Table of Contents

Appendix A - Pharmacist Call Tool Knowledge Check Items

Appendix A - Pharmacist Call 1 Tool Knowledge Check Items

Record ID

_____

Adherence: [pharm1_med1_name]

Can you tell me how you take your [pharm1_med1_name]?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Probe: What time of day, how often

_____

Have you ever missed a dose of [pharm1_med1_name]?

Probe: What did/would you do if this happened? Have you ever decided to purposely not take a dose? If so, why?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

_____

Interactions and Side Effects: [pharm1_med1_name]

Are you aware of any medications that you should avoid while taking your [pharm1_med1_name]?

Probe: Are there any medications that you are unsure about?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

_____

Are you aware of any food or beverages you should avoid while taking your [pharm1_med1_name]?

Probe: Are there any food/beverages that you are unsure about?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

_____

Can you tell me the common side effects of [pharm1_med1_name]?

Prompt: Have you experienced any of these or are you worried about any in particular?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Adherence: [pharm1_med2_name]

Can you tell me how you take your [pharm1_med2_name]?

Probe: What time of day, how often

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Have you ever missed a dose of [pharm1_med2_name]?

Probe: What did/would you do if this happened? Have you ever decided to purposely not take a dose? If so, why?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Interactions and Side Effects: [pharm1_med2_name]

Are you aware of any medications that you should avoid while taking your [pharm1_med2_name]?

Probe: Are there any medications that you are unsure about?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Are you aware of any food or beverages you should avoid while taking your [pharm1_med2_name]?

Probe: Are there any food/beverages that you are unsure about?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Can you tell me the common side effects of [pharm1_med2_name]?

Prompt: Have you experienced any of these or are you worried about any in particular?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Adherence: [pharm1_med3_name]

Can you tell me how you take your [pharm1_med3_name]?

Probe: What time of day, how often

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Have you ever missed a dose of [pharm1_med3_name]?

Probe: What did/would you do if this happened? Have you ever decided to purposely not take a dose? If so, why?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Interactions and Side Effects: [pharm1_med3_name]

Are you aware of any medications that you should avoid while taking your [pharm1_med3_name]?

Probe: Are there any medications that you are unsure about?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Are you aware of any food or beverages you should avoid while taking your [pharm1_med3_name]?

Probe: Are there any food/beverages that you are unsure about?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Can you tell me the common side effects of [pharm1_med3_name]?

Prompt: Have you experienced any of these or are you worried about any in particular?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Adherence: [pharm1_med4_name]

Can you tell me how you take your [pharm1_med4_name]?

Probe: What time of day, how often

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Have you ever missed a dose of [pharm1_med4_name]?

Probe: What did/would you do if this happened? Have you ever decided to purposely not take a dose? If so, why?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Interactions and Side Effects: [pharm1_med4_name]

Are you aware of any medications that you should avoid while taking your [pharm1_med4_name]?

Probe: Are there any medications that you are unsure about?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Are you aware of any food or beverages you should avoid while taking your [pharm1_med4_name]?

Probe: Are there any food/beverages that you are unsure about?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Can you tell me the common side effects of [pharm1_med4_name]?

Prompt: Have you experienced any of these or are you worried about any in particular?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Adherence: [pharm1_med5_name]

Can you tell me how you take your [pharm1_med5_name]?

Probe: What time of day, how often

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Have you ever missed a dose of [pharm1_med5_name]?

Probe: What did/would you do if this happened? Have you ever decided to purposely not take a dose? If so, why?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Interactions and Side Effects: [pharm1_med5_name]

Are you aware of any medications that you should avoid while taking your [pharm1_med5_name]?

Probe: Are there any medications that you are unsure about?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Are you aware of any food or beverages you should avoid while taking your [pharm1_med5_name]?

Probe: Are there any food/beverages that you are unsure about?

- ◯ Patient answered correctly
- ◯ Patient answered incorrectly
- ◯ No response/I don't know

Can you tell me the common side effects of [pharm1_med5_name]? Prompt: Have you experienced any of these or are you worried about any in particular?	◯ Patient answered correctly ◯ Patient answered incorrectly ◯ No response/I don't know

Storage and Organization: All Meds

Where do you typically store your medication? Probe: Which room of the household	◯ Patient answered correctly ◯ Patient answered incorrectly ◯ No response/I don't know
How do you currently organize your medications?	◯ Patient answered correctly ◯ Patient answered incorrectly ◯ No repsonse/I don't know

Contact Information

Do you know how to contact me, the study pharmacist if you have any questions? Probe: Safety net line (508-441-3562)	◯ Patient answered correctly ◯ Patient answered incorrectly ◯ No response/I don't know
during the complication (refills - e.g. explaining that our pharm tech will do benefits investigation for subsequent months)	◯ Addressed ◯ Not addressed

Topics discussed between pharmacist and patient

- ☐ Dose
- ☐ Side effects
- ☐ Med Interactions
- ☐ Storage
- ☐ Refills
- ☐ Risks
- ☐ Benefits
- ☐ Safety Net Phone Number (508-441-3562)
- ☐ Other antithrombotics
- ☐ Information about other medications
- ☐ Other

Other comments about discussion with patient

_____

Recommendations of Educational Materials from Pharmacist

Patient Preference for sending educational materials

- ☐ Mail
- ☐ Email
- ☐ Declined

Preferred or recommended format of educational materials

- ☐ Paper
- ☐ Pill Organizer
- ☐ Other

- ◯ 1x a day
- ◯ 2x a day
- ◯ 3x a day

Medications Detailed in Educational Material

- ☐ Apixaban
- ☐ Rivaroxaban
- ☐ Dabigatran
- ☐ Edoxaban
- ☐ Med Safety Tip

Notes in EPIC/Follow UpCall Status will need to be updated to branch the appropriate note template (call completed or lost to follow up)

Date of note in EPIC

_____

Time of note in EPIC

_____

LEAVE SAFE with DOACs Research Study Encounter

[name_first] [name_last] is participating in a research study, Leave Safe with DOACS.

Briefly, LEAVE Safe with DOACs is a medication safety research study focused on ambulatory patients prescribed direct oral anticoagulants (DOACs). Our primary study goal is to improve care transitions by assessing the impact of an intervention on clinically important medication errors.

Transition events which could have led to the patient being eligible include new venous thromboembolism event, worsening of existing venous thromboembolism event, new stroke or transient ischemic attack, bleeding, or change from one anticoagulant to another.

Our pharmacy team is ready to assist each patient with acquisition and affordability surrounding the use of DOACs. We will continue to follow patients for three months from study enrollment, even if they have discontinued the medication.

Prior to speaking with [name_first] [name_last], their chart was reviewed for contraindications and the following were found: [pharm_screen_constrain_detail].

Their chart was also reviewed for other recommended issues to consider and the following were found: [pharm_screen_recommend].

As part of the phone encounter, medication reconciliation was performed with the patient with the following outcome: [pharm1_med_rec_sum].

[med_name_1]: [pharm1_med_rec_1]

[med_name_2]: [pharm1_med_rec_2]

[med_name_3]: [pharm1_med_rec_3]

[med_name_4]: [pharm1_med_rec_4]

[med_name_5]: [pharm1_med_rec_5]

[med_name_6]: [pharm1_med_rec_6]

[med_name_7]: [pharm1_med_rec_7]

[med_name_8]: [pharm1_med_rec_8]

[med_name_9]: [pharm1_med_rec_9]

[med_name_10]: [pharm1_med_rec_10]

[med_name_11]: [pharm1_med_rec_11]

[med_name_12]: [pharm1_med_rec_12]

[med_name_13]: [pharm1_med_rec_13]

[med_name_14]: [pharm1_med_rec_14]

[med_name_15]: [pharm1_med_rec_15]

[med_name_16]: [pharm1_med_rec_16]

[med_name_17]: [pharm1_med_rec_17]

[med_name_18]: [pharm1_med_rec_18]

[med_name_19]: [pharm1_med_rec_19]

[med_name_20]: [pharm1_med_rec_20]

[med_name_21]: [pharm1_med_rec_21]

[med_name_22]: [pharm1_med_rec_22]

[med_name_23]: [pharm1_med_rec_23]

[med_name_24]: [pharm1_med_rec_24]

[med_name_25]: [pharm1_med_rec_25]

[med_name_26]: [pharm1_med_rec_26]

[med_name_27]: [pharm1_med_rec_27]

[med_name_28]: [pharm1_med_rec_28]

[med_name_29]: [pharm1_med_rec_29]

[med_name_30]: [pharm1_med_rec_30]

Additional Medications not listed: [pharm1_med_rec_add_rx] and [pharm1_med_rec_add_otc].

The following were discussed with the patient relating to their DOAC: [pharm1_topics]

Medication Adherence: [pharm1_faq_admin_notes]; [pharm1_faq_dosing_notes]

Medication Interactions: [pharm1_faq_interact_notes]

Food/Beverage Interactions: [pharm_1_food_notes]

Common Side Effects: [pharm1_faq_effects_notes]

Signs of Bleeding or Clotting: [pharm1_faq_bleeding_notes][pharm1_faq_clot_notes] [pharm1_faq_stroke]

Medication Storage: [pharm1_faq_storage_notes]

Medication Organization: [pharm1_faq_organize_notes]

Refills: [pharm1_faq_refill_comment]

The patient also discussed the following: [pharm1_pt_questions] [pharm1_pt_concerns]

Additional Comments: [pharm1_call_comments]

Feel free to reach out to us with any questions or concerns 508-441-3562 Ext. 0

Appendix A - Pharmacist Call 2 Tool Knowledge Check Items

Record ID _____

Patient Information

Patient Name: [name_first] [name_last]
Patient MRN: [mrn]
Patient Date of Birth: [dob] (Patient Age: [screen_age])
Anticoagulant(s): [cr_ac_name]
DOAC Start Date: [cr_ac_start_date]
Indication: [elig_rx_reason]
Phone: [phone_number]
Patient Preferred Language: [screen_pref_language]
Communication preferences (from call/consent form): [contact_preferred]
Patient Group: [randomize]

Planned Call 2 Date: [pharm1_plan_call2]

Review RefillsPatient Reported Start Date (from baseline): [base_acg_ptreport_start]

Start Date (from chart review): [cr_ac_start_date]

Dear [name_first],

We are reaching out because we believe the prescription for your anticoagulation medication may expire soon. If you require assistance in securing access to your prescription for the next month please let our study team know.

As a reminder, you may contact our study team at 508-441-3562 extension 1 or leave.safe@umassmemorial.org; you may also reply to this message.

If you do not respond to this message we will assume you have access to the medication you need and will not send further follow up about the upcoming month's prescription.

Thank you,
LEAVE Safe Study Team

Estimado [name_first],

Nos estamos comunicando con usted porque creemos que la receta para su medicamento anticoagulante est por caducar. Si necesita asistencia para garantizar el acceso a su receta para el prximo mes, avise a nuestro equipo del estudio.

Recuerde que puede comunicarse con nuestro equipo del estudio al 508-441-3562 o por email a leave.safe@umassmemorial.org; tambin puede responder a este mensaje.

Si no responde a este mensaje, asumiremos que tiene acceso al medicamento que necesita y no le enviaremos un seguimiento adicional sobre la receta del mes que viene.

Gracias,
El equipo del estudio LEAVE Safe

Prezado [name_first],

Estamos nos comunicando com voc porque acreditamos que a receita pelo seu medicamento anticoagulante est prestes a expirar. Se voc precisa de assistncia para garantir o acesso ao seu medicamento no prximo ms, informe a nossa equipe do estudo.

Lembre-se que pode contactar a nossa equipe do estudo pelo telefone 508-441-3562 ou pelo e-mail leave.safe@umassmemorial.org; tambm pode responder a essa mensagem.

Se voc no responder a essa mensagem, assumiremos que voc tem acesso ao medicamento que precisa e no lhe enviaremos um seguimento adicional sobre a receita do ms que vem.

Obrigado,
A equipe do estudo LEAVE Safe

Was the patient contacted via their preferred contact method? [base_refill_contact_pref]	◯ Yes; by preferred method of contact ◯ Yes; by other method of contact ◯ No
Why was the patient not contacted?	◯ The patient declined further follow up ◯ The patient previously indicated they were all set ◯ The patient is no longer taking the anticoagulant ◯ The patient has withdrawn from the study ◯ The patient is deceased ◯ Study staff were not available ◯ Other
When was the patient contacted?	_____
Did the patient respond? If so, what was the outcome?	◯ No Response ◯ Patient responded all set ◯ Patient responded needs help ◯ Patient responded please don't contact me about this again
Does patient appear to have a prescription for refill for the next 30 days?	◯ Yes; prescription is evident in EPIC ◯ Yes; previously discussed with study team member ◯ No; follow up with patient/PCP is needed (*For control patients RA will complete)
Was 30 day prescription obtained for patient?	◯ Yes; refill was obtained prior to expiration of previous prescription ◯ Yes; refill was obtained but after previous prescription expired (i.e. lapse in dose) ◯ No; new prescription was not obtained for the patient (*For control patients RA will complete)
Comments on process/status of obtaining refill for patient - Who was contacted and when? - Who assisted (leave safe study team member)? - What was the outcome?	_____ (*For control patients RA will complete)
Date to check with patient about refills (5 days before prescription expires):	_____ (*For control patients RA will complete)

Call Tracking:

Date of first attempt to reach patient for Initial Pharmacist Phone Call. _____

Who placed the call?

- ◯ Lauren Harding
- ◯ Dawn Swain
- ◯ Alok Kapoor
- ◯ Other

Comments:

Note dates and time of phone attempts, who attempted to reach (i.e. staff initials), any messages left, any contact, dates need to return a call. _____

Example: 6/23/2016, 10:30am, MES: Left message.

Control NotePatient Name: [name_first] [name_last]

Patient MRN: [mrn]

Patient Date of Birth: [dob] (Patient Age: [screen_age])

For Control Patients Only (do not complete interview)

LEAVE SAFE with DOACs Research Study Encounter

Enter the following text as a note in EPIC:

[name_first] [name_last] is participating in a research study, Leave Safe with DOACS.

Briefly, LEAVE Safe with DOACs is a medication safety research study focused on ambulatory patients prescribed direct oral anticoagulants (DOACs). Our primary study goal is to improve care transitions by assessing the impact of an intervention on clinically important medication errors.

Transition events which could have led to the patient being eligible include new venous thromboembolism event, worsening of existing venous thromboembolism event, new stroke or transient ischemic attack, bleeding, or change from one anticoagulant to another.

Our pharmacy team is ready to assist each patient with acquisition and affordability surrounding the use of DOACs. We will continue to follow patients for three months from study enrollment, even if they have discontinued the medication.

Feel free to reach out to us with any questions or concerns - 508-441-3562 Ext. 1

◯ Completed ◯ Not Completed

Date of note in EPIC _____

Who placed the note in EPIC?

- ◯ Lauren Harding
- ◯ Dawn Swain
- ◯ Alok Kapoor
- ◯ Other

Interview Information

Status:

- ◯ Reached/Completed Interview
- ◯ Reached/Declined to Complete
- ◯ Previously Declined Additional Pharm Calls
- ◯ Call Back (See Comments)
- ◯ Lost to Follow-Up (Did not reach within timeframe)
- ◯ Ineligible (please specify in Comments)

Date to Call Again

(If scheduled to call back) _____

Time to Call Again

(If scheduled to call back) _____

AFTER ASKING FOR AND CONFIRMING THAT YOU ARE SPEAKING WITH THE STUDY PARTICIPANT

Hello [name_first],

My name is [pharm2_name_caller]. I work on a research study at UMass that you've been participating in that's trying to improve care for patients who take blood thinners. Thank you again for participating in our study. I'm calling now to ask you some questions about your anticoagulant and how things have been going since we last spoke. I can also answer any questions you have about your medication.

Is this a good time for you to talk with me? We'll need about 15 minutes.

If NO
Can we set-up another time to talk? I'm happy to call back at a better time.

If YES
Great! Thank you for agreeing to talk with me.

Date of Pharmacist Call 2 _____

Start Time of Initial Pharmacist Phone Call _____

Reminder of Discussion from Pharmacist Call 1 ([pharm1_call_date])
Medication Reconciliation Summary: [pharm1_med_rec_sum]
Initial Patient Questions: [pharm1_pt_questions]
Initial Patient Concerns: [pharm1_pt_concerns]
Note to Provider after Pharmacist Call 1:
[pharm1_note_details]
Access Line Use (only date of first access provided; other information in form): [access_call1_date]
Reminder of Reconciled Medication List:
[med_name_1_new]
[med_name_2_new]
[med_name_3_new]
[med_name_4_new]
[med_name_5_new]
[med_name_6_new]
[med_name_7_new]
[med_name_8_new]
[med_name_9_new]
[med_name_10_new]

[med_name_11_new]
[med_name_12_new]
[med_name_13_new]
[med_name_14_new]
[med_name_15_new]
[med_name_16_new]
[med_name_17_new]
[med_name_18_new]
[med_name_19_new]
[med_name_20_new]
[med_name_21_new]
[med_name_22_new]
[med_name_23_new]
[med_name_24_new]
[med_name_25_new]
[med_name_26_new]
[med_name_27_new]
[med_name_28_new]
[med_name_29_new]
[med_name_30_new]

As a reminder, we spoke on [pharm1_call_date] about your medications. ◯ Yes ◯ No ◯ Unsure

[provide overview of pharmacist 1 call (and any intermediate conversations) using notes above].

We also sent you some educational materials via [edu_materials_mode].

Does this sound familiar to you?

If patient is familiar, continue with script; otherwise provide patient with additional information as a reminder of previous conversations

Before we get started, I just want to confirm whether or not you are still taking [cr_ac_name].

◯ Patient is still taking DOAC
◯ Patient is taking a different DOAC
◯ Patient is no longer taking DOAC but has switched to other anticoagulant
◯ Patient is no longer taking ANY anticoagulant
◯ Unsure
◯ Patient Refused to answer

Notes regarding AC status, if applicable,

_____

Great, thank you for letting me know that.

I want to give you the chance to let me know if you have any initial questions or concerns about your medications.

☐ Patient does not have questions/concerns
☐ Patient has NEW questions/concerns
☐ Patient has questions/concerns related to PREVIOUS conversation
☐ No Response/Refusal

Note patient questions and responses to those questions.

Clarify whether concerns are new or related to previous concerns

Note patient concerns and responses to those concerns

Clarify whether concerns are new or related to previous concerns

Medication Discrepancies

Have you missed any doses since our last call? ◯ Yes No

What did you do when you missed the dose?

Were any medication issues identified during the encounter? ◯ Yes No

Please select which medication issues were identified (Check all that apply)

- ☐ Medication Discrepancies
- ☐ Clinically Significant Interactions and High-Risk Medication Combinations
- ☐ Complaints or Potential Side Effects
- ☐ Medication Administration
- ☐ Medication Organization
- ☐ Medication Storage
- ☐ Medication Disposal
- ☐ Understanding

Medication Discrepancies (Please specify - check all that apply)

- ☐ Patient is taking additional medication(s) not included on discharge list, but included on outpatient list
- ☐ Patient is taking additional medication(s) not included on outpatient list, but included on discharge list
- ☐ Patient is taking additional medication(s) not included on discharge or outpatient lists
- ☐ Patient is not taking medication(s) included on discharge list
- ☐ Patient is not taking medication(s) included on outpatient list and should not be discontinued
- ☐ Patient is not taking DOAC medication
- ☐ Patient is taking the wrong medication(s) [drug, dose and/or frequency) related to DOAC use
- ☐ Patient is taking the wrong drug, dose or frequency of a medication besides the prescribed DOAC

Healthcare Services Utilization

Have you been hospitalized in the last 30 days? ◯ Yes ◯ No
(*Add July 2020)

Details about hospitalization/ER visit

(*Add July 2020)

Have you been hospitalized since [screen_index_date]? ◯ Yes ◯ No
(*Remove July 2020)

Could you provide the date of your hospitalization and tell me why you were hospitalized?

Have you been admitted to the ER since [screen_index_date]?
◯ Yes ◯ No
(*Remove July 2020)

Could you provide the date you were admitted to the ER and tell me why you were in the emergency department?

Have you been gone to the walk-in clinic [screen_index_date]?
◯ Yes ◯ No
(*Remove July 2020)

Could you provide the date you went to the walk-in clinic and tell me why you went there?

Have you followed up with any doctors/providers since we last spoke? If so, can you tell me who?
☐ PCP
☐ Cardiologist
☐ Hospitalist
☐ non-study Pharmacist
☐ Other

Notes about conversations with providers

Summary of Phone Call

Topics discussed between pharmacist and patient

☐ Dose
☐ Side effects
☐ Med Interactions
☐ Storage
☐ Refills
☐ Risks
☐ Benefits
☐ Safety Net Phone Number
☐ Other antithrombotics
☐ Information about other medications
☐ Other

Other Comments about Discussion with patient

At the end of the phone call thank the patient for their time and confirm any follow up, including scheduling for Pharmacist Call 3 in approximately 30 days.

Also remind the patient about how to contact study staff using the study phone line (508-441-3562).

Recommendations of Educational Materials from Pharmacist

Any educational materials to be sent to patient?	◯ Yes ◯ No
Patient Preference for sending educational materials	☐ Mail ☐ Email
Preferred or recommended format of educational materials	☐ Paper ☐ Pill Organizer ☐ Other
Medications Detailed in Educational Material	☐ Apixaban ☐ Rivaroxaban ☐ Dabigatran ☐ Edoxaban

Notes in EPIC/Follow UpCall Status will need to be updated to branch the appropriate note template (call completed or lost to follow up)

Date of note in EPIC

_____

Time of note in EPIC

_____

LEAVE SAFE with DOACs Research Study Encounter

[name_first] [name_last] is participating in a research study, Leave Safe with DOACS.

Briefly, LEAVE Safe with DOACs is a medication safety research study focused on ambulatory patients prescribed direct oral anticoagulants (DOACs). Our primary study goal is to improve care transitions by assessing the impact of an intervention on clinically important medication errors.

Transition events which could have led to the patient being eligible include new venous thromboembolism event, worsening of existing venous thromboembolism event, new stroke or transient ischemic attack, bleeding, or change from one anticoagulant to another.

Our pharmacy team is ready to assist each patient with acquisition and affordability surrounding the use of DOACs. We will continue to follow patients for three months from study enrollment, even if they have discontinued the medication.

A phone encounter, which focused on direct oral anticoagulants, was performed on [pharm2_call_date], with [name_first] [name_last] by [pharm2_name_caller].

The following was discussed with the patient:
[pharm2_pt_questions]
[pharm2_pt_concerns]

[name_first] [name_last] will be contacted again in approximately 30 days as part of this study.

Feel free to reach out to us with any questions or concerns - 508-441-3562 Ext. 0

For Intervention Patients Who Do Not Complete Interview

LEAVE SAFE with DOACs Research Study Encounter

Enter the following text as a note in EPIC:

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Briefly, LEAVE Safe with DOACs is a medication safety research study focused on ambulatory patients prescribed direct oral anticoagulants (DOACs). Our primary study goal is to improve care transitions by assessing the impact of an intervention on clinically important medication errors.

Transition events which could have led to the patient being eligible include new venous thromboembolism event, worsening of existing venous thromboembolism event, new stroke or transient ischemic attack, bleeding, or change from one anticoagulant to another.

Our pharmacy team is ready to assist each patient with acquisition and affordability surrounding the use of DOACs. We will continue to follow patients for three months from study enrollment, even if they have discontinued the medication. We attempted to contact this patient for a study interview but were unable to reach them, we will attempt to contact them again next month.

Feel free to reach out to us with any questions or concerns - 508-441-3562 Ext. 1

Any Follow Up Needed? ◯ Yes ◯ No

Detail Follow up Needed

End Time of Initial Pharmacist Phone Call

Detail of Note in EPIC

Follow Up

Plan or confirmed date for Pharmacist Call 3

Data Cleaning

Has this form been reviewed for data cleaning purposes?
◯ Yes; no errors found and form marked complete
◯ Yes; Data cleaning required

Detail data cleaning process

What needs to be fixed?
Who fixed and when?

Is data cleaning complete?
◯ Yes
◯ No

Appendix A - Pharmacist Call 3 Tool Knowledge Check Items

Record ID

Patient Information

Patient Name: [name_first] [name_last]
Patient MRN: [mrn]
Patient Date of Birth: [dob] (Patient Age: [screen_age])
Anticoagulant(s): [cr_ac_name]
DOAC Start Date: [cr_ac_start_date]
Indication: [elig_rx_reason]
Phone: [phone_number]
Patient Preferred Language: [screen_pref_language]
Communication preferences (from call/consent form): [contact_preferred]
Patient Group: [randomize]

Planned Call 3 Date: [pharm2_plan_call3]

Pharmacist Chart Review PRIOR to Pharmacist Call 3

Has the patient previously been referred to the anticoagulation Clinic?

What is the documented plan for duration of the anticoagulation medication?

What is the documented plan for follow up with the patient? Any relevant labs?

What is the documented plan for follow up with the patient? Who will prescribe refills?

Review RefillsPatient Reported Start Date (from baseline): [base_acg_ptreport_start]

Start Date (from chart review): [cr_ac_start_date]

Preferred Contact Method: [base_refill_contact_pref]

Dear [name_first],

We are reaching out because we believe the prescription for your anticoagulation medication may expire soon. If you require assistance in securing access to your prescription for the next month please let our study team know.

As a reminder, you may contact our study team at 508-441-3562 extension 1 or leave.safe@umassmemorial.org; you may also reply to this message.

If you do not respond to this message we will assume you have access to the medication you need and will not send further follow up about the upcoming month's prescription.

Thank you,
LEAVE Safe Study Team

Was the patient contacted via their preferred contact method? [base_refill_contact_pref]	◯ Yes; by preferred method of contact ◯ Yes; by other method of contact ◯ No
Why was the patient not contacted?	◯ The patient declined further follow up ◯ The patient previously indicated they were all set ◯ The patient is no longer taking the anticoagulant ◯ The patient has withdrawn from the study ◯ The patient is deceased ◯ Study staff were not available ◯ Other
When was the patient contacted?	_____
Did the patient respond? If so, what was the outcome?	◯ No Response ◯ Patient responded all set ◯ Patient responded needs help ◯ Patient responded please don't contact me about this again
Does patient appear to have a prescription for refill for the next 30 days?	◯ Yes; prescription is evident in EPIC ◯ Yes; previously discussed with study team member ◯ No; follow up with patient/PCP is needed (*For control patients RA will complete)
Was 30 day prescription obtained for patient?	◯ Yes; refill was obtained prior to expiration of previous prescription ◯ Yes; refill was obtained but after previous prescription expired (i.e. lapse in dose) ◯ No; new prescription was not obtained for the patient (*For control patients RA will complete)
Comments on process/status of obtaining refill for patient - Who was contacted and when? - Who assisted (leave safe study team member)? - What was the outcome?	_____ (*For control patients RA will complete)

Call Tracking:

Comments: Note dates and time of phone attempts, who attempted to reach (i.e. staff initials), any messages left, any contact, dates need to return a call. Example: 6/23/2016, 10:30am, MES: Left message.	_____

Interview Information

For Control Patients Only (do not complete interview)

LEAVE SAFE with DOACs Research Study Encounter

Enter the following text as a note in EPIC:

[name_first] [name_last] is participating in a research study, Leave Safe with DOACS.

Briefly, LEAVE Safe with DOACs is a medication safety research study focused on ambulatory patients prescribed direct oral anticoagulants (DOACs). Our primary study goal is to improve care transitions by assessing the impact of an intervention on clinically important medication errors.

Transition events which could have led to the patient being eligible include new venous thromboembolism event, worsening of existing venous thromboembolism event, new stroke or transient ischemic attack, bleeding, or change from one anticoagulant to another.

The patient has completed their interactions with the clinical pharmacist for this research study. The patient will be directed to follow up with their PCP for future questions regarding their DOAC use. Prescriptions for refills will not be provided by study staff.

◯ Completed ◯ Not Completed

Date of note in EPIC

_____

Date of first attempt to reach patient for Initial Pharmacist Phone Call.

_____

Who placed the call or put the note in EPIC?

◯ Lauren Harding
◯ Dawn Swain
◯ Alok Kapoor
◯ Other

Status:

◯ Reached/Completed Interview
◯ Reached/Declined to Complete
◯ Previously Declined Additional Pharm Calls
◯ Call Back (See Comments)
◯ Lost to Follow-Up (Did not reach within timeframe)
◯ Ineligible (please specify in Comments)

Date to Call Again

(If scheduled to call back)

_____

Time to Call Again

(If scheduled to call back)

_____

AFTER ASKING FOR AND CONFIRMING THAT YOU ARE SPEAKING WITH THE STUDY PARTICIPANT

Hello [name_first],

My name is [pharm2_name_caller]. I work on a research study at UMass that you've been participating in that's trying to improve care for patients who take blood thinners. Thank you again for participating in our study. I'm calling now to ask you some questions about your anticoagulant and how things have been going since we last spoke. I can also answer any questions you have about your medication.

Is this a good time for you to talk with me? We'll need about 15 minutes.

If NO
Can we set-up another time to talk? I'm happy to call back at a better time.

If YES
Great! Thank you for agreeing to talk with me.

Date of Pharmacist Call 2

_____

Start Time of Initial Pharmacist Phone Call

_____

Reminder of Discussion from Pharmacist Call 2 ([pharm2_call_date])
Medication Reconciliation Summary: [pharm1_med_rec_sum]
Patient Questions: [pharm2_pt_questions]
Patient Concerns: [pharm2_pt_concerns]
Note to Provider after Pharmacist Call 2:
[pharm2_note_details]
Access Line Use (only date of first access provided; other information in form): [access_call1_date]
Reminder of Reconciled Medication List:
[med_name_1_new]
[med_name_2_new]
[med_name_3_new]
[med_name_4_new]
[med_name_5_new]
[med_name_6_new]
[med_name_7_new]
[med_name_8_new]
[med_name_9_new]
[med_name_10_new]
[med_name_11_new]
[med_name_12_new]
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[med_name_21_new]
[med_name_22_new]
[med_name_23_new]
[med_name_24_new]
[med_name_25_new]
[med_name_26_new]
[med_name_27_new]
[med_name_28_new]
[med_name_29_new]

[med_name_30_new]

As a reminder, we spoke on [pharm2_call_date] about your medications. ◯ Yes ◯ No ◯ Unsure

[provide overview of pharmacist 2 call (and any intermediate conversations) using notes above].

We also sent you some educational materials via [edu_materials_mode].

Does this sound familiar to you?

If patient is familiar, continue with script; otherwise provide patient with additional information as a reminder of previous conversations

Before we get started, I just want to confirm whether or not you are still taking [cr_ac_name].

◯ Patient is still taking DOAC
◯ Patient is taking a different DOAC
◯ Patient is no longer taking DOAC but has switched to other anticoagulant
◯ Patient is no longer taking ANY anticoagulant
◯ Unsure
◯ Patient Refused to answer

Notes regarding AC status, if applicable,

_____

Great, thank you for letting me know that.

I want to give you the chance to let me know if you have any initial questions or concerns about your medications.

☐ Patient does not have questions/concerns
☐ Patient has NEW questions/concerns
☐ Patient has questions/concerns related to PREVIOUS conversation
☐ No Response/Refusal

Note patient questions and responses to those questions.

Clarify whether concerns are new or related to previous concerns

---

Note patient concerns and responses to those concerns

Clarify whether concerns are new or related to previous concerns

Medication Discrepancies

Have you missed any doses since our last call?	◯ Yes ◯ No (Only ask if patient is still taking DOAC)
What did you do when you missed the dose?	_____ (Only ask if patient is still taking DOAC)
Were any medication issues identified during the encounter?	◯ Yes ◯ No
Please select which medication issues were identified (Check all that apply)	☐ Medication Discrepancies ☐ Clinically Significant Interactions and High-Risk Medication Combinations ☐ Complaints or Potential Side Effects ☐ Medication Administration ☐ Medication Organization ☐ Medication Storage ☐ Medication Disposal ☐ Understanding
Medication Discrepancies (Please specify - check all that apply)	☐ Patient is taking additional medication(s) not included on discharge list, but included on outpatient list ☐ Patient is taking additional medication(s) not included on outpatient list, but included on discharge list ☐ Patient is taking additional medication(s) not included on discharge or outpatient lists ☐ Patient is not taking medication(s) included on discharge list ☐ Patient is not taking medication(s) included on outpatient list and should not be discontinued ☐ Patient is not taking DOAC medication ☐ Patient is taking the wrong medication(s) [drug, dose and/or frequency) related to DOAC use ☐ Patient is taking the wrong drug, dose or frequency of a medication besides the prescribed DOAC

DOAC Follow Up

Can you tell me how long you should be taking your DOAC? [pharm3_prep_ac_duration]	◯ Patient answers correctly ◯ Patient answers incorrectly ◯ Unsure ◯ Refusal/No Answer ◯ Patient no longer taking DOAC
Patient understands that therapy should continue for this amount of time:	_____
Can you tell me which pharmacy you plan to get refills from? [pharm3_prep_fup_prescriber]	◯ Patient answers correctly ◯ Patient answers incorrectly ◯ Unsure ◯ Refusal/No Answer ◯ Patient no longer taking DOAC
Patient will plan to refill DOAC at this pharmacy:	_____

Do you know how long your medications are authorized for?

[pharm3_prep_ac_duration]

- ◯ Patient answers correctly
- ◯ Patient answers incorrectly
- ◯ Unsure
- ◯ Refusal/No Answer
- ◯ Patient no longer taking DOAC

Patient's medications are authorized for: _____

Have you been referred to the Anti-Coagulation Clinic?

[pharm3_prep_acc_refer]

- ◯ Yes
- ◯ No
- ◯ Not Applicable
- ◯ Unsure
- ◯ Patient Refused Referral

If not, would you like to be referred?

- ◯ Yes
- ◯ No
- ◯ Not Applicable
- ◯ Unsure
- ◯ Patient Refused Referral

Summary of Phone Call

Recommended follow up by provider? ◯ Yes ◯ No

Detail follow up recommended (to be shared in EPIC note) _____

Topics discussed between pharmacist and patient

- ☐ Dose
- ☐ Side effects
- ☐ Med Interactions
- ☐ Storage
- ☐ Refills
- ☐ Risks
- ☐ Benefits
- ☐ Safety Net Phone Number
- ☐ Other antithrombotics
- ☐ Information about other medications
- ☐ Other

Other Comments about Discussion with patient _____

At the end of the phone call thank the patient for their time and confirm any follow up, including an exit interview in approximately 30 days.

Notes in EPIC/Follow UpCall Status will need to be updated to branch the appropriate note template (call completed or lost to follow up)

Date of note in EPIC

_____

Time of note in EPIC

_____

LEAVE SAFE with DOACs Research Study Encounter

[name_first] [name_last] is participating in a research study, Leave Safe with DOACS.

Briefly, LEAVE Safe with DOACs is a medication safety research study focused on ambulatory patients prescribed direct oral anticoagulants (DOACs). Our primary study goal is to improve care transitions by assessing the impact of an intervention on clinically important medication errors.

Transition events which could have led to the patient being eligible include new venous thromboembolism event, worsening of existing venous thromboembolism event, new stroke or transient ischemic attack, bleeding, or change from one anticoagulant to another.

A phone encounter, which focused on direct oral anticoagulants, was performed on [pharm3_call_date], with [name_first] [name_last] by [pharm3_name_caller].

The following was discussed with the patient:
[pharm3_pt_questions]
[pharm3_pt_concerns]

The patient understands the following about continuing their DOAC therapy:
- DOAC therapy to continue for [pharm3_doac_duration]
- Pharmacy for refill: [pharm3_doac_pharmacy]
- Prior authorization follow up: [pharm3_doac_pa]
- Was the patient previously referred to the Anticoagulation Clinic: [pharm3_ac_yn]
- Did the patient request a referral to the Anticoagulation Clinic: [pharm3_ac_refer]

I recommend the following for the patient: [pharm3_followup]

Level of anticoagulation may significantly be reduced with one missed dose. Daily compliance is essential. [cr_ac_name] requires routine monitoring of SCr, LFTs and CBC to ensure continued appropriateness of therapy. Compliance with follow-up appointments is essential.

The patient has completed their interactions with the clinical pharmacist for this research study. The patient will be directed to follow up with their PCP for future questions regarding their DOAC use. Prescriptions for refills will not be provided by study staff.

For Intervention Patients Who Do Not Complete Interview

LEAVE SAFE with DOACs Research Study Encounter

Enter the following text as a note in EPIC:

[name_first] [name_last] is participating in a research study, Leave Safe with DOACS.

Briefly, LEAVE Safe with DOACs is a medication safety research study focused on ambulatory patients prescribed direct oral anticoagulants (DOACs). Our primary study goal is to improve care transitions by assessing the impact of an intervention on clinically important medication errors.

Transition events which could have led to the patient being eligible include new venous thromboembolism event, worsening of existing venous thromboembolism event, new stroke or transient ischemic attack, bleeding, or change from one anticoagulant to another.

Level of anticoagulation may significantly be reduced with one missed dose. Daily compliance is essential. [cr_ac_name] requires routine monitoring of SCr, LFTs and CBC to ensure continued appropriateness of therapy. Compliance with follow-up appointments is essential.

The patient has completed their interactions with the clinical pharmacist for this research study. The patient will be directed to follow up with their PCP for future questions regarding their DOAC use. Prescriptions for refills will not be provided by study staff.

Any Follow Up Needed?	◯ Yes ◯ No
Detail Follow up Needed (not piped in to EPIC note template)	_____
End Time of Initial Pharmacist Phone Call	_____
Detail of Note in EPIC	_____

Follow Up

Plan or confirmed date for Exit Interview (if discussed)	_____

Data Cleaning

Has this form been reviewed for data cleaning purposes?	◯ Yes; no errors found and form marked complete ◯ Yes; Data cleaning required
Detail data cleaning process What needs to be fixed? Who fixed and when?	_____
Is data cleaning complete?	◯ Yes ◯ No

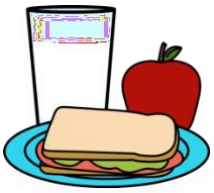
Appendix B - Patient Educational Materials Mailed to Intervention and Control Patients

Apixaban FAQs

Another name for apixaban is **Eliquis**®
An anticoagulant used to prevent blood clots in the legs, lungs, heart, or brain.

How should I take apixaban?

- Take with a drink of water.
- Take with food if it upsets your stomach.
- Take at the same time(s) every day.
- Plan ahead. Refill your prescription before you run out.



What should I do if I forget a dose?

- Take the missed dose as soon as you remember.
- *If it is almost time for your next dose…*
    - Take your next dose as usual.
- Do not take extra apixaban to make up for missing a dose.

How should I store apixaban?

- Store at room temperature, away from excess heat, light, and moisture.
- Do not store in the bathroom. The changes in humidity and temperature can affect the drug.

How should I organize my medication?

- Use a pill organizer or calendar.
- Keep the original prescription bottle so you have key information such as expiration date, administration instruction, and refill number.

What should I avoid?

- Do not start or stop any medication without talking to your doctor such as -over-the-counter medications or vitamins.
- Over-the-counter pain medications such as -ibuprofen, naproxen, or aspirin increase your risk of bleeding.

What side effects can apixaban cause?

- Bleeding
- Nausea

The main risk is bleeding. Call your doctor immediately if you have any of the following:

- Heavy or recurrent bleeding
- Blood in your urine, or blood during bowel movements or on wiping yourself
- Severe bruising
- Prolonged nosebleeds
- Bleeding gums
- Vomiting or coughing up blood

When should I call the Research Pharmacist?

- If you begin taking any new medication, including over the-counter medicine, supplements, and herbal or home remedies.
- If you have any questions about this form or your medications.

*FAQS: Frequently Asked Questions

Patient Education

What is apixaban?

Generic Name: Apixaban Brand Name: Eliquis®

Apixaban is an anticoagulant that stops blood clots from forming in the blood vessels.

Why am I taking this medication?

This medication is taken to help prevent and treat blood clots or stroke.

How do I take apixaban?

Apixaban comes as a tablet to be taken by mouth twice a day. Try to separate the doses by 12 hours, such as taking it at 8am and 8pm. This medication may be taken with or without food. Do not stop taking this medication without talking it over with your provider.

What if I miss a dose?

If you miss a dose, or forget to take your medication:

- If it is more than 6 hours until your next scheduled dose, take it as soon as you can.
- If it is less t ha n 6 hours until your next scheduled dose, skip the dose you forgot and take your next dose at the usual time.

Do NOT double the dose to make up for the missed do se. If you feel unsure, call your doctor or pharmacist for instructions.

Who should not take apixaban?

Patients who....

- have moderate to severe kidney or liver disease
- have an increased risk of serious bleeding
- are taking another anticoagulant
- are allergic
- have mechanical heart valves

Which drugs might interact with apixaban?

- Certain medications may increase your risk of bleeding, such as over-the-counter NSAIDs like ibuprofen, naproxen, or aspirin.
- Ask your provider or pharmacist before using any other medications including over-the-counter medications, vitamins, and herbal products.

What are the common side effects of apixaban?

Some people may experience nausea.

Warnings while taking apixaban:

It is not known how this medication will harm your unborn baby. If you think you have become pregnant while using apixaban, tell your doctor. Stay away from rough sports or other situations where you could be bruised, cut, or injured. Brush and floss your teeth gently. Be careful when using sharp objects, including razors and clippers.

Apixaban can increase your risk of bleeding or bruising. In cases of severe bleeding, an antidote may be required to reverse bleeding with the medication. Please contact your provider and seek emergency medical attention if you experience an of the following:

- headache, dizziness, or weakness after a head injury
- prolonged nosebleeds, bleeding from shaving or other cuts that do not stop within a few minutes
- blood in the vomit or sputum
- bruises for unknown reasons or bruises that change in size, shape, or color
- red, pink, or brown urine
- red or black stool

Members of* our *PFAC* are *routinely asked* to *review select educational materials* to *ensure patient-centered language etc.

Communicating with your health care provider

- Contact your provider if you plan to have any surgeries, medical procedures, or dental work or if you fall or injure yourself, especially your head.
- Make sure you tell everyone who takes care of you - doctors, nurses, pharmacists, dentists, optometrists, and emergency room staff - that you take this medication that affects your blood's ability to clot.

How do I store and dispose of apixaban?

Keep this medication at room temperature, away from heat and direct light. Keep all medication away from children and pets and never share your medication with anyone. Ask your pharmacist, doctor, or health care giver about the best way to dispose of any outdated medicine or medicine no longer needed.

Do you have any questions or comments for your doctor?

Suggest a few common questions.

University of Massachusetts Medical School

Medication Safety Tips

UMassMemorial Health Care

DO:

- ✓ Take your medications at the same time(s) every day.
- ✓ Use a pill organizer, or calendar, to help you remember to take your medications.
- ✓ Refill your prescriptions before you run out of medications.
- ✓ Keep the original prescription bottle so you have access to key information such as expiration date, administration instruction, and refill number.
- ✓ Tell your doctor about all medications you take, including over-the-counter medications, supplements, and herbal remedies.
- ✓ Follow all of your doctor's recommendations on how to take your medications.
- ✓ Ask if you should avoid alcohol or other substances while taking your medications.
- ✓ Know the side effects of your medications.
- ✓ Call your doctor if you experience bothersome or serious side effects.
- ✓ Keep emergency phone numbers on hand and around the house.
- ✓ Know what to do in an emergency; call 911 if you need immediate medical attention.

DO NOT:

- ✘ Stop taking medications without talking to your doctor.
- ✘ Take more or less medications than your doctor prescribes.
- ✘ Skip doses without talking to your doctor.
- ✘ Double up on doses, even if you miss a dose.
- ✘ Cut or split pills, unless instructed by your pharmacist.
- ✘ Store medications in direct sunlight or heat.
- ✘ Store medications where there is a lot of moisture.
- ✘ Store in the bathroom. The changes in humidity and temperature can affect the drug.
- ✘ Store medications where children may have contact to them.
- ✘ Share your medication with others.
- ✘ Take someone else's medications.

Appendix C – Leave Safe with Direct Oral Anticoagulants (DOACs) – Physician Reviewer Quick Reference Sheet

Appendix C: Leave Safe with Direct Oral Anticoagulants (DOACs) –
Physician Reviewer Quick Reference Sheet

ADE is an injury resulting from medical care involving medication use. Identifying something as an ADE does not imply error, negligence, or poor-quality care. It simply indicates that an undesirable clinical outcome resulted from some aspect of medication use, and not an underlying disease process. For our purpose this includes harm resulting from failure to use a medicine that is indicated or failure to give enough of it – e.g., withdrawal.

A "preventable" ADE is a drug-related injury relating to a medication error whether error is attributable to provider or patient

"Ameliorable" ADEs. ADEs are not entirely preventable but clinicians might be able to reduce their duration or severity

"Potential" ADEs (pADEs) - include discrepancies in prescribing, dispensing, administration/use, and monitoring with a high likelihood of harm. They also include patient non-adherence.

Anticoagulant related issues

1. If plan for length of anticoagulant treatment is incorrect as per documentation recorded in the 90 days after randomization, then call pADE (or ADE if actual event occurs within the 90 days)
2. Delay in starting because of affordability - no pADE for atrial fibrillation (AF)
3. If script correct but physician documentation wrong or misleading about dose or day of dose de-escalation, then exclude
4. Liver function elevated at baseline
    a. If baseline aspartate transaminase (AST) or alanine aminotransferase (ALT) 2x upper limit of normal for Eliquis OR bilirubin 1.5x upper limit of normal, LFTs (liver function tests) should be monitored and then if come back to normal, then pADE ; if shock liver, passive congestion from congestive heart failure (CHF), or other transitional reason expected to improve then no pADE ; if chronically elevated or idiopathic then pADE
    b. If baseline AST or ALT 3x upper limit for Xarelto, same as above for Eliquis
5. Events/potential events that are completely occurring in the hospital without opportunity for outpatient provider/pharmacist to rectify should be excluded
6. Continuing aspirin (ASA) or non-steroidal anti-inflammatory drug (NSAID) after initiation of anticoagulation (AC) (assuming 12 months after acute coronary syndrome / percutaneous coronary intervention).
    a. Call it a pADE if first provider within 90 days of randomization does not stop aspirin
        - Relevant provider would be primary care physician (PCP), cardiologist (for venous thromboembolism (VTE), atrial fibrillation or other cardiac indication for AC; pulmonologist (for VTE), or vascular surgeon (for peripheral arterial disease or VTE)
    b. Exclude if first provider defers to consultant who started it (typically cards provider) OR patient with extensive clotting history and heme consultant recommends both

    c. Exclude if patient also has a history of atherosclerotic stroke (no AF history)
7. ASA + DOAC (Direct Oral Anticoagulants) if no evidence of fills or use during exit interview, then do not count pADE
8. Pre-existing bleed that does not worsen and is not critical site or major (2-unit transfusion or requiring hospitalization), then exclude
9. If NSAID not stopped at the time of starting DOAC, call it a pADE as long as patient has a clinical encounter including telephone encounter with ambulatory provider (not the Emergency Department physician) over 90 days of follow-up; if bleeding occurs, call it a preventable ADE, and if patient already has bleeding history but it is worse since starting DOAC (in patient on NSAID), call it ameliorable.
10. Score pADE if patient has thrombosis/stroke on appropriate DOAC dose but team does not switch agent; If ADE occurs also, score as a preventable ADE
    a. (Related) If low apixaban dose appropriately used for stroke outcome, score it a pADE if team increases dose rather than switching to new agent. If ADE occurs also, score as a preventable ADE
11. Omitted refill without missed days - exclude
12. Count medication discrepancies between electronic health record-based list and patient report.
13. Bleeding requiring any consultation or intervention must be an in person or telehealth visit (not just a telephone note / encounter) with physician or midlevel provider should be scored as an ADE.
    a. If RN (Registered Nurse) speaks to patient and provider just gives some recommendation to convey to patient (or if provider has health portal correspondence), then do not count as ADE and do not count as pADE.
    b. If provider orders complete blood count (CBC) / hemoglobin / hematocrit, count this as sufficient concern to be called ADE.
    c. If not above situation, minor bleeding should be excluded
14. Creatinine, CBC in 1 month and hepatic 1 year before
    a. If not checked at first encounter after randomized, call it pADE.
15. Any worsening of VTE by radiography should be scored an ADE (and preventable)
16. Full loading dose of DOAC not given (unless many days of parenteral or warfarin and AC was therapeutic via partial thromboplastin time (PTT) or internationalized normal ratio (INR) and bleeding risk is low / acceptable), then pADE
17. Inappropriate DOAC prescription or dose
    a. Error should be assigned on the date of first clinical encounter (including telephone encounters) after randomization; if no clinical encounter can be detected based on unavailability of information or patient exit interview, exclude.
        i. A dosage too high or too low without clinical event is a potential ADE on that date. With clinical events it is a preventable ADE.
        ii. Prescription of DOAC in the setting of elevation in BMI (Body Mass Index) or weight above threshold recommended by International Society of Thrombosis and Haemostasias should not be scored as a pADE. Very high BMI or weight such that presenting clinical pharmacist would be uncomfortable, should be pADE.

iii. Lack of baseline labs without a clinical event as per hospital policy (creatinine and CBC within one month and hepatic within one year of prescription) should be scored as a potential ADE at the first clinical encounter with relevant provider after randomization.
    - Relevant providers would be PCP, cardiologist (for atrial fibrillation or other cardiac indication for AC, pulmonologist (for VTE), or vascular surgeon (for peripheral arterial disease).

18. If DOAC failure – call it an ADE unless heme consult ordered/discussion to continue, failure ruled out (blood testing), or patient has no other options available/previous difficulty with warfarin.
19. Low platelets without symptoms or disturbance of care plans (such as delay of chemo) should be excluded;
    i. With disturbance (platelet transfusion or delay in care or admission/ED visit) should be an ADE

<u>Other medication related ADEs and pADEs</u>

20. If symptom /ADE only mentioned at the exit interview (no phone calls), then call it non preventable.
21. Therapeutic class duplications that are not resolved/corrected at PCP or another qualified provider visit should be counted as pADE.
22. When in doubt about patient medication, use the medication list given the PharmD intervention should be cleaning up med lists.
23. Symptomatic events in the context of an abnormal blood pressure, glucose, INR value (i.e., bleeding) should be potential ADEs in general.
24. Asymptomatic events such as temporary elevated blood pressure, hyperglycemia, lab abnormality should not be rated as ADE. They could be pADEs.
    a. Elevated blood pressure (if isolated and returns to normal on repeat without intervention, then exclude)
        i. Systolic blood pressure between 140 and 180 or diastolic blood pressure 90 to 110 without symptoms = no pADE.
        ii. Systolic blood pressure >180 or diastolic > 110 without symptoms and without trip to ED or admission to hospital should be a pADE in general.
        iii. Systolic blood pressure >180 or diastolic > 110 without symptoms but requiring trip to ED (Emergency Department) or admission to hospital (i.e., clinician / Visiting Nurses Association (VNA) concerned enough to send to have further evaluation) should be an ADE.
    b. Low blood pressure (if isolated and returns to normal on repeat without intervention, then exclude)
        i. Implicit review / judgment call; most incidents of blood pressures below 90 or diastolic < 50 for patient of any adult age will be an ADE (exceptions may apply in patients with consistently low blood pressure such as those with advanced liver disease).

c. Elevated INR
    i. INR 3-4.5 without symptoms = no pADE
    ii. INR >= 4.5 without symptoms and no error = no pADE
    iii. INR >= 4.5 be scored pADE as long as there is an error (in dose, monitoring, etc.) to explain
d. Low INR
    i. INR 1.5-2.0 without symptoms and no ED trip / hospital admission to address = no pADE
    ii. INR < 1.5 for a patient who is supposed to be on warfarin should be a pADE
    iii. INR < 1.5 requiring trip to ED or admission to hospital (i.e., Physician or VNA concerned enough to send to have further evaluation) should be an ADE
e. Hyperglycemia
    i. Glucose 200-300 without symptoms and no ED / hospital visit to address this should not be a pADE
    ii. Glucose > 300 without symptoms should be a pADE in general;
    iii. Glucose > 300 without symptoms but requiring trip to ED or admission to hospital (i.e., Physician or VNA concerned enough to send to have further evaluation) should be an ADE
f. Low blood sugar
    i. Glucose 60-90 without symptoms and no ED or hospital visit to address this should not be a pADE
    ii. Glucose < 60 without symptoms should be a pADE in general; with symptoms, it is an ADE.
    iii. Glucose < 90 without symptoms but requiring trip to ED or admission to hospital (i.e., Physician or VNA concerned enough to send to have further evaluation) should be an ADE
g. Abnormal electrolyte including hyperkalemia or hypokalemia
    i. Asymptomatic electrolyte value greater or less than upper limit of normal, should be rated as a potential adverse drug event
    ii. Symptomatic with electrolyte value should be ADE
h. Jump in creatinine
    i. Use KDIGO criteria for acute kidney injury believed to be related to a medication
        - Increase in serum creatinine by ≥0.3 mg/dL (≥26.5 micromol/L) within 48, or
        - Increase in serum creatinine to ≥1.5 times baseline, which is known or presumed to have occurred within the prior seven days, or
        - Urine volume <0.5 mL/kg/hour for six hours
    ii. should be rated as adverse drug event

a. Low platelets induced by a medication that does not lead to symptoms/bleeding or disturbance of care plans (such as delay of chemo) should be excluded.
    i. With disturbance (platelet transfusion or delay in care or admission/ED visit) should be an ADE.

Appendix D – Key Characteristics for Enrolled Patients Stratified by Intervention vs Control Allocation as Well as Qualifying Condition for Entry into Study

Appendix D. Key Characteristics for Enrolled Patients Stratified by Intervention vs Control Allocation as Well as Qualifying Condition for Entry into Study

Category	All Frequency (% out of 561)	Intervention Group Frequency Stratified by Qualifying Condition[Ω]			Control Group Frequency Stratified by Qualifying Condition[Ω]		
		Total (% out of 281)	Venous condition (% out of 195)	Non-venous condition (% out of 86)	Total (% out of 280)	Venous condition (% out of 196)	Non-venous condition (% out of 84)
Demographics							
Age							
< 50	125 (22.3)	72 (25.6)	66 (34)	6 (7)	53 (18.9)	48 (25)	5 (6)
50 - 65	195 (34.8)	92 (32.7)	67 (34)	25 (29)	103 (36.8)	80 (41)	23 (27)
66 - 75	134 (23.9)	62 (22.1)	35 (18)	27 (31.4)	72 (25.7)	47 (24)	25 (30)
76+	107 (19.1)	55 (19.6)	27 (14)	28 (32.6)	52 (18.6)	21 (11)	31 (37)
Female sex	251 (44.7)	127 (45.2)	85 (44)	42 (49)	124(44.3)	93 (47)	31 (37)
Race/Ethnicity							
Asian/Other	14 (2.5)	7 (2.5)	5 (2.6)	2 (2)	7 (2.5)	5 (2.6)	2 (2.5)
Hispanic	54 (9.6)	24 (8.5)	21 (10.8)	3 (4)	30 (10.7)	24 (12.2)	6 (7)
Non-Hispanic Black	24 (4.3)	11 (3.9)	10 (5.1)	1 (1)	13 (4.6)	11 (5.6)	2 (2.5)
Non-Hispanic White	469 (83.6)	239 (85.1)	159 (81.5)	80 (93)	230 (82.1)	156 (79.6)	74 (88)
Income							
< 20,000	59 (10.5)	19 (6.8)	13 (6.7)	6 (7)	40 (14.3)[*]	24 (12.2)	16 (19)
20-49,999	120 (21.4)	59 (21.0)	33 (16.9)	26 (30.2)	61 (21.8)	48 (24.5)	13 (15.5)
50-99,999	122 (21.8)	71 (25.3)	52 (26.7)	19 (22.1)	51 (18.2)	38 (19.4)	13 (15.5)
> 100,000	132 (23.5)	69 (24.6)	49 (25.1)	20 (2.33)	63 (22.5)	48 (24.5)	15 (18)
Prefer not to answer/Don't know/Missing	128 (22.8)	63 (22.4)	48 (23.6)	15 (17.4)	65 (23.2)	38 (19.4)	27 (32)
Education							
High school or below[**]	198 (35.3)	96 (34.2)	69 (35.4)	27 (31.4)	102 (36.4)	70 (35.7)	32 (38.1)
Beyond high school[†]	363 (64.7)	185 (65.8)	126 (64.6)	59 (68.6)	178 (63.6)	126 (64.3)	52 (61.9)
Health Literacy							
Confidence in filling out medical forms							
Low health literacy[‡]	145 (25.8)	69 (24.6)	44 (22.6)	25 (29.1)	76 (27.1)	27 (32.1)	49 (25)
High health literacy[§]	416 (74.2)	212 (75.4)	151 (77.4)	61 (70.9)	204 (72.9)	57 (67.9)	147 (75)
Hard time understanding when people speak quickly							
Low health literacy[‖]	210 (37.4)	104 (37.0)	67 (34.4)	37 (43)	106 (37.9)	72 (36.7)	34 (40.5)
High health literacy[¶]	351 (62.6)	177 (63.0)	128 (65.6)	49 (57)	174 (62.1)	124 (63.4)	50 (59.5)
Anticoagulation prescribing-related issues							
Referral to Anticoagulation Clinic	23 (4.1)	12 (4.3)	7 (3.6)	5 (5.8)	11 (3.9)	7 (3.6)	4 (4.8)
Prior use of anticoagulation	147 (26.2)	81 (28.8)	53 (27.2)	28 (32.6)	66 (23.6)	40 (20.4)	26 (31)
Anticoagulant Prescribed							
Apixaban	486 (86.6)	245 (87.2)	163 (83.6)	82 (95)	241 (86.1)	163 (83.6)	78 (92.9)
Dabigatran	1 (0.2)	0 (0)	1 (0.5)	0 (0)	1 (0.36)	0 (0)	0 (0)
Rivaroxaban	74 (13.2)	39 (13.6)	31 (15.9)	4 (5)	35 (12.5)	32 (16.4)	6 (7.1)
Chronic Kidney Disease[±]							
Stage 1	320 (57.0)	156 (55.5)	119 (61)	37 (43)	164 (58.6)	131 (66.8)	33 (39.3)
Stage 2	132 (23.5)	70 (24.9)	44 (22.6)	26 (30.2)	62 (22.1)	36 (18.4)	26 (31)

Stage 3	74 (13.2)	35 (12.5)	16 (8.2)	19 (22.1)	39 (13.9)	18 (9.2)	21 (25)
Stage 4/5	8 (1.4)	6 (2.1)	3 (1.54)	3 (3.5)	2 (0.7)	1 (0.5)	1 (1.2)
Anemia[#]	187 (33.3)	107 (38.1)	70 (35.9)	37 (43)	80 (28.6)	56 (28.6)	24 (28.6)

[*]Comparison between intervention and control had a chi-square p value < 0.05 ; for all other comparisons p value > 0.05

[**]High school or below includes high school graduate, ≤ high school, prefer not to answer, missing

[†]Beyond high school includes: 1-3 years college/post high school trade or technical, college graduate, post graduate education

[‡]Patients with low confidence rated their confidence as: a little bit, somewhat, not at all, prefer not to answer, and missing responses

[§]Patients with high confidence rated their confidence as: extremely, quite a bit

[‖]Patients with low health literacy answered: agree, strongly agree, and prefer not to answer in response to the statement: I have a hard time understanding when people speak quickly). Missing responses were counted as low health literacy.

[¶] Patients with high health literacy answered: strongly disagree and disagree in response to the statement: I have a hard time understanding when people speak quickly)

[Ω]Non-venous condition includes atrial fibrillation, systemic embolism / acute limb ischemia, resumption of anticoagulation after bleeding; venous indication included new or worsened episode (e.g., extension or propagation of previously diagnosed DVT)

[#]Hemoglobin <13 g/dL (Male), <12 g/dL (Female). Percentages based on the original patient count.

[±] Defined by established criteria as a creatinine clearance calculated in mL/min/1.73m^2 units for each stage: >90 (stage 1), 60-80 (stage 2), 30-59 (stage 3), 15-29 (stage 4), <15 (stage 5).

Appendix E – Full Model Results for Incidence Rate of Anticoagulant-Related Clinically Important Medication Errors as a Function of Randomization Group and Other Demographic and Thromboembolism-Related Covariated

Appendix E: Full Model Results for Incidence Rate of Anticoagulant-Related Clinically Important Medication Errors as a Function of Randomization Group and Other Demographic and Thromboembolism-Related Covariates

Randomization group and other demographic and thromboembolism related covariates	Incidence Rate Ratio*	95% Confidence Interval	
		Lower Bound	Upper Bound
Intervention vs. control randomization group	1.17	0.98	1.42
Age			
Age 50–65 vs. < 50	1.33	1.02	1.74
Age 66–75 vs. < 50	1.23	0.89	1.70
Age 76+ vs < 50	0.96	0.64	1.44
Gender Male vs. Female	0.98	0.81	1.19
Minority individual[¥] yes vs. no	0.90	0.68	1.19
Income			
< 20,000 vs. > 100,000	1.30	0.69	1.22
20–49,999 vs. > 100,000	1.10	0.82	1.46
50–99,999 vs. > 100,000	0.91	0.69	1.22
Prefer not to answer/don't know/missing vs. > 100,000	1.15	0.87	1.52
High School Education – beyond high school vs high school or below	1.10	0.90	1.36
Health Literacy			
Confidence filling out medical forms – Low[¶] versus High[₸]	0.90	0.71	1.13
Hard time understanding when people speak quickly Low[#] vs. High[‖]	0.97	0.80	1.19
Non-Venous Indication[Ω] (Indication other than venous thromboembolism) vs. Venous Indication (i.e., VTE)	0.97	0.78	1.19
Anticoagulant prescribed – Apixaban vs. Not Apixaban	0.87	0.67	1.13
Previous anticoagulant use – Yes vs. No + all other categories	1.13	0.92	1.39
Referral to Anticoagulation Clinic	0.83	0.50	1.38
Chronic Kidney Disease			
Stage 1	0.67	0.40	1.13
Stage 2	0.95	0.73	1.23
Stage 3	1.04	0.73	1.48
Stage 4/5	0.59	0.20	1.70
Anemia			
Yes vs. No	1.07	0.87	1.31
Unknown vs. No	1.76	1.05	2.96
Total Medications			
16+ vs. 0–5	0.91	0.66	1.26
11–15 vs. 0–5	1.05	0.78	1.41
6–10 vs. 0–5	0.95	0.72	1.25
Missing vs. 0–5	0.72	0.54	0.97

*To computer the ratio, we constructed a multivariable Poisson regression model with the count of anticoagulant-related clinically important medication errors over 90 days from randomization as the dependent outcome.

[¥] Defined as a patient whose race/ethnicity composite identity is anything other than Non-Hispanic White including Asian, Hispanic, non-Hispanic Black, and other. Also includes anyone whose language preference is not English.

[¶] A little bit, somewhat, not at all, prefer not to answer, missing

ǂ Extremely, quite a bit
Agree, strongly agree, prefer not to answer, missing (in response to the statement: I have a hard time understanding when people speak quickly)
‖ Strongly disagree, disagree (in response to the statement: I have a hard time understanding when people speak quickly)
Ω Non-venous condition includes atrial fibrillation, systemic embolism / acute limb ischemia, resumption of anticoagulation after bleeding; venous indication included new or worsened episode (e.g., extension or propagation of previously diagnosed DVT)
Ÿ Defined by established criteria[1] as a creatinine clearance calculated in mL/min/1.73m^2 units for each stage: >90 (stage 1), 60-80 (stage 2), 30-59 (stage 3), 15-29 (stage 4), <15 (stage 5).
ž Defined using established criteria, i.e., Hemoglobin <13 g/dL (Male), <12 g/dL (Female)[1]

References

1. Levey AS, Eckardt KU, Tsukamoto Y, et al. Definition and classification of chronic kidney disease: a position statement from Kidney Disease: Improving Global Outcomes (KDIGO). *Kidney international.* 2005;67(6):2089-2100.