



# Risk Factors for Major Bleeding – Non-Ortho Surgical

## General risk factors

- Active bleeding
- Previous major bleeding
- Known, untreated bleeding disorder
- Severe renal or hepatic failure
- Thrombocytopenia
- Acute stroke
- Uncontrolled systemic hypertension
- Lumbar puncture, epidural, or spinal anesthesia within previous 4 h or next 12 h
- Concomitant use of anticoagulants, antiplatelet therapy, or thrombolytic drugs

## Procedure-specific risk factors

### *Abdominal surgery*

- Male sex, preoperative hemoglobin level < 13 g/dL, malignancy, and complex surgery defined as two or more procedures, difficult dissection, or more than one anastomosis

### *Pancreaticoduodenectomy*

- Sepsis, pancreatic leak, sentinel bleed

## Procedure-specific risk factors (continued)

### *Hepatic resection*

- Number of segments, concomitant extrahepatic organ resection, primary liver malignancy, lower preoperative hemoglobin level, and platelet counts

### *Cardiac surgery*

- Use of aspirin
- Use of clopidogrel within 3 d before surgery
- BMI > 25 kg/m<sup>2</sup>, nonelective surgery, placement of five or more grafts, older age
- Older age, renal insufficiency, operation other than coronary artery bypass graft, longer bypass time

### *Thoracic surgery*

- Pneumonectomy or extended resection

## Procedures in which bleeding complications may have especially severe consequences

- Craniotomy
- Spinal surgery
- Spinal trauma
- Reconstructive procedures involving free flap



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How long will each patient take  
to risk assess?

Is this complicated enough for  
you yet?



# Antithrombotic Recommendations Non-orthopedic Surgery

## General and Abdominal-Pelvic Surgery patients<sup>1\*</sup>

- Very Low Risk of VTE – Early ambulation
- Low Risk for VTE – Mechanical, IPC preferred (2C)
- Moderate Risk for VTE, low bleeding risk, LMWH / LDUH, (2B) or Mechanical, IPC preferred (2C) \*\*
- High Risk for VTE, low bleeding risk, LMWH / LDUH (1B). Suggest GCS or IPC be added to pharmacologic prophylaxis (2C) \*\* / \*\*\*
- Abdominal or Pelvic Surgery for Cancer and High Risk for VTE, recommend extended duration LMWH (4 weeks) over limited duration prophylaxis (1B)

\* Inferior vena cava filter (IVCF) should not be used for primary prevention and periodic surveillance with venous compression ultrasound (VCU) should not be performed

\*\* At risk for bleeding or patients in whom bleeding consequences are thought to be severe, mechanical, IPC preferred (2C). Initiate pharmacologic when bleeding risk diminishes.

\*\*\* If LMWH/UFH contraindicated/unavailable ASA, Fonda, or mechanical, IPC Preferred (All 2C)



# Antithrombotic Recommendations Non-orthopedic Surgery

## CARDIAC Surgery patients with an uncomplicated postoperative course <sup>1</sup>

- Mechanical prophylaxis preferably with **optimally applied IPC**, over no prophylaxis (2C) or pharmacologic prophylaxis (2C)
- If hospital course is prolonged by any non-hemorrhagic surgical complications, add LDUH or LMWH to the mechanical prophylaxis (2C)

## CRANIOTOMY patients <sup>1</sup>

- Mechanical prophylaxis preferably with **IPC**, over no prophylaxis (2C) or pharmacologic prophylaxis (2C)
- High Risk for VTE (e.g. undergoing craniotomy for malignant disease), suggest adding LDUH or LMWH to the mechanical prophylaxis once adequate hemostasis is achieved and bleeding risk decreases(2C)



# Antithrombotic Recommendations Non-orthopedic Surgery

## Thoracic Surgery patients <sup>1</sup>

- Moderate Risk for VTE, low bleeding risk, LMWH / LDUH (2B) or mechanical prophylaxis with **optimally applied IPC** (2C)
- High Risk for VTE, low bleeding risk, LMWH / LDUH (1B). Suggest GCS or IPC be added to pharmacologic prophylaxis (2C)
- High Bleed risk, mechanical prophylaxis, preferably with **optimally applied IPC**, until bleeding risk diminished and pharmacologic prophylaxis may be initiated. (2C)



# Antithrombotic Recommendations Non-orthopedic Surgery

## Spinal Surgery patients <sup>1</sup>

- Mechanical prophylaxis, preferably with IPC, **over** no prophylaxis (Grade 2C), LDUH (2C), or LMWH (2C)
- Those at High Risk for VTE (e.g. malignant disease or combined anterior-posterior approach), suggest adding pharmacologic prophylaxis once adequate hemostasis is established and the risk of bleeding decreases.



# Antithrombotic Recommendations

## Non-orthopedic Surgery

### Major Trauma patients <sup>1</sup>\*

- LMWH / LDUH, (2C) or Mechanical, IPC preferred (2C)
- High Risk for VTE (including acute spinal cord injury, traumatic brain injury, spinal surgery for trauma), suggest GCS or IPC be added to pharmacologic prophylaxis when not contraindicated due to lower extremity injury(2C)
- If LMWH/LDUH are contraindicated , suggest mechanical prophylaxis, preferably with IPC (2C) when not contraindicated by lower extremity injury. **Add** LDUH/LMWH when the bleeding risk diminishes or the contraindication to heparin resolves. (2C).

\* Inferior vena cava filter (IVCF) should not be used for primary prevention and periodic surveillance with venous compression ultrasound (VCU) should not be performed



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# Risk Assessment for VTE and Bleeding— **ORTHOPEDIC Patients**



# Orthopedic VTE Risk Factors

- There is evidence of varying risk factors but the **surgery-specific risk** is the primary driver for VTE Risk. (i.e. surgery-specific risk far outweighs the contribution of patient-specific risk factors)
- Total Knee Arthroplasty (TKA), Total Hip Arthroplasty (THA), and Hip Fracture Surgery (HFS) are all high risk surgeries for developing VTE



# Orthopedic Bleeding Risk Factors

- Previous major bleeding (and previous bleeding risk similar to current risk)
- Severe renal failure (CrCl < 30 mL/min)
- Concomitant antiplatelet agents
- Surgical factors: history of or difficult-to-control surgical bleeding during the current operative procedure, extensive surgical dissection, and revision surgery



# Antithrombotic Recommendations ORTHO

## TKA/THA <sup>1</sup>

- Minimum 10-14 days of LMWH, fondaparinux, rivaroxaban, LDUH, adjusted dose warfarin, aspirin (all 1B) or IPC (1C)

## HFS

- Minimum 10-14 days of LMWH, fondaparinux, LDUH, adjusted dose warfarin, aspirin (all 1B) or IPC (1C)

## TKA/THA/HFS

- LMWH preferred over other agents irrespective of concomitant use of IPC or length of treatment
- Suggest using dual prophylaxis with an antithrombotic and IPC *during* the hospital stay.
- Suggest extending TP for up to 35 days from surgery (2B)
- ***At risk for bleeding***, IPC

1. Falck-Ytter et al. *CHEST* 2012; 141:(2 Suppl): e278S-325S



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## ***What about the Cancer Patient?***

Often make up a majority of the medical patient group and cancer is frequent in Surgical patients as well



# Predictive model for calculating risk of chemotherapy-associated thrombosis

Patient characteristics	Odds ratio (95% CI)	VTE risk score
Site of cancer		
Very high risk (stomach, pancreas)	4.3 (1.2–15.6)	2
High risk (lung, lymphoma, gynecologic, genitourinary excluding prostate)	1.5 (0.9–2.7) 1.0 (reference)	1 1
Low risk (breast, colorectal, head and neck)		
Prechemotherapy platelet count $\leq 350,000/\text{mm}^3$	1.8 (1.1–3.2)	1
Hemoglobin level $>10$ g/dl or use of red cell growth factors	2.4 (1.3–4.2)	1
Prechemotherapy leukocyte count $<11,000/\text{mm}^3$	2.2 (1.2–4)	1
BMI $\leq 35$ kg/m <sup>2</sup>	2.5 (1.3–4.7)	1

\*\*\* Validated, both prospectively and retrospectively, in several other studies \*\*\*

[Khorana AA et al. \*Blood\* 2008; 111: 4902–4907.](#)



# Cancer Patients

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- Suggest using American Society of Clinical Oncology (ASCO) **OR** National Comprehensive Cancer Network (NCCN) guidelines for cancer specific patients.
- These guidelines are more detailed than ACCP

1. Lyman GH, Khorana AA et al. J Clin Oncol 2007; 25 (34): 5490-5505

2. NCCN website Version 2/2011:

[https://subscriptions.nccn.org/gi\\_login.aspx?ReturnURL=http://www.nccn.org/professionals/physician\\_gls/pdf/vte.pdf](https://subscriptions.nccn.org/gi_login.aspx?ReturnURL=http://www.nccn.org/professionals/physician_gls/pdf/vte.pdf) Accessed 7/25/2012



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# Interventions to Reduce VTE in the Hospital Setting



# Background

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- Globally, approximately 70 intervention programs/studies to date to reduce VTE and/or improve prophylaxis
- Few are randomized controlled trials. Many are pre-post interventions
- Most state an increase in “appropriate” prophylaxis but few measure appropriate type, dose and ***duration***
- Is it ethical with this level of knowledge to still complete randomized controlled trials when “usual medical care” is known to be sub-optimal ?



# IMPART Intervention Study

- Design - Prospective, Observational, Multi-site Comparison of different Clinical Decision Support (CDS) systems in Swiss Hospitals
- Electronic Alerts vs. Pocket digital assistant vs. Pocket cards vs electronic alerts (4 arms)
- Unifaceted
- Results
  - No effect on increasing prophylaxis rates on any arm
  - Improvement on reducing over-prescribing of inadequate prophylaxis (56 vs. 31%,  $P = 0.01$ )
- How could there be no effect on improving PX ????
  - Possibly because the intervention was unifaceted, not multifaceted



# Maynard et al. Results

- Low, moderate and high risk groups were 4%, 84%, and 12%, respectively.
- Adequate prophylaxis increased from 58%, 78% to 93% ( $p < 0.001$ ) in 2005, 2006 and 2007, respectively.
  - Reached 98% in the last 6 months of 2007 and sustained throughout 2008.
- Hospital Acquired VTE
  - From 2005 to 2007, a 39% RRR was achieved ( $P < 0.001$ )
- Preventable Hospital Acquired VTE
  - From 2005 to 2007, a 86% RRR was achieved ( $p < 0.01$ )
- Comment -- supported by a large AHRQ grant



# VTE Pharmacy Intervention Management Program

2006 vs 2007	Appropriate Prophylaxis		Preventable VTE	
	Improvement (95% LCL, UCL)	P-Value	Reduction (95% LCL, UCL)	P-Value
Critical Care	2.483 (1.668, 3.697)	0.0001	84% (98%,116%)	0.0699
Surgical	1.582 (1.308, 1.914)	0.0001	89% (18%, 99%)	0.0313
Medical	2.057 (1.504, 2.814)	0.0001	57% (85%, 123%)	0.1134
<b>Total Discharges</b>	<b>1.839 (1.589, 2.129)</b>	<b>0.0001</b>	<b>74% (44%, 88%)</b>	<b>0.0006</b>

- Multi-faceted Intervention reduced incidence of Preventable VTE by **74% (p < 0.0006)**
- Non-significant reduction from 10 to 4 “Preventable” PE’s.



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GREAT DATA!! But ***HOW*** do we  
**REALLY** make this work in our  
hospital?

**EXPERIENCE BASED  
RECOMMENDATIONS**



# What VTE Interventions Should Entail

- Programs should be multifaceted and perpetual
- Patient, Provider, and Staff Education
- An **ACTIVE** Reminder or Reminders at multi-levels
- Audit and Feedback of **IGNORED** alerts to individual physicians and medical staff to counter “ALERT FATIGUE”
- Clinical Decision Support Systems
  - Either Manual or Computerized - tied into computerized order entry (CPOE) with clinical decision support based off of coding and “discrete data” best
- Mandatory Stops forcing providers to address Prophylaxis
- Minimize unnecessary prophylaxis of patients **NOT at risk**
- Maximize adjustment and monitoring of pharmacologic and mechanical prophylaxis to optimize use.
- Pharmacy Programs are favored in the US as of late
- “Measure-vention”<sup>2</sup> as described in previous presentation

1. Mahan CE, Spyropoulos AC, *Hospital Practice* February 2010; 38;1;97-108

2. Maynard G, Stein J. *J Thromb Thrombolysis* 2010 Feb;29(2):159-166.



# Recommendations - Program

- Identify a “physician” champion and an “operational” champion
  - Both should be experts in knowledge of VTE prevention
  - If no physician champion is available, team up with other professions (e.g. nursing, pharmacy, case management, administration) until one becomes available.
  - If you are not an expert, become one. Learn the data.
- Decide upon risk assessment approach – computerized or manual
  - Individualized risk assessment in guidelines will take longer.
- Who is “Calling the Ball” and who is risk assessing?
  - ≡ Physicians only **OR** nurses / pharmacists with an ACTIVE ALERT to physicians
  - ≡ ALERT needs to be part of the medical record



# Recommendations - Program

- Get buy-in from all departments and parties as possible.
- Go Computerized utilizing the electronic medical record (EMR) and computerized clinical decision support (CCDS) if possible.
  - Get the information technology (IT) department involved.
  - Utilize admission coding, or real-time concurrent Coding, and EMR data (e.g. CrCL, mobility) in the CCDS as this becomes available
- Include education to the patient on admission regarding VTE risk. <sup>1</sup>
  - The patients' values and preferences are important
- Get administrative support. The VTE core measures will be mandatory in FY 2015 and SCIP VTE and VTE post-ortho will all have a financial impact on value based purchasing incentive payments. VTE post TKA/THA is already a non-reimbursed hospital acquired condition. <sup>2</sup>

1. Piazza G Am J Med. 2012 Mar;125(3):258-64.

2. Mahan CE. Thromb Res In Press. Epub August 2012



# Recommendations - Patient Risk Assessment

- Try to risk assess **ALL** patients within 12 hours of hospital presentation (i.e. **presentation**, ***NOT*** admission)
  - Due to long holding times in ERs, this is an ideal place to start the risk assessment process with ED physicians, ER nursing , ER pharmacist personnel, or computerized clinical decision support
  - If this isn't feasible, start a chosen specific areas, but do it well in that area, and then expand when ready. Medical patients are an ideal group. (“lowest-hanging fruit”)
- START with the Bleed Risk Assessment FIRST. If the patient is at-risk for, or actively, bleeding, this simplifies the initial approach.
- Re-assess the patient every 24 hours for changes in clinical status. Utilize multi-disciplinary rounds. Hardwire VTE prevention into this process.



# Recommendations - Patient Risk Assessment

- Consider mechanical prophylaxis as an adjunct to pharmacologic TP. <sup>1</sup>
  - ≡ This has shown better efficacy in certain patient groups (e.g. surgical) and also **covers the patient** for the frequent holding of pharmacologic TP for procedures, intermittent low blood counts etc.
  - ≡ With average lengths of stay (LOS) around 4-5 days now, it is unlikely that skin breakdown is as common as in the stroke patients who wore stockings for 30 days. <sup>2,3</sup>
  - ≡ For longer LOS, appropriate skin care should be prioritized for patients with graduated compression stockings (GCS) or intermittent pneumatic compressions (IPC)

1. Geerts WH *CHEST* 2008; 133 (6 Suppl): 381S-453S
2. Gould et al. *CHEST* 2012; 141:(2 Suppl): e227S-277S
3. *Ann Intern Med* 2010; 153; 553-562



# Recommendations – How to make the program stronger

- Monthly audit and feedback to medical staff groups (e.g. hospitalists, ortho, general surgery, critical care)
  - Blinded physician results at meetings of preventable VTE and TP rates.
  - Un-blinded physician results to lead physician so he/she knows who needs to improve.
  - As the program matures, measure “duration” of prophylaxis as compared to length of stay in addition to appropriateness
- Consider preventable VTE rates as a peer-reviewed outcome for medical staff
- Report Preventable VTE that results in harm to risk-management and TJC as appropriate (i.e. considered a sentinel event if preventable harm occurs)
- Be stubborn. Expect lively, and sometimes heated, debate on recommendations if risk assessment is being completed by a non-physician team. Be prepared to respond appropriately and re-focus the discussion on the patient’s care and risks.



# Recommendations – How to make the program stronger

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- Lean towards over-prophylaxis as compared to under-prophylaxis
- Further VTE resource and implementation recommendations for hospitals may be located at the Society for Hospital Medicine Website

[http://www.hospitalmedicine.org/ResourceRoom/Redesign/RR\\_VTE/html\\_VTE/00\\_ImplementationGuide.cfm#](http://www.hospitalmedicine.org/ResourceRoom/Redesign/RR_VTE/html_VTE/00_ImplementationGuide.cfm#)



# Conclusions

- Recent ACCP guidelines have become more complicated and shifted from a “group” to an “individualized” (more time consuming) risk assessment approach for VTE and bleeding
- Currently, prophylaxis rates are low internationally.
- The burden of disease, mortality, and costs of VTE in the hospitalized patient are significant
- Risk Assessment Models are beneficial in determining a patient’s TP needs.
  - For patients at-risk of VTE but with low-risk for bleeding, pharmacologic prophylaxis should be utilized. Combo mechanical and pharmacologic may be beneficial.
  - For patients at-risk of VTE and at high-risk of bleeding, mechanical prophylaxis may be used.
- VTE core measures will be mandated in FY2015