VENOUS THROMBOEMBOLISM (VTE): SAFETY RECOMMENDATIONS TARGETING MATERNAL PATIENTS
Panelists

Sue Gullo, MS, RN
Director, Perinatal Improvement Community
Institute for Healthcare Improvement

Peter Cherouny, MD
Lead Faculty, Perinatal Improvement Community,
Institute for Healthcare Improvement

Michael Wong, JD
Executive Director
Physician-Patient Alliance for Health & Safety
Maternal Death Rate Has More Than Doubled

http://www.cdc.gov/reproductivehealth/MaternalInfantHealth/PMSS.html
“These statistics may represent a conservative estimate of the problem. Why? Not all pregnancy-related deaths are accurately identified and reported. Hence, pregnancy-related deaths identified at the national level likely undercount the true number.”

William M. Callaghan, MD, MPH
Chief, Maternal and Infant Health Branch
Division of Reproductive Health
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
# US Maternal Death Rate Compared to Other Countries

<table>
<thead>
<tr>
<th>RANK</th>
<th>COUNTRY</th>
<th>(DEATHS/100,000 LIVE BIRTHS 2010)</th>
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<td>26</td>
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[Source](https://www.cia.gov/library/publications/the-world-factbook/rankorder/2223rank.html)
US Spending More, Getting Poorer Results

The United States has a higher ratio of maternal deaths than at least 40 other countries, even though it spends more money per capita for maternity care than any other:¹

- Venous thromboembolism costs the health care system more than $1.5 billion/year²
- Cost of managing an initial episode:²
  - deep vein thrombosis $7,712-$10,804 (est.)
  - pulmonary embolism $9,566-$16,644 (est.)

Why Focus on VTE

Pregnancy is a major risk factor for developing venous thrombosis and pulmonary embolism, especially following cesarean delivery and up to one month post partum.¹

“For pregnant women, the risks of VTE is 4-5 times higher than women who are not pregnant. Moreover, this risk is at least twice as much following cesarean delivery.”²

Dr. Andra James
Professor of Obstetrics & Gynecology,
Division of Maternal Fetal Medicine
University of Virginia School of Medicine

To ensure VTE Prevention is maximally used, harm reduction strategies should be used:
- consistently by clinicians
- effectively with hand off communications

VTE Risk for Maternal Patients

1. “Pregnancy-Related Mortality Surveillance” – Centers for Disease Control & Prevention, Feb. 21, 2013
2. http://ppahs.org/2013/05/02/preventing-death-following-cesarean-delivery/
One Patient is One Too Many:  
The True Reason for OB VTE Prevention

Amber Scott:
• On May 22, 2012, husband came home from work and found her unresponsive.
• After determining that Amber had a blood clot in her brain, doctors performed an emergency caesarian section.

One Patient is One Too Many:  
The True Reason for OB VTE Prevention

- Adeline was born, 6.5 pounds, healthy and beautiful
- While Adeline was thriving, Amber was fighting for her life:
  - lay in a coma as doctors performed a series of surgeries to remove the clot in her brain.
  - weeks later, came out of the coma, when Amber held up two fingers after being shown a picture of Adeline.

Amber’s progress:

• Continues with rehabilitation more than a year after delivery.
• Amber continues to make great progress in her daily outpatient therapy sessions.
• She is now able to pull herself up and stand on her own as she steadily regains strength in both the left and right side of her body.

One Patient is One Too Many: Preventable Deaths

Amee VanTassell
Died of blood clot just four days after cesarean delivery of healthy daughter

Jim Hamburger poses with his daughter, Amee VanTassell. VanTassell died on April 1, four days after giving birth, at the age of 36.

Eleven days after undergoing what she thought was “an uncomplicated C-section,” **Samara McAuliffe** developed a blood clot in her lungs.

**Lisa Boyd** suffered a blood clot in her leg a week after giving birth to her second child. She nearly died.

**Jessica Phillips** survived a life-threatening blood clot right after giving birth by C-section.
VENOUS THROMBOEMBOLISM (VTE) SAFETY RECOMMENDATIONS:

TARGETING MATERNAL PATIENTS

Peter Cherouny, M.D.
Emeritus Professor, Obstetrics, Gynecology and Reproductive Sciences, University of Vermont
Chair and Lead Faculty: IHI Perinatal Improvement Community
VENOUS THROMBOEMBOLISM (VTE) SAFETY RECOMMENDATIONS: TARGETING MATERNAL PATIENTS

Dr. Cherouny has nothing to disclose.
VENOUS THROMBOEMBOLISM (VTE) SAFETY RECOMMENDATIONS: TARGETING MATERNAL PATIENTS

*Note: Number of pregnancy-related deaths per 100,000 live births per year.
VENOUS THROMBOEMBOLISM (VTE) SAFETY RECOMMENDATIONS: TARGETING MATERNAL PATIENTS

Percent of First Births* by Mother’s Age, 1970-2010

Percentages may not add up to 100 due to rounding.

VENOUS THROMBOEMBOLISM (VTE) SAFETY RECOMMENDATIONS: TARGETING MATERNAL PATIENTS

Figure 2. Cesarean delivery at 37, 38, 39, and 40 weeks of gestation: United States, final 1996–2010 and preliminary 2011

NOTES:Singletons only. Thirty-seven and 38 weeks are considered early term; 39 and 40 weeks are considered full term. Access data table for Figure 2 at: http://www.cdc.gov/nchs/data/databriefs/db124_tables.pdf#1.
Joint Commission Sentinel Event
Alert Issue #44

- Relationship between route of delivery and maternal death

<table>
<thead>
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VENOUS THROMBOEMBOLISM (VTE) SAFETY RECOMMENDATIONS: TARGETING MATERNAL PATIENTS
### MMWR Pregnancy Related Mortality

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<td>Preeclampsia/Eclampsia</td>
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Maternal Death NYS

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<th>All Causes</th>
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<td>PIH</td>
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New York State Department of Health
Causal relationship between route of delivery and maternal death

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<tr>
<td>Total Cesarean</td>
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<tr>
<td>Totals</td>
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*p<0.001 for VD

**Joint Commission Sentinel Event**  
**Alert Issue #44**

*Causal relationship between route of delivery and maternal death excluding PE*

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<tr>
<th>Route of Delivery</th>
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<td>0.08</td>
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VENOUS THROMBOEMBOLISM (VTE) SAFETY RECOMMENDATIONS: TARGETING MATERNAL PATIENTS

4.0 million USA deliveries
X 33.7% cesarean =

- 1.34 million Cesarean Sections
  - Even low incidence outcomes become important
VENOUS THROMBOEMBOLISM (VTE) SAFETY RECOMMENDATIONS: TARGETING MATERNAL PATIENTS

Definitions
- Deep Venous Thrombosis -DVT
- Pulmonary Embolism –PE
- DVT + PE = VTE
- Thromboembolic disease
VENOUS THROMBOEMBOLISM (VTE) SAFETY RECOMMENDATIONS: TARGETING MATERNAL PATIENTS
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VENOUS THROMBOEMBOLISM (VTE) SAFETY RECOMMENDATIONS: TARGETING MATERNAL PATIENTS

Incidences

- 1-2/1000 pregnancies
- 4-5 fold relative risk in pregnancy
- ½ during pregnancy and ½ postpartum
- >1/100,000 maternal deaths (10%)
VENOUS THROMBOEMBOLISM (VTE) SAFETY RECOMMENDATIONS: TARGETING MATERNAL PATIENTS

• **Risk Factors**
  - Prior history VTE
  - Thrombophilias
  - Bed rest
  - Obesity
  - Smoking
  - Operative delivery
Although bed rest and hydration have been recommended to women with symptoms of preterm labor to prevent preterm delivery, these measures have not been shown to be effective for the prevention of preterm birth and should not be routinely recommended. Furthermore, the potential harm, including venous thromboembolism, bone demineralization, and deconditioning, and the negative effects, such as loss of employment, should not be underestimated.
Cesarean delivery

- All in moderate risk unless surgery is less than 30 minutes and patient under 40 without other risk factors
VENOUS THROMBOEMBOLISM (VTE) SAFETY RECOMMENDATIONS: TARGETING MATERNAL PATIENTS

- Prevention
- Recognition
- Treatment
VENOUS THROMBOEMBOLISM (VTE) SAFETY RECOMMENDATIONS: TARGETING MATERNAL PATIENTS

- Prevention
  - Risk assessment
  - Risk appropriate prophylaxis
  - REPEAT
VENOUS THROMBOEMBOLISM (VTE) SAFETY RECOMMENDATIONS: TARGETING MATERNAL PATIENTS

- Effective Risk Assessment
  - Initial visit
  - During pregnancy
  - Admission for delivery
Effective Risk Assessment

- Low risk (surgery less than 30’, patient <40yo)
- Moderate risk
- High risk
- Highest risk
Effective Prophylaxis Assessment

- Risk-based
- All patients having a cesarean delivery should have PCD (pneumatic compression devices) placed
VENOUS THROMBOEMBOLISM (VTE) SAFETY RECOMMENDATIONS: TARGETING MATERNAL PATIENTS

- Prevention
  - Risk assessment
  - Risk appropriate prophylaxis
  - REPEAT
Will, Ideas, EXECUTION: A Quality Improvement Framework

Sue Leavitt Gullo, MS,RN
Director
Institute for Healthcare Improvement (IHI)
Creating a New System

The Traditional Way

Improving  Implementing  Spreading

A Better Way

Improving

Implementing (Holding the Gains)

Spreading
Quality Measurement Journey

- **Aim**
- **Changes**
- **Measure**
  - Operational definition - what
  - Data collection plan – when, where, how, who
- Understand if data tells a story of improvement
  - What is the story the data tells?
Important Uses of the Run Chart

- Displaying data to make process performance visible
- Determining if changes tested resulted in improvement
- Determining if we are holding the gains made by our improvement
Using Run Charts for Quality Improvement

Run charts are used in QI to:

- Identify and assess problems
- Make informed decisions
- Show if a change resulted in improvement and by how much
- Monitor processes over time to see if improvements are maintained
- Communicate the effects of improvement work to others

Data are collected and analyzed at regular time intervals (as opposed to pre/post intervention data)
The Sequence for Improvement

Theory and Prediction
Developing a change

Testing a change

Implementing a change

Make part of routine operations

Sustaining and Spreading a change to other locations

Act
Plan
Study
Do

Test under a variety of conditions
Testing v. Implementation

- **Testing** – Trying and adapting existing knowledge on small scale; learning what works in your system.

- **Implementation** – Making this change a part of the day-to-day operation of the system:
  - Would the change persist even if its champion were to leave the organization?
To Implement . . .

- Use PDSA cycles to test implementation steps.
- **Establish buy-in, build consensus.**
- Create an infrastructure and support.
- **Build communication channels.**
- Create education and training.
- **Review policies & procedure.**
- Assign accountability.
- **Cultivate leadership.**
Implementation....

- The change is **permanent** - need to develop all support infrastructure to maintain change

- High **expectation** to see improvement (no failures)

- Increased scope will lead to increased **resistance** (Value of evidence from successful tests)
Improvement Concepts Associated with less than 95% Performance

(Primarily can be described as intent, vigilance, and hard work)

- Common equipment, standard order sheets, multiple choice protocols, and written policies/procedures
- Personal check lists
- Feedback of information on compliance
- Suggestions of working harder next time
- Awareness and training
Improvement Concepts Associated with 95% Performance

(Uses human factors and reliability science to design sophisticated failure prevention, failure identification, and mitigation)

- Decision aids and reminders built into the system
- Desired action the default (based on scientific evidence)
- Redundant processes utilized
- Scheduling used in design development
- Habits and patterns know and taken advantage of in the design
- Standardization of process based on clear specification and articulation is the norm
Standardization vs. Customization

- **Are the patient segments the same or different?**
  - Scheduled versus unscheduled
  - Risk differentiation

- **Are the processes the same?**
  - Prenatal
  - Labor and Delivery
  - Postpartum
  - Readmissions

Guidance- test under a variety of conditions. If it does not work in controlled conditions, it will NOT work when in uncontrolled conditions.
What Leaders Should Expect of Teams to Reliably Achieve the Safety Goals

- Expect the initial focus of work should be on “getting the process right” with a known connection to an outcome.
- Expect the team to take a set of processes to an agreed upon level of reliability within a specified timeline.
- Expect the teams to use good design principles in improvement work, not just hard work and vigilance.
- Expect teams to develop good designs by using rapid cycle small tests of change.
- Expect adequate process structure to sustain the work.
Miles to go before we rest—disparity issues also exist.

PPAHS VTE Checklist Group: Health Expert Panel

Rose Mary Ainsworth, RN, MSN
Mother/Baby Unit
Huntsville Hospital for Women and Children

Richard Berkowitz, MD
Quality Assurance Director
Columbia University Medical Center

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Chief, Maternal & Infant Health Branch
Division of Reproductive Health National Center
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Obstetrics and Gynecology, UNC School of Medicine

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Hospital Corporation of America

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CeeShell Consulting
editor of “Glass’ Office Gynecology”

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Columbia University Medical Center

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Women’s Health and Ambulatory Care Services
Hartford Hospital

Frank Federico, RPh
Patient Safety Advisory Group, The Joint Commission
Executive Director, Institute for Healthcare Improvement

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Institute for Healthcare Improvement

Roy Jackson, MD, B.Sc., MB.BCh., F.R.C.S
Southern Health Centre

Andra James, MD
John M. Nokes Professor of Obstetrics & Gynecology
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University of Virginia

Betty Janey
Project Manager, Perinatal Community
Institute for Healthcare Improvement

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Nurse Educator, Frontier Nursing University

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President and Medical Director, California HealthFirst Physicians
member, ACOG’s Patient Safety & Quality Improvement Committee

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Maternal/Perinatal Patient Safety Officer
Montefiore Medical Center

Michael Paidas, MD
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Department of Obstetrics, Gynecology and Reproductive Sciences
Yale University School of Medicine

Jody Paxton
Coordinator, Statewide Intensive Care Liaison Network
Department of Health, Queensland, Australia

Janet N. Press, RNC, MS, CT
Perinatal/Obstetrical Coordinator
C.N.Y. Regional Perinatal Program
Perinatal Bereavement Services Coordinator
Crouse Hospital

Peter Pronovost, MD, PhD, FCCM
Professor, Depts. of Anesthesiology/Critical Care Medicine & Surgery
The Johns Hopkins University School of Medicine

Richard Smiley, MD
Chief, Obstetric Anesthesia
Columbia University Medical Center

Facilitators Physician-Patient Alliance for Health & Safety:
Michael Wong, JD (Executive Director)
Lynn Razzano, RN, MSN, ONCC (Clinical Nurse Consultant)
Simple, Cost-Effective Solutions: Easily Adopted and Ensures Maximal VTE Prevention

“Ensuring the identification of pregnant women at-risk for VTE and applying measures to reduce VTE risks would assist in reducing blood clots, particularly for women following cesarean delivery.”

Dr. John Keats
(ex-officio member of ACOG’s Patient Safety and Quality Improvement Committee)

“Fortunately, risk factors for VTE can be reduced by simple and cost-effective measures, such as fitting inflatable compression devices on a woman’s legs before cesarean delivery and using inflatable compression sleeves until the woman is able to walk after delivery.”

Dr. Andra James
(Professor of Obstetrics & Gynecology, Division of Maternal Fetal Medicine, University of Virginia School of Medicine)

http://ppahs.org/2013/05/02/preventing-death-following-cesarean-delivery/
Ob/Gyn VTE Safety Recommendations for the Prevention of VTE in Maternal Patients

Apply to: Cesarean and Vaginal Delivery

STEP 1: Admission/Transfer of Care

Assess Patient for VTE Risk and Document

Risk Factor(s)
(check all that apply)

- Minor surgery planned
- Age over 35 years old
- Prior major surgery < 1 month
- Pregnancy or < 1 month postpartum
- Varicose veins (current)
- Inflammatory bowel disease (history / current)
- Overweight (obesity BMI > 30 kg/m²)
- Oral contraceptives or hormone replacement therapy (history)
- Preeclampsia (history / current)
- Smoking (history / current)
- Postpartum hemorrhage (current)
- Unexplained stillbirth (history)
- Major surgery (> 45 min.)
- Laparoscopic surgery (> 45 min.)
- Patient confined to bed > 72 hrs.
- Currently on bedrest / restricted mobility in the antepartum / postpartum period
- Immobilizing plaster cast (current)
- Central venous catheter (current)
- Cesarean-section delivery (current)
- Diabetes (including pre-gestational diabetes) (history / current)
- Malignancy and/or chemotherapy (history / current)
- Parity > 5
- Assisted reproduction (current)
- Patient admitted for chronic major illness:
  - Myocardial infarction
  - Congestive heart failure
  - Kidney disease
  - Chronic hypertension
  - Severe sepsis / Infection (current)
  - VTE (DVT or PE) (history)
  - Factor V Leiden / Activated protein C resistance (history / current)
  - Antithrombin III deficiency (history / current)
  - Protein C or S deficiency (history / current)
  - Prothrombin 20210A (history / current)
  - Homocysteinemia (history / current)
  - Other congenital or acquired thrombophilia (history / current)
  - Blood transfusion (history / current)

# of Risk Factors

1 point

# of Risk Factors

2 points

# of Risk Factors

3 points

# of Risk Factors

5 points

Risk Factor Assessment (RFA) =

These recommended steps maximize VTE prevention, promote patient safety and health outcomes. There may be other indications for VTE prophylaxis that are not listed.

November 2013
## Recommended Prophylaxis Regimen

### LOW

#### Antepartum
- Pharmacological prophylaxis not recommended unless indicated.
  - Ordered: Prophylactic low-molecular weight heparin
  - If LMWH unavailable: unfractionated heparin 5000 IU BID
  - Not ordered (why?)

#### Postpartum
- Early ambulation as prescribed by health provider
- Pharmacological prophylaxis not recommended (not administered until 12 hours after vaginal delivery/apirdural removal or 24 hours after cesarean delivery)
  - Ordered if previous VTE, thrombophilia BMI>25kg/m² & antepartum immobilization
  - Mechanical prophylaxis: ventilated compression stockings & either: intermittent pneumatic compression or venous foot pump
  - Mechanical prophylaxis ongoing:
    - On patient
    - Properly worn
    - Patient provided with information on proper use and wearing
  - Initiate discharge planning:
    - Discussed with patient/family
    - Anticipated discharge date determined
    - Evaluate patient for home use:
      - Intermittent pneumatic compression (IPC) or venous foot pump (VFP)
      - If evaluated for IPC/VFP, initiate availability on discharge

### MEDIUM

#### Antepartum
- Pharmacological prophylaxis not recommended unless indicated.
  - Ordered: low-molecular weight heparin
  - LMWH unavailable: unfractionated heparin 5000 IU BID
  - Not ordered (why?)

#### Mechanical prophylaxis prescribed:
- Graduated compression stockings & either: intermittent pneumatic compression or venous foot pump

#### Postpartum
- Early ambulation as prescribed by health provider
- Pharmacological prophylaxis considered (not administered until 12 hours after vaginal delivery/apirdural removal or 24 hours after cesarean delivery)
  - Ordered if multiple postpartum VTE Risk Factors
  - Prophylactic low-molecular wt. heparin
  - LMWH unavailable: unfractionated heparin (UFP) 5000 IU BID
  - Not ordered (why?)

#### Mechanical prophylaxis initiated:
- Graduated compression stockings & either: intermittent pneumatic compression or venous foot pump

#### Mechanical prophylaxis ongoing:
- On patient
- Properly worn
- Patient provided with information on proper use and wearing

#### Initiate discharge planning:
- Discussed with patient/family
- Anticipated discharge date determined
- Evaluate patient for home use:
  - Intermittent pneumatic compression (IPC) or venous foot pump (VFP)
  - If evaluated for IPC/VFP, initiate availability on discharge

### HIGH

#### Antepartum
- Pharmacological prophylaxis:
  - Ordered if VTE unprovoked and/or thrombophilia and/or hormonally provoked
  - Prophylactic low-molecular wt. heparin
  - LMWH unavailable: unfractionated heparin BID (1 trimester 5000 IU, II trimester 7500 IU, III trimester 10000 IU)
  - Not ordered (why?)

#### Mechanical prophylaxis initiated:
- Graduated compression stockings & either: intermittent pneumatic compression or venous foot pump

#### Mechanical prophylaxis ongoing:
- On patient
- Properly worn
- Patient provided with information on proper use and wearing

#### Initiate discharge planning:
- Discussed with patient/family
- Anticipated discharge date determined
- Evaluate patient for home use:
  - Intermittent pneumatic compression (IPC) or venous foot pump (VFP)
  - If evaluated for IPC/VFP, initiate availability on discharge

### HIGHEST

#### Antepartum
- Pharmacological prophylaxis:
  - Ordered:
    - Prophylactic low-molecular wt. heparin
    - LMWH unavailable: unfractionated heparin BID (1 trimester 5000 IU, II trimester 7500 IU, III trimester 10000 IU)

#### Mechanical prophylaxis initiated:
- Graduated compression stockings & either: intermittent pneumatic compression or venous foot pump

#### Mechanical prophylaxis ongoing:
- On patient
- Properly worn
- Patient provided with information on proper use and wearing

#### Initiate discharge planning:
- Discussed with patient/family
- Anticipated discharge date determined
- Evaluate patient for home use:
  - Intermittent pneumatic compression (IPC) or venous foot pump (VFP)
  - If evaluated for IPC/VFP, initiate availability on discharge

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**Ob/Gyn VTE Safety Recommendations for the Prevention of VTE in Maternal Patients**

**Recommended Steps Maximize VTE Prevention, Promote Patient Safety and Health Outcomes.**

There may be other indications for VTE prophylaxis that are not listed.

**November 2013**
**OB/GYN VTE Safety Recommendations for the Prevention of VTE in Maternal Patients**

**STEP 3**

**Patient Reassessment**

Repeat assessment if Patient hospitalized longer than 24 hrs., before surgery or with any significant change in patient condition.

- Assess Patient for VTE Risk and Document (see step 1)
- Pharmacological prophylaxis:
  - continued as prescribed
  - not ordered
  - (why?)
- Mechanical prophylaxis:
  - not prescribed
  - graduated compression stockings
  - intermittent pneumatic compression
  - venous foot pump
- Mechanical prophylaxis, if prescribed:
  - on patient
  - properly worn
  - patient provided with information on proper use and wearing
- Initiate discharge planning:
  - discussed with patient/family
  - anticipated discharge date determined
  - evaluate patient for home use of:
    - intermittent pneumatic compression (IPC)
    - venous foot pump (VFP)
    - no IPC/VFP
  - if evaluated for IPC/VFP, initiate availability on discharge

**STEP 4**

**Patient Discharge**

- Discharge instructions include:
  - healthcare provider contact information
  - signs and symptoms of DVT and PE
  - evaluate patient for home use of:
    - intermittent pneumatic compression (IPC)
    - venous foot pump (VFP)
    - no IPC/VFP
- Discharge instructions:
  - reviewed with patient and read back
  - received by patient
- Patient understands DVT/PE risk factors and how to prevent in postpartum period
- Follow up appointment made
- If immobility or bedrest required in antepartum period or extending 6 weeks postpartum:
  - healthcare provider orders completed, including:
    - evaluate patient for home use of:
      - intermittent pneumatic compression (IPC)
      - venous foot pump (VFP)
    - length of IPC/VFP treatment
    - durable medical equipment unit notified of start date of IPC/VFP treatment
    - patient provided with information on:
      - purpose of IPC/VFP
      - proper use and wearing
      - importance on maintaining use at home until MD discontinues
      - removed for ambulation and skin inspections (every 8 hrs)
      - worn minimally 18-20 hours per day

**THESE RECOMMENDED STEPS MAXIMIZE VTE PREVENTION, PROMOTE PATIENT SAFETY AND HEALTH OUTCOMES.**

**THESE RECOMMENDED STEPS MAXIMIZE VTE PREVENTION, PROMOTE PATIENT SAFETY AND HEALTH OUTCOMES.**

**November 2013**
Questions/ Discussion

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