Title:
Patient Education Bundle vs. Nurses feedback and Coaching to Prevent Missed Doses of Venous Thromboembolism (VTE) prophylaxis: A crossover, cluster randomized controlled trial

Acronym:
ENACT (Patient **E**ducation Bundle vs. **N**urses Feedb**A**ck and **C**oaching Trial)

Primary Investigator:
Elliott R. Haut, MD, PhD

Location:
The Johns Hopkins Hospital, Baltimore, MD

Overview
VTE associated harm is underappreciated among hospitalized patients and may be associated with missed doses of VTE prophylaxis medications. In order to ensure best practices, and administer a defect-free VTE prevention nurses must understand and educate patients on the importance of the VTE prophylaxis. We propose to conduct a randomized trial comparing the effect of a validated, real-time patient education bundle (PEB), to a program of nurse feedback and coaching (NFC) provided by nurse leaders.

Background
Missed doses of prescribed Venous Thromboembolism (VTE) pharmacologic prophylaxis is significant problem. Data on patients admitted to The Johns Hopkins Hospital found approximately 12% of prescribed doses of pharmacologic VTE prophylaxis were not administered. There were several reasons for these missed doses. The leading reason (nearly 60% of missed doses) was patient or family member refusal for any reason.

Based on data collected by the Maryland Health Services Cost Review Commission (HSCRC) in the Maryland hospital-acquired conditions (MHAC) program, during 2011 half of patients who developed confirmed VTE at The Johns Hopkins Hospital were not administered one or more doses of prescribed VTE prophylaxis. These data indicate that missed or refused doses of VTE prophylaxis represent a significant and under-recognized contributor to sub-optimal VTE prophylaxis that will erode the beneficial impact of current efforts to improve rates of VTE prophylaxis ordering by physicians.

As part of a Patient-Centered Outcomes Research Institute (PCORI)-funded project, the investigators have developed a registry of missed doses of VTE prophylaxis that includes data on missed doses of VTE prophylaxis.

Primary hypothesis
Both interventions (PEB and NFC) will improve medication administration (as measured by missed doses)

Secondary hypotheses
1. Combining both interventions (PEB and NFC) will decrease patient refusal of VTE prophylaxis
2. Combining both interventions (PEB and NFC) will decrease missed doses for reasons other than patient refusal

3. Overall, PEB intervention will be more effective than NFC in reducing missed doses for any reason:
    a. The PEB intervention will be more effective than NFC in reducing in reducing patient refusal
    b. The NFC intervention will be more effective than PEB in reducing missed doses for other reasons of missed doses other than patient refusal
4. There will be a differential effect on medicine and surgery floors
5. There will be a differential effect by patient level characteristics (race, age, sex)
6. There will be a differential effect on high vs. low performing floors
7. There will be a differential effect dependent on pharmacological dosing regimen (i.e. medication, frequency)
8. There will be an overall decline in the incidence of VTE events (all, DVT, PE)

Design
A single institution, crossover, cluster randomized controlled trial (x-cRCT).

Participants
Eligibility Criteria
Participating floors will be assigned one of two interventions based on a randomization sequence.
Eligible floors are defined as:

A. All medical and surgical floors (non- intensive care units)
B. 16 total floors (10 medicine, 6 surgery)

Eligible Patients are defined as: All patients on assigned floors except:

A. Patient data for those transferred between floors will be excluded.
B. Patient data for those on floors during the cross-over time will be excluded.

Intervention
In the PEB arm, the intervention will include:
A charge nurse will intervene in real-time via an EHR-triggered alert when there is documentation that a dose of VTE prophylaxis medication is not given for any reason. The charge nurse will speak to the bedside nurse and one of them will provide the patient with the education bundle including one-on-one personalized discussion, supplemented by a 2-page paper handout and patient education video.

In the NFC arm, the intervention will include:
Nurse leadership (i.e. managers, directors) will provide data to all nurses on their personal clinical effectiveness with the proportion of doses of VTE prophylaxis administered. The data will have comparisons to their nurse peers on the same floor. Coaching for nurses will include one-on-one conversations with bedside nurses with lower performance than their peers.

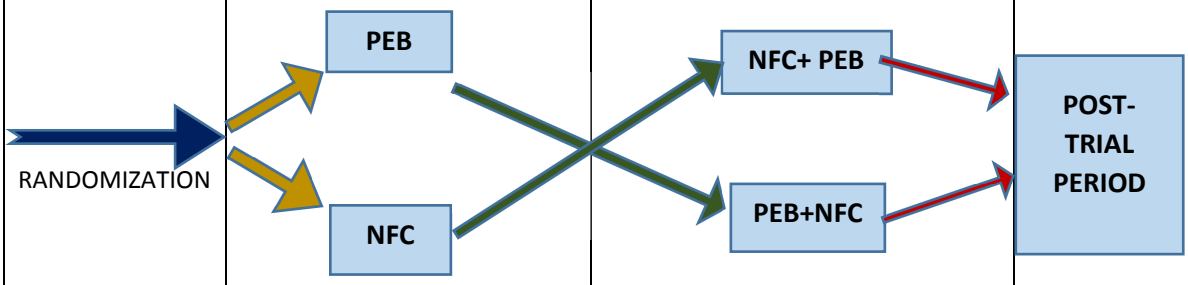
Primary Outcome:
Missed doses of VTE prophylaxis

Secondary outcomes:
Patient refused doses of VTE prophylaxis
Missed doses of VTE prophylaxis for reasons other than patient refusal
VTE events (all VTE, DVT, PE)
Patient satisfaction (via surveys and HCAHPS scores)

Nurse satisfaction

Analysis plan

We will have a blinded biostatistician team perform all analyses.
We will use the intention-to-treat (ITT) approach.
We will compare outcomes across intervention periods.
We will compare outcomes based upon randomized floor.
We will use multiple outputation to reduce the levels of hierarchical structure to the floor and nurse level by randomly selecting one VTE prophylaxis dose per patient and reiterate the procedure 1000 times to bootstrap the p values for the comparisons. This methodology will be similar that taken previously in our prior work in similar circumstances.
We will adjust by floor type (medicine vs. surgery) and patient level characteristics (race, sex, age, insurance) when calculating proportions and risk of missed doses.
We will conduct a sensitivity analysis (excluding floors where prior intervention occurred).
Check for differential effect that may eliminate biases in pre-implementation data (by race, age, sex)

PRE-TRIAL (6 MONTHS)	PERIOD I (3 MONTHS)	PERIOD II (3 MONTHS)	POST-TRIAL (3 MONTHS)	
				
Randomization with sequence generator	Block (Medicine): 5 Medicine floors- PEB 5 Medicine floors- NFC Block (Surgery): 3 Surgery floors- PEB 3 Surgery floors- NFC	Block (Medicine): 5 Medicine floors- PEB+NFC 5 Medicine floors- NFC+PEB Block (Surgery): 3 Surgery floors- PEB+NFC 3 Surgery floors- NFC+PEB	Observation assessment	