injury was more likely to be accidental?

- ▪ Indicate if provider documented that the injury was likely accidental, not NAT.

If you answered "yes" to question C0, the following questions will open.

Was blood work ordered in the NAT workup?

- Indicate if blood work was ordered

If yes, then the form will sequentially ask if a CBC (Complete Blood Count), PT/PTT/INR (Prothrombin time/Partial thromboplastin time), Amylase, Lipase, Chem 14 (includes Glucose, Calcium, Sodium, Potassium, Bicarbonate, Chloride, Blood urea nitrogen or BUN, Creatinine, Albumin, Total protein, Alkaline phosphatase or ALP, Alanine aminotransferase or ALT, Aspartate aminotransferase or AST, Bilirubin), Urinalysis with RBC, and Urinalysis with tox screen

- o First, indicate if each blood work was done. Indicate "Yes" if any of the values were obtained. For example, we would indicate "Yes" for Chem 14 even if only a Creatinine test was ordered.
- o Indicate if the results were normal or abnormal.
- o Check all of the components that were abnormal and specify their values.

Skeletal Survey

- Indicate if a skeletal survey was done. If "Yes," indicate if additional fractures were observed and check the other fractures identified.

Advanced spine imaging

- Indicate if advanced spine imaging was completed. If "Yes," indicate if the results were normal or abnormal

Abdominal imaging

- Indicate if abdominal imaging was completed. If "Yes," indicate if the results were normal or abnormal

Head CT or MRI

- Indicate if a head CT/MRI was completed. If "Yes," indicate if the results were normal or abnormal

Ophthalmology consult for retinal exam
- Indicate if an ophthalmology consult for retinal exam was completed. If "Yes," indicate if the results were normal or abnormal

Social worker consulted
- Indicate if social worker was consulted

Trauma team consulted
- Indicate if trauma team was consulted

Child Abuse Team consulted
- Indicate if your institution's child abuse team was consulted

  If Social worker, Trauma team, and/or Child Abuse team were consulted, indicate none if nothing further was done. Indicate if Child Protective Services (CPS) was contacted, if CPS has plans to follow up with the patient, and/or if another action was taken. If "Other," was selected, please specify.

Any follow up test recommended
- Indicate "Yes" or "No"
  - If "Yes," select which follow up tests were recommended. If "Other," please specify
  - Indicate if recommended FU (follow up) tests were completed
    - If "Yes," indicate if the testing resulted in a new diagnosis that explains the fracture other than NAT.
      - If "Yes," indicate the new diagnosis. If "Other," please specify.

NAT Diagnosis

NAT diagnosed as a result of this visit for femur fracture based on at least one of the study definitions of NAT (see Study-Specific Definitions above)
- Indicate "Yes" or "No"
  - If "Yes," indicate the suspected abuser or mark "Unknown." If "Other," please specify.

Were there any subsequent evaluations for NAT?
- Indicate if patient was evaluated for NAT at visits following this one