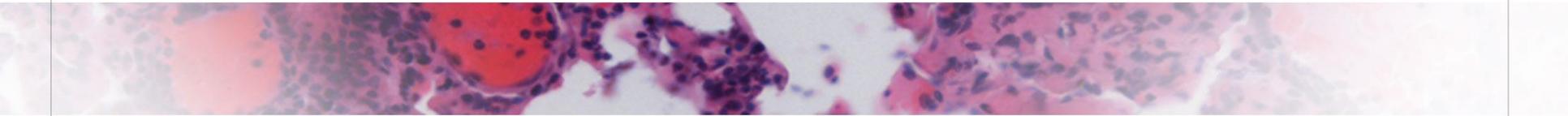




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**Choosing
Wisely[®]**

An initiative of the ABIM Foundation

**Ten Things Physicians & Patients
Should Question**



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What is Choosing Wisely?

- Choosing Wisely is a national medical stewardship campaign led by the ABIM Foundation in collaboration with leading Specialty Societies
- The campaign challenges Medical Professional Societies to identify five tests, treatments or procedures that physicians and patients should question
- The ABIM Foundation recommends that Societies consider evidence, cost, frequency, and clinical purview in making their recommendations
- ASH identified a fifth and preeminent guiding principal: avoidance of harm to patients



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How These Lists Were Created

- The first ASH Choosing Wisely list was released in December, 2013, and the second in December, 2014
- For each list, the ASH Choosing Wisely Task Force solicited suggestions from relevant ASH Committee and task force members and then selected 20 high priority items (guided by the principles outlined previously)
- The task force then independently scored these 20 items based on priority; these scores were used to select a shortlist of 10 items



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How These Lists Were Created

- Systematic reviews were completed for each of the 10 shortlisted items
 - A hierarchical search strategy was used, literature searches abridged if relevant, recent, evidence-based guidelines were found
- Directed by its five guiding principles and by the systematic reviews, the Task Force selected five tests, procedures or treatments to question
- Final recommendations were reviewed for clarity and accuracy by 2-4 content experts for each item
- Final items were approved by the ASH Executive Council



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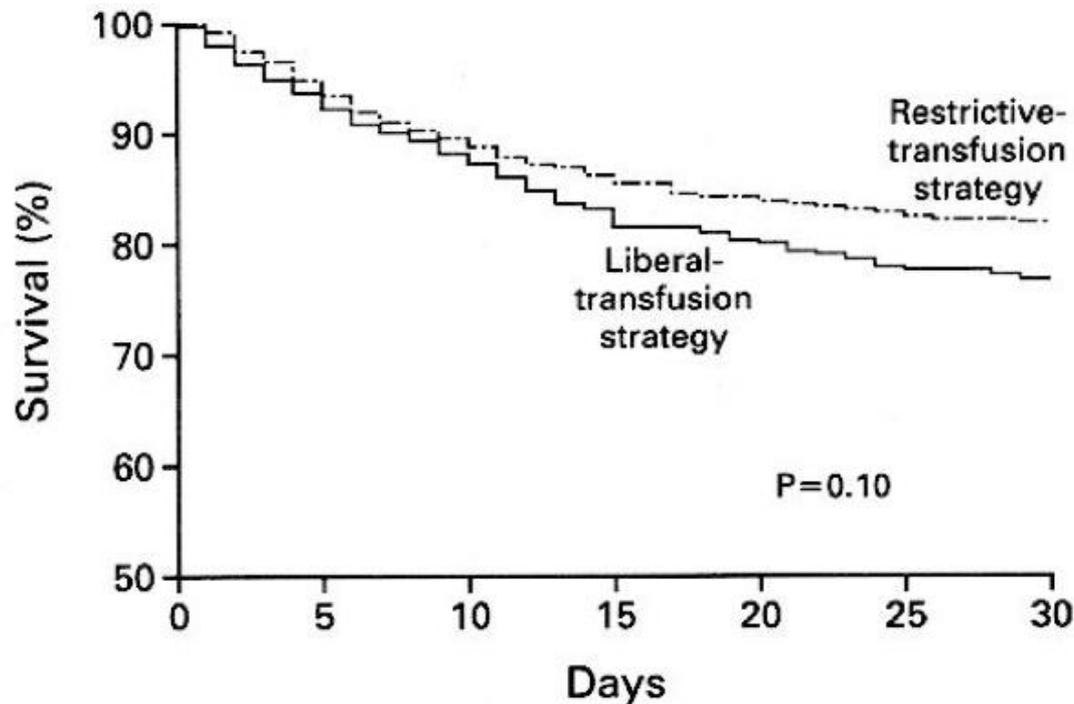
1 Don't transfuse more than the minimum number of red blood cell (RBC) units necessary to relieve symptoms of anemia or to return a patient to a safe hemoglobin range (7 to 8 g/dL in stable, non-cardiac inpatients).

- A large body of evidence demonstrates that liberal RBC transfusion strategies do not benefit patients
- Thus, liberal transfusion should be avoided in most clinical settings
- Transfusion of RBC is associated with a risk of adverse events, is expensive at approximately \$200-300 per unit, and is a limited resource



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30-Day Overall Survival is Not Reduced with Restrictive Transfusion in ICU Patients



- A multicenter, randomized, controlled clinical trial of transfusion requirements in critical care
- Compared restrictive transfusion (transfuse if Hgb < 7 g/dL) vs. liberal (transfuse if Hgb < 10g/dL)

n = 838, euvolemic ICU patients with Hgb < 9 g/dL



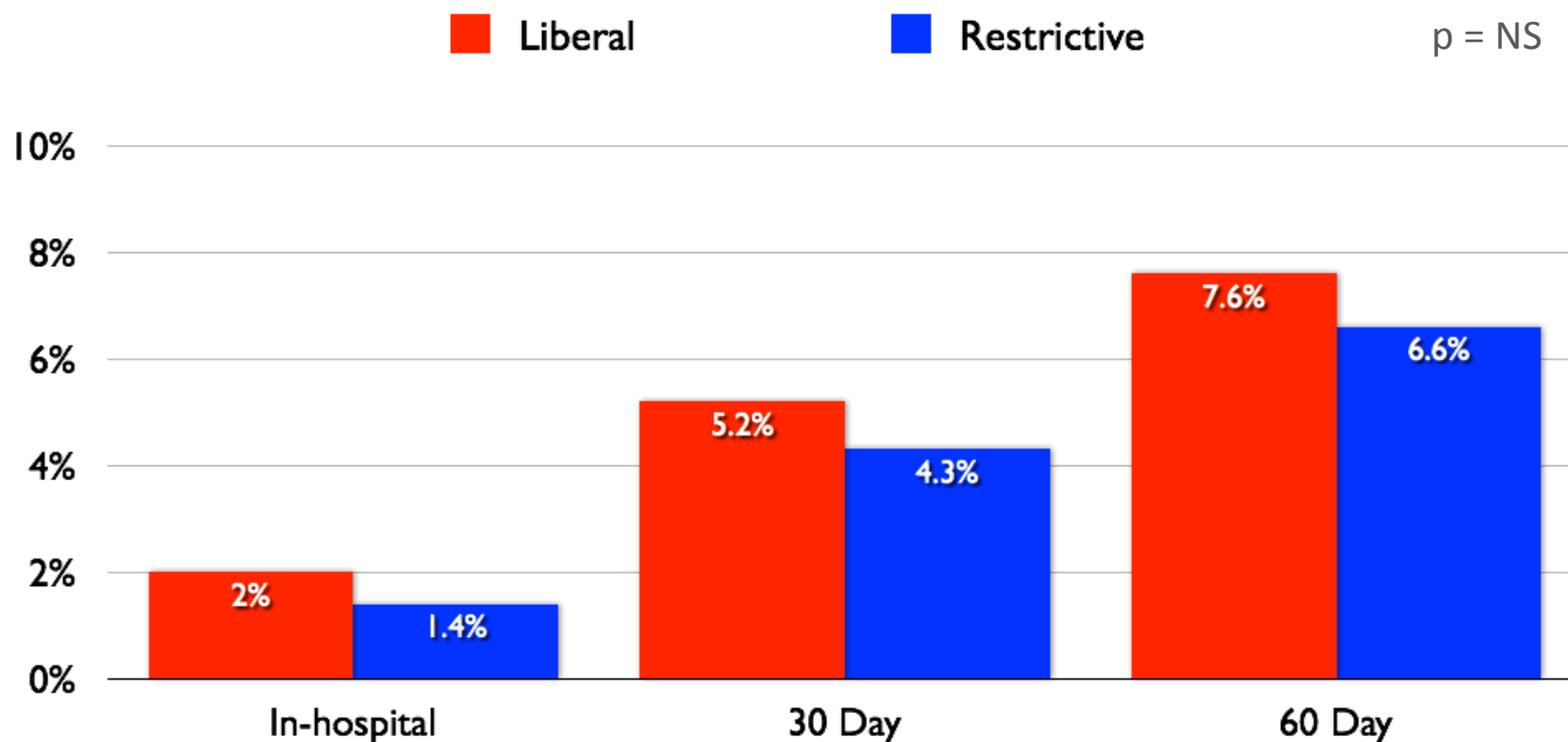
Mortality is Not Increased with Restrictive Transfusion in Hip-Fracture Patients

- Carson et al. studied liberal versus restrictive transfusion in high-risk patients after hip surgery
- N = 2016, patients with hip # and Hgb < 10 g/dL
- Compared restrictive transfusion (transfuse if Hgb < 8 g/dL or symptoms) vs. liberal transfusion (transfuse if Hgb < 10 g/dL)
- As illustrated on the next slide, restrictive transfusion strategy was not associated with increase in-hospital, 30 day, and 60 day mortality compared with liberal transfusion strategy



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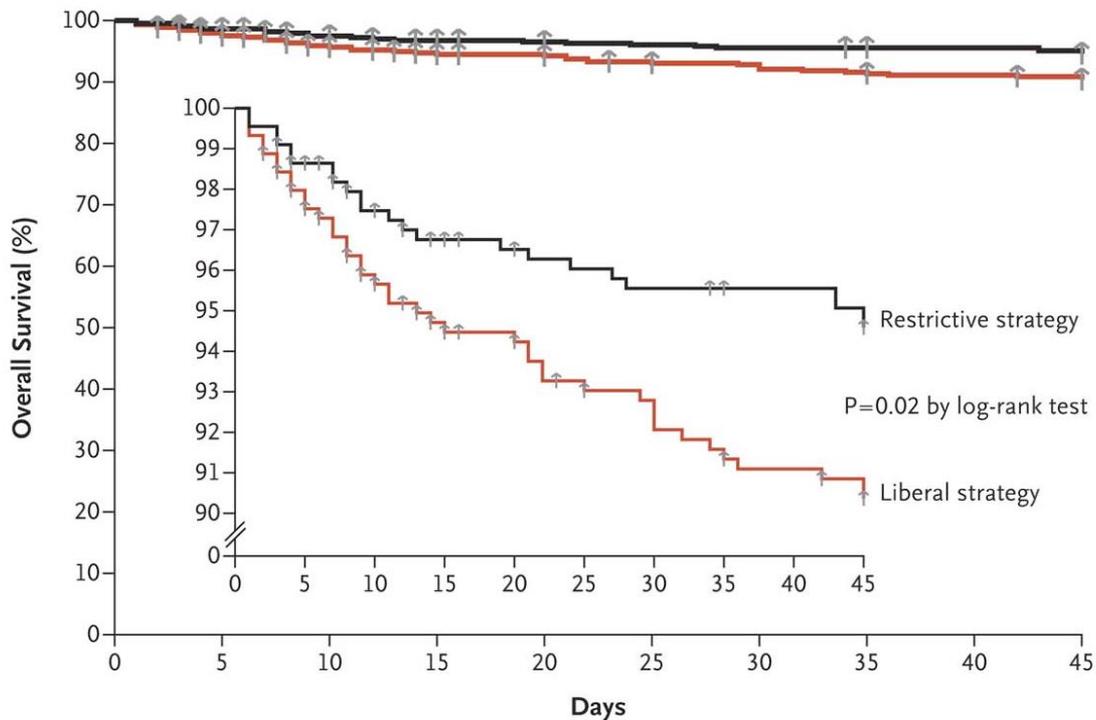
Mortality is Not Increased with Restrictive Transfusion





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Overall Survival May Be Better with Restrictive Transfusion in Patients with Upper GI Bleeding



- Transfusion strategies for acute upper gastrointestinal bleeding
- Compared restrictive transfusion (transfuse if Hgb < 7 g/dL) vs. liberal transfusion (transfuse if Hgb < 9 g/dL)

n = 921, patients with acute upper GI bleed



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Overall Survival is Not Reduced with Restrictive Transfusion

- Evidence from 14 studies in a 2012 meta-analysis showed that overall survival is not significantly reduced with restrictive versus liberal transfusion (RR 0.84, 95% CI 0.69 to 1.01)



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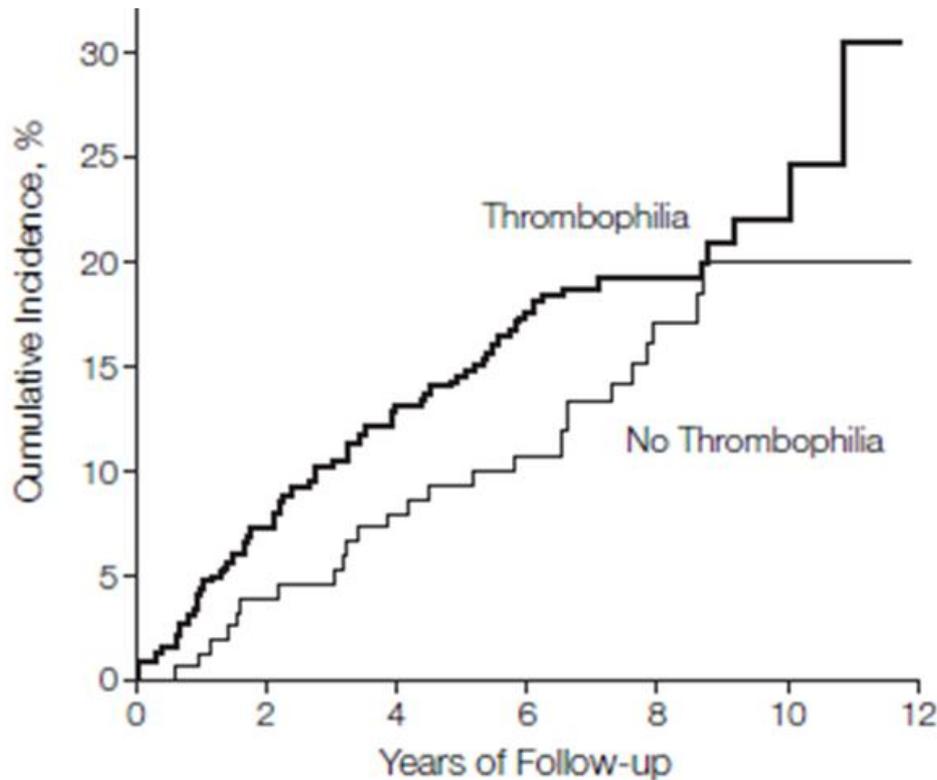
2 Don't test for thrombophilia in adult patients with venous thromboembolism (VTE) occurring in the setting of major transient risk factors (surgery, trauma or prolonged immobility).

- Thrombophilia can result in harm if the duration of anticoagulation is inappropriately prolonged, if a patient is inappropriately labeled as thrombophilic, or if negative testing is misinterpreted to suggest a patient does not have a risk of recurrent thrombosis.
- Testing is expensive (\$500 - \$1300 and up)
- For a VTE occurring in the setting of major, transient risk factors, the results of thrombophilia testing should not impact anticoagulant management



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Thrombophilia is not associated with Risk of VTE Recurrence



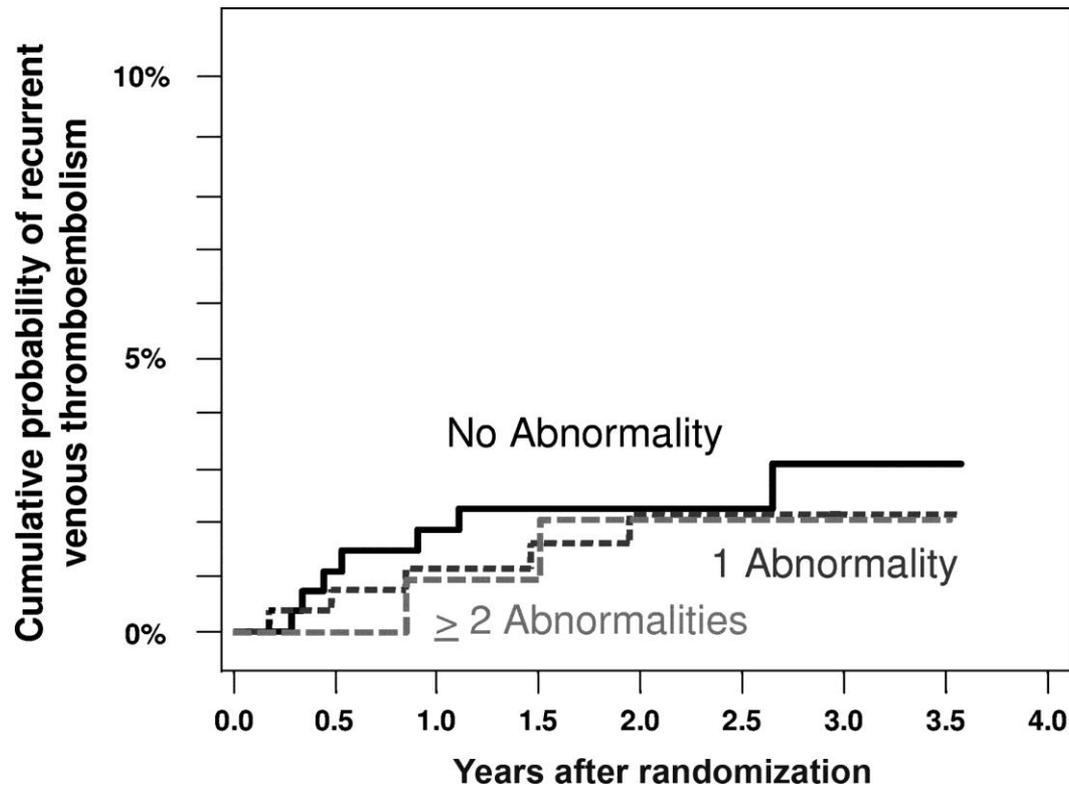
N = 474

HR = 1.3 (95% CI, 0.8 – 2.0)



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Thrombophilic Defects Are Not Associated with a Higher Risk of Recurrent VTE





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Reported Predictors of VTE Recurrence

- Prior history of thrombosis
 - Increasing patient age at incident VTE
 - Male sex
 - Idiopathic incident VTE
 - Incident VTE associated with active cancer
- ➔ **Presence of ≥ 1 inherited thrombophilias is not a predictor of VTE recurrence**



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3 Don't use inferior vena cava (IVC) filters routinely in patients with acute VTE.

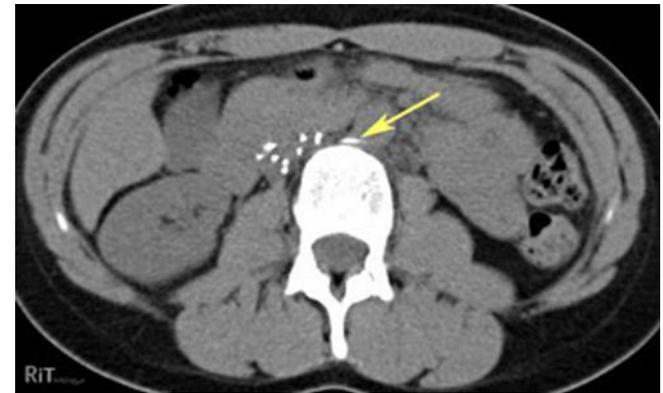
- IVC filters can harm patients, they are costly, and their use is not well supported by evidence



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IVC Filters

- Introduced in the 1960's as a physical device to impede embolization of DVTs
- No prospective trials demonstrating net benefit
- Many reports of adverse events including increased risk of DVT, vessel erosion, device embolization etc.
 - 08/09/2010 FDA Safety Alert - Inferior Vena Cava (IVC) Filters: Initial Communication: Risk of Adverse Events with Long Term Use



IVC filter that has perforated the inferior vena cava



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IVC Filters

- Single RCT of IVC filters compared permanent IVC filter + anticoagulation to anticoagulation alone in patients with proximal DVT

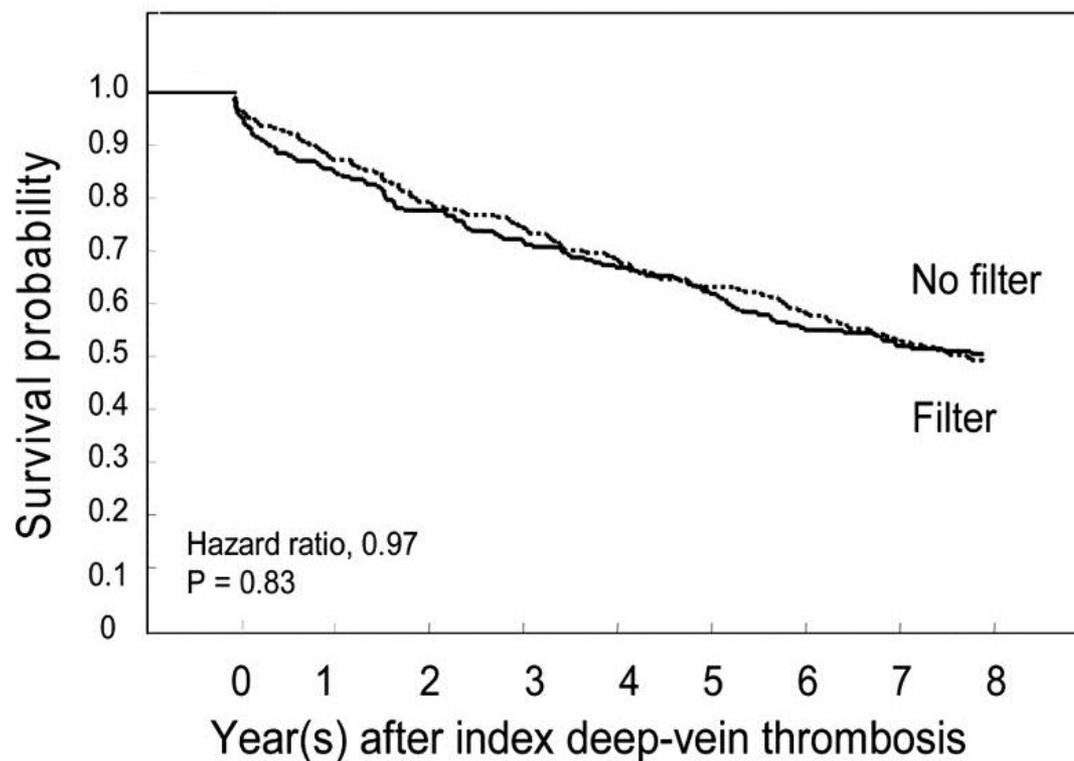
Conclusion:

- “...vena cava filters reduced the risk of pulmonary embolism but increased that of deep-vein thrombosis and had no effect on survival”
 - PREPIC Study Group. *Circulation* 2005;112:416-22



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IVC Filters Have No Impact on Survival



- Kaplan-Meier analysis of time to pulmonary embolism



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IVC Filters are Rarely Removed

- Expert consensus guidelines recommend *temporary* IVC filters be considered in patients with acute DVT and a contraindication to anticoagulation *and* that they be removed when anticoagulation can be safely resumed
 - ACCP, AHA, NICE, ICSI, BCSH, SIGN Guidelines

But...

- Of the approx. 250,000 IVC filters placed in the US each year, estimated that only 5,000 are placed for this indication
 - Sarosiek S et al. JAMA Intern Med 2013;173(7):513-7

And...

- A retrospective cohort study at a large US teaching institution reported: “Of 679 retrievable IVC filters that were placed 58 (8.5%) were successfully removed”
 - Sarosiek S et al. JAMA Intern Med 2013;173(7):513-7, Angel LF et al. J Vas Interv Radiol 2011;22(11):1522-30.e3



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4 Don't administer plasma or prothrombin complex concentrates for non-emergent reversal of vitamin K antagonists (i.e. outside of the setting of major bleeding, intracranial hemorrhage or anticipated emergent surgery).

- Blood products can cause serious harm to patients, are costly and are rarely indicated in the reversal of vitamin K antagonists (VKAs)
- In non-emergent situations, elevation in the INR is best addressed by withholding the VKA and/or by administering vitamin K



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FFP Is Potentially More Dangerous Than Other Blood Products

Transfusion-Related Fatalities Reported to FDA 2008-2012

TRALI	HTR	Infection	TACO	Anaphylaxis	Other
37%	27%	11%	18%	6%	1%

TRALI 12-fold more likely with plasma than with red cell transfusion



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FFP Is Often Unnecessary

Non-Bleeding Medical ICU Patients with INR ≥ 1.5

Outcome	FFP (n=44)	No FFP (n=71)	p Value
Median INR	2.7	2.5	0.532
New bleeding episode	3 (6.8%)	2 (2.8%)	0.369
Hospital mortality	11 (25.6%)	20 (28.2%)	0.763
Median ICU Length of Stay	2.4 d	2.0 d	0.184
New onset acute lung injury	8 (18.2%)	3 (4.2%)	0.021



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Clinical Guidelines Recommend Against Plasma for Vitamin K Antagonist Reversal

- Elevated INR from VKA without bleeding
 - INR 4.5-10, recommend against routine use of vitamin K (Grade 2B)
 - INR > 10.0, recommend oral vitamin K (Grade 2C)
- Elevated INR from VKA with major bleeding
 - Recommend rapid reversal of anticoagulation with PCC rather than with plasma (Grade 2C)
 - Recommend also give vitamin K 5-10 mg slow IV injection rather than reversal with coagulation factors alone (Grade 2C)



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Plasma is Often Used Inappropriately

- 47.6% of FFP orders were for non-bleeding ICU patients with modest elevation of INR, or in preparation for surgery
 - Lauzier et al. Crit Care Med 2007;35(7):1655-9
- 43% of FFP transfused to non-bleeding patients to correct INR, reverse warfarin, prepare for surgery
 - Stanworth SJ et al. Transfusion 2011;51(1):62-70
- 28.6% of FFP transfused to non-bleeding patients with INR \leq 1.5 and normal PTT, for reversal of warfarin, or in preparation for surgery
 - Tinmouth A et al. Transfusion 2013;53(10):2222-9



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An Opportunity to Avoid Harm and to Save \$

- Approximately 4 million units of plasma are transfused annually in US
 - The United States Department of Health and Human Services 2011 National Blood Collection and Utilization Survey
 - Approximately 1.2 million units (30%) are ordered inappropriately
 - Tinmouth et al. Transfusion 2013;53(1):2222-9
- ➔ Potential to save approximately \$1.87 million, avoid > 600 cases of TRALI per year in the US and save 120 lives



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5 Limit surveillance computed tomography (CT) scans in asymptomatic patients following curative-intent treatment for aggressive lymphoma.

- CT surveillance in asymptomatic patients in remission from aggressive lymphoma may be harmful, is costly (approximately \$1000 per scan), and has not been demonstrated to improve survival
- In particular, surveillance CT scans more than 2 years beyond the completion of curative treatment for lymphoma are rarely advisable



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A Minority of Relapses of Non-Hodgkin Lymphoma are Detected by CT

- Retrospective study of 341 patients with Diffuse Large B Cell Lymphoma or Grade 3 Follicular lymphoma, 113 relapses
 - 60% of relapses detected due to patient symptoms
 - 13% of relapses detected due to physical exam findings
 - 4% of relapses detected due to abnormal lab work
 - 22% of relapses detected due to findings on routine CT
 - Survival not different between patients whose lymphoma was detected by CT vs. those detected by other means



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Potential Harms of CT Scans

- Small, but cumulative risk of radiation-induced cancer
 - Estimated life-time cancer incidence associated with 1 full-body CT in a 70yo M, 0.044%; in a 20yo W, 0.108% (Shenoy et al. Clin Lymphoma Myeloma Leuk 2010;10(4):270-7)
- False positive results can cause anxiety, and can trigger unnecessary investigations which may cause harm



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Potential Harms of CT Scans

- Has been reported that 30% CT scans report incidental findings (Lumbreras et al. Br J Radiol 2010; 83(988):276-89)
 - With the passage of time the probability of a true positive decreases, but the false positive rate is constant
- Thus over time, the cumulative risk of a false positive becomes substantially higher than the probability of a true positive



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6 Don't treat with an anticoagulant for more than three months in a patient with a first venous thromboembolism (VTE) occurring in the setting of a major transient risk factor.

- Patients with secondary VTE have a particularly low risk of recurrent thrombosis and have the same risk of bleeding as other patients
- After three months, the consequences of anticoagulation probably outweigh the risks, suggesting discontinuation is preferred strategy
- Patient values and preferences should also be considered



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Foundational Basis for Recommendation

- A decision to terminate anticoagulants should always weigh the relative risks and benefits of discontinuation
- Risks - recurrent thrombosis (DVT, PE, fatal PE, CTPH, PTS)
- Benefits - return to baseline risk of bleeding, elimination of cost, complexity and inconvenience of anticoagulants
- Since risks are so consequential this decision should be carefully considered



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Practice Guidelines

- ACCP: “In patients with a proximal DVT of the leg provoked by surgery, we recommend treatment with anticoagulation for 3 months over (i) treatment of a shorter period (Grade 1B) , (ii) treatment of a longer time-limited period (eg, 6 or 12 months) (Grade 1B) , or (iii) extended therapy (Grade 1B regardless of bleeding risk)”



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Summary

- Based on our current understanding of risks and benefits, extending anticoagulation beyond three months in patients with clear secondary episodes of VTE probably causes net harm due to otherwise avoidable bleeding that outweighs the risk of thrombosis



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7 Don't routinely transfuse patients with sickle cell disease (SCD) for chronic anemia or uncomplicated pain crisis without an appropriate clinical indication.

- Transfusion for stable chronic anemia or painful vaso-occlusive crisis does not help the patient
- Transfusion carries risks for complications – particularly in patients with SCD



Is Blood Transfusion Indicated?

- Know or Determine the Sickle Cell Patient's Specific Circumstances
 1. SCD genotype
 - SS/Sβ⁰Thal vs. SC/Sβ⁺ Thal
 - Baseline Hb and risk of complications varies (less severe in the latter group)
 2. Baseline “steady state” hemoglobin concentration
 - Varies greatly from patient to patient
 3. Current or recent clinical event which might affect hemoglobin concentration
 - Acute illness
 - Hospitalization
 - Recent transfusion
 - Hemoglobin above steady state level
 - Hemoglobin below steady state level (e.g., following hemolytic transfusion reaction)



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Indications for Transfusion

Acutely

- Rapid decline in hemoglobin below “steady state” level
 - Acute chest syndrome
 - Splenic sequestration crisis
 - Aplastic crisis (parvovirus)
 - Multisystem organ failure
 - Intrahepatic cholestasis
 - Unexplained symptomatic anemia
- Prior to most surgical procedures requiring general anesthesia, for patients with HGB less than 10 (TAPS study)
- Stroke

Chronically

- Primary stroke prevention in children (elevated TCD)
- Secondary stroke prevention in children and adults
- Prevention of severe recurrent vaso-occlusive events when hydroxyurea is not feasible



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Transfusion Carries Risks for Complications

Acute Sequelae

- Hyperviscosity, which can lead to stroke
- Acute volume overload which can result in pulmonary edema and/or chest syndrome
- Immediate or delayed hemolytic transfusion reaction

Long-term Sequelae

- Alloimmunization against RBC antigen
- Iron overload



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When Not to “Routinely” Transfuse a Patient with Sickle Cell Disease

- Chronic asymptomatic anemia
 - Steady state
- Uncomplicated vaso-occlusive (pain) crisis
 - Usually no or minimal hemoglobin decline
- As immediate treatment of priapism prior to trial of more conservative measures
 - Conservative measures include vigorous oral or intravenous hydration and oral or intravenous analgesia
- Acute kidney injury, unless multisystem organ failure



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8

Don't perform baseline or routine surveillance computed tomography (CT) scans in patients with asymptomatic, early-stage chronic lymphocytic leukemia (CLL).

- CT scans introduce risks, including acute toxicity from IV contrast and small increased risk of secondary malignancy
- CT scans can lead to increased patient anxiety related to the presence of lymph nodes or other incidental findings that likely have no clinical significance but often prompt additional CT scans or testing at increased cost and risk to the patient
- CT scans are costly (approximately \$1000 per scan)
- There is no evidence of a survival or other clinical benefit with the use of baseline or routine surveillance scans in patients with early stage CLL



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Chronic Lymphocytic Leukemia

- Most prevalent adult leukemia seen in hematology practice
- Majority of patients have absent symptoms at time of diagnosis
- CLL diagnosis and initial staging requires
 - Flow cytometry with immunophenotype showing CD3, CD5, CD10, CD20, and CD23. If atypical phenotype, cyclin D1 negative stain to rule out MCL
 - Absolute monoclonal B lymphocyte count ($> 5 \times 10^9/L$)
 - CBC to assess for cytopenias
 - Physical exam for palpable lymph nodes, spleen, and liver
- CLL diagnosis and initial staging does not require CT scans



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Limitations of Clinical Staging

- Majority of patients at diagnosis have early stage disease (Rai 0-1 or Binet A). Ability of clinical staging to differentiate outcome of early stage patients is limited
- This can be improved with additional diagnostic testing
 - Chromosomal aberrations by FISH or stimulated karyotype
 - *IGHV* mutational status
 - ZAP-70 expression by flow cytometry, methylation, or immunohistochemistry



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So What is the Wise Choice in CLL Patients at Early Diagnosis?

- Do routine history focusing closely on new symptoms, physical, lab tests for traditional staging assessment
- Counsel patients about biomarkers that predict CLL outcome and consider ordering if patients desires more prognostic data
- In absence of active symptoms referable to CLL disease activity in abdomen/chest do not perform CT scans or PET scans
- This approach is in line with NCCN guidelines and minimizes costly interventions that ultimately will not change care



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9 Don't test or treat for suspected heparin-induced thrombocytopenia (HIT) in patients with a low pre-test probability of HIT.

- Use the 4T score to estimate the clinical probability of HIT
- A low probability 4T score excludes HIT
- Do not test or treat patients with a low probability 4T score:
 - Testing may lead to false-positive results and misdiagnosis
 - Alternative anticoagulants are costly and increase bleeding risk
 - Unnecessary suspension of heparin may increase thrombotic risk



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4T Scoring

4 T's	2 points	1 point	0 points
T hrombocytopenia	>50% and nadir ≥ 20	Fall 30-50% or nadir 10-19	Fall <30% or nadir <10
T iming of platelet fall	5-10 days or ≤ 1 day (prior exposure last 30 days)	After day 10 or ≤ 1 day (prior exposure 30-100 days ago)	<4 days w/o recent exposure
T hrombosis or other sequelae	New events on heparin	Progressive or recurrent thrombosis	None
O ther causes of thrombocytopenia	None	Possible	Definite

High probability: 6-8 points

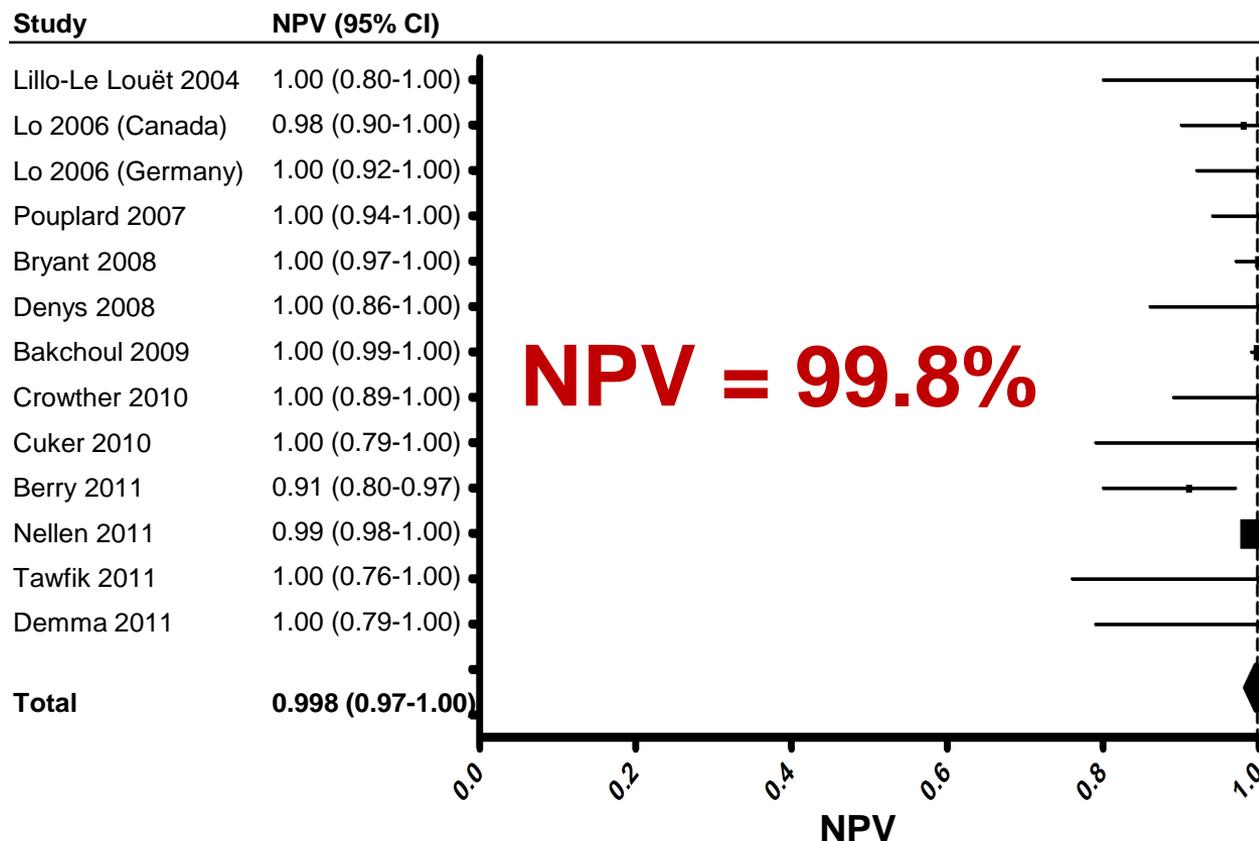
Intermediate probability: 4-5 points

Low probability: 0-3 points



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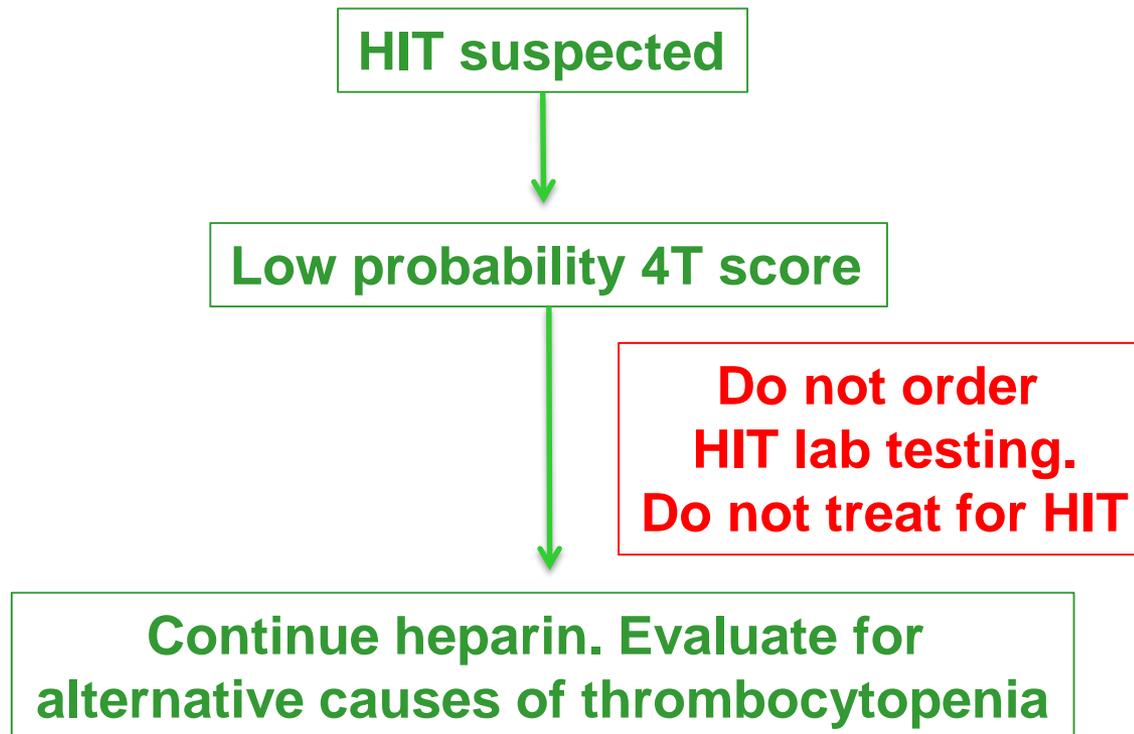
A low probability 4T score excludes HIT





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Evidence-Based Approach to the Patient with a Low Probability 4T Score





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Do Not Label a Low Probability Patient with HIT

- Once heparin is entered as an allergy in the chart, it is almost never removed
- Patients are denied heparin and treated with alternative anticoagulants during subsequent encounters



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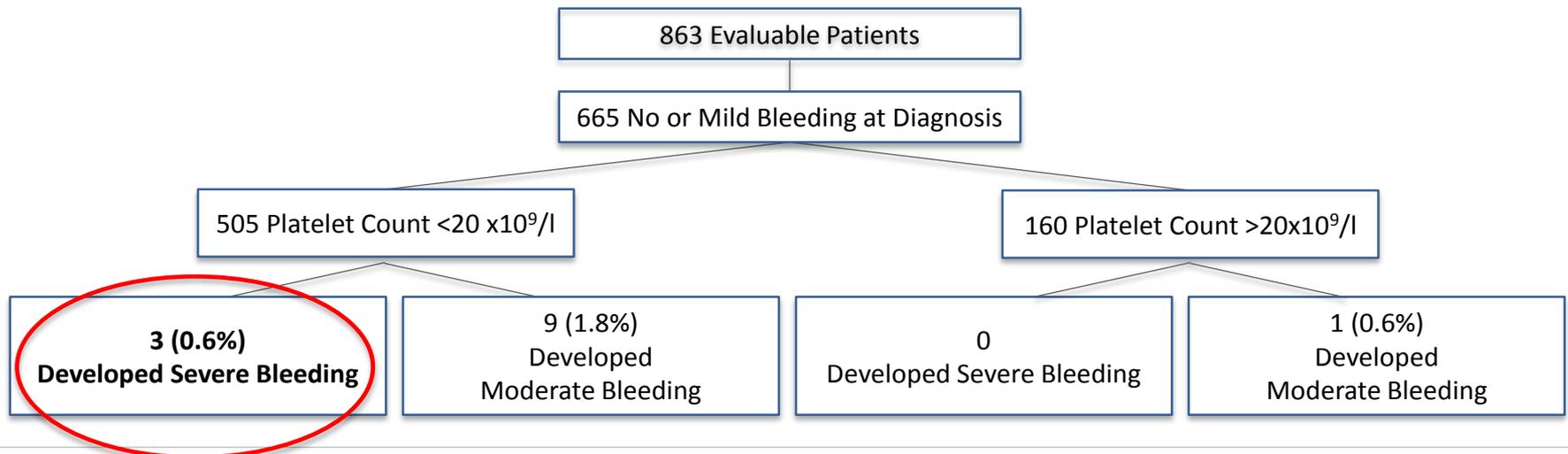
10 Don't treat patients with immune thrombocytopenic (ITP) in the absence of bleeding or a very low platelet count.

- Many patients are able to maintain low but safe platelet counts without treatment
- Treatment should be aimed at resolving bleeding episodes and improving health-related quality of life (HRQoL)
- Unnecessary treatment exposes patients to potentially serious treatment side effects and can be costly



Management with Observation can be Appropriate

- Children with no or mild bleeding can be managed with observation regardless of the platelet count
- Even with a low platelet count, the risk of developing severe bleeding is low





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Treatment Threshold for Adults

- In adults treatment should be reserved for a platelet count $< 30 \times 10^9/L$ and/or bleeding (Grade 2C)
 - Neunert, Lim, et al., Blood 2011;117:4190-4207
- Most adults with ITP have a good outcome
- Platelet count $< 30 \times 10^9/L$ is associated with increased all-cause mortality (RR: 1.5, 95% CI 1.0-2.2), due to bleeding AND infection
 - Portielje et al., Blood 2001;97: 2549-2554



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Treatment Threshold for Adults

- In patients with platelet counts persistently $< 30 \times 10^9/L$, modeling data suggests a predicted 5-year fatal bleeding risk of 48% in patients > 60 years old and of 2.2% in patients < 40 years old
 - Cohen et al., Arch Intern Med 2000;160: 1630-1638
- Unclear if offering treatment to all patients will result in decreased bleeding



Side Effects and Cost

- Treatment is associated with adverse events
 - Patients with a platelet count $> 30 \times 10^9/L$ receiving therapy had 5 times more ITP-related hospitalizations than patients receiving no therapy
 - Portielje et al., Blood 2001;97:2549-2554
 - Rituximab pooled data showed that 10 patients (3.7%) developed severe or life-threatening events and 9 (2.9%) patients died; 4 from fatal infections
 - Arnold et al., Ann Int Med 2007;25-33
- Publications on cost-analysis lack observation as a comparator
 - O'Brien et al., Pediatr Blood Cancer 2007;48:173-180
 - Lee et al., Appl Health Econ Health Policy 2013;11:457-469



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Side Effects and Cost

Treatment	Side Effects
Corticosteroids	Mood changes, hypertension, hyperglycemia, gastritis, adrenal suppression, increased risk of infection
IVIg	Infusion reaction, headache, aseptic meningitis, thrombosis
Anti-D Immunoglobulin	FDA black box warning, hemolysis (2.0 gram decrease in hemoglobin)
Splenectomy	Risk of anesthesia and surgery, life-threatening infections, thrombosis
Rituximab	Fatal infections, viral reactivation, infusion reactions, serum sickness, cost
TPO-RAs	Thrombosis, bone marrow changes, no durable response, cost



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Treating ITP: Balancing Risk Versus Benefit

- Majority of patients with ITP have a favorable outcome with observation alone

Potential Benefits of Treatment

- Rise in platelet count
- Possible reduction in bleeding
- Improved HRQoL



Potential Risks of Treatment

- Adverse events (including death from infections)
- Costs
- Inconvenience
- Serious bleeding



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ASH Choosing Wisely Recommendations

- 1 Don't transfuse more than the minimum necessary units of red blood cells
- 2 Don't test for thrombophilia in patients with major transient risk factors for VTE and acute VTE
- 3 Don't use IVC filters routinely in the management of VTE
- 4 Don't use plasma or prothrombin concentrate concentrates for non-emergent reversal of vitamin K antagonists
- 5 Limit CT surveillance scans in asymptomatic people following curative intent chemotherapy for aggressive lymphoma



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ASH Choosing Wisely Recommendations

- 6 Don't treat with an anticoagulant for more than three months in a patient with a first venous thromboembolism (VTE) occurring in the setting of a major transient risk factor
- 7 Don't routinely transfuse patients with sickle cell disease (SCD) for chronic anemia or uncomplicated pain crisis without an appropriate clinical indication
- 8 Don't perform baseline or routine surveillance computed tomography (CT) scans in patients with asymptomatic, early-stage chronic lymphocytic leukemia (CLL)
- 9 Don't test or treat for suspected heparin-induced thrombocytopenia (HIT) in patients with a low pre-test probability of HIT
- 10 Don't treat patients with immune thrombocytopenic (ITP) in the absence of bleeding or a very low platelet count