



PREDICTING SEVERE PNEUMONIA IN THE EMERGENCY DEPARTMENT

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Dear PERN pneumonia collaborators,

We are making great progress for the first two months of enrollment at many sites! Thank you for all of your hard work. We are now up to 52 sites that are “regulatory ready” with ethics and data sharing agreements in place - these sites have been granted access to the study database and most have started to enroll children in the study. For those remaining sites that have not yet completed regulatory requirements (submitted ethics approval letter to PERN@cchmc.org and obtaining a data sharing agreement if required by your institution), PLEASE continue to work with our team to get these approvals as soon as possible. We would like all sites up and running by August-September 2019.

We are currently under our enrollment goal. Our team has discussed this and suggest the following to help meet enrollment goals: (1) you can enroll as many patients during a shift as you are able, there is no maximum; (2) you can enroll during pre-specified shifts when you are not working clinically if this is easier; (3) while we can only accommodate 2 site investigators per site on manuscripts, you can enlist more than 2 people to help with enrollment if you would like. These are just a few suggestions to help increase enrollment numbers. We will continue to monitor enrollment progress and if we continue to be under enrollment goals, we may expand the number of enrolling shifts per month. After enrolling patients ourselves and hearing from all of you, we can confidently say that the enrollment process is really straightforward and does not take more than 5-10 minutes.

As always, please let us know if you have questions or concerns at PERN@cchmc.org. Let's keep moving towards our goal of 5,000 children enrolled globally!

Yours in collaboration and appreciation,
Todd Florin & Nate Kuppermann

PERN PEDIATRIC EMERGENCY RESEARCH NETWORKS



Predicting Severe Pneumonia in the Emergency Department: A Global Study of the Pediatric Emergency Research Networks (PERN)

Top Enrolling Sites as of May 22, 2019

Enrollment Total: 289

(as of 5/22/19)

Sites	Enrollment Total
Complejo Hospitalario Universitario Insular - Materr	25
DC Children's National	22
Miguel Servet University Hospital	14
Policlinico Umberto I	14
Los Angeles - Children's Hospital	12
BASURTO UNIVERSITY HOSPITAL	12
Lurie	10
Montefiore Children's Hospital	10
Columbia - Morgan Stanley Children's Hospital of NY	10
Alberta Children's Hospital	10
Hackensack -Sanzari Children's Hospital	10

STUDY BEST PRACTICES: KAPPA FORM

The KAPPA form should only be completed if the two clinicians are both physically present in the ED and can examine the patient independently within 60 minutes of each other. A KAPPA form should not be completed after the fact by a clinician who did not physically examine the patient. We only need KAPPA forms completed on 5-10% of patients per site, so it is ok if this is left blank for many patients.

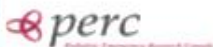
STUDY BEST PRACTICES: ENROLLMENT

- Enroll as many patients during a shift as you are able, there is no maximum
- You can enroll during pre-specified shifts when you are not working clinically if this is easier

When filling out the Inclusion/Exclusion Form, please remember:

- If the subject was **eligible** and approached for consent, but consent was **not** obtained, the answer to "Was informed consent/assent obtained?" should be marked as **'no'**
- If the patient is **ineligible**, the answer to "Was informed consent/assent obtained?" should be marked as **'no'**

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REDCap Data Entry Reminders

- ❖ If there is no data to enter in the case report forms, please mark the blank form 'complete' so that we know that data is not missing from the form
- ❖ Please remember to record the Missed Eligibles in REDCap in a timely manner

Study SharePoint Site

An important source of study information is the study SharePoint site <http://portal.cchmc.org/sites/PERNpna> – you should have received log-in information for this site where all study documents, including a frequently asked questions document, are stored for your reference. Please feel free to reach out to us at PERN@cchmc.org for any study related questions that you cannot find in the newsletter or the study SharePoint site.

FREQUENTLY ASKED QUESTION (FAQ) OF THE MONTH



For the repeating forms like the cultures and follow up visits- if there is no data to enter - do you mark as complete and not input any data? Or are you supposed to not even open that data entry page? If the latter, what should I do if I accidentally open the page?



If there is no data to enter in the form (for example, no cultures have been performed, so there is not data to enter into the culture log), please mark the blank form 'complete' so that we know that the data is not truly missing but rather there was no data to be entered.

Guidance for completing Screening & Eligibility Form and Missed Eligible Form

Scenario	Forms to Complete
Patient approached, eligible & consents to participate	Arm 1: ALL FORMS
Patient approached, eligible & does not consent	Arm 1: Screening & Demographics form ONLY & Arm 2: Missed Eligible
Patient approached, has pneumonia, but meets one or more exclusion criteria	Arm 1: Screening & Demographics form ONLY
Patient approached, does not have pneumonia	No Forms
Patient not approached and appears eligible by record review	Arm 2: Missed Eligible

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