

# INTERVAL OBSERVATIONS FROM THE STUDY OF COMPLICATIONS OF PERIPHERALLY INSERTED CATHETERS IN PEOPLE WITH CF (PICC-CF)

Alex H Gifford, MD<sup>1</sup>, Alexandra C Hinton, MPH<sup>2</sup>, Amanda Cass, CRC<sup>3</sup>, Jonathan B Zuckerman, MD<sup>3</sup> on behalf of the PICC-CF investigators  
 1. Pulmonary and Critical Care Medicine, Dartmouth-Hitchcock Medical Center, Lebanon, NH 2. Center for Outcomes Research & Evaluation, Maine Medical Center, Portland, ME  
 3. Division of Pulmonary and Critical Care, Maine Medical Center, Portland, ME



## Introduction

People with CF often choose to have peripherally inserted central venous catheters (PICCs) placed for administration of intravenous antibiotics. In a retrospective study, we identified risk factors for thrombotic complications and bloodstream infections in CF patients with PICCs (1). We also observed practice variation among sites. Here, we present data from the first 325 people with CF enrolled in PICC-CF, an ongoing prospective study of PICC complications in adults and children with CF followed at ten U.S. centers.

## Study Sites



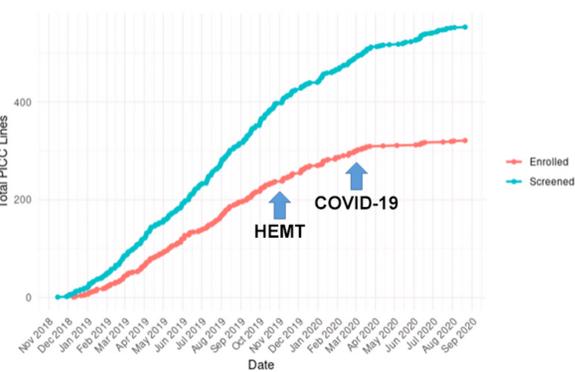
| Sites                                   | Principal Investigators           | Research Coordinators |
|-----------------------------------------|-----------------------------------|-----------------------|
| Children's Hospital Colorado            | Edith Zemanick                    | Dana Coyle            |
| Cleveland Clinic                        | Elliott Dasenbrook                | Dave Weaver           |
| Columbia University Medical Center      | Hossein Sadeghi, Emily Dimango    | Carmen Liriano        |
| Dartmouth-Hitchcock Medical Center      | Alex Gifford, Margaret Guill      | Kate O'Neil           |
| Johns Hopkins University Medical Center | Rebecca Dezube, Natalie West      | Shivani Patel         |
| Maine Medical Center                    | Jonathan Zuckerman                | Amanda Cass           |
| Medical University of South Carolina    | Patrick Flume                     | Angela Millare        |
| University of Kansas Medical Center     | Joel Mermis, Deepika Polineni     | Megan White           |
| University of Michigan Medical Center   | Shijing Jia, Samya Nasr           | Nicole Schafer        |
| University of Vermont Medical Center    | Thomas Lahiri, Charlotte Teneback | Julie Sweet           |

Epidemiologist: Lee Lucas  
 Database Manager: Deanna Williams  
 Biostatistician: Alexandra Hinton  
 Website Administrator: Steve Prato

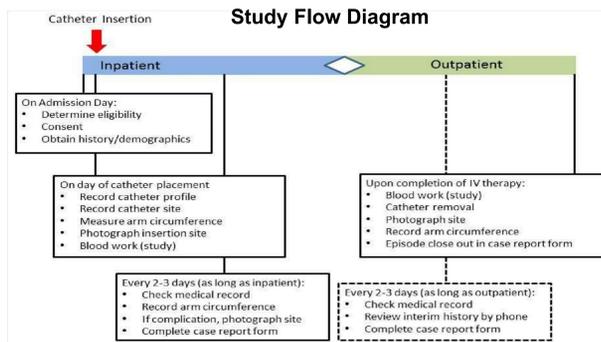
## Methods

We collected clinical and demographic data from people with CF on the day of PICC insertion (usually the first hospital day), every 2-3 days thereafter, and on the day of catheter removal. We tracked procedural details of line attributes and data related to catheter care. We also recorded arm circumference and patient signs and symptoms at regular intervals. The primary study endpoint was the rate of vascular complications, defined as occlusion of the catheter requiring removal or symptomatic venous thrombosis, utilizing the Constans Clinical Decision Score (2). Secondary endpoints included rates of difficulty with line placement, bloodstream infection, local skin reactions, and superficial phlebitis.

## Screening and Enrollment



Curves illustrating numbers of subjects with PICCs who were screened (blue) and numbers of subjects who were enrolled (orange). HEMT = highly effective modulator therapy



## Study Design

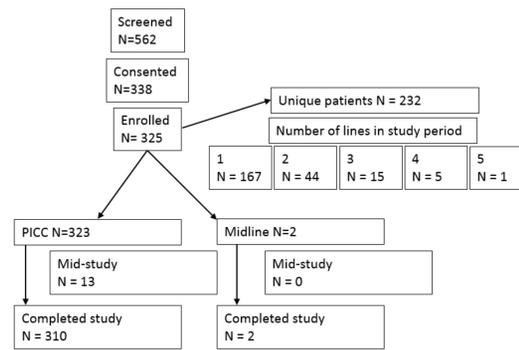
| Task/Procedure               | SCHEDULE OF EVENTS |                  |                                |                                |                                |                                |                                 |                                 |
|------------------------------|--------------------|------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
|                              | Screen             | Visit 1<br>Day 1 | Visit 2<br>Day 3<br>(+/-1 day) | Visit 3<br>Day 5<br>(+/-1 day) | Visit 4<br>Day 7<br>(+/-1 day) | Visit 5<br>Day 9<br>(+/-1 day) | Visit 6<br>Day 11<br>(+/-1 day) | Visit 7<br>Day 14<br>(+/-1 day) |
| Informed Consent             | X                  |                  |                                |                                |                                |                                |                                 |                                 |
| Obtain Demographics          |                    | X                |                                |                                |                                |                                |                                 |                                 |
| Obtain Relevant History      | X                  | X                |                                |                                |                                |                                |                                 |                                 |
| Akron PES                    |                    | X                |                                |                                |                                |                                |                                 |                                 |
| Line insertion details       |                    | X                |                                |                                |                                |                                |                                 |                                 |
| Confirm catheter details     |                    | X                |                                |                                |                                |                                |                                 | X                               |
| CBC, INR (hospital)          |                    | X                |                                |                                |                                |                                |                                 |                                 |
| CRP, D-dimer (study)         |                    | X                |                                |                                |                                |                                |                                 | X                               |
| Picture of insertion site    | X                  |                  | (X)                            | (X)                            | (X)                            | (X)                            | (X)                             | X                               |
| Line Management Survey       |                    |                  | X*                             | X*                             | X*                             | X*                             | X*                              | X                               |
| Evaluation for Complications |                    |                  | X*                             | X*                             | X*                             | X*                             | X*                              | X                               |
| Review line removal          |                    |                  |                                |                                |                                |                                |                                 | X                               |

Notes: (X)-Optional event based on signs/symptoms of the patient. X\*-Patients who receive in-hospital care will have face-to-face follow-up evaluations. Those who are treated at home will have a check-in by phone call.

**Primary Endpoint** The primary endpoint is the occurrence of vascular complications, defined as occlusion of the catheter requiring removal or symptomatic venous thrombosis in the extremity with the line as indicated by a Constans Clinical Decision Score  $\geq 2$  during the time the catheter is in place (the definition does not require ultrasound confirmation, though this information will be collected, if an ultrasound is performed). **Constans Clinical Decision Score:** Add one point for each of the following: PICC or midline catheter in place; localized pain; unilateral edema. Subtract one point: Other diagnosis at least as plausible.

**Secondary Endpoints** Bacteremia, fungemia, local phlebitis or superficial thrombophlebitis, hematoma, bleeding (including incident hemoptysis after use of thrombolytic agents), site pain, arm circumference at the level of catheter insertion, catheter fracture, temporary occlusion of the catheter cleared by thrombolytic agent, non-occlusive venous thrombosis as evidenced by ultrasound or DVT at another site, blood markers of inflammation and measures of coagulation status.

## CONSORT Diagram



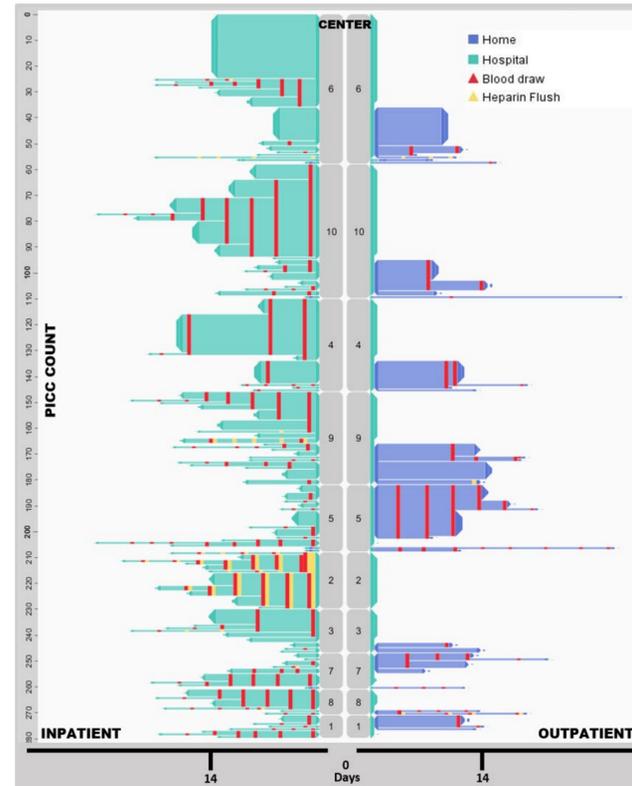
To date, we have enrolled 232 unique patients who had a total of 325 vascular catheters. Most (~72%) of the cohort has had only one catheter. All but two of these catheters were PICCs. Some PICCs (N = 13) are still being observed.

## Patient and Catheter Data

| Characteristic                                                 | N   | N = 325*    |
|----------------------------------------------------------------|-----|-------------|
| Sex                                                            | 325 |             |
| Female                                                         | 153 | (47%)       |
| Male                                                           | 172 | (53%)       |
| Age                                                            | 325 | 21 (15, 29) |
| Age group                                                      | 325 |             |
| Adult                                                          | 211 | (65%)       |
| Pediatric                                                      | 114 | (35%)       |
| FEV1 % predicted                                               | 323 | 73 (48, 91) |
| Unknown                                                        | 2   |             |
| Akron score                                                    | 323 | 10 (7, 13)  |
| Unknown                                                        | 2   |             |
| Lumens                                                         | 324 |             |
| 1                                                              | 297 | (92%)       |
| 2+                                                             | 27  | (8.3%)      |
| Unknown                                                        | 1   |             |
| French size                                                    | 321 |             |
| 3 Fr                                                           | 60  | (19%)       |
| 4 Fr                                                           | 168 | (52%)       |
| 4.5 Fr                                                         | 57  | (18%)       |
| 5 Fr                                                           | 32  | (10.0%)     |
| >5 Fr                                                          | 4   | (1.2%)      |
| Unknown                                                        | 4   |             |
| Venue of PICC placement                                        | 324 |             |
| Bedside                                                        | 84  | (26%)       |
| Procedure Room                                                 | 68  | (21%)       |
| Radiology Suite                                                | 172 | (53%)       |
| Unknown                                                        | 1   |             |
| Guidance                                                       | 323 |             |
| Rewire                                                         | 1   | (0.3%)      |
| Ultrasound                                                     | 318 | (98%)       |
| Unguided                                                       | 4   | (1.2%)      |
| Unknown                                                        | 2   |             |
| Number of needle sticks                                        | 318 |             |
| 1                                                              | 277 | (87%)       |
| 2                                                              | 26  | (8.2%)      |
| 3 or more                                                      | 5   | (1.6%)      |
| Unable/Aborted                                                 | 10  | (3.1%)      |
| Unknown                                                        | 7   |             |
| Prophylactic-dose anticoagulation                              | 321 | 30 (9.3%)   |
| Unknown                                                        | 4   |             |
| Routine blood draw(s) via PICC                                 | 322 | 266 (83%)   |
| Unknown                                                        | 3   |             |
| Maximal change in arm circumference (mm) in pediatric patients | 44  | 6 (5, 14)   |
| Unknown                                                        | 281 |             |
| Maximal change in arm circumference (mm) in adult patients     | 68  | 7 (4, 14)   |
| Unknown                                                        | 257 |             |
| Increase in arm circumference among pediatric patients         | 114 | 44 (39%)    |
| Unknown                                                        | 211 |             |
| Increase in arm circumference among adult patients             | 211 | 68 (32%)    |
| Unknown                                                        | 114 |             |
| Day of maximal change in arm circumference                     | 112 | 9 (6, 13)   |
| Unknown                                                        | 213 |             |
| Difficult line placement                                       | 325 | 41 (13%)    |

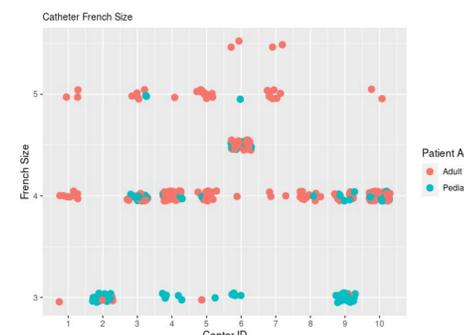
\* Statistics presented: n (%); median (IQR)

## EventFlow Diagram

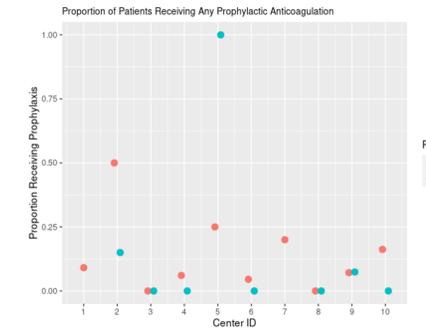


We are using EventFlow software to view catheter- and program-level data simultaneously. Each center has a number in the central gray boxes. The number of catheters is indicated by the ordinate. Duration and venue of catheter use is shown on the abscissa.

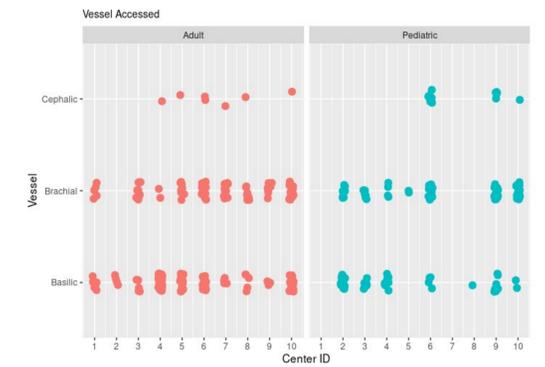
## Program-Level Practice Variation



Variation in use of PICCs measuring 3, 4, and 5 Fr in diameter



Variation in the use of prophylactic anticoagulation



Variation in location of vessels accessed for PICC line placement

## Conclusions

Despite practice variation across sites, there have been no occurrences of deep venous thrombosis or catheter-related bloodstream infection to date. Based on previous reports we would have expected approximately 15 complications to date. The low complication rate might reflect recent changes in practice patterns pertaining to line placement and management.

## Future Directions

- We plan to study risk factors for difficult line placement
- For details on the study design please visit: [www.picccf.org](http://www.picccf.org)

## References

- May TL, et al. *J Cyst Fibros* 2018; 17: 96-104
- Constans et al. *Thromb Haemost* 2008;; 99: 202-7

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- We thank all the patients who have participated in this study

