

# **POCUS Utility in the Free Clinic Setting**

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## **1.0 Background & Rationale**

Street medicine is an emerging model of healthcare that provides health and social services directly to people experiencing unsheltered homelessness (**PEH**) in their own environments. Rather than requiring patients to come to a traditional clinic or hospital, street medicine practitioners meet individuals where they are—in alleyways, under bridges, in encampments, or other public spaces. Many cities have also incorporated formal brick-and-mortar, low-barrier free clinics to address acute and chronic healthcare concerns of the uninsured and unsheltered individuals of the community.

According to the 2025 PIT (Point-in-time) count, there were 1,815 individuals identified as PEH in Marion County. This represents a 7% increase from 2024 and is the highest total since 2021. Nationwide, this increase is even more alarming. In 2024, the PIT count identified 770,000 PEH, representing an 18% rise from the previous year. (IndyStar, 2025)

Point of care ultrasound is an underutilized resource in the street and free-clinic setting. Despite its long history of clinical application in the hospital setting, ultrasound has been limited in resource poor settings by portability, cost, and quality of image acquisition. But the past 10 years have shown promising growth for the democratization of portable POCUS: improved image quality, AI integration, and wireless connectivity now existing in multiple handheld device models for only a few thousand dollars. This technology both expedites diagnosis and reinforces the physician-patient relationship through its immediacy, portability, and facility of patient education as a visual aid. The convergence of street medicine and innovation in portable POCUS technology, particularly in the backdrop of an alarming increase in PEH across the nation, introduces a potential use-case in these settings.

However, the data up to this point on street-medicine POCUS is sparse. The purpose of this prospective observational study is to perform POCUS in the free clinic setting of Indianapolis, IN and catalogue the types of ultrasound exams performed based on already established chief-complaint driven indications. This will include 30-day follow up of relevant formal US comparison (if indicated) and overall clinical course. Additionally, this study serves to identify barriers to POCUS in these resource limited settings in order to formulate best practices for street medicine teams and free clinics moving forward.

## **2.0 Objective(s)**

### **2.1 Primary Objective**

The primary objective of this study is to explore the frequency of utilization of point of care ultrasound in a free clinic setting.

### **2.2 Secondary Objective**

The secondary objectives of this study are to compare findings of POCUS to formal ultrasounds and gather data on frequency of visits where POCUS changed medical management.

### **3.0 Outcome Measures/Endpoints**

#### **3.1 Primary Outcome Measures**

The primary outcome for this study is the amount of POCUS scans performed by the primary investigator per patient encounter

#### **3.2 Secondary Outcome Measures**

The secondary outcomes for this study are included below:

- Agreement of findings between POCUS and subsequent radiology-performed US (if performed within 1 month and available)
- % of studies with positive findings
- % of studies with subsequent referral to subspecialist teams
- % of studies with change in medical care plan (% of avoided hospital referrals) secondary to POCUS
- % of different types of studies performed
- Time spent performing each study by type
- % time of encounter spent on POCUS (measure total time of encounter, time of study)

### **4.0 Eligibility Criteria**

#### **4.1 Inclusion Criteria**

- Patients >18 years old OR Patients <18 years old with adult/guardian consenting to data collection AND
- Presenting to either: street medicine team in Indianapolis, IN OR patients presenting to free clinic in Indianapolis, IN, AND
- Being treated by the Primary Investigator AND
- Meeting one or more of specific indications (see study design)

#### **4.2 Exclusion Criteria**

- <18 years old without adult/guardian consenting to data collection
- Patients unable to provide verbal consent
- Patient refusal of ultrasound

### **5.0 No clinical indications met as detailed under study design**

This study is a prospective observational trial designed to assess the pragmatic clinical utility of POCUS imaging in the workflow of patients visiting the Free Outreach Clinic.

Patients being treated by the Primary Investigator in the Outreach Clinic or as part of the Street Medicine team selection will be eligible for recruitment. Imaging decisions will be made based on a list of pre-determined indications for POCUS provided to free clinic volunteers and staff. These indications are included below:

#### **Indications:**

1. **Thoracic:** 4 or 6 view (anterior, lateral, +/- posterior) ultrasound unilateral or bilateral as indicated
  1. shortness of breath
  2. cough with fever
  3. chest pain
2. **Renal/GU:** 2 view (short and long axis) renal ultrasound (unilateral or bilateral) with or without 2 view bladder ultrasound as indicated
  1. flank pain
  2. urinary retention
  3. hematuria
3. **GI:** 2 view (short and long axis) gallbladder US with GB wall thickness and CBD measurement if visible
  1. RUQ/epigastric pain
  2. Unexplained nausea and vomiting
4. **Aorta:** 3 point short axis proximal, mid, and distal abdominal aorta ultrasound
  1. Screening for men age 65-75 in current/previous smokers
5. **Cardiac:** 5 view (PSLA, PSSA, A4ch, subxiphoid, and IVC) with EPSS, color doppler regurgitation assessment, pericardial evaluation, diastolic assessment, and right heart assessments as indicated
  1. Shortness of breath
  2. bilateral leg swelling
  3. Palpitations
  4. Current/prior IVDU history with signs and/or symptoms of endocarditis (new skin lesions, unexplained fevers, new murmur)
  5. Chest pain
  6. Syncope/Presyncope
6. **DVT:** 3 point short axis compressive ultrasound assessment (CFV, SFV, and Popliteal) unilateral or bilateral as indicated
  1. Unilateral leg swelling/pain/discoloration
7. **Soft Tissue:** 2 view (short and long axis) ultrasound with or without compression and color assessment
  1. Soft tissue mass - acute or chronic
  2. Soft tissue redness/warmth/swelling - evaluation for abscess vs cellulitis vs other
8. **MSK:** local 2 view ultrasound
  1. Traumatic injuries or deformities
  2. Acute joint pain/swelling
9. **Ocular:** 2 view (short and long axis) ultrasound unilateral or bilateral as indicated with ONSD measurement

1. vision loss
  2. Chronic headache
  3. Ocular trauma
10. **OB/GYN:** 2 view (short and long axis) ultrasound with FHR, CRL, or BPD as indicated
1. confirmed or suspected pregnancy
  2. Pelvic pain/vaginal bleeding

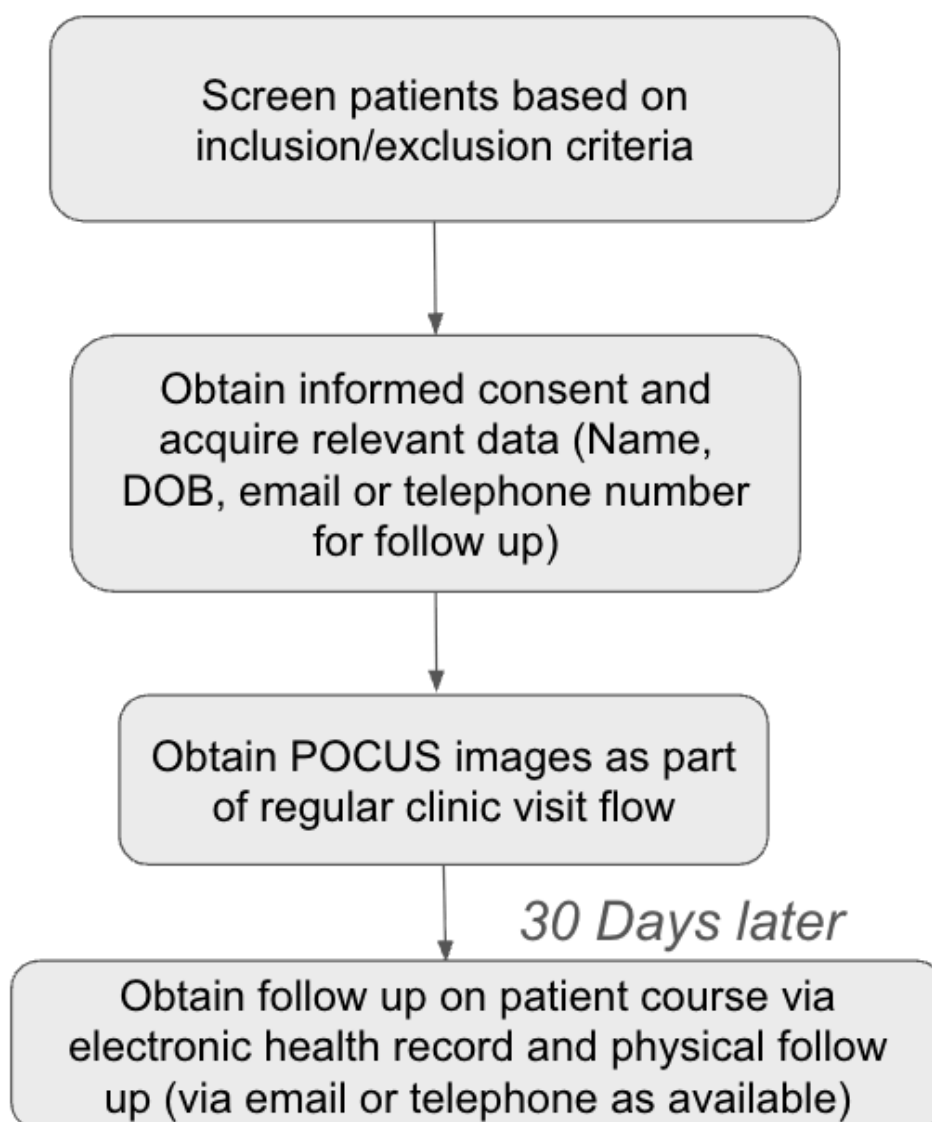
Ultrasound will be obtained exclusively with portable POCUS devices, including Butterfly IQ+ (Butterfly Network, Burlington MA) and VScan Air SL (GE Healthcare, Chicago IL ). A Samsung Galaxy Tab S9 (Samsung Electronics, Seoul South Korea) with Butterfly application integration will be used for on-screen display.

Data will be acquired during regular hours of a Indiana University School of Medicine Student Outreach Clinic (Wednesday and Saturday) bimonthly or monthly between the time intervals of 11/2025 and 06/2026.

Patient information (Name, date of birth, contact information [email or phone]) will be collected from encounters in which a POCUS was performed.

30 Day follow up of the electronic medical record and 30 day email or telephone follow up will be performed based on the date the initial scan was acquired.

Flow Diagram for Prospective Observational Study:



## 6.0 Enrollment/Randomization

Enrollment of participants will take place from patients presenting to free student clinic. Inclusion and exclusion criteria will then be applied to this patient pool to determine final study participants. No randomization or blinding will take place during this observational study.

## 7.0 Study Procedures

The primary procedure of this study will be point of care ultrasound examination. This will be integrated into the flow of a physical exam portion of patient visits following initial screening and consent acquisition. Participants will be instructed to change positions in order to obtain quality images (e.g. left lateral decubitus position for apical 4 chamber cardiac assessment, supine for gallbladder assessment). Additionally, with assistance of sheets and gowns as available, participants will be covered throughout the examination except for the skin region of interest with a consistent attempt made to provide patient comfort and obtain skin exposure only as necessary for image acquisition (e.g. exposure of the inner thigh or lower abdomen for DVT and transabdominal ultrasound respectively). Length of ultrasound examination are expected to be between 2-5 minutes in total.

Pending availability in access to telephones or email addresses, each participant will be contacted 30 days following initial ultrasound imaging in order to determine course of care, taking note of only pertinent components of the medical history related to the imaging obtained on visit #1. Additionally, 30 day follow up of medical course will be conducted through available EHR information - taking note specifically of relevant formal imaging or other clinical events relevant to imaging obtained on visit #1.

## 8.0 Study Calendar

Visit #1	POCUS assessment and initial data acquisition
30 Days post Visit #1	EHR review and patient follow-up via telephone/email

## 9.0 Reportable Events

Reportable events will be managed in accordance with university policy and IRB guidelines. The following types of events will be reported to the IRB:

- **Unanticipated Problems Involving Risks to Participants or Others (UPIRSOs):** Any event that is unexpected, related to the research, and suggests that the research places participants or others at a greater risk of harm than previously known. Examples include a serious emotional reaction to a survey question or a breach of data confidentiality. These events will be reported to the IRB immediately, but no later than 24-48 hours after discovery.
- **Protocol Deviations:** Any failure to follow the IRB-approved protocol. Minor deviations that do not involve risk to participants (e.g., a missing data point) will be logged internally and reported to the IRB at the time of continuing review. Serious deviations that may affect participant safety or data integrity (e.g., enrolling an ineligible participant) will be reported immediately.
- **Complaints:** Any formal participant complaint that involves a research-related issue or risk.



- **New Information:** Any new information from literature, sponsor, or other sources that could affect the safety, welfare, or rights of the participants.

The research team will conduct regular reviews of all adverse events and unanticipated problems. A summary of all adverse events, whether or not they are deemed related to the research, will be included in the continuing review report to the IRB.

## **10.0 Data Safety Monitoring**

POCUS image acquisition will follow the ALARA (as low as reasonably achievable) principle. That is to scan at the lowest dose for the shortest time to obtain the necessary image. In line with this principle, pulse-wave doppler imaging will be avoided in transabdominal ultrasound imaging during the first trimester. Additionally, ophthalmic POCUS will be conducted exclusively with the ocular preset so as to ensure lowest and safest thermal and mechanical indices (Miller, 2020). When applying these principles, in accordance with the FDA and American Institute of Ultrasound in Medicine, POCUS is a modality that is considered safe when used prudently by appropriately trained healthcare providers.

## **11.0 Study Withdrawal/Discontinuation**

A patient may elect during data acquisition or call the IU free clinic at any time to elect to have their information/scanning data withdrawn from the record.

## **12.0 Statistical Considerations**

The goal sample size of this study is 50 or greater individual scans

## **13.0 Statistical Data Management**

Primary data will be collected via the *RedCap database that details basic patient demographics (age, comorbidities, indication for scan, type of scan performed, contact information (if available) and attempted 30 day follow up (via available EMR data and/or direct patient phone/email follow up)*

## **14.0 Privacy/Confidentiality Issues**

Patient protected information will be stored exclusively on RedCap. Each patient will have a predetermined reference number (for example 001, 002, 003, etc.) corresponding to their file on RedCap which will be input onto the Butterfly image database for reference.

## **15.0 Follow-up and Record Retention**

This study will last until July 1st, 2026 and the record will be retained until July 1st, 2027. As these images may prove useful for future clinical reference, the scans will not be destroyed, but the associated patient identifiers on RedCap will be destroyed after this time while retaining non-identifying information.

## **16.0 References**

IndyStar. (2025, July 23). *Here's how many people are homeless in Indianapolis in 2025.*

IndyStar. Retrieved from

<https://www.indystar.com/story/news/local/indianapolis/2025/07/23/heres-how-many-people-are-homeless-in-indianapolis-in-2025/85321860007/>

Miller, D. L., Abo, A., Abramowicz, J. S., Bigelow, T. A., Dalecki, D., Dickman, E., Donlon, J., Harris, G., & Nomura, J. (2020). Bioeffects and Safety of Diagnostic Ultrasound. *Journal of Ultrasound in Medicine*, 39(6), 1069-1084. doi:10.1002/jum.15202

## **17.0 Appendix**

N/A