### Implementation of Pharmacist-Led Quality Initiative for Direct Oral Anticoagulant (DOAC) Monitoring

Chelsea Vuu, PharmD

Anticoagulation Management Services Clinical Pharmacist, Carle Health



#### Conflict of Interest Disclosure

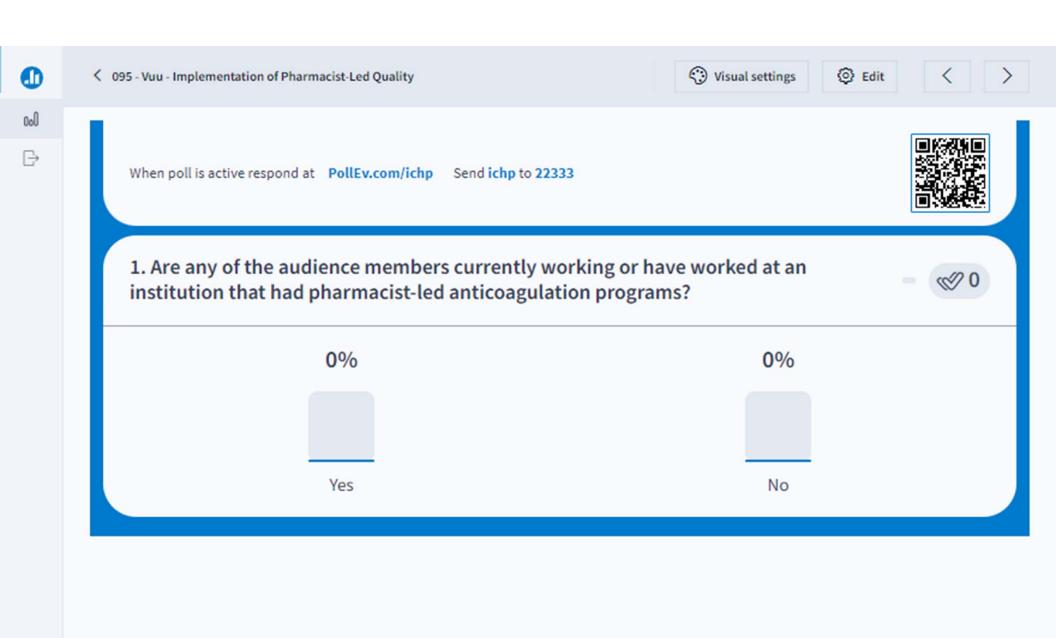
Presenter does not have any relevant financial relationships or conflicts with the content of the presentation.



#### Objectives

- 1. Explain the development and workflow process of a pharmacist-based DOAC monitoring program within a health system
- 2. Identify the gaps in care and barriers for DOAC management
- 3. Describe the intervention types found with the pharmacist-based DOAC monitoring program





### Development and Workflow of Pharmacist-Based Direct Oral Anticoagulant Monitoring Program



#### Pharmacist-Led Anticoagulation Management

- Improved time in therapeutic range for warfarin patients
- Improved patient satisfaction and education
- Increased adherence
- Decreased thromboembolic and bleeding complications

Haché J, Bonsu KO, Chitsike R, Nguyen H, Young S. Assessment of a pharmacist-led direct oral anticoagulant monitoring clinic. Can J Hosp Pharm. 2021; 74(1):7-14.

Hou K, Yang H, Ye Z, Wang Y, Liu L, Cui X. Effectiveness of pharmacist-led anticoagulation management on clinical outcomes: a systematic review and meta-analysis. *J Pharm Pharm Sci.* 2017;20(1):378-396.

Perlman A, Horwitz E, Hirsh-Raccah B, et al. Clinical pharmacist led hospital-wide direct oral anticoagulant stewardship program. Isr J Health Policy Res. 2019; 8: 19.

Young S, Bishop L, Twells L, Dillon C, Hawboldt J, O'Shea P. Comparison of pharmacist managed anticoagulation with usual medical care in a family medicine clinic. *BMC Fam Pract.* 2011;12:88.

Witt DM, Sadler MA, Shanahan RL, Mazzoli G, Tillman DJ. Effect of a centralized clinical pharmacy anticoagulation service on the outcomes of anticoagulation therapy. *Chest*. 2005;127(5):1515-22.

#### Roles of Pharmacists in Anticoagulation

Improving adherence

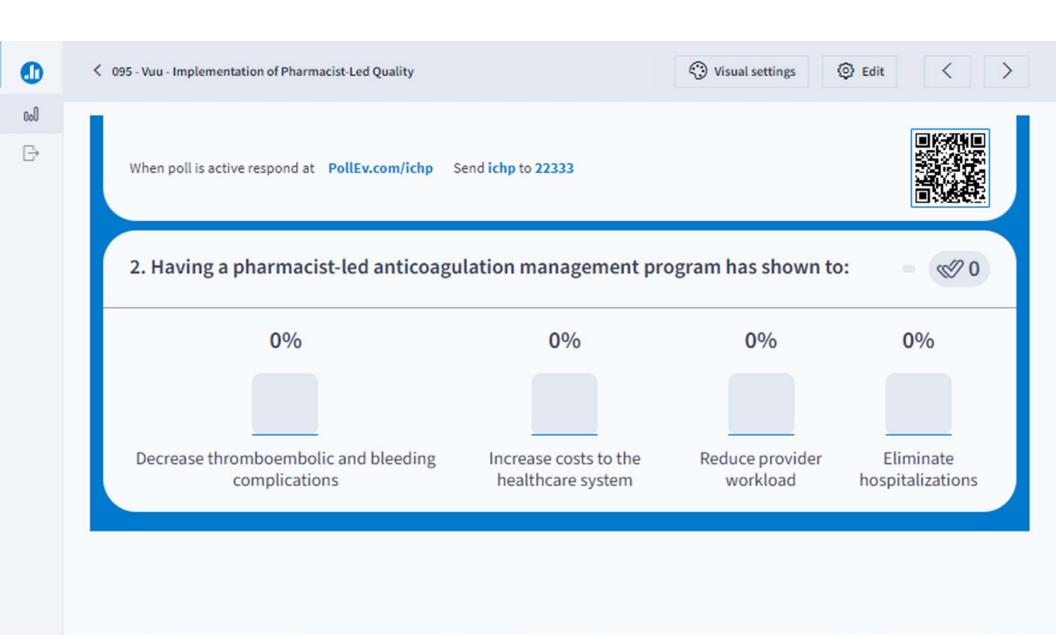
Optimizing treatment

Improving safety

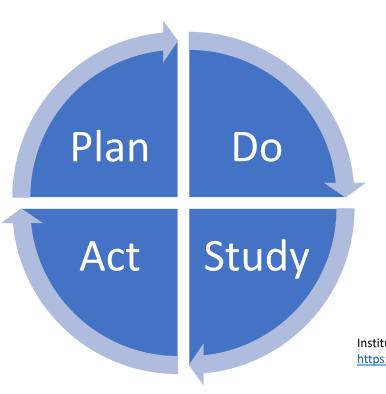
Supporting transition of care

Smythe MA. Advances in anticoagulation management: the role of pharmacy. Ann Pharmacother. 2007;41(3):493-495.





#### Model for Improvement: PDSA



Plan: Test/observation and collecting data

Do: Perform the test/observation

- Document issues and unexpected observations
- Initiate data analysis

Study: Analyze data

Compare results to predictions

Act: Based on information learned from test/observation, fine-tune the process by determining what adjustments need to be made

Create a plan for the next test

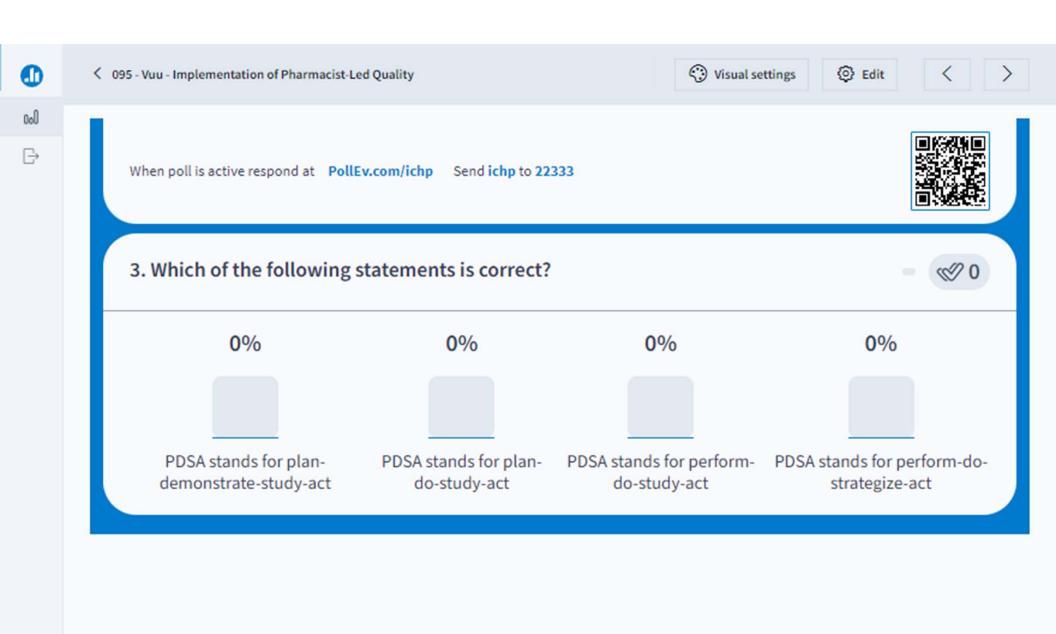
Institute for Healthcare Improvement . How to improve-science of improvement: testing changes. Available at: https://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementTestingChanges.aspx. Accessed June 16, 2023.



#### Anticoagulation Stewardship Team

- Consists of:
  - Pharmacists
  - Anticoagulation Management Services manager
  - Anticoagulation Nurse Educator
  - Project Managers
  - Cardiology and primary care physicians
  - Clinical and Business Intelligence (CBI) Developers
  - EPIC Information Technology Developers





#### Plan

- Objective: To create a pharmacist-led anticoagulation program that will assist with standardizing care, improving adherence, and optimizing treatment
- Predictions: Development of this program will standardize care, improve adherence, and optimize anticoagulation treatment



#### Plan

#### Plan:

Workflow between pharmacists and providers

#### Pharmacists will:

#### Chart reviews

- Initial and annual
- Appropriateness of DOAC therapy

#### Review

- Labs
- Hospitalization records

#### Provide

- Patient education
- Perioperative DOAC recommendations
- Anticoagulation transitions

#### Collaborate

- Provider
- Social work
- Prescription assistance



#### Plan: Program Builds

- DOAC Pharmacists work pool
  - In-basket messages alerting:
    - New, refill, or renewal prescriptions of any DOAC has been placed
    - Patients with DOAC flags who have been hospitalized within our hospital system
    - Patients with DOAC flags who have renal, liver, or complete blood count (CBC) labs done
  - DOAC flag
    - Placed on charts that have been reviewed
    - Used in tracking patients reviewed, used to fire off in-basket messages listed above



#### Plan: Tracking Data

- CBI developed a DOAC Dashboard
  - Tracks total number of prescriptions of DOACs within our health system
  - Number of patients with DOAC flags (intake review occurred)
  - Larger-scale trends:
    - Number of patients on antiplatelets, non-steroidal anti-inflammatory medications, cytochrome P (CYP) or P-glycoprotein (P-gp) inhibitors/inducers
    - Number of patients with abnormal creatinine, total bilirubin, hemoglobin, hematocrit
  - Individual patients with any issues such as abnormal labs or interacting medications highlighted
- Pharmacists also track interventions via excel



## Do: Initial and Annual Chart Intake Assessment

- Review for appropriateness of:
  - Indication
  - Dose
  - Drug-drug interactions
  - Renal and liver function
  - Weight and BMI
  - Contraindications (example: mechanical valve replacements)
  - Lab safety monitoring frequencies
  - Existing provider perioperative recommendations
  - Cost affordability issues



Monitoring of Direct Oral Anticoagulants

	Healthy patients	Renal Impairment (eGFR <60ml/min)	Elderly (age <u>&gt;</u> 75 years)	Liver impairment (Child-Pugh B or C)	Concomitant drugs (PGP or CYP3A4 inhibitors/inducer <sup>1,2</sup> , NSAIDs, antiplatelets <sup>3</sup> )
Complete Blood Count (CBC)	Baseline and annually	Baseline and at least annually.	Baseline and at least annually	Baseline and at least every 6 months	Baseline and every 3 to 6 months
Renal Function	Baseline and every 6-12 months	Baseline and every 3 to 6 months	Baseline and every 3 to 6 months	Baseline and at least every 6 months	Baseline and every 3 to 6 months
Hepatic Function	Baseline and annually	Baseline and annually	Baseline and annually	Baseline and at least every 6 months*	Baseline and annually

Conway SE, Hwang AY, Ponte CD, Gums JG. Laboratory and clinical monitoring of direct acting oral anticoagulants: what clinicians need to know. Pharmacotherapy. 2017; 37: 236-248.

Gladstone DJ, Geerts WH, Douketis J, et al. How to monitor patients receiving direct oral anticoagulants for stroke prevention in atrial fibrillation: a practice tool endorsed by thrombosis Canada, the Canadian Stroke Consortium, the Canadian Cardiovascular Pharmacists Network, and the Canadian Cardiovascular Society. *Ann Intern Med.* 2015;163(5):382–5.

Kearin C, Akl EA, Comerota AJ, et al. Antithrombotic therapy and prevention of thrombosis. 9th ed: American college of chest physicians evidence-based clinical practice guidelines. Chest. 2016; 141 (2): e419S-e496S.

#### **Financial**

- Cost affordability assessment not done prior to drug initiation
- Coverage gaps (ex: donut hole)

#### Care at multiple facilities

- Initiation of interacting drugs
- Duplicate or conflicting instructions provided to patient



#### Education

- Limited time in provider-patient office visits
- Some important topics not discussed:
  - Importance of avoiding missed doses
  - How to take the drug
  - How to handle upcoming procedure or surgeries



#### Drug-drug interactions

#### Lab monitoring and dosing

- Lack of exact lab frequencies outlined by guidelines
- Large variation amongst how providers were managing lab monitoring
- Patients are unaware of the importance of labs while on the DOAC

Laboratory and Clinical Monitoring of Direct Acting Oral Anticoagulants: What Clinicians Need to Know. *Pharmacotherapy* 2017;37:236-48.



#### Resumption post-bleeding or post-procedure

- Lost to follow-up
  - Delay in resumption

#### Weight and BMI considerations

 Lack of risks versus benefits discussions on DOAC use in morbidly obese BMI or weight



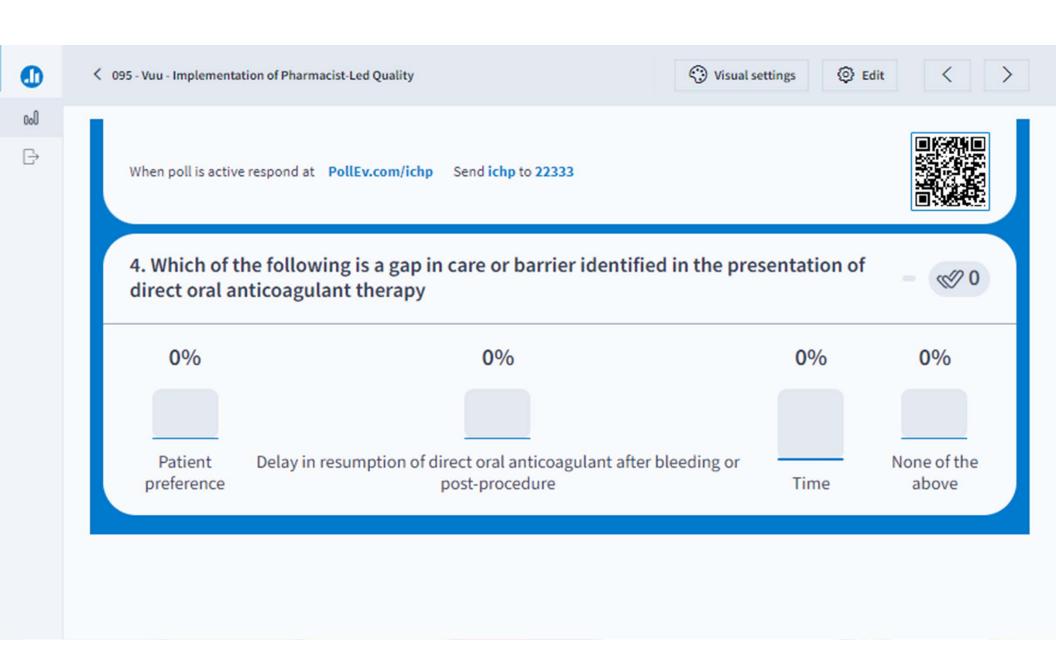
#### Switching from warfarin to DOAC

- Unfamiliarity with INR requirements by providers
  - Could lead to inappropriately overlapped anticoagulation

#### Dosing

- Under: didn't meet at least 2 characteristics for apixaban 2.5mg twice daily for AFIB
- Over: development of renal impairment that requires a dose reduction





#### Discussion

What are some barriers you see in your practice with direct oral anticoagulation management?



#### Do-Study-Act: Problem With Refills on Late Labs

Cardiology and Medication Refill Center Lab Conflicts

- Internal refill protocol: just need complete blood count (CBC) and complete metabolic panel (CMP) annually
- DOAC program: lab frequencies depending on patient characteristics

Collaborated with departments

• Other departments' DOAC refill protocol now aligns with DOAC program lab monitoring

Pharmacists add lab frequencies into DOAC flag comments

- Lab frequencies easily accessible in patient charts for all users
- Lab monitoring standardized



# Do-Study-Act: Problem with Unstandardized Monitoring

- Some not having labs for over 3 years
- Variation amongst providers on how often safety labs were being monitored

Large percentage of patients with late labs

Collaborated with EPIC IT

- Created DOAC smartsets for providers to order DOACs and labs
- Internal clinical guidance documents embedded

- Not aware that this smart-set exists
- Not conducive to their workflow while seeing patients

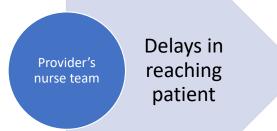
Providers not using the smart-sets

Collaborating with EPIC IT to embed the information into care plans

- More accessible
- Coordinated within provider workflow



# Do-Study-Act: Delays in Patients Getting Safety Labs Done





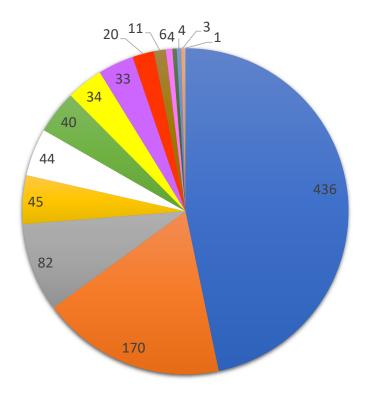


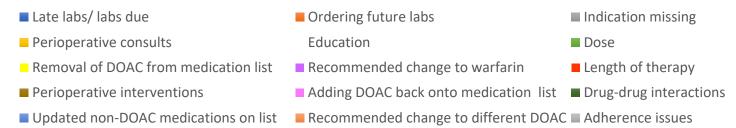
Reduces providers' nurse workload



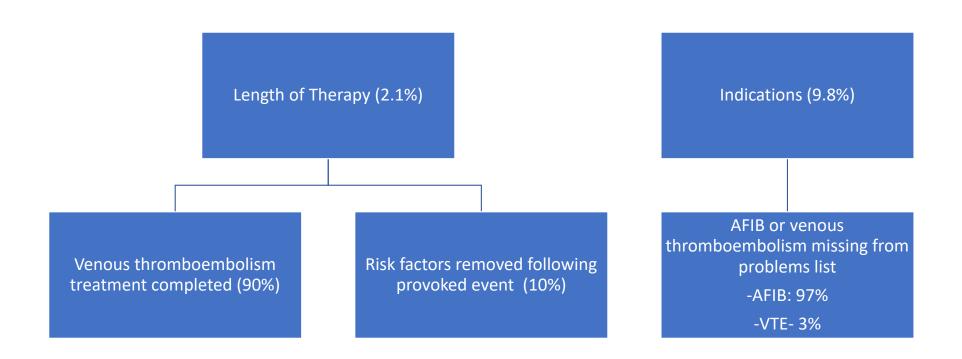
# Intervention types found with the pharmacist-based direct oral anticoagulant monitoring program



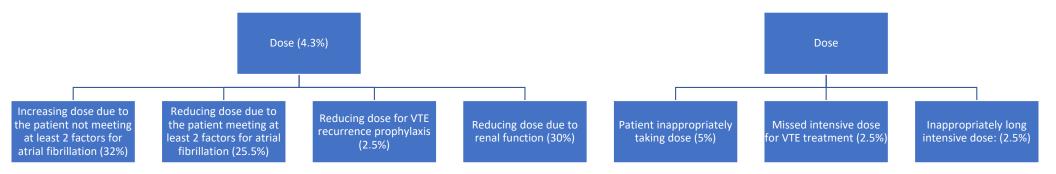












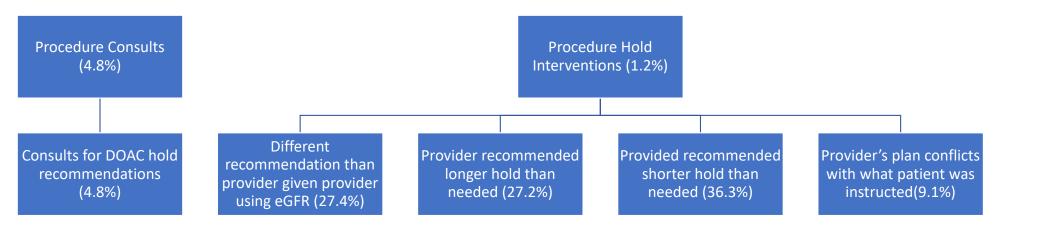
2023 ICHP ANNUAL MEETING Late Labs

Ordering Future Labs

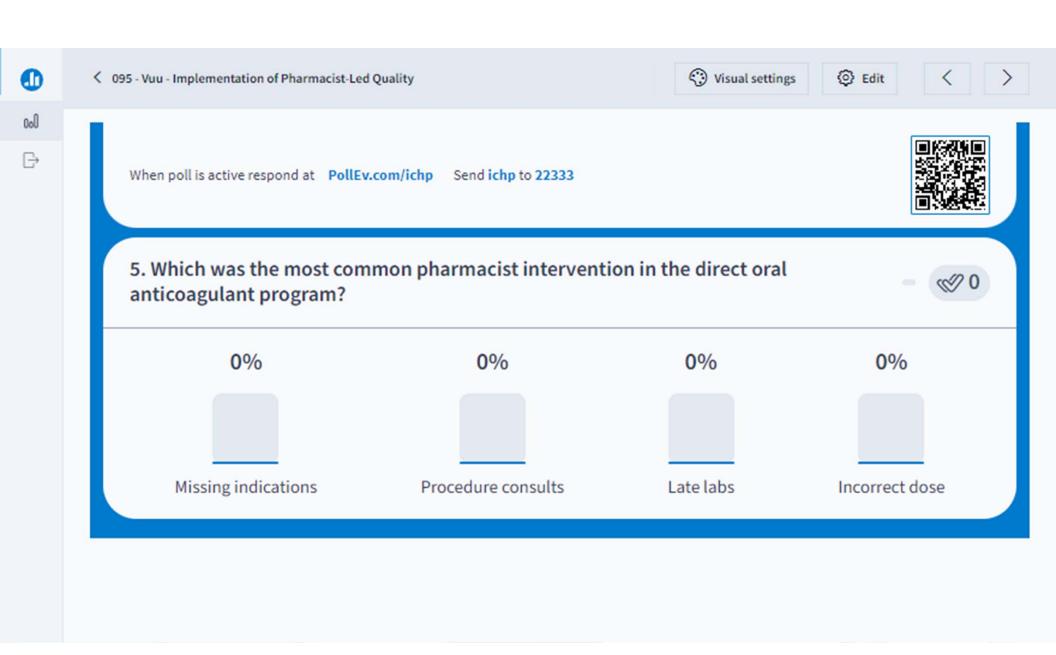
CBC, renal function, or liver function labs late (46.8%)

Ordering labs due within the next 3 months (18.2%)









# Removal of DOAC From Medication List (3.6%)

- Patient was instructed by provider to stop medication: 64.7%
- Duplicate scripts with 2 different doses: 35.3%

#### Recommended Alternative Warfarin (3.5%)

- Poor renal function, no longer qualified for DOACs: 42.4%
- Major interaction with CYP inducer: 6.1%
- BMI exceeding 50 or weight exceeding 180kg: 48.5%
- Gastric bypass surgery that affected absorption of DOAC:
   3%



# Updated Medication List for Nonanticoagulant Medications (0.4%)

- Removal of non-steroidal anti-inflammatory medications after education: 50%
- Removal of major interacting medication patient was no longer on: 50%

Adding DOAC Back
Onto Medication List
(0.6%)

- Surgeon only intending for temporary hold: 33.3%
- DOAC on hold after bleed and resumed after pharmacy prompting re-evaluation: 66.7 %



## Phone Education (4.7%)

New DOAC initiation

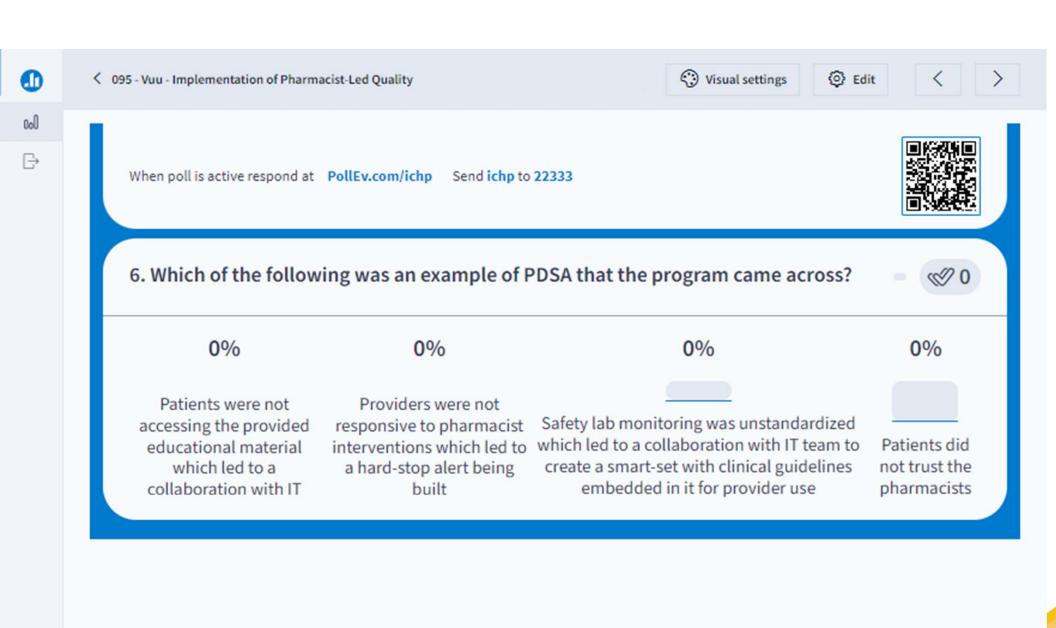
#### **DOAC Booklets**

 Initiated within the last 12 months

## MyChart Patient Message

 All patients signed up for MyChart communication





#### Discussion

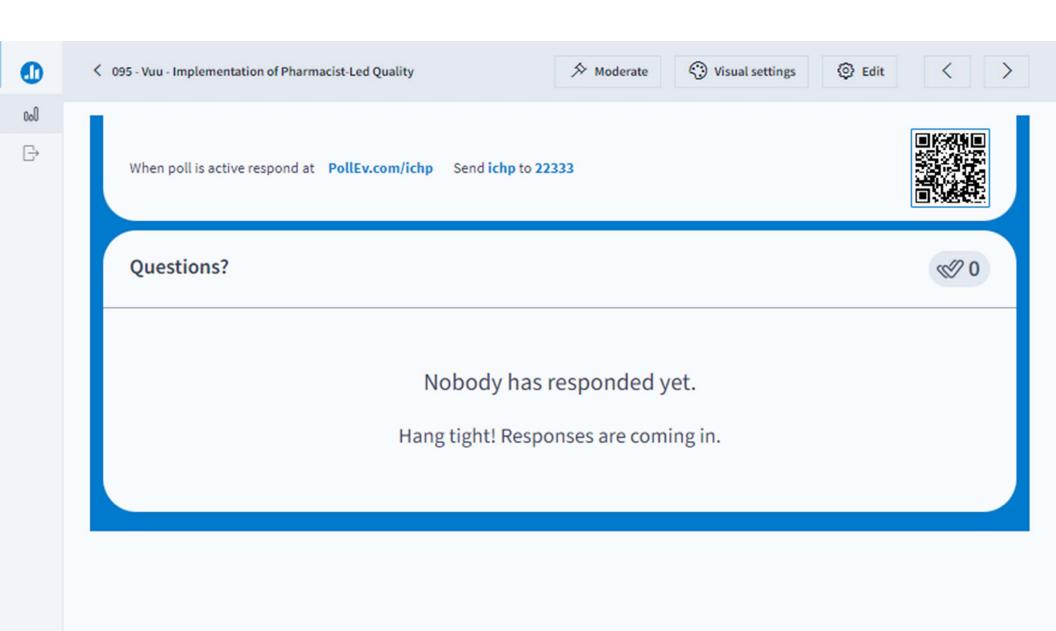
What are the most impactful or common interventions you have seen or done so far with direct oral anticoagulants?



#### Pharmacist-Led Anticoagulation Program

- Objective: To create a pharmacist-led anticoagulation program that will assist with standardizing care, improving adherence, and optimizing treatment for DOAC use
- Standardize care:
  - Safety lab monitoring and refills
  - Perioperative management
- Improving adherence:
  - Education- correct dosing
- Optimize treatment:
  - Revise dosing errors, inappropriate perioperative plans, choice of anticoagulant, dosing for VTE recurrence prophylaxis, length of therapy, drug-drug interactions





#### References

- Haché J, Bonsu KO, Chitsike R, Nguyen H, Young S. Assessment of a pharmacist-led direct oral anticoagulant monitoring clinic. *Can J Hosp Pharm.* 2021; 74(1):7-14.
- Hou K, Yang H, Ye Z, Wang Y, Liu L, Cui X. Effectiveness of pharmacist-led anticoagulation management on clinical outcomes: a systematic review and meta-analysis. *J Pharm Pharm Sci.* 2017;20(1):378-396.
- Perlman A, Horwitz E, Hirsh-Raccah B, et al. Clinical pharmacist led hospital-wide direct oral anticoagulant stewardship program. Isr J Health Policy Res. 2019; 8: 19.
- Young S, Bishop L, Twells L, Dillon C, Hawboldt J, O'Shea P. Comparison of pharmacist managed anticoagulation with usual medical care in a family medicine clinic. *BMC Fam Pract*. 2011;12:88.
- Witt DM, Sadler MA, Shanahan RL, Mazzoli G, Tillman DJ. Effect of a centralized clinical pharmacy anticoagulation service on the outcomes of anticoagulation therapy. *Chest*. 2005;127(5):1515-22.
- Smythe MA. Advances in anticoagulation management: the role of pharmacy. Ann Pharmacother. 2007;41(3):493-495.
- Institute for Healthcare Improvement . How to improve- science of improvement: testing changes. Available at: <a href="https://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementTestingChanges.aspx">https://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementTestingChanges.aspx</a>. Accessed June 16, 2023.
- Conway SE, Hwang AY, Ponte CD, Gums JG. Laboratory and clinical monitoring of direct acting oral anticoagulants: what clinicians need to know. *Pharmacotherapy*. 2017; 37: 236-248.
- Gladstone DJ, Geerts WH, Douketis J, et al. How to monitor patients receiving direct oral anticoagulants for stroke prevention in atrial fibrillation: a practice tool endorsed by thrombosis Canada, the Canadian Stroke Consortium, the Canadian Cardiovascular Pharmacists Network, and the Canadian Cardiovascular Society. *Ann Intern Med.* 2015;163(5):382–5.
- Kearin C, Akl EA, Comerota AJ, et al. Antithrombotic therapy and prevention of thrombosis. 9<sup>th</sup> ed: American college of chest physicians evidence-based clinical practice guidelines. Chest. 2016; 141 (2): e419S-e496S.
- Laboratory and Clinical Monitoring of Direct Acting Oral Anticoagulants: What Clinicians Need to Know. Pharmacotherapy 2017;37:236-48.



### Implementation of Pharmacist-Led Quality Initiative for Direct Oral Anticoagulant Monitoring

Chelsea Vuu, PharmD

Anticoagulation Management Services Clinical Pharmacist, Carle Health

