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DOAC Ambulatory Risk Assessment

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Background

- Within a large medical group in Oregon, we have identified a trend in reported safety events (errors/near misses) involving the direct oral anticoagulant (DOAC) class of medications. In 2021, nine safety events reported in Datix (our voluntary event reporting software) involved DOACs. DOACs were prioritized for further risk assessment given the frequency of event reports, the potential risk for patient harm, and unreliable methods for error detection.

- DOACs are considered high-alert medications per the medical group's policy. A high-alert medication is one that bears "a heightened risk of causing significant patient harm when used in error." Several actions have been taken to reduce the risk of error involving DOACs, including the development of an EPIC order panel, a pharmacy Oral Anticoagulation Guideline to support evidence-based management, and the completion of a Sentinel Event Alert (#61) DOAC Gap Analysis in 2020. One of the recommended actions from the 2020 gap-analysis was to perform an "assessment of all anticoagulant [safety] events to identify trends among ministries and assess opportunities for improvement." While there have been various assessments and actions for acute-care anticoagulation management, there has not yet been a coordinated effort to analyze the risk within our ambulatory prescribing and management of DOACS.

- Action Planning
  - Resident will perform a risk assessment, support the presentation of findings to key stakeholders, and facilitate interdisciplinary brainstorming for action planning.

Purpose

- To identify common themes in Ambulatory Care Safety Events involving DOACs and possible error prevention interventions to share broadly across a large medical group and the network of clinic providers

Objectives

- Primary outcomes
  - Identify top areas of risk and opportunity with DOAC use at outpatient ambulatory clinics
  - Identify opportunities for intervention

Methods

- Study design
  - Common Cause Analysis (CCA) of reported safety events compiled through Datix and analyze common themes with use of a density map
  - Medication use evaluation of DOAC prescription in the ambulatory environment
    - Retrospective review of 100 EPIC patient charts
    - Assess DOAC use for appropriate indication, dose, and duration
    - Assess drug selection, contraindications and drug-drug interactions
  - Collate results from CCA and MUE

- Inclusion criteria
  - All adults with a DOAC prescription managed by a large medical group in Oregon during 2021

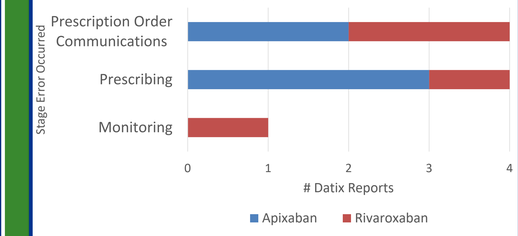
- Exclusion criteria
  - Inpatient management of DOAC prescriptions

Common Cause Analysis

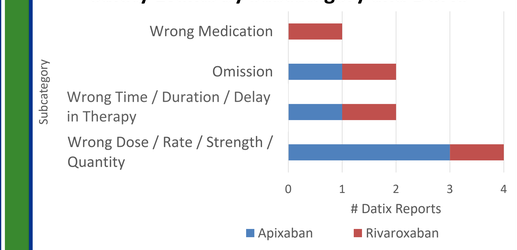
Year	Number of DOAC Datix Events
2019	14
2020	15
2021	9

Indications	Apixaban	Rivaroxaban
Atrial Fibrillation	4	1
Atypical Atrial Flutter	1	0
Venous Thromboprophylaxis	0	2
Post COVID-19 Pneumonia Thromboprophylaxis	0	1

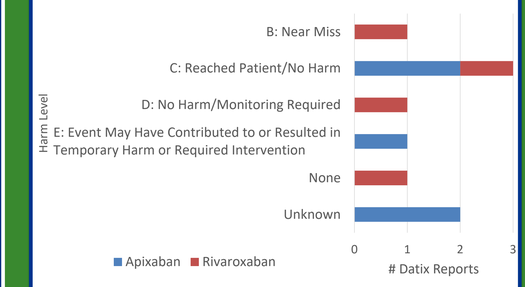
Safety Events by Stage Error Occurred and DOAC



Safety Events by Subcategory and DOAC



Safety Events by Harm Level and DOAC



Extrapolated Systemic Failures

Process
- Omitted Actions (key activity is missing or incomplete)
- Poorly Sequenced (poor flow, excessive branching of work process activities)
- Inadequate Interface (lack of or poorly designed handoffs of information, resources or products)
- Inadequate Checks (lack of poorly designed checks, inspections or reviews)

Structure
- Collaboration Mechanisms (wrong or inadequate)

Technology and Environment
- Human Capability (symbols, codes, anthropometry, devices, human control, physical work)

Medication Use Evaluation

Characteristics	Apixaban (n =75)	Rivaroxaban (n = 22)	Dabigatran (n = 3)
Mean Age, yr (SD)	71 ± 12	73 ± 10	67 ± 16
• 35-64 y	17	2	4
• 65-80 y	41	0	15
• >80 y	17	1	3
Male	35	8	2
Female	40	14	1
White	70	21	3
Asian	5	1	0
Weight, kg – median (range)	88 (44-162)	91 (85-142)	101 (82-120)
• <60 kg	8	2	1
• 60-120 kg	58	18	1
• >120 kg	9	2	1
Creatinine Clearance, mL/min, mean	68	64	76
• <30	4	0	2
• 30-60	27	1	8
• 60-90	28	1	7
• 90-120	12	1	5
• >120	4	0	0
Antiplatelets			
• Aspirin	15	2	0
• Clopidogrel	4	0	0
• Dual Therapy	1	0	0
DOAC duration			
• New start	23	8	0
• <1 year	18	2	0
• 1-3 years	18	5	0
• >3 years	16	7	3
Yearly labs done	11	4	0
Encounter Type			
• Refill Request	33	8	1
• Periprocedural	4	3	0
• Transitions of Care	5	2	0
• Anticoagulation Transition	1	1	0
Pharmacy Involved	11	1	2

Indications	Apixaban (n =75)	Rivaroxaban (n = 22)	Dabigatran (n = 3)
FDA Approved Indications			
Non-valvular Atrial Fibrillation	48	13	2
• CHA_2DS_2-VASc Score			
• <3	13	3	1
• ≥3	36	10	1
DVT Treatment	4	2	0
PE Treatment	8	0	0
Venous Thromboembolism (VTE) Prophylaxis	6	4	1
Non-FDA Approved Indications			
Atrial Flutter	6	1	0
Valvular Atrial Fibrillation	2	0	0
Factor V Leiden Deficiency	1	2	0
Raynaud's Syndrome	1	0	0

Safety Outcomes	Apixaban (n =75)	Rivaroxaban (n = 22)	Dabigatran (n = 3)
Identified GAPS*	9	5	0
Possible GAPS	27	8	2
No Identified GAPS	41	11	1
Medication Error Subtype			
• Incorrect Dose	5	3	0
• Drug/Drug Interactions	3	2	0
GAPS related to			
• Indication	2	0	0
• Duration	5	2	0
• Renal function	6	5	0
• Hepatic function	1	0	0
• Weight	5	3	2
• BMI	11	2	0
Alerts Overridden	6	2	0
Bleeding event within 1 year	4	1	0
Thrombosis event within 1 year	1	0	0
Hospitalization/ED visit/Urgent Care within 1 year	4	1	0

*GAPS = a deviation from generally accepted performance standards (GAPS)
Some safety outcomes may be overlapping

Discussion

Common Cause Analysis

- Nine safety events were identified from six different departments where most resulted in no harm. Most events involved a breakdown in prescription order communications and improper dosing.
- One safety event that needed intervention involved a patient that needed three weeks of anticoagulation before cardioversion, but the prescription was not received by the pharmacy and delayed the procedure.
- Two events where unknown harm occurred involved (1) incorrect dosing of apixaban for atrial fibrillation (MD prescribed dosing for DVT treatment) and (2) continued dispensing of apixaban despite discontinuation by provider due to improved CHA2DS2-VASc score (patient had memory problems and pharmacy unaware).
- One event where no harm occurred involved a refill specialist who refilled an apixaban prescription without forwarding to clinical pharmacist for review.
- Corrective actions mainly involved modifying prescriptions after review and notifying providers/leadership of error. No system-focused interventions were pursued, and only one instance of education/training was done.

Medication Use Evaluation

- 14 safety events were identified in 100 patient chart reviews. Similar to trends found in CCA, errors involved incorrect dosing and a breakdown of communication. None resulted in major harm requiring hospitalization or ED/urgent care visits.
  - Five patients had major DDIs; one involving Biktarvy and Prezcobix, another carbamazepine, and three took NSAIDs
  - Nine involved incorrect renal dosing
  - Two patients where indication was not appropriate
- 35 additional patients were found to have possible GAPS
  - One patient was diagnosed with cirrhosis but with an unknown Child-Pugh score and limited lab information. Possible contraindication to DOAC use.
  - Five patients were on appropriate DOACs but experienced minor bleeding events (hematuria, groin/vaginal bleeding, and epistaxis). One had borderline renal function.
  - Four patients with no history of VTE may have met criteria for a dose reduction given duration of therapy for VTE treatment. Potential cost savings for patient.
  - 20 patients with extreme weights and/or high BMI may have benefit from a transition to warfarin per inpatient protocol; only three of these patients were previously on warfarin. DOACs have limited data in this population.

DOAC Analysis Limitations

- Small sample size, could benefit in including more patients for chart reviews to identify and recognize error trends
- Interpretation of Datix report trends and failure modes limited to quantity and quality of self-reported errors from caregivers
- Limited to available data in EPIC. Patients may be seen by other institutions not connected to EPIC and have updated labs or encounters that could not be utilized in this project.

Going Forward

- Continue surveillance of Datix reports involving DOACs
- Present findings to different key stakeholders to gather input on top risks, emphasizing proper management of those with renal dysfunction, DDIs, and extreme weights.
  - Explore safeguard options through EPIC, education, or policies and procedures

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