Improving Care Disparities for Black Americans in Mississippi with VTE: The Role of Care Transitions in Critical Access Hospitals

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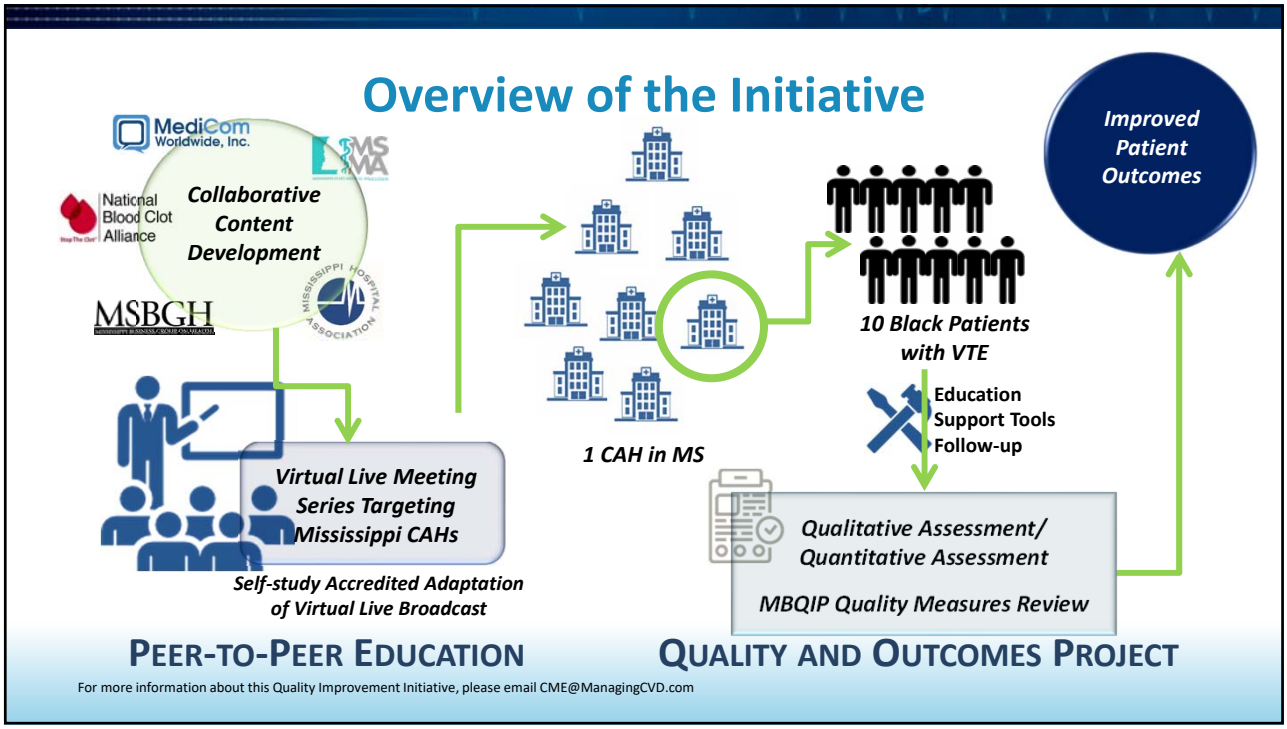
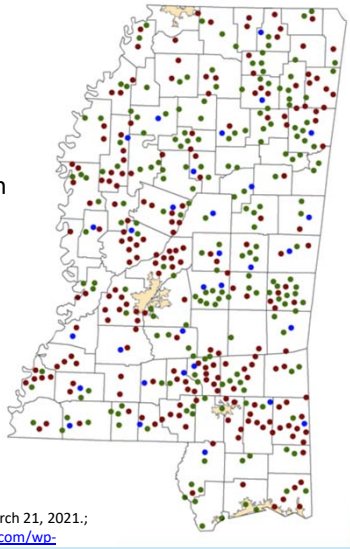


Why Mississippi?

- Black Americans in Mississippi have a high number of comorbidities that place them at greater risk for both initial and recurrent VTE
- Mississippi ranks last, or close to last, in almost every leading health outcome. Evaluated within the context of nationally reported CAH data on care transitions, Mississippi CAHs also rank low
- Collectively, this body of information indicates a pressing need for clinician education, support tools, and resources aligned with hospital quality improvement initiatives and measures in CAHs in Mississippi. These efforts should lead to better clinician and hospital practices for care transitions among Black Americans discharged home on oral anticoagulant therapy

Critical Access Hospitals in Mississippi

- CAHs play a primary role in the care of rural Black patients
  - 22.7% of Blacks in Mississippi are rural; they constitute 36.5% of the rural population in the state
- CAHs underperform compared with urban counterparts, particularly on care transition and post hospitalization care
- 49% of rural hospitals in Mississippi are “at-risk” for potential closure
- Mississippi ranks last or close to last on all health care measures
  - Mississippi minorities, including Black Americans, are disproportionately impacted by poor health measures
  - Rural hospital closures will exacerbate this problem



Health Equity - Mississippi State Department of Health. https://msdh.ms.gov/msdhsite/_static/44,0,236.html. Accessed March 21, 2021.; McDoom M, et al. The economic impact of potential closures of rural hospitals in Mississippi. 2015. https://mshealthpolicy.com/wp-content/uploads/2015/11/Economic-Impact-of-Potential-Closures-of-Rural-Hospitals-in-Mississippi_MSU-Aug15.pdf. Accessed March 22, 2021.

Effects of Race on the Incidence of VTE

Venous Thromboembolism (VTE)

- A continuum of disease from deep venous thrombosis (DVT) to pulmonary embolism (PE) and potential nonfatal sequelae such as chronic thromboembolic pulmonary hypertension (CTEPH) and post-thrombotic syndrome (PTS)
- DVT typically starts in the lower extremities (less commonly in the upper extremities) or pelvis
  - Produces pain and distal edema
  - Can propagate, leading to further symptoms
  - Can embolize, resulting in PE
- VTE kills more Americans each year than breast cancer, HIV disease, and road traffic accidents . . . ***combined***
- Except when it occurs in inpatients, VTE is typically first evaluated and treatment is initiated in the emergency department (ED)

Bates SM, et al. *Chest.* 2012;141(2)(Suppl):e351S–e418S.
http://www.cdc.gov/ncbddd/aboutus/annualreport2012/documents/ncbdddannualrepor2012-full-report.pdf. Accessed 8/17/13.

VTE Epidemiology: Why More Cases?

- Consider the risk factors for VTE:
  - Increasing age
    - Population is aging; fastest growing US demographic is >75
  - Obesity
    - Incidence never higher
  - Cancer
    - More common, and patients live longer after diagnosis
  - Heart failure
    - Better medical and device therapy prolongs (at-risk) life
  - Other chronic illnesses/debilities with longer lifespan

Understanding risk factors for VTE is vital to identify patients at risk who would benefit from thromboprophylaxis.

Cushman M. *Semin Hematol.* 2007;44:62-69.; Stein PD, et al. *Arch Intern Med*. 2004;154:2260-2265.; Lee AYY, et al. *Circulation.* 2003;107:I-17-I-21; Deitelzweig SB, et al. *Am J Hematol.* 2011;86:217-220.; Nicholson M, et al. *J Clin Med*. 2020;9(8):2467. https://doi.org/10.3390/jcm9082467

The Impact of VTE

- VTE is a serious health problem with a high mortality rate
  - One of the most common causes of death among hospitalized patients
- Each year, VTE affects as many as 900,000 Americans and 60,000-100,000 die of DVT/PE
- Sudden death is the first symptoms in 25% of PE cases
- 5% to 8% of Americans have one of several genetic risk factors for VTE

CDC. Data and Statistics on Venous Thromboembolism. https://www.cdc.gov/ncbddd/dvt/data.html. Accessed March 20, 2021.; Lau B, et al. *Med Care*. 2015;53(1):18-24.

Burden of Disease

- **Death occurs in up to one-third of patients within 1 month of VTE**
  - 50% of patients experience long-term complications
- **DVT**
  - 25% of calf vein DVTs will progress to involve proximal lower extremity veins (popliteal, femoral, or iliac veins)
  - Up to 50% of patients develop long-term complications, such as post-thrombotic syndrome and chronic venous insufficiency

50% of proximal lower extremity DVTs result in PE

- **PE**
  - Leading preventable cause of death in hospitalized patients
  - Up to 25% of cases present as sudden death
  - Without treatment, approximately 30% of patients die

Adequate treatment reduces mortality to 8%

Simes J, et al. *Circulation*. 2014;130:1062-1071.; Raskob GE, et al. *Am J Prev Med*. 2010;38(4 Suppl):S502-S509.; Reyes N, et al. Deep vein thrombosis & pulmonary embolism. In*: CDC 2014 The Yellow Book*. Available at: http://wwwnc.cdc.gov/travel/ yellowbook/2014/chapter- the-pre-travel-consultation/deep-vein-thrombosis-and-pulmonary-embolism. Accessed January 27, 2015.; Beckman MG, et al. *Am J Prev Med*. 2010;38:S495-S501.; Walter RJ, et al. *Curr Med Res Opin*. 2014;30:1975-1989.; Carson JL, et al. *N Engl J Med*. 1992;326:1240-1245.

Social Determinants of Health

Healthy People 2030. Social Determinants of Health https://health.gov/healthypeople/objectives-and-data/social-determinants-health. Accessed April 23, 2021.

Patient Advocacy

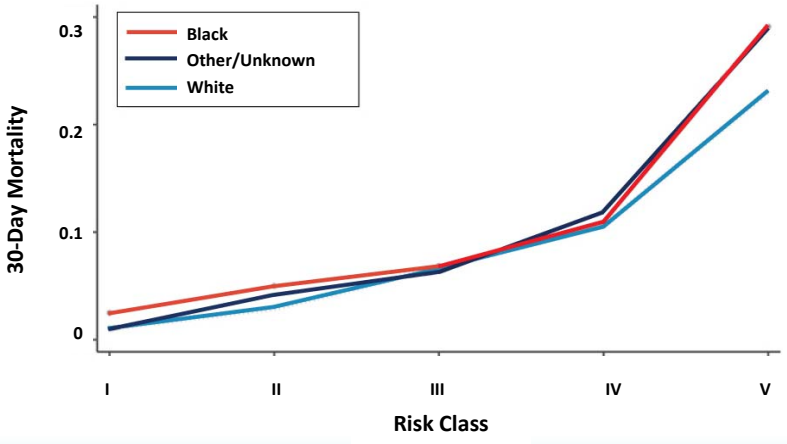
Leslie Lake
Board President
National Blood Clot Alliance
Philadelphia, PA

Racial Disparities in Incidence of VTE

- Incidence of VTE, including DVT and PE, is 30-60% higher for Blacks than Whites
  - Sickle-cell trait associated with increased risk of VTE
    - Up to 8% of Black Americans carry the sickle-cell trait
  - Idiopathic VTE, especially idiopathic PE, is higher among Blacks (18% vs 10%)
  - Pregnancy related VTE rates are also higher in African American patients
- 30-day mortality 30% higher for Blacks
- Blacks who passed away for VTE were typically 9 years younger than Whites
- Incidence of out-of-hospital fatal PE was 3 times higher for Blacks than Whites
- Significantly higher incidence of VTE in Blacks in rural Southeast than in Blacks in the rest of the country, something not seen among Whites

Buckner T, et al. *Circulation.* 2012;125:837-839.; Zakai N, et al. *Circulation*. 2014;129(14):1502-1509.; Ibrahim S, et al. *Am J Public Health.* 2006;96(12):2161-2164.; Heit J, et al. Am *J Hematol.* 2010;85:467-471.; Frydman G, et al. *Clin Appl Thromb Hemost*. 2020;26:1-8.

VTE Risk of Mortality by Race and Risk Class



Buckner T, et al. *Circulation.* 2012;125:837-839.; Zakai N, et al. *Circulation*. 2014;129(14):1502-1509.; Ibrahim S, et al. *Am J Public Health.* 2006;96(12):2161-2164.; Heit J, et al. Am *J Hematol.* 2010;85:467-471.; Frydman G, et al. *Clin Appl Thromb Hemost*. 2020;26:1-8.

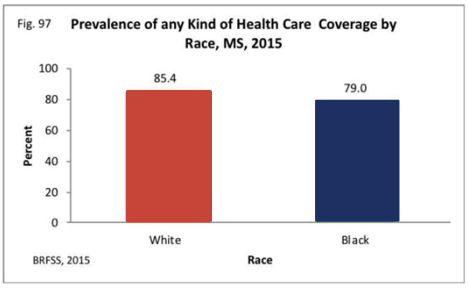
Barriers to Better Health Care in the Black Mississippi Population

- Distrust of the medical profession
- Lack of health insurance
  - May be related to the high cost of insurance (as high as 20% of the average household income)
  - Lack of Medicaid Expansion and other subsidized programs
  - Coverage gaps - the person may earn too much to qualify for the traditional Medicaid program, but also may not earn enough to be eligible for premium tax credits under marketplace plans
  - Most states that have not expanded Medicaid are in the south (Mississippi is one of them)
- Blacks in Mississippi have the highest mortality rate from cardiovascular diseases, diabetes, renal disease, and cancer
- Nationwide, Blacks are less likely to receive a full course of anticoagulation after VTE or direct-acting anticoagulants than other racial or ethnic groups
  - Odds ratio 0.86

Annual Mississippi Health Disparities and Inequities Report. 2018. http://www.msdh.state.ms.us/msdhsite/index.cfm/44,8072,236,63,pdf/HealthDisparities2018.pdf. Accessed March 22, 2021.; Nathan A, et al. *Circ Cardiovasc Qual Outcomes.* 2019;12:e005600.; Buckner T, et al. *Circulation.* 2012;125:837-839.; Racism, Inequality, and Health Care for African Americans. 2019, Dec. 19. Taylor, Jamila. The Century Foundation.tcf.org

Barriers to Health Care in Mississippi in Black Patients with VTE

- Barriers to better health care in the Black Mississippi population
  - Poverty
    - Food insecurities
    - Lack of safe and affordable housing
  - Inequities in education
  - Lack of access to HCP in their areas
  - Lack of transportation and transportation infrastructures
  - Racial bias



Of adult Mississippians, a significantly higher prevalence of Whites (85.4%) is covered by any health care in comparison to Blacks (79.0%)

Annual Mississippi Health Disparities and Inequities Report. 2018. http://www.msdh.state.ms.us/msdhsite/index.cfm/44,8072,236,63,pdf/HealthDisparities2018.pdf. Accessed March 22, 2021.; Nathan A, et al. *Circ Cardiovasc Qual Outcomes.* 2019;12:e005600.; Buckner T, et al. *Circulation.* 2012;125:837-839.; Racism, Inequality, and Health Care for African Americans. 2019, Dec. 19. Taylor, Jamila. The Century Foundation.tcf.org

COVID-19 Increases the Risk of VTE

- VTE incidence among patients hospitalized with COVID-19 runs as high as 7.7% to 17%
  - Severe COVID-19 induces a prothrombotic state
- Black patients are 2.9 times more likely to be hospitalized with COVID-19 and 1.9 times more likely to die
  - Health care disparities and socioeconomic status play major role in this
  - Black patients less likely to be prescribed anticoagulants and when prescribed tend to spend less time within the therapeutic range for warfarin treatment

  - Despite increase in prescriptions of DOACs in the US overall, Black Americans less likely to receive them, even when controlling for socioeconomic variables
  - Black patient underrepresented in clinical trials: Only 4% of the clinical trial population for many of these anticoagulants has been Black

Jimenez D, et al. *Chest*. 2021;159:1182-1196.; Ramasamy R, et al. *Br J Haematol*. 2020;190(2):e78-e80. doi: 10.1111/bjh.16869. CDC. Risk for COVID-19 infection, hospitalization, and death by race/ethnicity. Accessed March 23, 2019.; Frydman G, et al. *Clin Appl Thromb Hemost*. 2020;26:1-8.

Mechanism of Thrombus Formation in COVID- 19

- Multifactorial
- Believed to be stimulated by endothelial injury caused by SARS-Co V-2 infection
- Leads to micro- and macro-thrombosis
- Causes:
  - Vaso endothelial dysfunction
  - Loss of anticoagulant properties
  - Associated with the increase of von Willebrand factor, Factor VIII, Angiopoietin 2, increased fibrinogen, presence of antiphospholipid antibodies, and dysregulated inflammation.
  - African Americans may have a high risk secondary to fact that they may have higher circulation levels of VWF, Factor VIII and fibrinogen

Iba T, et al. *Int J Hematology*. 2021;113(3):330-336.

Factors that Increase the Risk of Hospitalizations

- One study completed in a Louisiana Health System between March 1, 2020-April 11, 2020
  - 3481 patients who tested positive for SARS-CoV-2, the virus that causes COVID-19 were included in the study
- 76.9% of the patients who were hospitalized with COVID-19 and 70.6% of those who died were Black, whereas Blacks comprise only 31% of the Ochsner Health population
- Demonstrated the following factors that affected the rate of COVID hospitalizations
  - Race
  - Increasing age
  - Higher score on the comorbidity index
  - Public insurance (Medicare or Medicaid)
  - Residence in a low-income area
  - Obesity

Price-Haywood EG, et al. *N Engl J Med*. 2020; 382:2534-2543.

Interactive VTE Case Study with COVID-19 Considerations

- Mrs. CJ is a 46 y/o African American female who presented to a local emergency department with chief complaint of having shortness of breath for the last 2 days. Subjectively she states that she has not been able to ambulate much. When she walks for short distances, she feels as if she is going to pass out. Patient also reports having a fever, chills nausea/vomiting, and some diarrhea. The patient states that she has been exposed to some relatives recently who may have been infected with COVID-19
- Past medical history
  - Hypertension
  - Diabetes mellitus
  - Morbid obesity
  - Diabetic nephropathy
  - History of CVA
  - Hyperlipidemia
  - Anemia

Clinical Case Continued

- Social history: patient currently is disabled, she lives on a fixed income. She does not smoke drink or use any illicit drugs
- Allergies: NKDA
- Family history is positive of blood clots on her mother's side
- Upon arrival, patient was seen and evaluated; she subsequently was noted to have an elevated LDH of 734, a CK-MB that was normal at 0.22, a troponin that was normal at 0.012, and a D-dimer 5898. Hgb. She also had a hemoglobin of 6.2 and a rapid COVID test was positive
- Because of her D-Dimer being elevated, a CTA of the chest was obtained
- Chest CTA revealed:
  - Right middle and right lower lobe emboli
  - Groundglass consolidation considered consistent with COVID pneumonia and possible pulmonary infarct
- Patient was transferred to a tertiary facility for further management of her condition

Discussion Points

- There are multiple DOACs available, which one to chose?
- Which VTE patients are (and are not) good candidates for DOAC therapy?
- How should DOACs be initiated for VTE treatment?
- What social determinants of health should be considered for this patient?

DVT Diagnosis

Establishing an **accurate** diagnosis of PE or DVT in the lower or upper extremities is critical

Diagnostic strategies for VTE combine estimates of **pre-test probability** with **diagnostic testing**, although these tests are associated with error

Ortel TL, et al. *Blood Adv*. 2020;4:4693-4735.

Prevalence and PTP

- Venous thromboembolism (VTE) diagnosis is based on an assessment of the clinical probability of VTE in a population, prior to diagnostic testing *(pre-test probability; PTP)*
- Patients are classified into *low/intermediate/high* probability **or** *likely/unlikely* to have VTE
  - *Low* PTP *(unlikely)* = *low* prevalence of VTE
  - *(Intermediate)/High* PTP *(likely)* = *high* prevalence of VTE
- Prevalence of VTE within a population influences predictive value of diagnostic tests

Ortel TL, et al. *Blood Adv*. 2020;4:4693-4735.

Optimal Approaches to VTE Diagnosis: Wells Criteria

Wells Score for DVT	
Clinical Parameter Score	**Score**
Active cancer (treatment ongoing, or within 6 months or palliative)	+1
Paralysis or recent plaster immobilization of the lower extremities	+1
Recently bedridden for >3 days or major surgery <4 weeks	+1
Localized tenderness along the distribution of the deep venous system	+1
Entire leg swelling	+1
Calf swelling >3 cm compared with the asymptomatic leg	+1
Pitting edema (greater in the symptomatic leg)	+1
Previous DVT documented	+1
Collateral superficial veins (nonvaricose)	+1
Alternative diagnosis (as likely or greater than that of DVT)	-2
Total of Above Score	
High probability	≥3
Moderate probability	1 or 2
Low probability	≤0

Wells PS, et al. *Lancet*. 1997;350(9094):1795-1798.

Assessing and Diagnosing PE

Clinical Feature	Score
Clinical signs and symptoms of DVT (minimum of leg swelling and pain with palpation of the deep veins)	3
An alternative diagnosis is less likely than PE	3
Heart rate >100 beats per minute	1.5
Immobilization or surgery in the previous 4 weeks	1.5
Previous DVT/PE	1.5
Hemoptysis	1
Malignancy (ongoing treatment, treatment within 6 months, or receiving palliative care	1

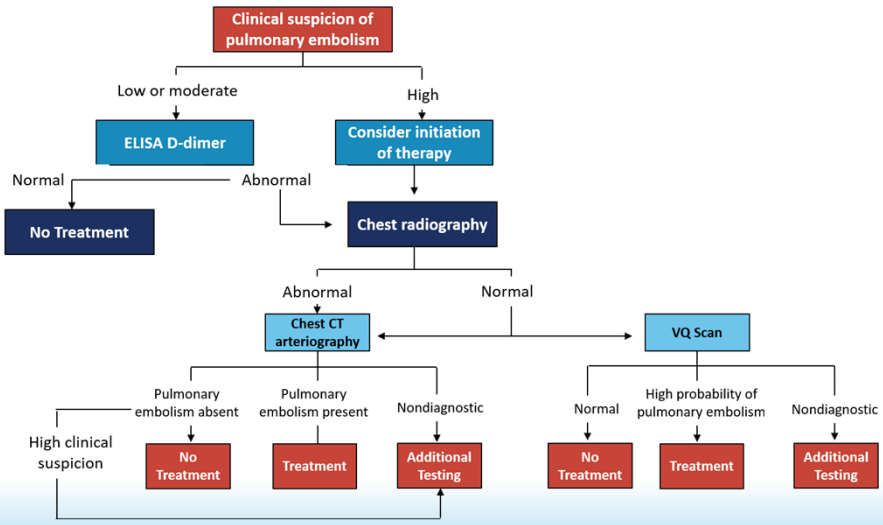
Wells PS, et al. *Thromb Haemost*. 2000;83(3):416-420.

Value of Assessment of Pretest Probability in DVT Diagnosis

- DVT was documented in 3%, 17%, and 75%of patients with low, moderate, and high pretest probabilities, respectively
- Serial ultrasonography was required in 28% and venography in 6% of patients; venous thromboembolism was diagnosed during a 3-month follow-up period in only 0.6% of patients thought not to have a DVT by this algorithm

Wells PS, et al. *Lancet*. 1997;350(9094):1795-1798.

Clinical Suspicion of Pulmonary Embolism



Adapted from Anand SS, et al. *JAMA*. 1998;279(14):1094-1099.

Clinical Probability Score

Symptoms and signs of DVT	3.0
Heart rate >100 beats/min	1.5
Recent immobilization or surgery (≤4 wks)	1.5
Previous DVT or PE	1.5
Hemoptysis	1.0
Cancer	1.0
PE more likely than alternative diagnosis	3.0

Low score (<2.0 or intermediate score (2.0-6.0)

High score (>6.0)

D-Dimer assay (highly sensitive)

Positive

Multidetector CT

Negative

No pulmonary embolism

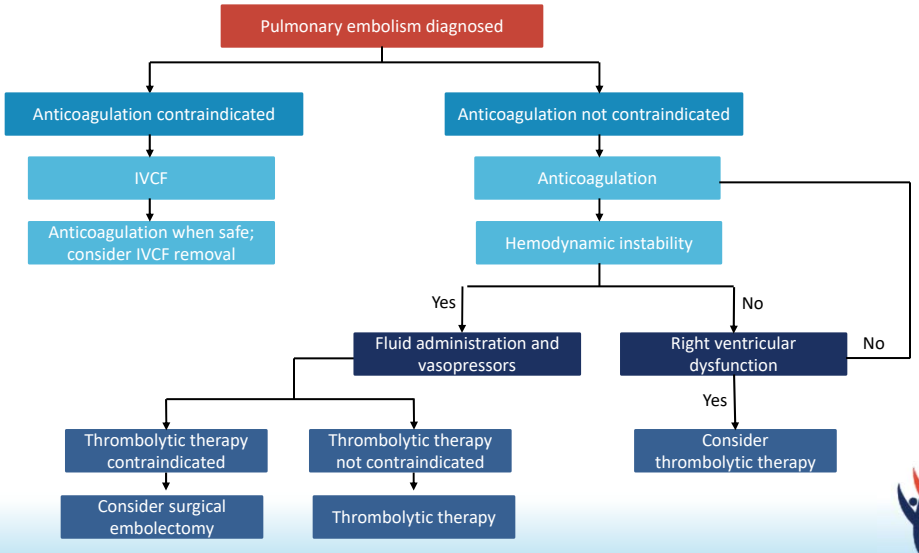
Pulmonary embolism confirmed

Do not treat

Treat

Adapted from Anand SS, et al. *JAMA.* 1998;279(14):1094-1099.

Pulmonary Embolism Diagnosed



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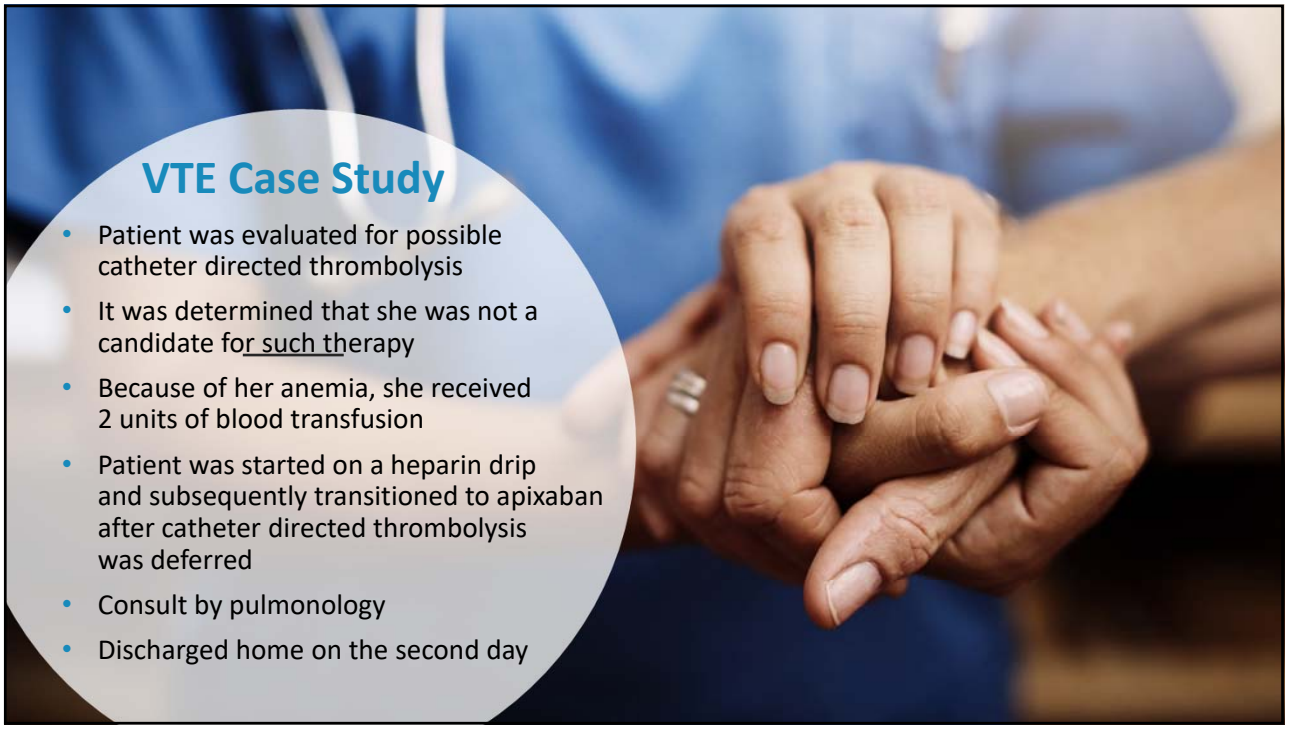


Discussion Points

- What are concerns associated with anemia and the use of anti-coagulants?
- What are the contraindications in some of the agents?
- How should the anticoagulant activity of DOACs be measured?
- How long to keep a patient on DOAC; time to return for monitoring; barriers to monitoring in rural areas

VTE Treatment and Prevention: Non-Pharmacologic Measures

- External pneumatic compression
- Early ambulation
- A study found that intraoperative transcutaneous electrical nerve stimulation (TENS) had a significant effect in preventing DVT in patients receiving knee replacement surgery

- Avoiding sitting, particularly in women, decreases the incidence of PE

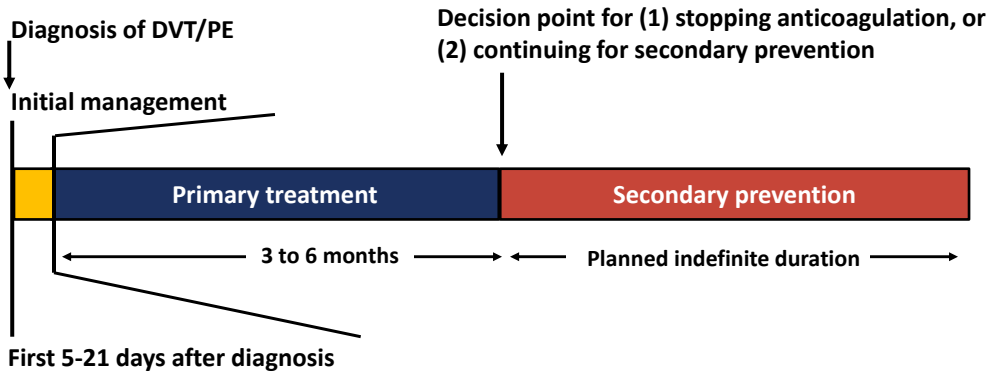
De Paolo V, et al. *Medscape*. Nov 5, 2020. https://www.medscape.com/answers/1267714-124603/what-are-the-nonpharmacologic-interventions-for-venous-thromboembolism-vte-prevention. Accessed March 23, 2021.; Izumi M, et al. *Knee Surg Sports Traumatol Arthosc*. 2015;23(11):3317-3323.; Kabrhel C, et al. *BMJ*. 2011;343:d3867.

Guideline-Recommended Therapy for VTE

- American Society of Hematology Guidelines for VTE and PE treatment suggest DOACs as first-line over VKA
- DOACs preferred for most patients without severe renal insufficiency (creatinine clearance <30 mL/min), moderate-severe liver disease, or antiphospholipid antibody syndrome
- American College of Chest Physicians (CHEST) Guidelines for VTE without Cancer recommend DOACs as first-line over VKA
- VTE with Cancer, LMWH or DOACs preferred over VKA

Ortel TL, et al. *Blood Adv*. 2020;4:4693-4735.; Kearon C, et al. *Chest*. 2016:149(2):315-352.

Phases of VTE Treatment



Ortel TL, et al. *Blood Adv*. 2020;4:4693-4735.

Summary of Evidence

- 24 systemic reviews and 12 randomized trials included patients with symptomatic proximal DVT or PE
- Randomized to DOACs or initial treatment with LMWH (5-10 days) with dose-adjusted warfarin (INR range, 2.0-3.0)
- Dabigatran and edoxaban given after 5-10 days LMWH
- Excluded patients with CrCl <25 mL/min (apixaban) or <30 mL/min (all others) and patients with high risk of bleeding
- Benefit – use of DOAC vs VKA does not impact mortality or risk of PE

DOAC use associated with decreased risk of major bleeding

DOAC use less burdensome for patients

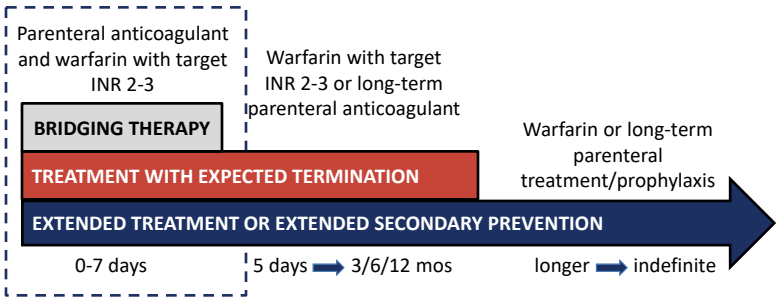
Ortel TL, et al. *Blood Adv*. 2020;4:4693-4735.

Conventional Therapy—Warfarin

- Warfarin is effective for treating VTE and is often preferred option for patients with:
  - Severe renal or liver disease
  - Poor adherence to medication
  - A high risk for bleeding complications
  - Highly pro-thrombotic state such as antiphospholipid antibody syndrome or HIT
- But it has:
  - A narrow therapeutic index
  - Wide interindividual dosing variability
  - Numerous food and drug interactions
  - Requires frequent monitoring by experienced practitioners

Witt D, et al. *J Thromb Thrombolysis*. 2016;41:187-205.

Traditional Management of DVT



- Duration of therapy is based on individual patient factors, such as cause of DVT and risk of bleeding
  - Patients with a first episode of DVT, secondary to a transient risk factor, are recommended to receive long-term treatment for 3 months
  - Patients with either unprovoked DVT and low-to-moderate bleeding risk, or DVT with active cancer are recommended to receive extended treatment longer than 3 months
  - Additionally, ACCP guidelines stratify recommendations for duration of therapy by bleeding risks, such as age >65 years, previous bleeding, thrombocytopenia, frequent falls, and alcohol abuse

Guyatt GH. *Chest* 2012;141(2)(Suppl):7S–47S.

Direct Oral Anticoagulants—DOACs

- DOACs are safe and effective treatments for VTE and are preferred for:
  - Patients who have transportation issues, difficult venous access, inflexible work or school schedules or other reasons for difficulty complying with INR monitoring
    - ***But renal function should be monitored, and a CBC done at least annually***
  - Patients who reliably report all pertinent medical issues, including concomitant medication
  - Cancer-associated thrombosis
    - Must be able to hold down food and medication - use LMWH if not
- Be aware of specific dosing adjustments and drug interactions that may prohibit use

Burnett A, et al. *J Thromb Thrombolysis*. 2016;41:206-232.

DOACs Indication for Use

Apixaban	Dabigatran	Edoxaban	Rivaroxaban
FDA-approved indications -Stroke prevention in NVAF -Prevention of TE after total knee/hip replacement -Tx of DVT/PE -Prevention of recurrent DVT/PE *Off-label indications* -Tx of heparin-induced thrombocytopenia -Prevention and tx of cancer-associated DVT -Prevention of TE in hospitalized acutely ill medical pts -Prevention of TE after PCI w/ NVAF	*FDA-approved indications* -Stroke prevention in NVAF -Tx of DVT/PE -Prevention of recurrent DVT/PE -Prevention of TE after total hip replacement *Off-label indications* -Prevention of TE after total knee replacement -Prevention of TE after PCI w/ NVAF	*FDA-approved indications* -Stroke prevention in NVAF -Tx of DVT/PE *Off-label indications* -Prevention and tx of cancer associated DVT -Prevention of TE after total knee/hip replacement -Prevention of TE after PCI w/ PAD	*FDA-approved indications* -Stroke prevention in NVAF -Tx of DVT/PE -Prevention of recurrent DVT/PE -Prevention of TE after total knee/hip replacement -Prevention of TE in hospitalized acutely ill medical pts -Prevention of major CV events in pts w/ chronic CAD/PAD *Off-label indications* -Prevention of TE after PCI w/ NVAF

Chen A, et al. *J Am Heart Assoc*. 2020;9:e017559. . https://doi.org/10.1161/JAHA.120.017559Journal

Drug Characteristics to Consider When Deciding Which DOAC to Prescribe for VTE

DOAC	Parenteral lead-in	Single-drug approach	Switch or dose de-escalation	Dosing frequency	Renal elimination	Potential for increased adverse effects
Dabigatran	√		√	BID	++++	MI, GIB, dyspepsia
Rivaroxaban		√	√	BID × 21 days, then once daily	++	GIB
Apixaban		√	√	BID	+	N/A
Edoxaban	√		√	Once daily	++	N/A

Burnett A, et al. *J Thromb Thrombolysis*. 2016;41:206-232

Direct Factor Xa Inhibitors

Drug	Dose	Reduced Dose	Cautions
Apixaban (Eliquis)	10 mg BID X 7 days then 5 mg BID	2.5 mg BID IF used with combined P-gp and strong CYP3A4 inhibitors (eg, ketoconazole, itraconazole, ritonavir)	• Avoid use with strong dual inducers of CYP3A4 and P-gp (eg, rifampin, phenytoin and carbamazepine) • Avoid use in patients with mechanical heart valves • Avoid use in severe hepatic disease
Rivaroxaban (Xarelto)	15 mg BID X21 days then 20 mg daily with meal	No reduced dose indication	• Avoid use with CrCl <15 mL/min • Avoid use with combined P-gp and strong CYP3A4 inhibitors or inducers (eg, ketoconazole and ritonavir) • Avoid in patients with mechanical heart valves • Avoid use in moderate-severe hepatic disease
Edoxaban (SAVAYSA)	60 mg daily **after 5-10 days of parenteral therapy**	30 mg daily IF CrCl 15-50 mL/min, wt ≤60 kg, or if taking verapamil, quinidine, azithromycin, clarithromycin, erythromycin, oral itraconazole or ketoconazole	• Avoid use with rifampin • Avoid in patients with mechanical heart valves • Avoid use in moderate-severe hepatic disease
Direct Thrombin Inhibitors			
Dabigatran (Pradaxa)	150 mg BID (if CrCl >30 mL/min) **after 5-10 days of parenteral therapy**	No reduced dose indication	• Avoid use with P-gp inducers (eg. Rifampin) • Avoid use with P-gp inhibitors if Cr Cl <50 mL/min • Avoid in patients with mechanical heart valves • Avoid use if CrCl <30 mL/min

Eliquis: https://packageinserts.bms.com/pi/pi_eliquis.pdf.; Xarelto: https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/XARELTO-pi.pdf.; SAVAYSA:https://dsi.com/prescribing-information-portlet/getPIContent?productName=Savaysa&inline=true.; Pradaxa: https://docs.boehringer-ingelheim.com/Prescribing%20Information/PIs/Pradaxa/Pradaxa.pdf

Risks and Benefits of DOACs vs VKAs

Advantages

- No routine monitoring
- Improved safety profile
- Rapid onset (may preclude the need for induction or bridging therapy)
- Short half-life (advantageous for invasive procedures or in the setting of active bleed)
- Fixed dosing
- Greater convenience, patient satisfaction, and quality of life
- Potentially more cost-effective from health system perspective
- Fewer drug, disease, and diet restrictions

Disadvantages

- No reliable, readily available measurement assay
- Dose reduction or avoidance in renal impairment and avoidance in moderate or severe hepatic impairment
- No specific antidote
- Short half-life (mandates strict adherence)
- Less flexibility in dosing
- Fewer studies and approved indications (eg, contraindicated in mechanical valve replacement)
- Potentially higher drug acquisition costs for patients
- DOAC drug interactions do exist that may preclude use

Burnett A, et al. *J Thromb Thrombolysis*. 2016;41:206-232.

Barriers and Solutions to Optimal Treatment

Cost of DOAC therapy

- Covered by most insurance, including MS Medicaid
- Manufacturer patient assistance programs
  - Free 30-day trial cards
  - Copay card for patients with non-government insurance
  - Yearly patient assistance for qualified self-pay patients
    - Need patient advocate to handle paperwork

Transportation issues

- Mail-order pharmacies or delivery pharmacies
- Telemedicine follow-up appointments

Resources

- www.eliquisformulary.com – Can identify patient's insurance co-pay cost and print co-pay assistance card
- www.bmspaf.org – BMS Patient Assistance Program for Eliquis
- www.janssencarepath.com – Can access co-pay cards, Janssen select and J&J patient assistance for Xarelto
- Janssen Select – Offers assistance for Xarelto for patients with high deductibles, Medicare Part D coverage gaps ("Donut Holes") if copays are >$85/month
- www.sanofipatientconnection.com – Lovenox patient assistance
- 340B Programs – There are many federally qualified health clinics and hospitals in MS that have these programs to provide medications at discounted prices

Discussion Points - Individualized Patient Care

- How should VTE patients who require temporary interruption of DOAC therapy be managed?
- How should patients with DOAC drug-drug interactions be managed?
- How should patients transition between anticoagulants?
- How should DOAC-associated bleeding be managed?

Patient Advocacy

Leslie Lake
Board President
National Blood Clot Alliance
Philadelphia, PA

Components of a High-Quality Discharge System

- Effectively transitioning patients from hospital to home is complex
  - Requires coordinating care with outside physicians and educating patients
  - Both adverse events post-hospital discharge and readmissions are high
- A safe and patient-centered transition should:
  - Provide consistent, high-quality transitional care with follow-up appointments and easily understood discharge instructions
  - Be patient-centered, providing adequate notice of and preparation for discharge, resulting in high levels of patient satisfaction
  - In the case of VTE patients, they will need ongoing anticoagulation therapy appropriate for the underlying condition

Horwitz L, et al. *JAMA Intern Med*. 2013;173(18)1715-1722.; Lenchus JD. *Adv Ther*. 2016;33:29-45.

DOAC Discharge Checklist for Optimal Care Transitions

- ✓ Patient is an appropriate DOAC candidate
- ✓ Assess patient's eligibility for outpatient treatment
- ✓ Consistent access to DOAC (affordability, retail availability)
- ✓ If transitioning to rehabilitation or skilled nursing facility, ensure DOAC on formulary
- ✓ DOAC identified and understood as an oral anticoagulant by patient, caregivers, and providers
- ✓ Provision of thorough DOAC education to patient and/or caregiver in their preferred language and at an appropriate literacy level
- ✓ Safety net phone number provided to patient/caregiver (who to call with questions)
- ✓ Referral or handoff to appropriate provider (anticoagulation clinic, PCP, etc.)
- ✓ Time of last drug administration in current setting and time of next scheduled dose in new setting
- ✓ Prescribed strategy for appropriate dose change after initial therapy (either switch to DOAC or DOAC dose de-escalation)

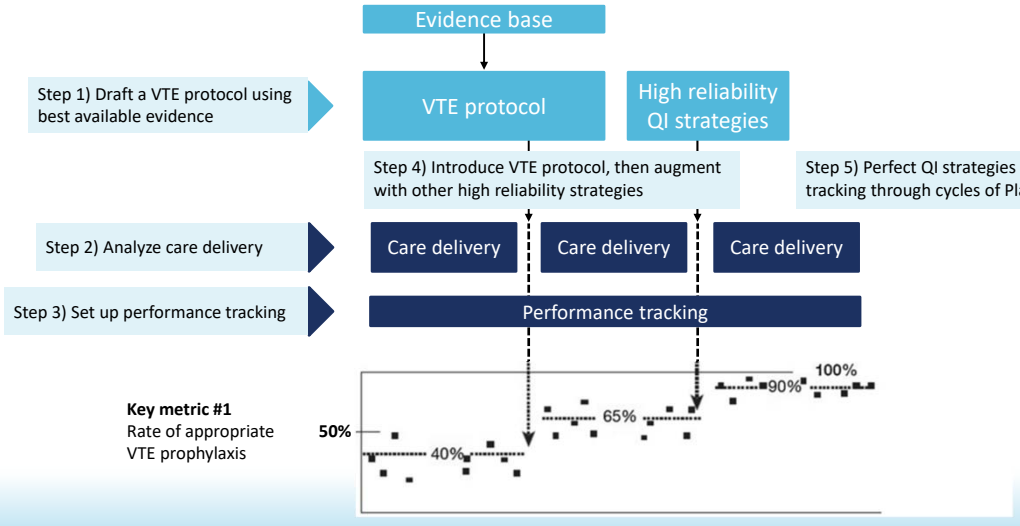
Barriers to Safe and Effective Anticoagulation During Care Transitions in Black Patients in CAHs in Mississippi

- Among 395 hospitalized patients, 95.6% reported understanding the reason for their hospitalization. However, a post-discharge interview found only 59.6% actually understood
- Of those discharged with a scheduled primary care or cardiology appointment, only 43.9% accurately recalled the details of their appointment
- Among patients in CAHs in Mississippi, only 54.4% indicated that they understood their care when they left the hospital

Potential Barriers to Safe and Effective Care Transitions
Level of patient health care literacy
Transportation Issues
Level of home support
Insurance issues
Ability to pay for medication

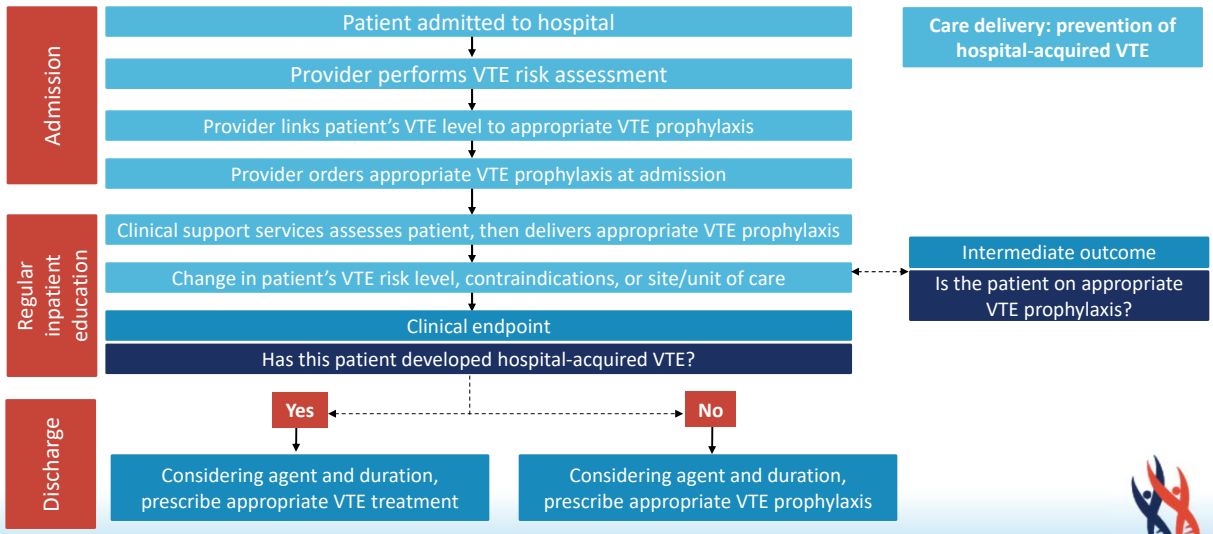
Horwitz L, et al. *JAMA Intern Med*. 2013;173(18)1715-1722.; Quick, et al. Patients' Experiences with CAHs: HCAHPS Results, 2018. https://www.flexmonitoring.org/publication/patients-experiences-cahs-hcahps-results-2018. Accessed March 22, 2021.

Framework for Improving VTE Prevention and Care



Lenchus JD. *Adv Ther*. 2016;33:29-45

Framework for Improving VTE Prevention and Care



Lenchus JD. *Adv Ther*. 2016;33:29-45

VTE Case Continuation

- Upon release from the hospital patient did follow-up with her PCP
- DOAC was continued
- Her symptoms subsequently resolved but she still had some issues with anemia secondary to her heavy menstrual cycles
- Three months after diagnoses of the pulmonary embolus, a VQ scan was obtained which showed normal perfusion
- DOAC was discontinued

Successful Care Transition Strategies

- Retrospective chart study of a quality improvement intervention
  - Racial disparities in prescription of best-practice VTE prophylaxis in the pre-implementation period between Black and White patients
  - Implementation of a mandatory computerized clinical decision support (CCDS) tool eliminated racial disparities in VTE prophylaxis
- Randomized controlled trial of a care transitions intervention designed to encourage patients and their caregivers to take a more active role during care transitions
  - Intervention patients had lower rehospitalization rates at 30 days (8.3% vs 11.9%) and at 90 days (16.7% vs 22.5%) and at 180 days (8.6% vs 13.9%) than controls
  - Costs were lower for intervention patients ($2058) vs controls ($2546) at 180 days
  - Coaching chronically ill older patients and caregivers to ensure their needs are met during care transitions may reduce subsequent rehospitalizations
- The inclusion of a culturally appropriate peer support program to complement chronic illness management is recommended

Coleman E, et al. *Arch Intern Med*. 2006;166:1822-1828.; Lau B, et al. *Med Care*. 2015;53(1):18-24.; Okoro F, et al. *Front Pub Health*. 2018;6(340).

Tenets of a Successful Care Transition Interventions

Care Transitions Intervention Activities by Pillar and by Stage of Intervention

	Four Pillars			
Stage of Intervention	**Medication Self-management**	**Patient-centered Record**	**Follow-up**	**Red Flags**
Goal	Patient is knowledgeable about medications and has medication management system	Patient understands and uses PHR to facilitate communication and to ensure continuity of care plan across providers and setting; patient manages PHR	Patient schedules and completes follow-up visit with PCP or specialist and is prepared to be an active participant in interactions	Patient is knowledgeable about indications that condition is worsening and how to respond
Hospital visit	Discuss importance of knowing medications and having a system in place to ensure adherence to regimen	Explain PHR	Recommend PCP follow-up visit	Discuss symptoms and drug reactions
Home visit	Reconcile prehospitalization and posthospitalization medication lists; Identify and correct discrepancies	Review and update PHR; Review discharge summary; Encourage patient to update and share PHR with PCP or specialist at follow-up visits	Emphasize importance of follow-up visit and need to provide PCP with recent hospitalization information; Practice and role-play questions for PCP	Assess condition; Discuss symptoms and adverse effects of medications
Follow-up telephone calls	Answer remaining medication questions	Remind patient to share PHR with PCP or specialist; Discuss outcome of visit with PCP or specialist	Provide advocacy in getting appointment, if necessary	Reinforce when PCP should be telephoned

Coleman E, et al. *Arch Intern Med*. 2006;166:1822-1828.

ED Case Study

- 31 y/o AAF presents to ED with chest pain, SOB, BLE swelling w/ paresthesia in BLE, joint stiffness, persistent cough, and back/ shoulder pain; s/p hysterectomy 2 months ago prior to ER visit
- Past medical history: Pt presents to ER 2 weeks post-trauma: depression, fibromyalgia, HTN, scoliosis, PE (2015) while on etonogestrel/ethinyl estradiol vaginal ring, anemia
  - Treated for 6 months on DOAC
- Past surgical history: bilateral tubal ligation (2019), hysterectomy (2020)
- Family history: HTN, CHF, hemochromatosis, scoliosis, autism
- Social history: denies tobacco, alcohol, and drug use
- Allergies: NKA
- Medications: atenolol and chlorthalidone 50-25, duloxetine 20 mg, cyclobenzaprine 5 mg, gabapentin 300 mg, potassium chloride 20 mEq, trazodone 20 mg

Case Study

- Vitals: BP 107/75, HR 83, Temp 98.4, O2 99%, Wt 220, Ht 5’7”; HR increased with a walk test in the ER with increased chest pain and SOB
- Labs: K+ 3.4, TP 8.8, Mg 2.5
- Imaging: CT Chest – LLL branching arterial pulmonary embolism
- Dx: acute pulmonary embolism, unspecified pulmonary embolism type, unspecified whether acute cor pulmonale present and pleural effusion
- Admit to hospital from ED to floor (hospitalists will assume care with transition of care to PCP upon discharge)
- Duration of hospital stay – 3 days
- Transition of care with PCP

Transition of Care

- Begins once the patient has been discharged from hospital or emergency department to follow up with PCP
- Requires coordination and communication among health care professionals to ensure optimal outcomes for the patient
- Includes multidisciplinary communication, collaboration and coordination that enables the electronic exchange of information between health care providers is crucial at discharge
- Patient education is also an important component. This is done to help the patient understand their treatment and the importance of extended/long-term treatment
- Patient education and engagement is essential to improve adherence to therapy post discharge

Transition of Care

- Listen to the patient concerns, address their needs, inquire about medical coverage, discuss adherence to the medication, side effects, expected length of anticoagulation therapy, current medical diagnosis/medications and cost
- Barriers to care – literacy, finances, insurance, transportation, and follow up
- Patient safety is the responsibility of all who deliver care whether directly or indirectly
- Goal is to avoid preventable poor outcomes in all patients and especially those with multiple chronic conditions
- Continue to keep the patient, family, and/or caretaker involved in every aspect of the care
- Telephone follow-up
  - Answer any questions
  - Let the patient know you are available

Putting it All Together

- Treat early
- Individualize care plan
- Assess and plan for potential barriers
- Choose best therapeutic option at the correct dosage based on patient factors and home care plan
- Patient education and clear expectations on length of therapy
- Plan for follow-up after discharge with patient and caregivers
- Communicate with patient, family and care team

Q & A

Improving Care Disparities for Black Americans in Mississippi with VTE: The Role of Care Transitions in Critical Access Hospitals

Thank you for your participation!

Please visit *ManagingCVD.com/vte-olpt* to take the Evaluation and Post-test.

Please note, free account activation will be required to complete the post test and evaluation after the webinar has concluded.

Certificates for CME and CNE credit may be printed immediately after successfully completing the post-test and activity evaluation. CPE Credit will be awarded upon completion of a self-assessment and evaluation. Participation verification must be completed within 4 weeks of the activity. Your online CPE certificate will be reported to CPE Monitor within 4 weeks of receiving post-activity documentation.

For more information on the Quality and Outcome Project please email *cme@ManagingCVD.com*