PEPPER

Pulmonary Embolism Prevention after hiP and kneE Replacement

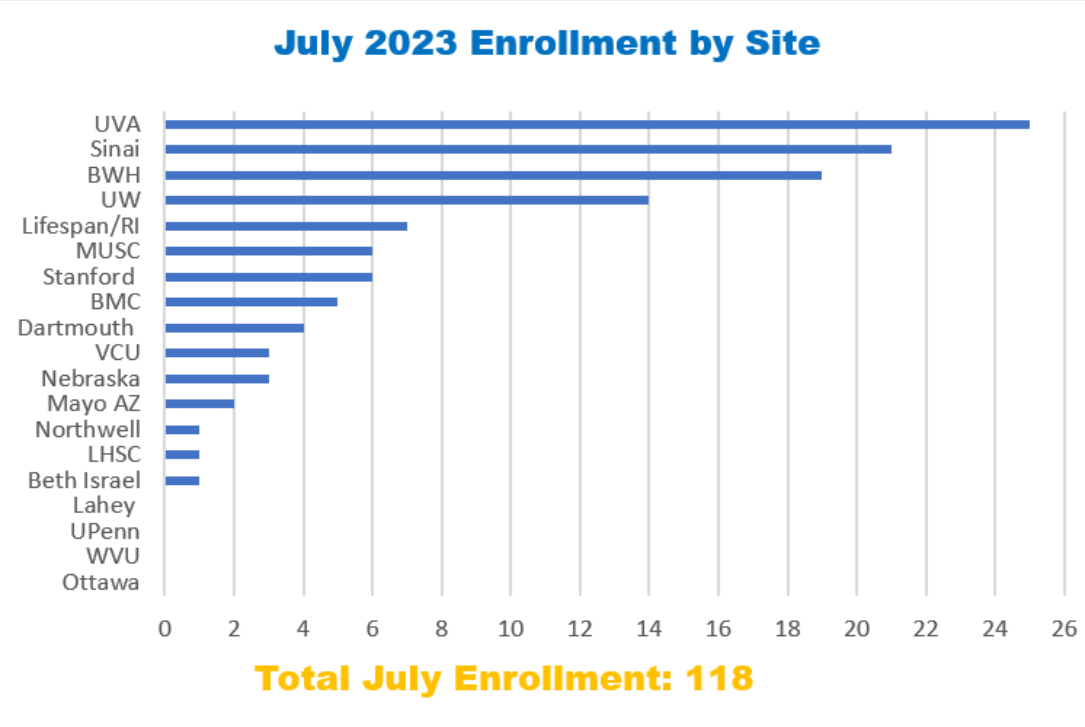
August 2023

In this issue:

- Recruitment
- LTFU
- Global Call
- PEPPER Puzzler
- Reminder
- Coordinator Profile

Recruitment

With an easier protocol to now present to patients, let's concentrate on getting enrollment up! One way to increase our numbers is to have a larger population to enroll from, if you have a surgeon interested in PEPPER—let us know!



Edson De Guzman, Tanya Khatri and **Eric Jordan** lead the charge in July at UVA, Sinai and BWH.

Ann at UW, **Melanie Morgan** at VCU and **Angela Bye** at Stanford posted their highest month of 2023 in June. **Anthony Lancellotti** at Lifespan and **Emma McLeod** at MUSC posted their highest totals for the year in May.

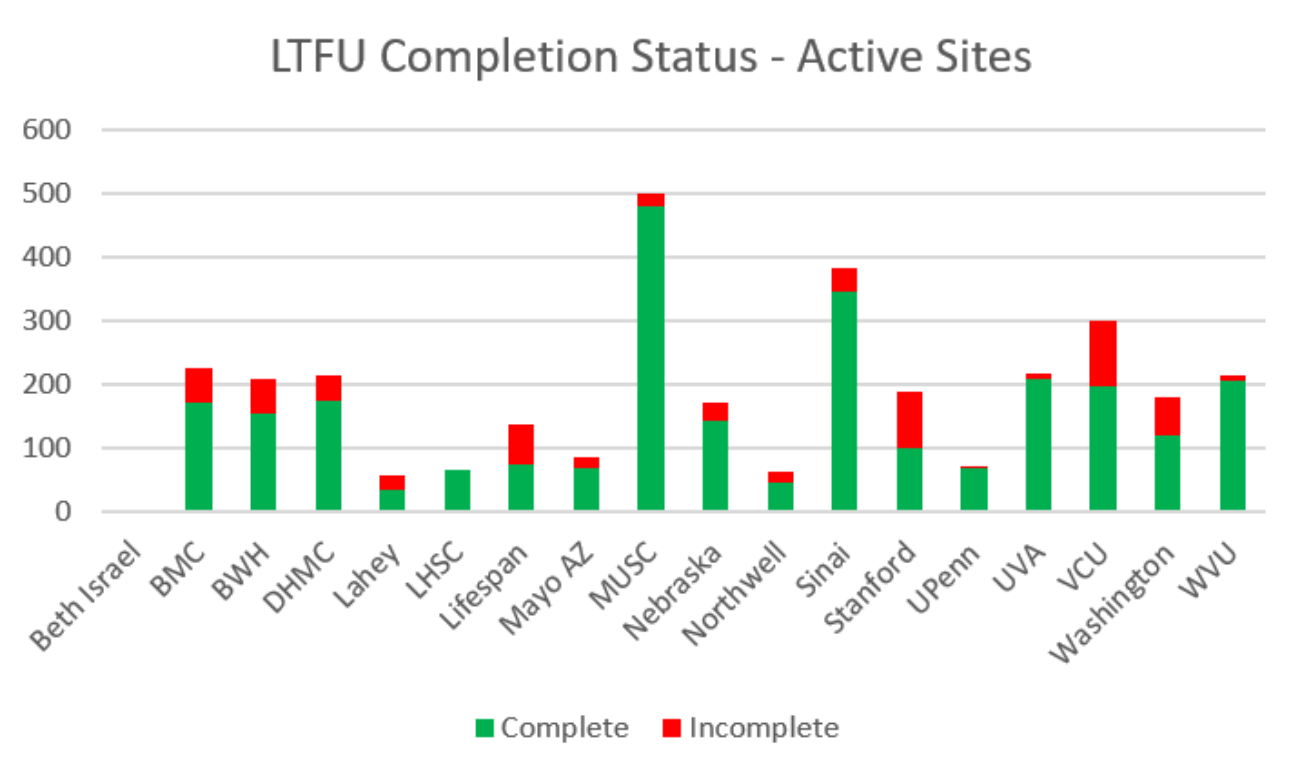
Lost to Follow Up

Interim Analysis Update

Thank you for attending to your lost to follow up! We were able to provide the **PEPPER** data safety monitoring board with a 96% follow up rate at our 75% interim analysis in June. This represents your hard work of calling patients who did not fill out their 6 month survey. The board reported no safety concerns and encouraged continuation of the study to our goal recruitment numbers. We still need you to attend to this important work though as the next analysis will be at study end and will be our last chance to record patient outcomes!

Remember:

1. We ask you to attempt to contact a patient three times
2. Then attempt to contact their alternate (if they provided one) three times
3. If you are unable to retrieve a six month survey: **Do a medical record review**



Global Call

Enrollment

Thank you to all who attended our latest global call focused on enrollment. We had 17 coordinators from 14 sites! Thanks again to **Eric Jordan** for presenting

Here are just few takeaways form the call:

Establish Familiarity

If calling a patient, in order to establish familiarity, **let them know you are from their surgeons office**

If the surgeon has already talked to the patient about the study, let them know that **the surgeon recommended they speak to you**

Be Prepared

Have a **general structure** in place to explain **PEPPER** to patients but **be flexible** to changing this to suit a particular patient

Prepare for the conversation by **learning their history**. If they have had this kind of surgery before or take chronic aspirin it can make it easier to start talking about blood thinners

Emphasize Safety

Let them know there is **no experimental medication**, dose, or placebo involved, that both **medications are in standard use** for this type of operation. We are just trying to figure out **which one is best for patients like them**

While it's important to explain about blood clots and the reason for a blood thinner, it's also **important to let the patient know that blood clots are rare**

Explain the **pluses and minuses of the two drugs**. For example Xaralto may be slightly better than aspirin at preventing clots, but has a higher risk of bleeding complications than aspirin

Many patients will ask what their doctor typically uses and in many case this is aspirin. Explain to them that this is because **aspirin is convenient and inexpensive, not because it is necessarily better**

Persistence and Patience

Approach each patient with an open mind, don't make assumptions. **Be persistent**, some who are hesitant at first will come around once their questions are answered

Be kind to yourself. Some weeks will go better than others. Just keep plugging along trying your best and making changes where you think you can adjust your approach

PEPPER Puzzlers

These are **real life situations** that happened to Coordinators. What would you do? **What *should* you do according to protocol?**

A patient is randomized to aspirin. After discharge you are notified the patient returned to the hospital several days later with nausea and stomach pain and was switched to a non PEPPER medication.

Do you need to fill out a PD for missed medication or an AE form since they returned to the hospital?

a. Yes, fill out both forms since we'll want to know about any missed doses and any problems a patient has
b. Only fill out the PD form to let us know about the missed doses
c. No need to fill out any paperwork (YAY!)
d. Fill out only the AE, we don't need to know about missed doses after the patient is discharged

See the bottom of page 5 for the answer!

Reminder!

Make sure to call patients randomized to Rivaroxaban at home to get the day and time they took their first dose. Your call can also serve as a reminder for those patients who forgot to take it!

Meet: Tanya Khatri

Site: Rubin Institute for Advanced Orthopedics (Sinai)

What is your background?

I have a medical degree (MBBS) from Kathmandu University, Nepal Medical College Teaching Hospital. I also have a Master of Public health (MPH) degree from University of Maryland School of Medicine.

What do you enjoy most about working on PEPPER?

I enjoy the sense of belonging due to the constant support from the team members and receiving feedback and improving my skills.

Favorite movie, music or food?

Favorite movie – Forest Gump

Favorite music– Everything

Favorite food – Meatballs, mashed potatoes and peas from IKEA

Fun fact or hobby:

I love nature, sports activities and travelling

PEPPER Puzzler — **Answer**

The answer is c—no paperwork. You only need to fill out a PD for medication doses missed while the patient is in the hospital, the 1 month survey is designed to pick up missed doses or medication switches after discharge. While stomach pain and nausea are very uncomfortable for the patient it is not an AE that we collect, so no AE will need to be submitted for this patient. But if you are ever unsure—just ask!