

UPDATE ON THE PICC-CF OBSERVATIONAL STUDY OF PERIPHERALLY INSERTED CATHETERS IN PEOPLE WITH CYSTIC FIBROSIS

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Introduction

Cystic fibrosis (CF) patients often require intravenous antibiotics for treatment of lower respiratory tract infections using totally implantable venous access devices (TIVADs) and peripherally inserted central venous catheters (PICCs). Complications (e.g., thrombosis or infection) may be associated with substantial morbidity, and specific patient characteristics or care practices related to complications have not been clearly established. Vascular and infectious complications of TIVADs and PICCs in CF patients have been described primarily in single center studies. In this observational study we examine variation in practice patterns and complication rates of PICCs and midline catheters within a nationwide group of CF centers.

We plan to evaluate 1000 catheters placed over the course of 3 years. Here we present our methodology and early evidence of variation in practice patterns among participating centers for the first 150 catheters.

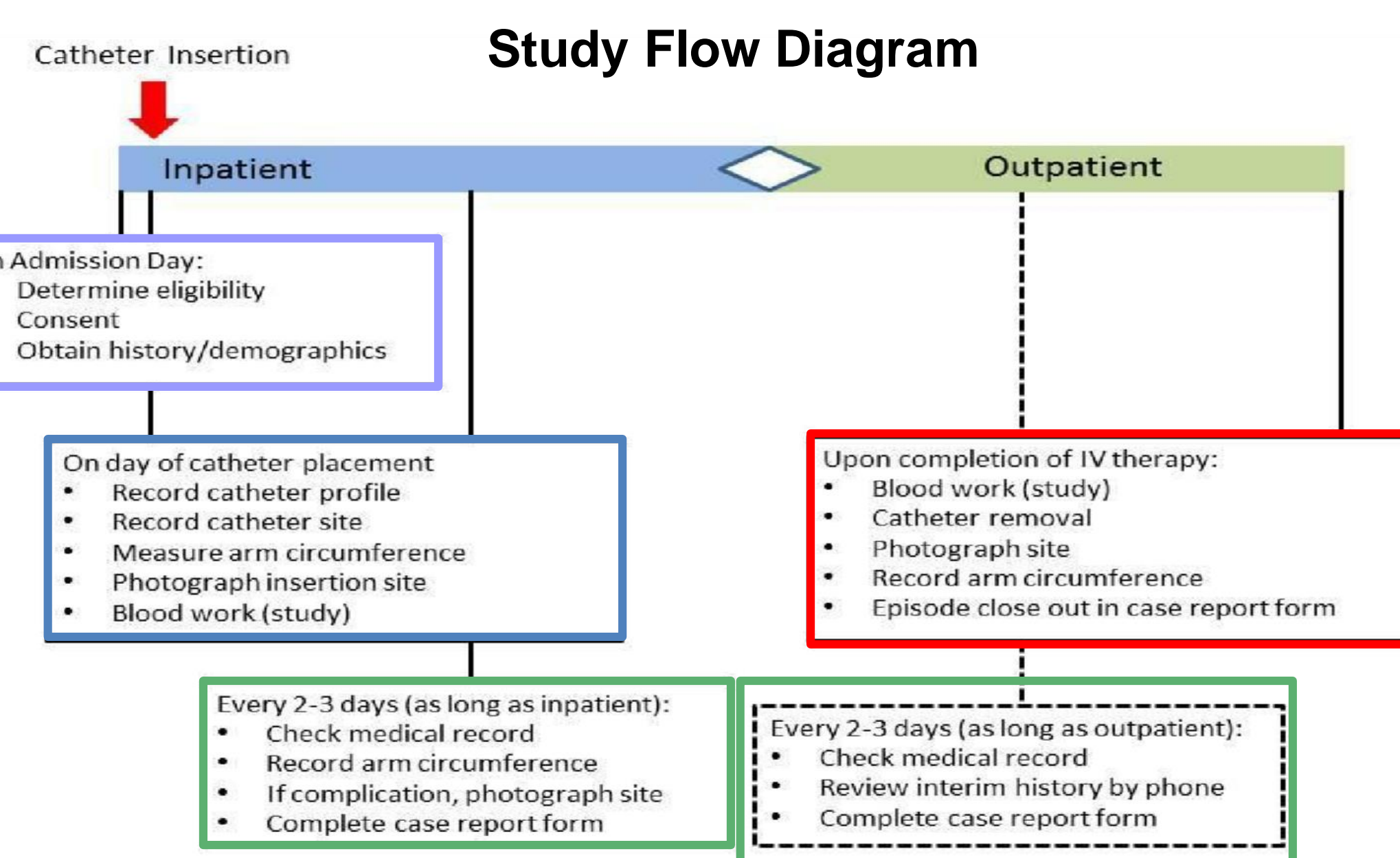
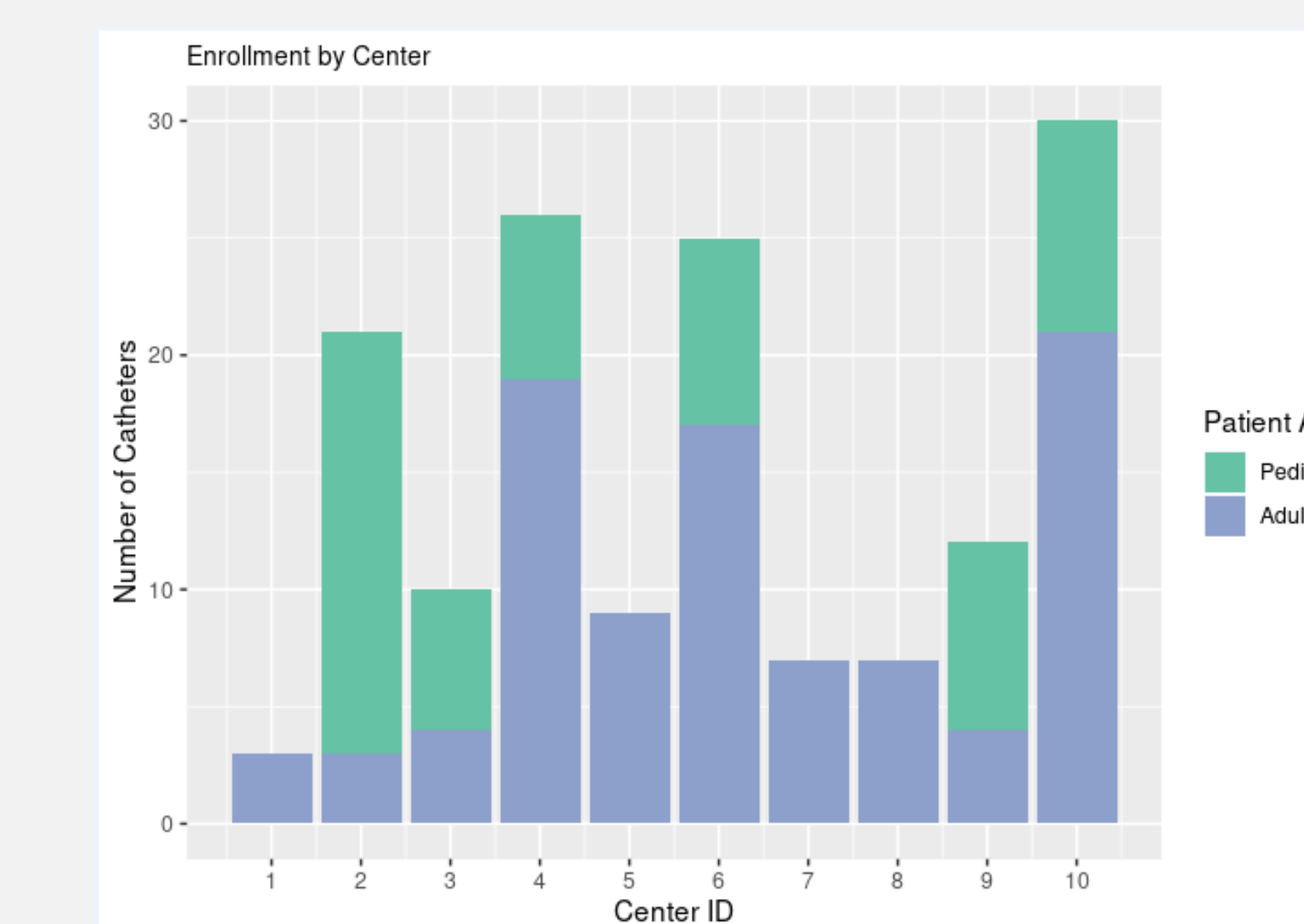
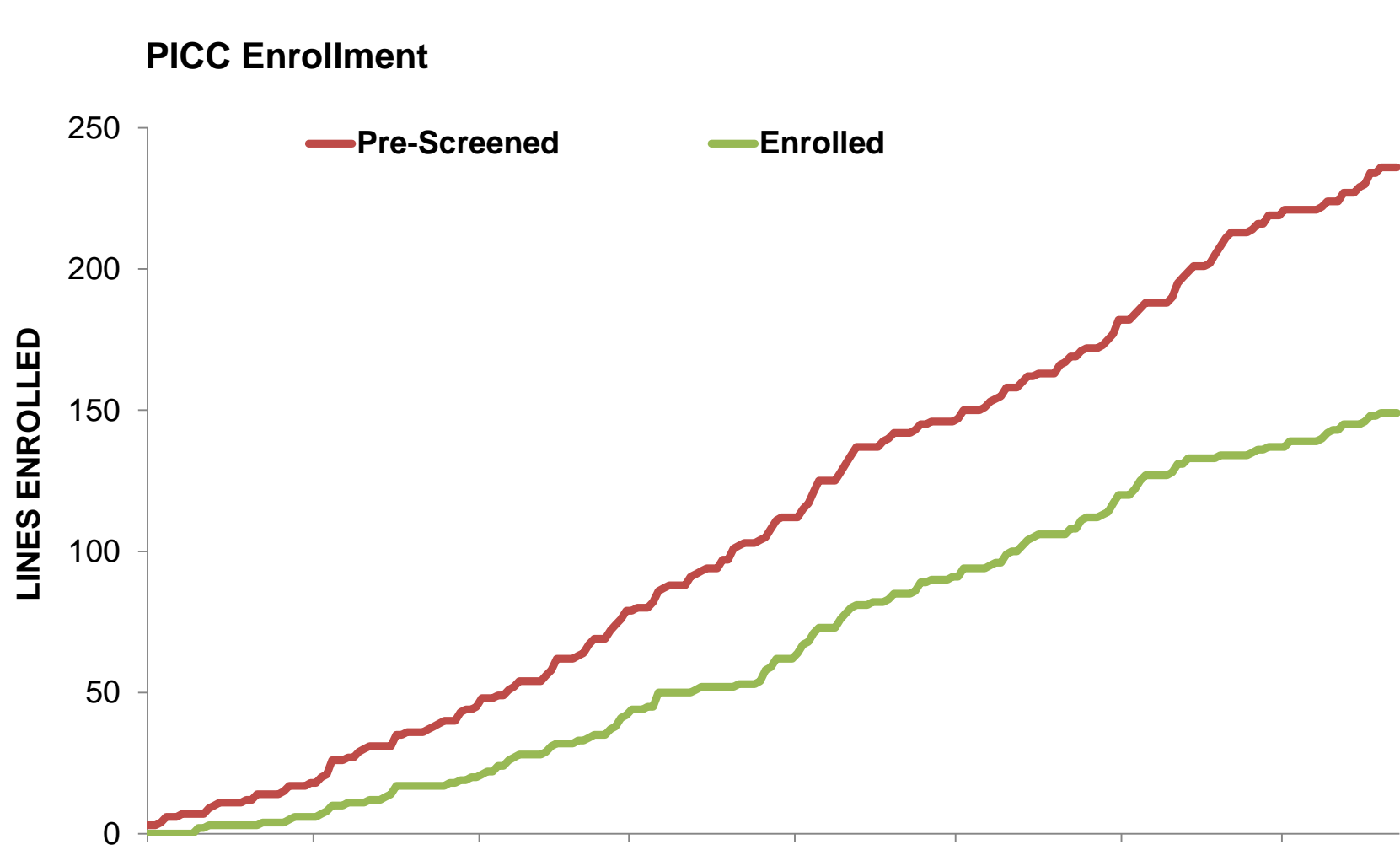
Study Sites



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	Brooke Alexander
University of Kansas Medical Center	Joel Merris, Deepika Polineni	Megan White
University of Michigan Medical Center	Shijing Jia, Samya Nasr	Marianne Heffner
University of Vermont Medical Center	Thomas Lahiri, Charlotte Teneback	Julie Sweet

Biostatistician: Lee Lucas
 Data Analyst 1: Deanna Williams
 Data Analyst 2: Alexandra Hinton
 Website Administrator: Steve Prato

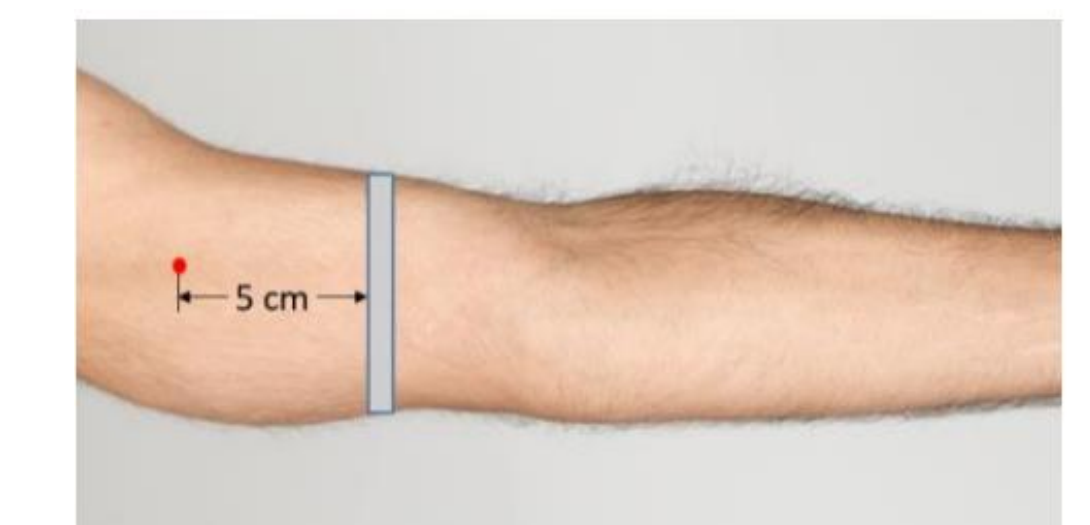
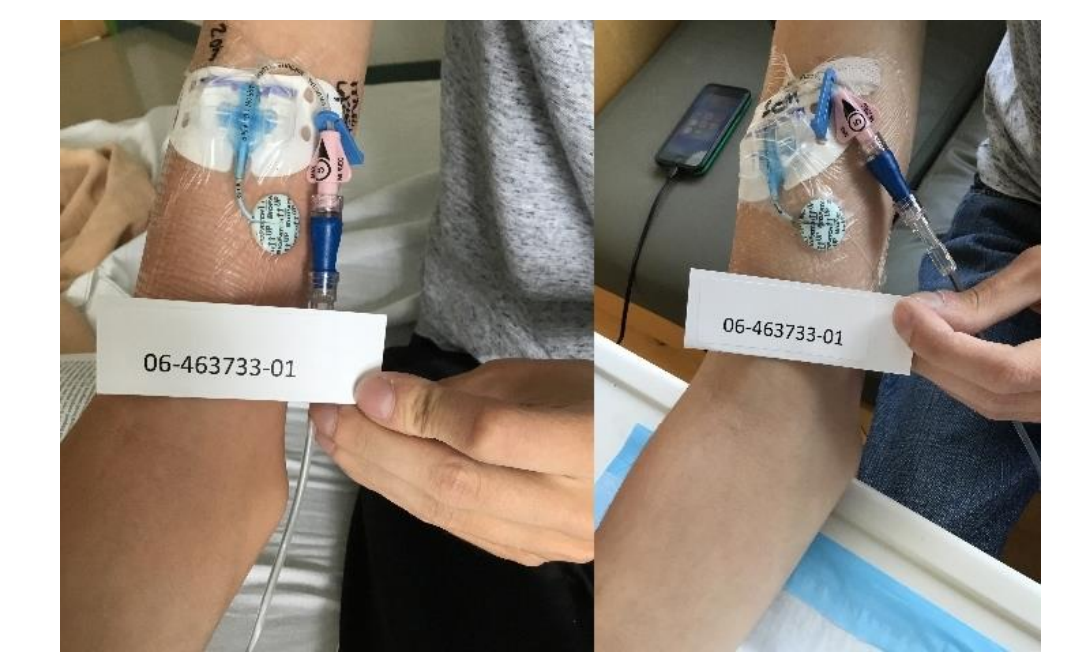
Enrollment



Methods and Results

Task/Procedure	Screen	Visit 1 Day 1	Visit 2 Day 3 (+/-1 day)	Visit 3 Day 5 (+/-1 day)	Visit 4 Day 7 (+/-1 day)	Visit 5 Day 9 (+/-1 day)	Visit 6 Day 11 (+/-1 day)	Visit 7 Day 14 (+/-1 day)
	Informed Consent	X						
Obtain Demographics		X						
Obtain Relevant History	X	X						
Akron PES								
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



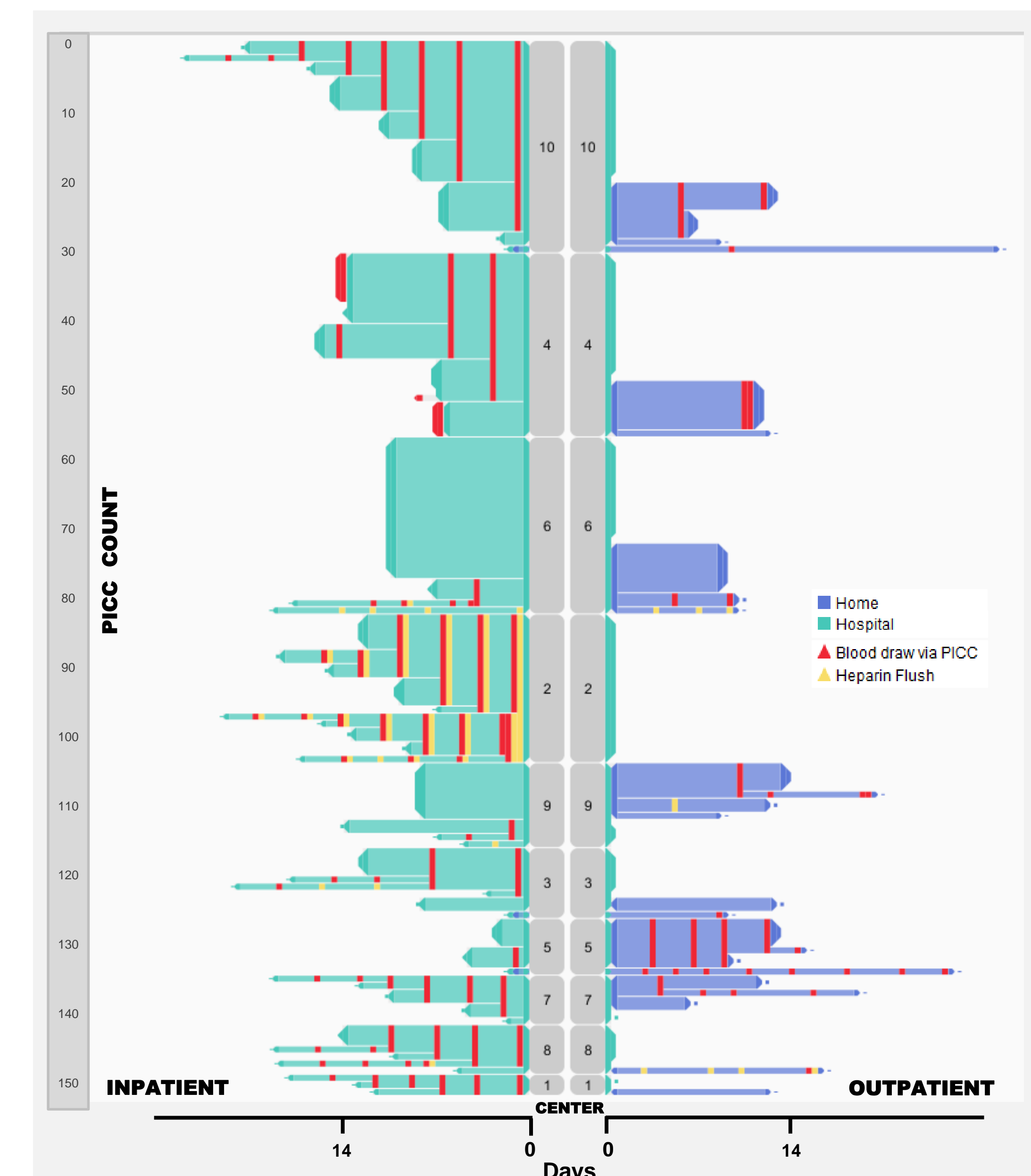
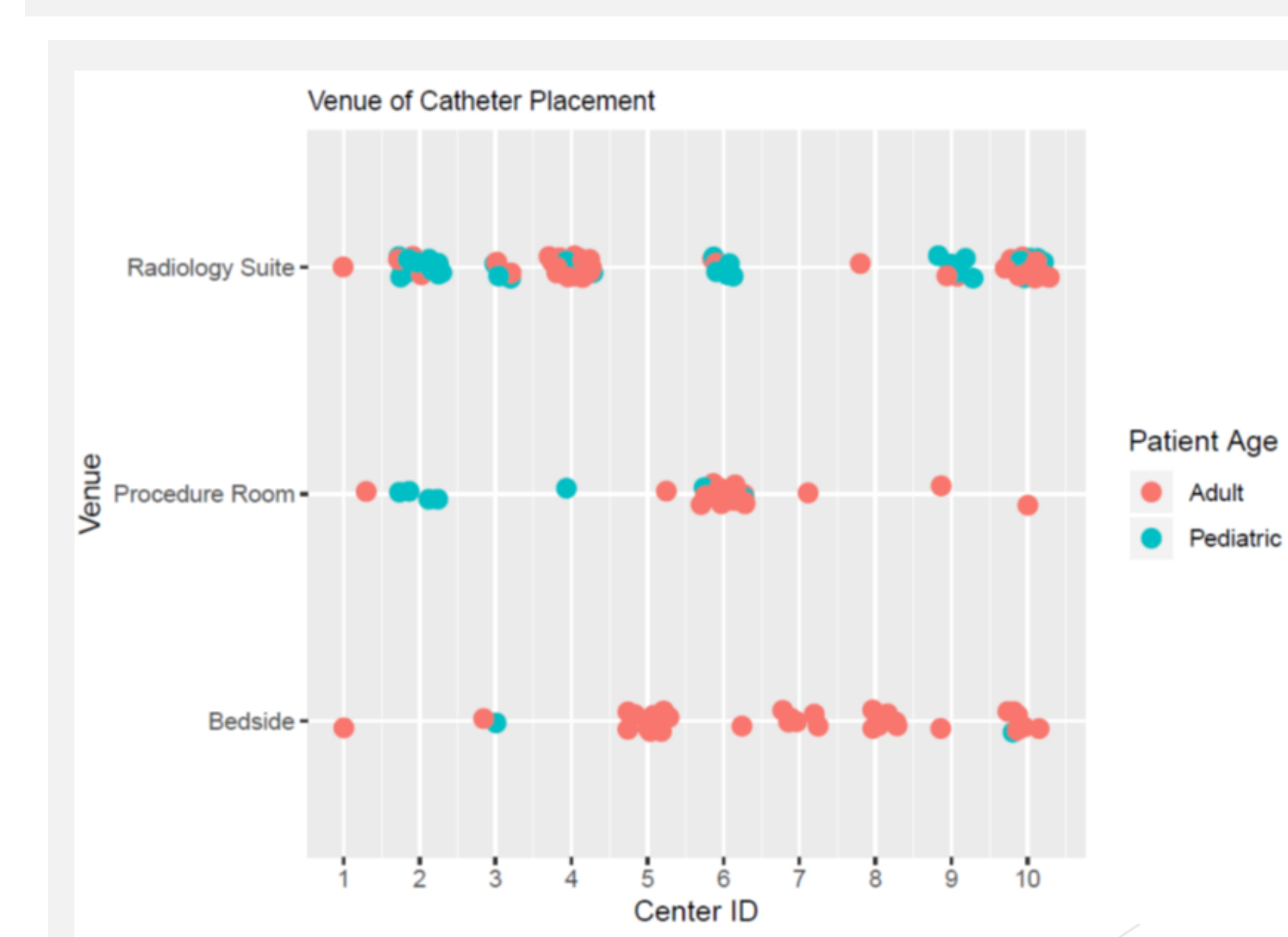
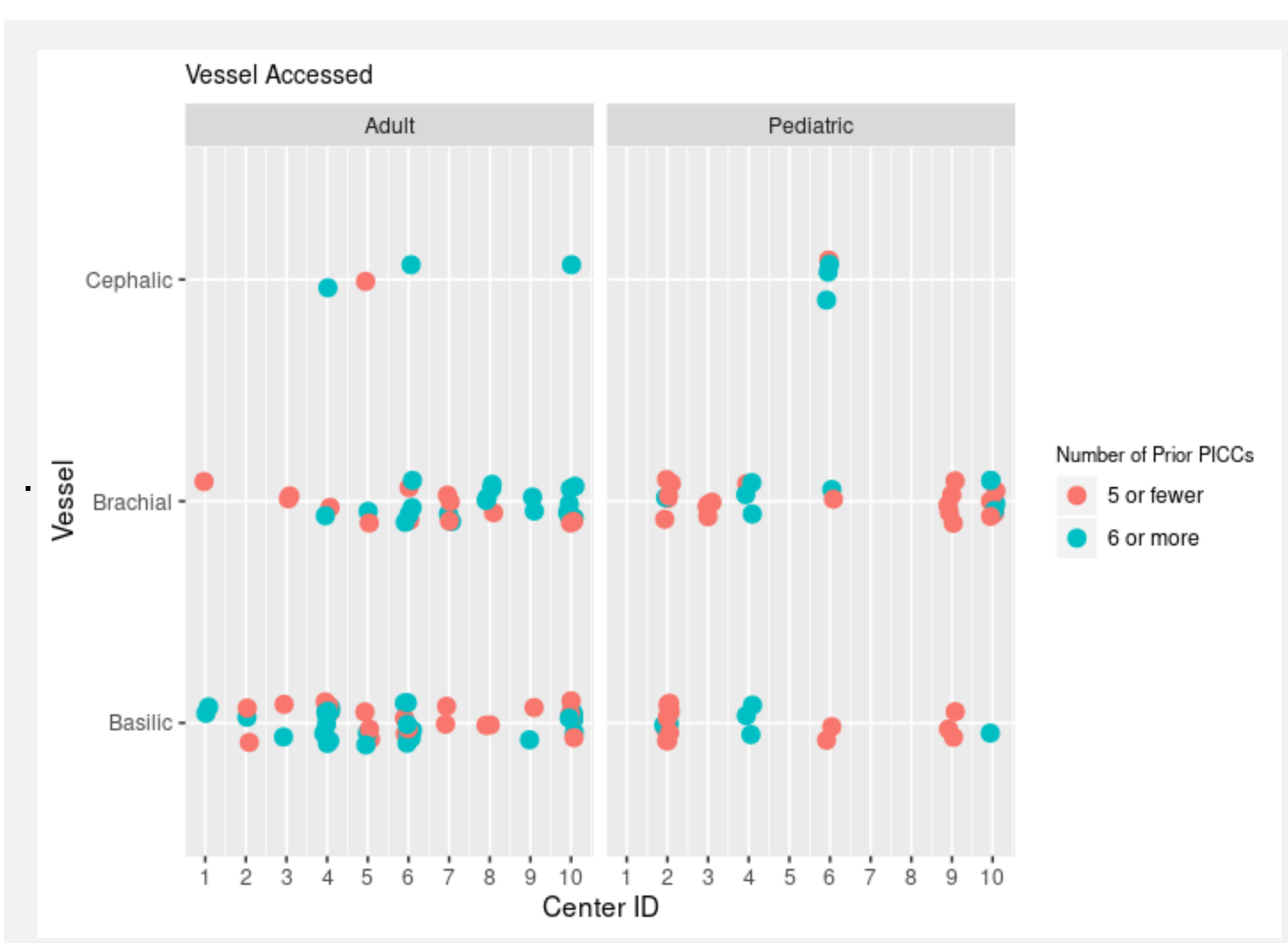
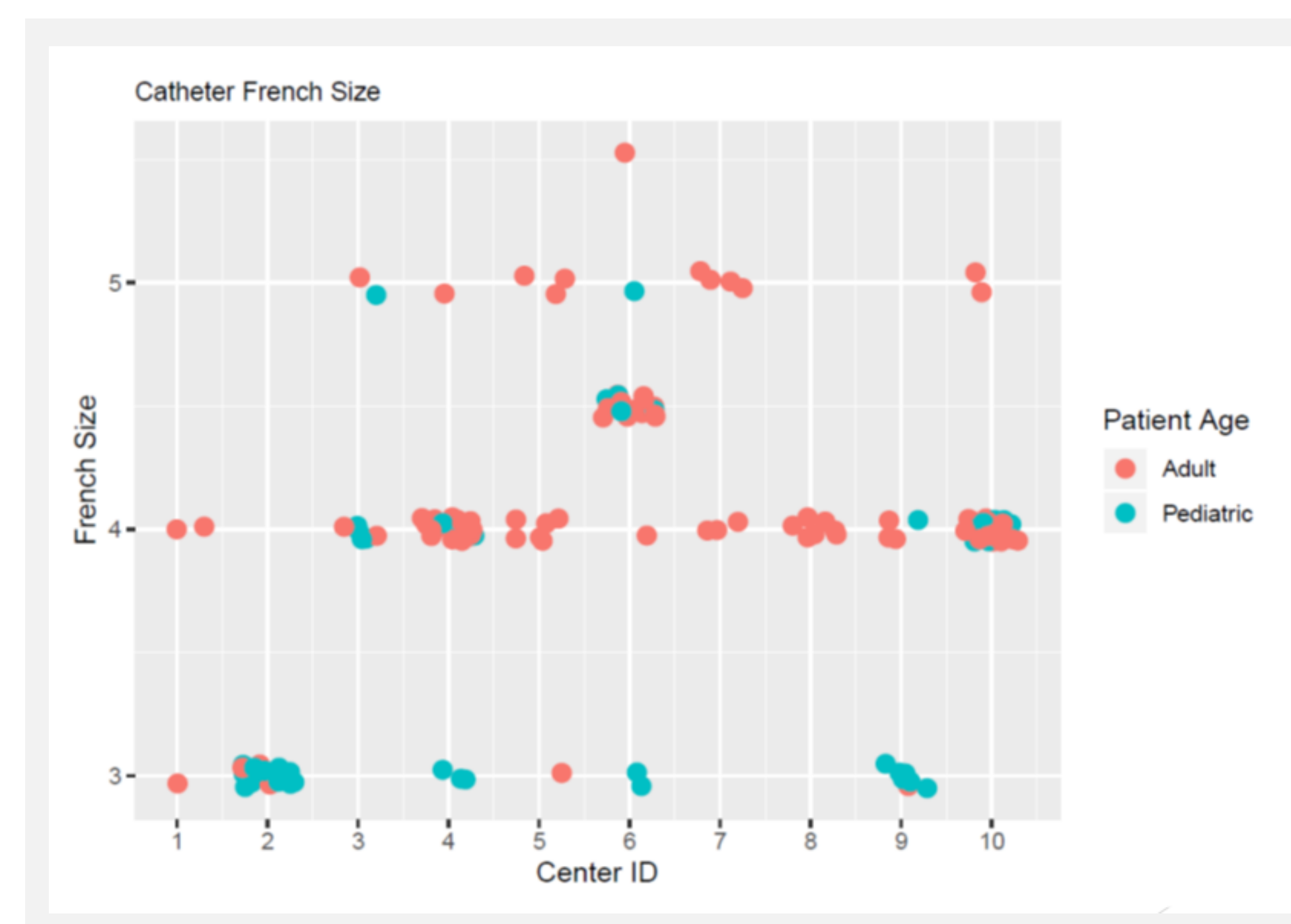
Primary Endpoint The primary endpoint is the occurrence of vascular complications, defined as occlusion of the catheter requiring removal or symptomatic venous thrombosis in the extremity with the line as indicated by a Constans Clinical Decision Score ≥ 2 during the time the catheter is in place (the 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.

Characteristic	N=150	median (IQR); n (%)
Female	150	62 (41%)
Age (years)	150	21 (15, 30)
Prior PICCs	138	5.0 (3.0, 9.0)
Unknown		12
BMI kg/M ² for age > 21 years	64	21.6 (19.8, 24.0)
BMI percentile for age ≤ 21 years	71	35 (19, 60)
Unknown		15
Diabetes	150	55 (37%)
Oral contraceptive use	150	3 (2.0%)
Genotype	148	
Homozygous F508del		65 (44%)
Heterozygous F508del		71 (48%)
Other		12 (8.1%)
Unknown		2
FEV1 % Predicted (best in past 12 months)	150	73 (50, 91)
Sputum Culture (All recorded in last 12 months):		
<i>Pseudomonas aeruginosa</i>	150	96 (64%)
<i>Staphylococcus aureus</i> (MSSA)	150	64 (43%)
<i>Staphylococcus aureus</i> (MRSA)	150	50 (33%)
<i>Burkholderia cepacia</i> spp	150	4 (2.7%)
Non-tuberculous mycobacteria	150	11 (7.3%)
Other	150	73 (49%)

	N	1 N=3	2 N=21	3 N=8	4 N=28	5 N=10	6 N=25	7 N=7	8 N=7	9 N=11	10 N=30
Length of treatment (Days)	150	15 (14,18)	9 (7, 11)	14 (10, 16)	14 (9, 15)	14 (11, 15)	13 (13, 14)	15 (14, 16)	14 (14, 14)	18 (14, 20)	12 (10, 13)
Received home treatment	150	1 (33%)	0 (0%)	2 (25%)	8 (29%)	9 (90%)	10 (40%)	5 (71%)	1 (14%)	8 (73%)	9 (30%)
Percent treatment at home	48	36 (36, 36)	NA	82 (78, 86)	52 (48, 61)	85 (78, 88)	57 (53, 69)	73 (62, 80)	64 (64, 64)	68 (52, 86)	75 (57, 88)

Statistics presented: median (IQR); n (%). *Only for those receiving treatment at home



Visual overview of aggregate data by center with Eventflow[®] software showing varying patterns of line care in the inpatient and outpatient settings. The ordinate indicates the individual catheter count. Line care events are shown by colored bands. The central gray bar indicates the transition from inpatient to outpatient care by study site.

Conclusions

- We see early evidence of practice variation across sites
- The current rate of enrollment suggests that we will reach our target of 1000 patients during the anticipated 3 year study period

Future Directions

- The 3 year study is designed to measure rates of the following complications of PICC placement: venous thrombosis, phlebitis and catheter associated blood stream infections
- We plan to also evaluate risk factors for these complications based on patient characteristics, catheter factors, and catheter management factors
- For details on the study design please visit: www.picccf.org

Acknowledgements:

• This study was funded by CF Foundation Grant ZUCKER18A0

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

• Production team for Eventflow software. For more information, visit the development website: <http://hci.umd.edu/eventflow>

