**Critical Care Research Subcommittee Protocol Submission Template**

**Title of the study:** Dual-plane ultrasound imaging during vascular access procedures
**Principal Investigator:** Robert Anderson APRN
**Co-investigators:** Ben Daxon, MD; Anesthesia Resident MD (TBD).
**Research Coordinators**: ACRU
**Statistician:** TBD

## Abstract

Obtaining reliable vascular access is "one of the most basic yet critical components of patient care both in hospital and ambulatory patient settings".[1] Over one billion peripheral intravenous catheters (PIVCs) are placed annually worldwide, with nearly 300 million annually in the United States; this does not take into account additional vascular catheters such as central venous catheters and arterial catheters.[2] Given that incidence it is concerning that still, first-attempt success incidence varies between 18-79%; illustrating a 21-82% first-attempt failure rate.[3] The use of ultrasound guidance in vascular access procedures has gained significant traction by both medical and nursing staff in inpatient and outpatient settings. Standard ultrasound training for vascular access utilizes a cross-sectional viewing plane; however, the use of a longitudinal viewing plane is also beneficial. Utilization of both planes is challenging by the end-user due to mechanical manipulation (rotation of probe) that must be done intra-procedure. The goal of this protocol is to evaluate the rate of cannulation success and efficiency of a dual-plane ultrasound probe (Butterfly iQ+; Butterfly Network, Inc.; FDA approved) in ultrasound-guided vascular access procedures as compared to a standard single-view ultrasound probe in the operating room setting during placement of arterial catheters.

## Research Plan

### I. Specific Aims

Utilization of ultrasound guidance for vascular access procedures is commonplace in inpatient and outpatient care settings, specifically procedural and critical care settings. Standard ultrasound probes offer the operator a single-plane view, necessitating rotation of probe to attain dual views which are complimentary to one another, albeit dual-plane viewing is thus not simultaneous; such a rotation maneuver increases the technical difficulty of ultrasound utilization. Consequently, our proposed study has the following aims and hypothesis.

1. Assess the clinical efficiency of utilization of a dual-plane simultaneous view ultrasound probe (Butterfly iQ+; Butterfly Network, Inc.) during arterial catheter placement in the operating room. Outcome metrics to include: number of attempts for successful cannulation, amount of time to complete procedure, percent of failed attempts / total attempts.
2. Assess end-user response to use of dual-plane probe via subjective feedback.

### II. Background and Significance

Obtaining reliable vascular access is "one of the most basic yet critical components of patient care both in hospital and ambulatory patient settings".[4] Over one billion peripheral intravenous catheters (PIVCs) are placed annually worldwide, with nearly 300 million annually in the United States; this does not take into account additional vascular catheters such as central venous catheters and arterial catheters.[5] Given that incidence it is concerning that still, first-attempt success incidence varies between 18-79%; illustrating a 21-82% first-attempt failure rate.[6] Couple that with reported infiltration and extravasation rates of up to 69.8% related to mispositioned vascular catheters; the issue to solve is clear.[7] Ultrasound-

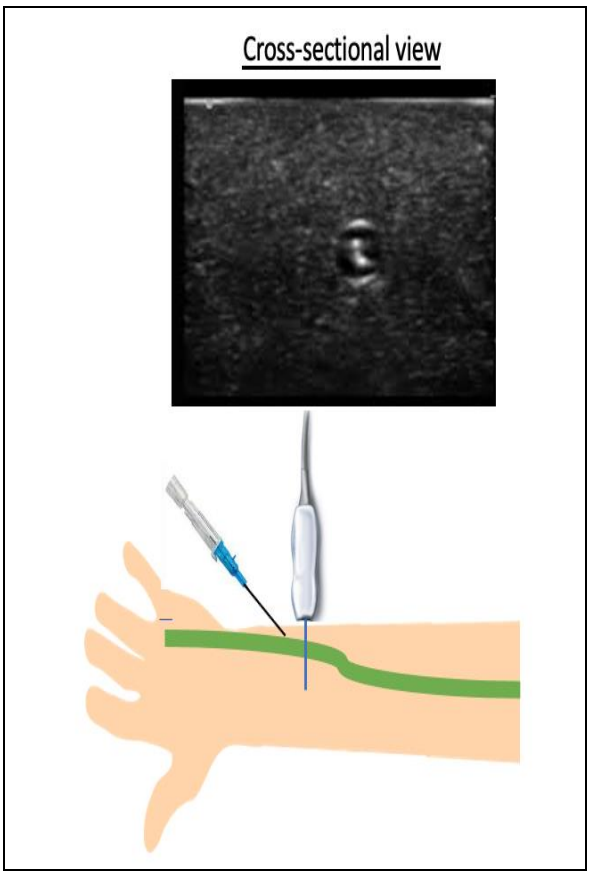
guidance is a tool that increases success of accurately placed vascular catheters, yet the technology at present does not setup the end-user for as much success as possible.[1] In providing the end-user multiple views during cannulation, the success rate and adoption of ultrasound as standard-of-practice across all vascular catheter placements is likely to increase, thereby reducing the aforementioned negative sequelae of mispositioned catheters thereby improving patient care. The patient experience is also purported to improve by reducing the number of repeated failed placement or replacement attempts, a frequently cited healthcare-fault on patient satisfaction surveys thus improving time-to-treatment and the efficiency of care.

## III. Progress Report and Preliminary Studies

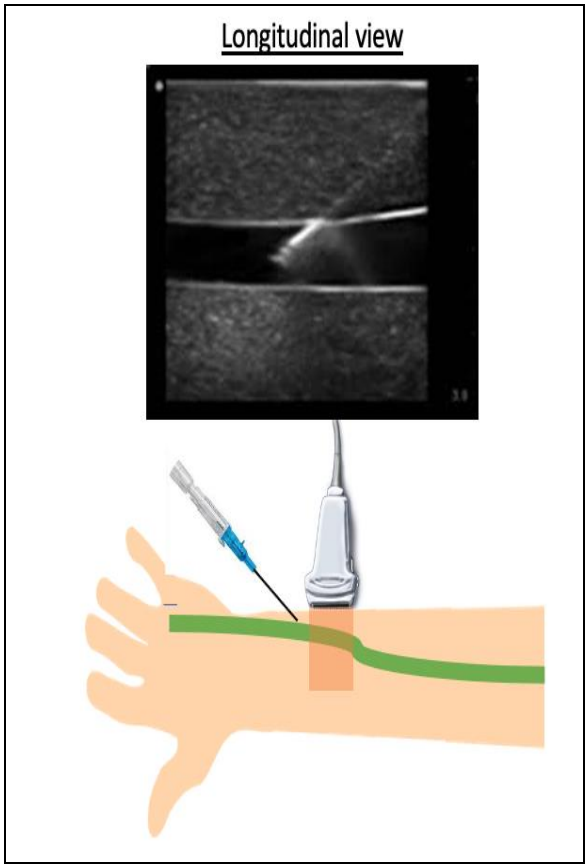
Standard, or common, ultrasound training for vascular access utilizes a cross-sectional or short-axis view (Figure 1). Additional benefit can be gained by the end-user utilizing a longitudinal or long-axis to assist in guiding the catheter into the vessel once initial venipuncture is obtained via a cross-sectional view (Figure 2); this view, however, can be challenging to maintain intra-procedure given the narrow ultrasound array window and the narrow anatomical size of vasculature. However, current single-plane probes require the end-user to rotate the probe 90-degrees intra-procedure in order to switch between cross-sectional and longitudinal views. Therefore, the utilization of simultaneous dual-plane imaging incorporating both cross-sectional and longitudinal viewing would provide the end-user with the most comprehensive viewing strategy without necessitating manual rotation of the probe intra-procedure (Figure 3).

Overall, there is limited literature regarding bi-plane or multi-plane imaging during vascular access procedures. The literature does attest that utilization of numerous views during vascular access procedures is beneficial, yet manual rotation of the probe during cannulation is seen as a limitation.[8] There is also support for improved success rates and less redirection with trainees when using a long-axis approach as compared to short-axis, specifically for subclavian placement.[9] Convissar, et al (2021)[10] describe a case study utilizing the Butterfly iQ+ for arterial line insertion with success after many failed attempts with standard ultrasound. In conclusion, it seems reasonable to use this literature as a base to do a small research study evaluating number of sticks, time to get IV, % of overall failures, etc – all the aforementioned literature is either case study or very small sample size.

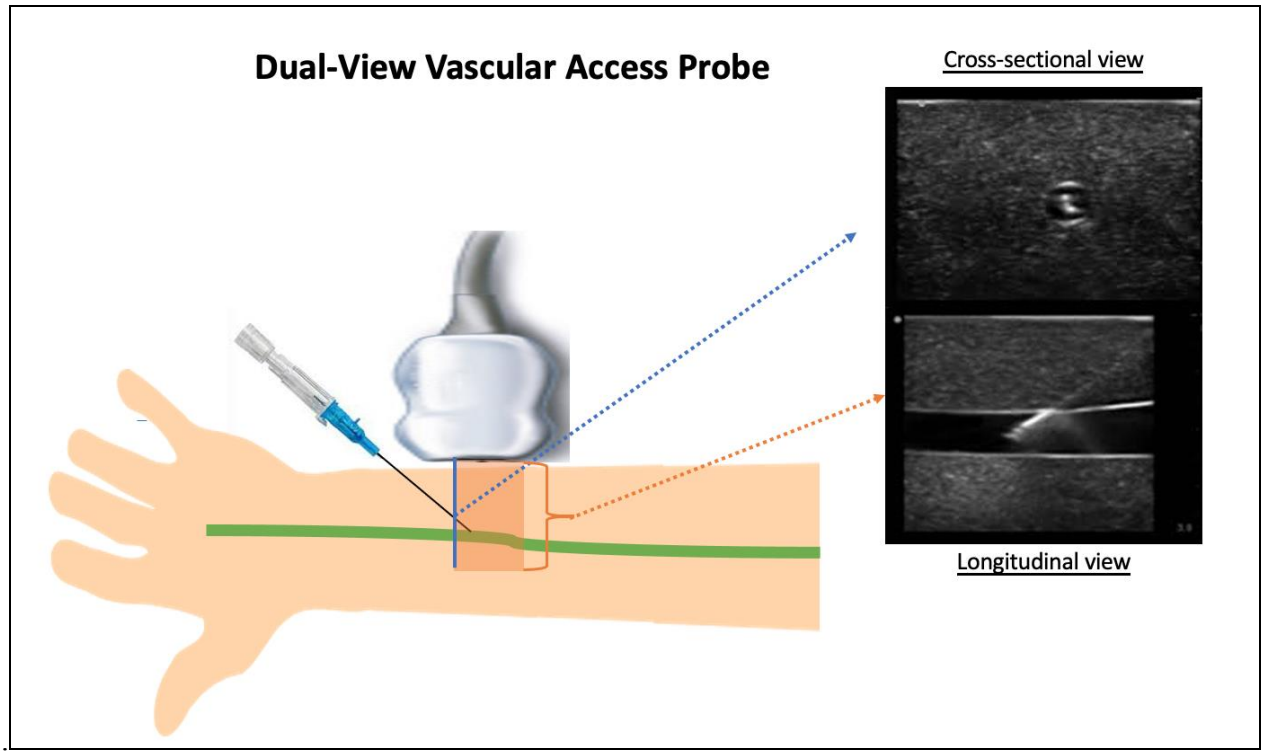
In addition to the Butterfly iQ+ probe, the Phillips XL14-3 xMATRIX Linear Array Transducer is a diagnostic probe on-market capable of dual-plane viewing. The xMATRIX is limited for this application given its design for diagnostic use with extra measurement and processing functions and therefore, too high-cost and presumed low durability for point-of-care procedural applications.




(Figure 1)




(Figure 2)




(Figure 3)

**Investigators**
The principal investigator in our study, Robert Anderson APRN (Pulmonary / Critical Care), has extensive experience in ultrasound-guided vascular access both clinically and in the development of a didactic and hands-on training course for bedside staff nurses at the University of Iowa Hospitals and Clinics. Dr. Benjamin Daxon (Anesthesia Consultant) along with a team of Anesthesia Residents (to be named and added to protocol) will also be members of the research team. A study coordinator will be enlisted for this study to assist with patient screening, data collection and data transcription.

## IV. Research Design and Methods

**Study Design**
This investigation will employ a prospective, non-blinded randomized-control study.

Study Subjects – 50 patients who meet enrollment criteria.

Control Subjects – 50 patients who meet enrollment criteria.

Provider subjects – Up to 50 anesthesia providers (trainee, CRNA, anesthesia staff physician)

**Inclusion criteria**

- Elective surgical patients requiring non-emergent ultrasound-guided radial arterial catheter placement
- Anesthesia providers to include trainees, certified registered nurse anesthetists (CRNA) and attending anesthesia providers.

**Exclusion Criteria**

- Age younger than 18 years or older than 85 years.
- Pregnant
- Patients in a moribund state or palliative care only
- Vulnerable patients (i.e. Severe mental handicap, non-decisional)
- History of peripheral arterial disease
- Placement of arterial catheter without ultrasound guidance
- Provider: Medical students or CRNA students.

**Methods**

Anesthesia providers assigned to an upcoming rotation in the main operating rooms will receive a recruitment message via e-mail regarding participation in this study. If they consent to participate, they will be asked to view an online educational video sent to them via email (see below) and will be given an opportunity to practice use of the dual-view probe prior to use on a patient. Some providers may have utilized the dual-view technology previously.

Instructional Video for Providers: *https://www.youtube.com/watch?v=rBS3GaIrqqc*

Enrolled patients will be randomized to two groups:

- Control: Arterial line placement via "standard" mechanism; utilization of a single-plane ultrasound probe
- Intervention: Arterial line placement utilizing dual-plane, Butterfly iQ+ ultrasound probe.

A Butterfly iQ+ with attached large iPAD or alternate tablet device will be utilized for this study to allow for a larger screen visualization as compared to a portable phone device.

The anesthesia provider (attending physician, CRNA, or trainee) staffed in the patient's operating room will place the arterial line using standard practice besides randomization to the type of ultrasound probe. It will be recorded if the provider has previously utilized the dual-view probe.

The anesthesia residency program is already providing their trainees with an individual Butterfly iQ+ ultrasound probe system; therefore, these already purchased and implemented devices will be utilized in this study.

The research coordinator will utilize a stopwatch to record the amount of time required for successful placement of a peripheral arterial catheter; time recording will begin with the initial skin puncture and cease with observation of an appropriate arterial waveform on the in-room monitor.

If a patient is enrolled in the "Intervention" group and the anesthesia provider requires more than 3 attempts to achieve successful arterial catheter cannulation; the provider will discontinue use of the dual-plane probe and attempt placement with a technique of their choosing.

A picture of the ultrasound image at the completion of the procedure, successful or unsuccessful, will be obtained; no patient-specific information will be recorded.

All data will be collected, organized, and analyzed with the aid of a dedicated biostatistician from the Health Science Research office. Estimate for their work are included in the attached budget.

**Endpoints**

Successful placement of peripheral radial arterial catheter as evidenced by transduction of arterial waveform on bedside monitor.

**Primary Outcome**

First-stick success rate of ultrasound-guided peripheral arterial catheter placement.

**Secondary Outcomes**

- Number of attempts to achieve successful arterial catheter cannulation; "attempt" will be defined as a single insertion of the needle into the skin.
- Amount of time required for successful arterial catheter cannulation.
- Number of failed attempts leading to unsuccessful arterial catheter cannulation
- Subjective response from anesthesia provider regarding their experience utilizing a single-plane versus a dual-plane ultrasound probe.
    - Please explain your experience using this ultrasound probe.
    - If you used the dual-view probe, how do you feel that this dual-view probe impacted your procedure as compared to a single-view ultrasound probe?

- Do you feel that the dual-view ultrasound probe provides a procedural benefit over the single-view ultrasound probe; please explain.

## V. Data, Safety, and Monitoring Plan

### Data Collection

The data collected for this study will be:

- Number of attempts to achieve successful arterial catheter cannulation; "attempt" will be defined as a single insertion of the needle into the skin.
- Amount of time required for successful arterial catheter cannulation.
- Number of failed attempts leading to unsuccessful arterial catheter cannulation
- Subjective response from anesthesia provider regarding their experience utilizing a single-plane versus a dual-plane ultrasound probe.
- Level of training of anesthesia provider: Trainee, CRNA, Attending physician

This data will be recorded on a paper form in the operating room at the time of surgery; the paper form will then be transcribed into RedCap by a member of the research team. No patient-specific or provider-specific data will be collected.

### Feasibility and Time Frame

Given the high incidence of peripheral arterial catheter placement during elective cases in the main operating room at both Saint Mary's Campus and the Rochester Methodist Campus (approximately 75-100 per day); we will plan to collect this data over the course of 2 months pending sufficient enrollment.

### Subject Safety

Enrolled patients will be exposed to minimal additional risk. The additional risk may include additional peripheral arterial catheter placement attempts which may lead to hematoma formation, bleeding, artery injury, and necessitation to identify alternative anatomic sites for successful arterial catheter placement.

There will be no additional risk posed to the anesthesia providers.

Given the fact that this is considered a low-risk intervention, we will apply for a waiver of documentation of informed consent from the patient and anesthesia provider.

### Monitoring

No additional patient monitoring will be required for this study.

### Data Integrity

All clinical data will be entered and compiled in a secure database maintained by the principal investigator, co-investigators, and study coordinator. This database will be located in the Mayo Clinic intranet, behind the Mayo Clinic firewall and restricted only to authorized research group members by password. No laptops, USB and/or websites will be used.

### Data Confidentiality

All data recorded on paper forms at the time of surgery will be transcribed by a member of the research team into a RedCap database. Immediately following transcription, the paper data copy will be destroyed. Access to the RedCap database will be limited to the research team and study coordinator.

**Strengths**

This study is simple, short, and straightforward and should be completed within a year—more likely within six months. The study will be used to evaluate the potential beneficial impact of a dual-plane ultrasound probe and its impact on efficiency and success of vascular catheter placement procedures. Pending positive results from this study, consideration of incorporating dual-plane imaging training into central line placement courses and peripheral catheter placement practices (PIVC / PICC / Midline). This will also serve as the first identifiable randomized trial in the literature comparing simultaneous dual-plane ultrasound imaging versus single-plane ultrasound imaging in vascular access procedures.

**Limitations**

Simultaneous dual-plane ultrasound imaging is a new technology, therefore experience by providers with such technology is inherently limited.

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[1] Cheung, E., Baerlocher, M., Asch, M., Myers, A. (2009). Venous access: a practical review for 2009. *Canadian Family Physician,* 55(5)-494-496.

[2] Alexandrou, E., Barruel, G., Carr, P., et al. (2015). International prevalence of the use of peripheral intravenous catheters. *Journal of Hospital Medicine,* 10(8), 530-533.

[3] Carr, P., Rippey, J., Budgeon, C., et al. (2015). Insertion of peripheral intravenous cannulae in the emergency department: factors associated with first-time insertion success. *Journal of Vascular Access,* 17(2), 182-190.

[4] Cheung, E., Baerlocher, M., Asch, M., Myers, A. (2009). Venous access: a practical review for 2009. *Canadian Family Physician,* 55(5)-494-496.

[5] Alexandrou, E., Barruel, G., Carr, P., et al. (2015). International prevalence of the use of peripheral intravenous catheters. *Journal of Hospital Medicine,* 10(8), 530-533.

[6] Carr, P., Rippey, J., Budgeon, C., et al. (2015). Insertion of peripheral intravenous cannulae in the emergency department: factors associated with first-time insertion success. *Journal of Vascular Access,* 17(2), 182-190.

[7] Danski, M., Mingorance, P., Johann, D., et al. (2016). Incidence of local complications and risk factors associated with peripheral intravenous catheter in neonates. *Journal of Nursing University Sao Paulo,* 50(1).

[8] Vogel, J., Haukoos, J., Erickson, C., et al. (2015). Is long-axis view superior to short-axis view in ultrasound-guided central venous catheterization? *Critical Care Medicine,* 43(4).

[9] Zhong, X., Hamill, M., Collier, B., et al. (2015). Dynamic multiplanar renal time ultrasound guided infraclavicular subclavian vein catheterization. *The American Surgeon,* 81.

[10] Convissar, D., Bittner, E., Chang, M. (2021). Biplane imaging using portable ultrasound devices for vascular access. *Cureus,*13.