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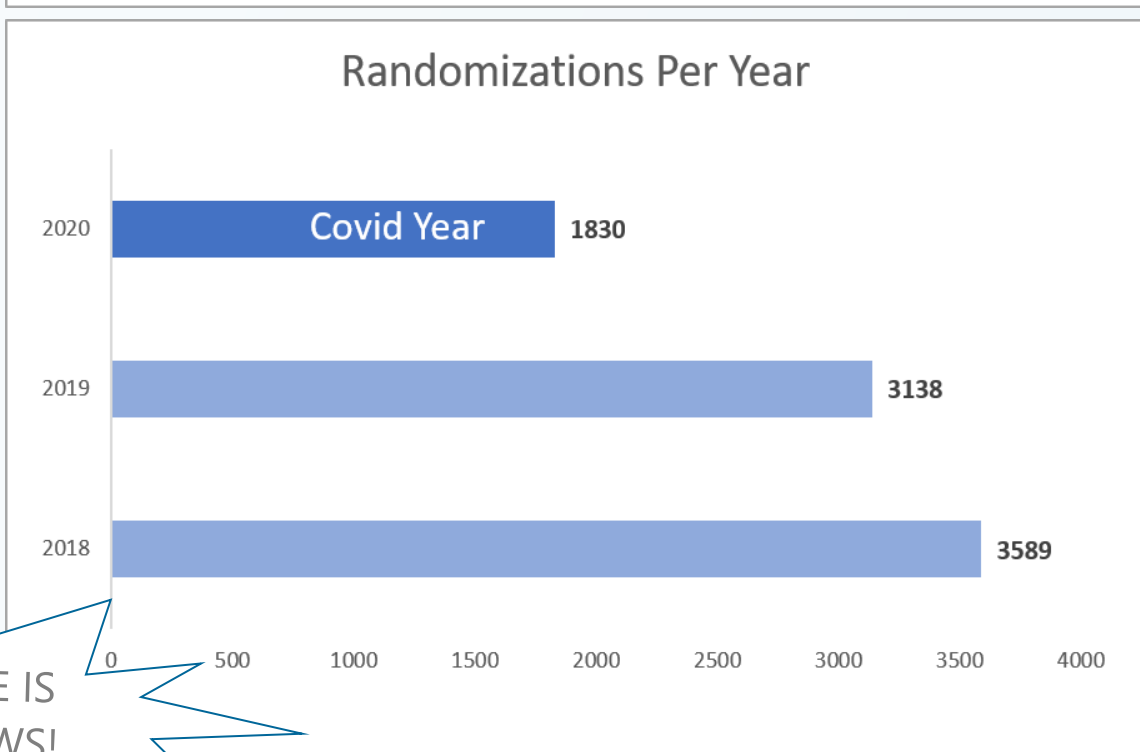
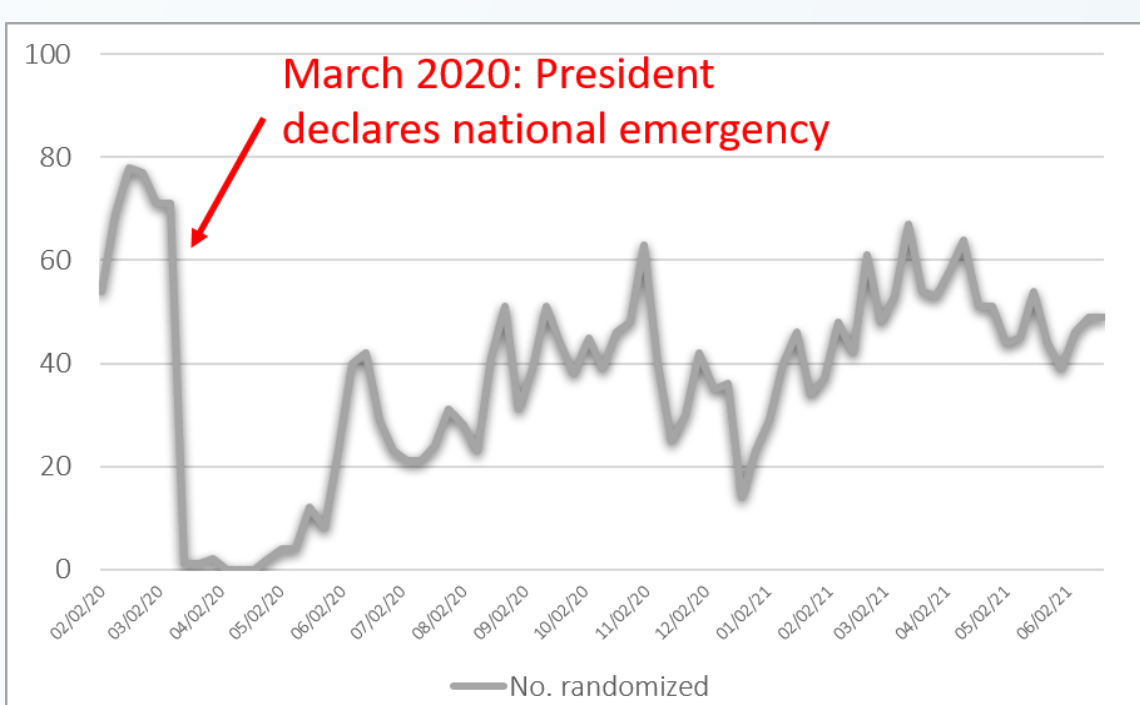
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COVID Recruitment Review

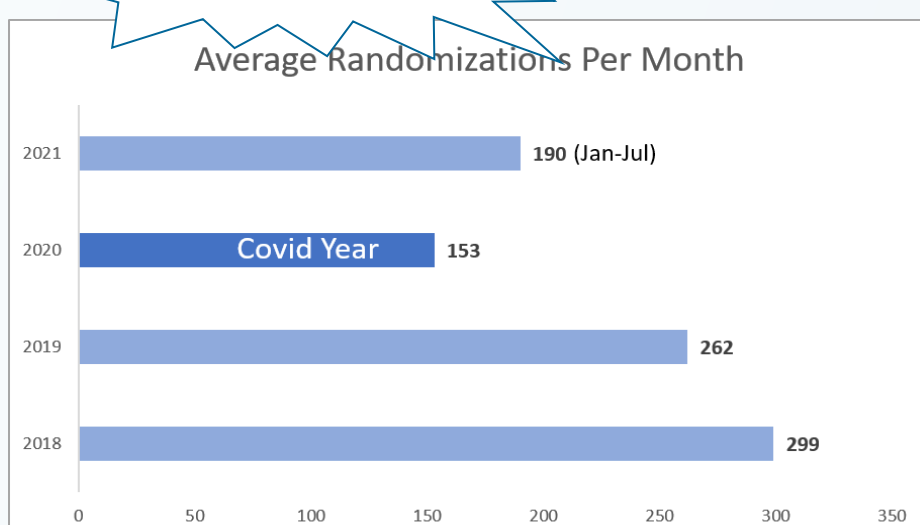
The Covid-19 pandemic brought along many challenges for the PEPPER team. As elective surgeries were put on pause across the country, the PEPPER study certainly felt the effects.

Study-wide recruitment dropped down to just 3 patients enrolled in April of 2020 as surgeries were canceled and in-person research was prohibited.

Our overall randomizations during 2020 was cut in half compared to our previous pre-Covid years.



BUT THERE IS GOOD NEWS!



Recruitment is making a comeback in 2021!

Our monthly averages are increasing as surgical cases have been ramping up. Coordinators should be prepared for pre-covid recruitment volumes*.

*New Covid variants and their effect on surgical volumes are being monitored by the lead team.

Enrollment Enhancements

Tips and Tricks from your fellow coordinators to ensure a smooth enrollment process!



- Ask the patient if their surgeon has discussed the blood thinner with them. Reiterate that this is a standard of care practice after these types of procedures—Ebony P., MUSC
- Make sure patients understand what the medication is for. The surgery can put the patient at risk of clotting, and the medication helps to prevent this — Melanie M., VCU
- Use simple phrases to help patients understand and reduce fear of the unknown. Instead of saying 'DVT' or 'PE', try saying 'clots in the legs or lungs' —Angela B., Stanford
- Point out that the best blood thinner is not known. This is where the research comes in! All care related to the surgery remains exactly the same, a blood thinner is simply chosen for you.—Eric J., BWH
- When a patient asks what they would receive if they are not a PEPPER participant, tell them what the standard of care is at your hospital. However, make it known that their surgeon has experience with all medications involved and must approve the patient's participation in the study. —Melanie M., VCU

Do you have any tips that you use to make enrolling easier for you and your patients? Share them with us on our next Global Site Call, or send them to pepper@muscd.edu

E-Consenting: Is it for you?

YES!

All PEPPER sites have been approved to use e-consenting and a REDCap e-consent platform is already up and running. There are two ways to use this platform:

Remote E-Consenting

- Consent the patient either via phone or video call
- Patient must have an email address to receive REDCap consent/surveys via email

Face-to-Face E-Consenting

- Consent the patient in person using the REDCap platform on a tablet or computer

Benefits of Remote E-Consenting

- Consent patients on your own time
- More flexibility for patients
- No waiting around in clinic
- No traveling to clinic specifically for consenting for PEPPER
- Patients are not tired after a long clinic day

Tips for Successful E-Consenting

- REDCap emails may go to junk folders—make sure the patient checks there too!
- Use "Save and Return Later" button if patients want to complete surveys later
- Quick turn-around time to surgery? Let the surgeon know they may be receiving a sign off form to complete

Statix 2.0

Thank you all for a nearly seamless transition to Statix 2.0! This updated database had been in the works for some time and we appreciate all of your patience and understanding as it was built and implemented.

Our #1 FAQ

Pre-Screening Form Question #1

“Was this participant previously prescreened in Statix v1?”

Answer ‘Yes’: Patient has been pre-screened in v. 1 and is now ready to be screened (pass or fail) for that same operation.

Answer ‘No’: Patient is a brand new patients; Patient has been previously enrolled/Screenfailed for one operation and is now returning for a different surgery.

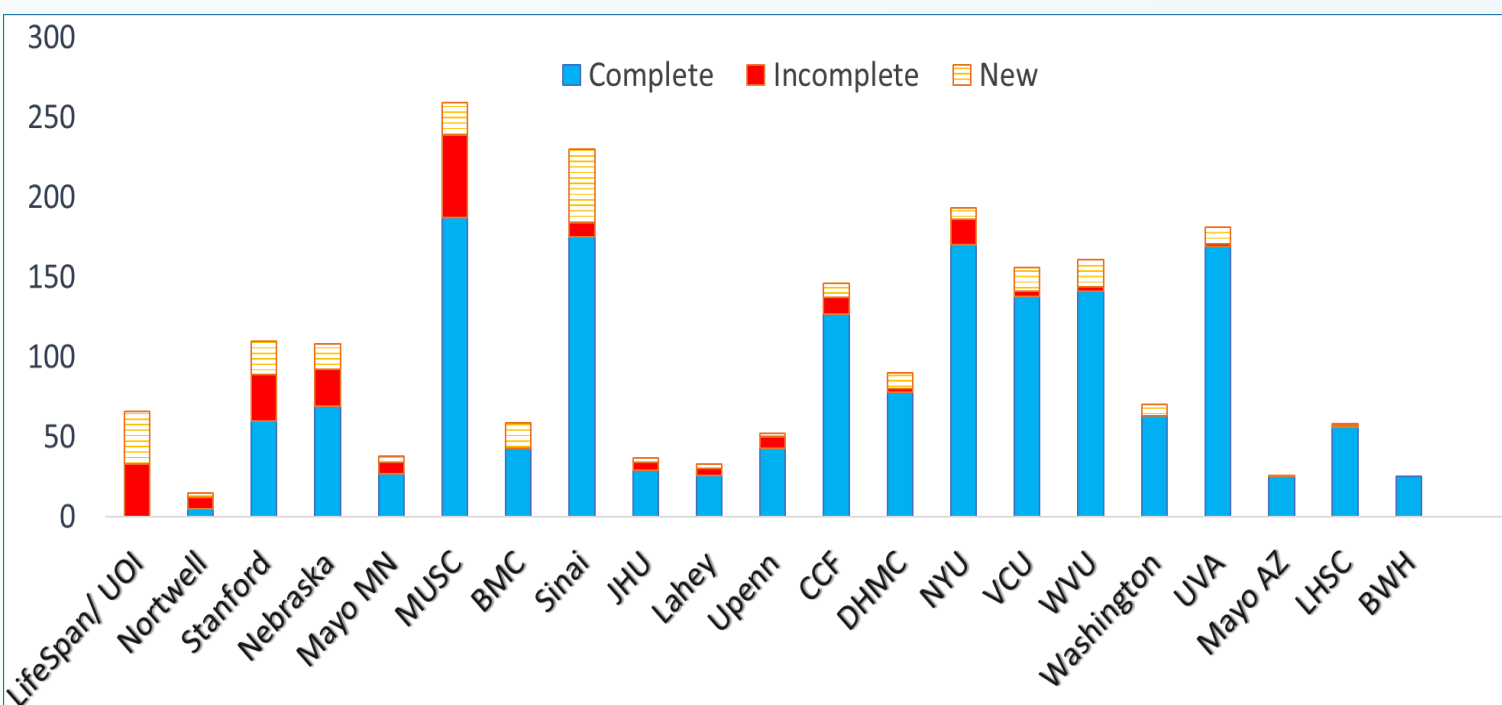
Other Statix 2.0 Reminders:

- **Date of Birth** must be entered with a 4 digit year otherwise they will default to ‘20XX’. Example: When you enter ‘57’—this becomes 2057. Please specify ‘1957’.
- **Edit function** is coming soon! If you need to edit data you have already entered, please reach out and let us know!
- **Dashboard Power BI** reports coming soon! Let us know if there is anything specific you’d like to see on these reports!



Lost to Follow Up

New patients have recently been added to the LTFU REDCap database. A study-wide email with brief instructions was sent on 8/10/21. **Is your site in the red?** Log in to REDCap and help us close the loop on these patients!



ALERT!

DUPLICATE ENROLLMENT ERRORS

- Patients should **never** be enrolled in PEPPER twice
If a previous PEPPER patient returns for a second/ third/etc. joint replacement, they must be pre-screened but Screenfailed based on exclusion criteria #2
- Patients who refuse participation should **never** be approached again for PEPPER
This can be viewed as coercion!

CHECK YOUR ENROLLMENT LOG

Ensure that the patient has not already been enrolled in the study or has previously refused participation prior to approaching them for PEPPER

Interim Analysis Results

The PEPPER study DSMB recently met to perform the interim analysis of 10,000 randomized patients with a 97% 6-month follow-up rate. The results?

No safety Concerns in any medication arm of the trial

No clear “winner” out of the 3 medications

ONWARD TO 20,000 PATIENTS!

“See” You Soon!

Virtual PEPPER Investigator Meeting

Monday August 30th

12pm– 5pm EST

Please send any topics, ideas, or questions you’d like to discuss during the meeting to Monica Baczko (Baczko@musc.edu) by Friday August 27th.

PEPPER Website

Enrollment numbers, FAQs, training guides, and more can all be found on the secure Investigator section* of the PEPPER website.

www.pepperstudy.org

Password: PEPPERstudy1

*This password protected side of the website should only be accessed by PEPPER study staff. The password and information displayed on the Investigator portion of the website should never be shared with patients or others not associated with PEPPER.