

# COVERAGE GUIDANCE: INFERIOR VENA CAVA FILTERS FOR PREVENTION OF PULMONARY EMBOLI

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## HERC COVERAGE GUIDANCE

Inferior vena cava (IVC) filters are recommended for coverage in:

- Patients with active deep vein thrombosis/pulmonary embolism (DVT/PE) for which anticoagulation is contraindicated (*strong recommendation*)
- Some hospitalized patients with trauma\* (*weak recommendation*)

Retrieval of removable IVC filters is recommended for coverage if the benefits of removal outweigh harms (*weak recommendation*)

IVC filters are not recommended for coverage for patients with DVT who are candidates for anticoagulation (*strong recommendation*)

\*Examples of trauma for which IVC filters may be indicated include patients with severe trauma and prolonged hospitalization.

Note: Definitions for strength of recommendation are provided in Appendix A. GRADE Element Description

## RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

## EVIDENCE SOURCES

### Trusted sources

- Scottish Intercollegiate Guidelines Network. (SIGN). (2010). *Prevention and management of venous thromboembolism*. Edinburgh: SIGN. Retrieved on October 2, 2014, from <http://sign.ac.uk/pdf/sign122.pdf>
- Singh, S., Haut, E.R., Brotman, D.J., Sharma, R., Chelladurai, Y., Shermock, K.M., et al. (2013). *Pharmacologic and mechanical prophylaxis of venous thromboembolism among special populations*. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ). Retrieved on October 2, 2014, from <http://effectivehealthcare.ahrq.gov/ehc/products/341/1501/venous-thromboembolism-special-populations-130607.pdf>
- Sobieraj, D.M., Coleman, C.I., Tongbram, V., Lee, S., Colby, J., Chen, W.T., et al. (2012). *Venous thromboembolism in orthopedic surgery*. Rockville, MD: AHRQ. Retrieved on October 2, 2014, from [http://effectivehealthcare.ahrq.gov/ehc/products/186/992/CER-49\\_VTE\\_20120313.pdf](http://effectivehealthcare.ahrq.gov/ehc/products/186/992/CER-49_VTE_20120313.pdf)
- Young, T., Tang, H., & Hughes, R. (2010). Vena caval filters for the prevention of pulmonary embolism. *Cochrane Database Syst Rev*, 2(2). DOI: 10.1002/14651858.CD006212.pub4

### Additional sources

- Decousus, H., Leizorovicz, A., Parent, F., Page, Y., Tardy, B., Girard, P., et al. (1998). A clinical trial of vena caval filters in the prevention of pulmonary embolism in patients with proximal deep-vein thrombosis. *New England Journal of Medicine*, 338(7), 409-416. Retrieved October 15, 2014, from <http://www.nejm.org/doi/pdf/10.1056/NEJM199802123380701>
- Decousus, H., Barral, F., Buch-muller, A., Charbonnier, B., Girard, P., Lamer, C., et al. (2005). Eight-year follow-up of patients with permanent vena cava filters in the prevention of pulmonary embolism. The PREPIC (Prévention du Risque d'Embolie Pulmonaire par Interruption Cave) Randomized Study. *Circulation*, 112(3), 416-422. Retrieved October 15, 2014, from <http://circ.ahajournals.org/content/112/3/416.full.pdf+html>
- Fullen, W. D., Miller, E. H., Steele, W. F., & McDonough, J. J. (1973). Prophylactic vena caval interruption in hip fractures. *Journal of Trauma-Injury, Infection, and Critical Care*, 13(5), 403-410.
- Guyatt, G.H., Cook, D.J., Jaeschke, R., Pauker, S.G., & Schunemann, H.J. (2008). Grades of recommendation for antithrombotic agents: ACCP evidence-based clinical practice guidelines (8<sup>th</sup> Edition). *Chest*, 133(6), 123S–131S.
- Kearon, C., Kahn, S. R., Agnelli, G., Goldhaber, S. Z., Raskob, G., Comerota, A. J., & American College of Chest Physicians. (2008). Antithrombotic therapy for venous thromboembolic disease: ACCP evidence-based clinical practice guidelines. *Chest*, 133(6), 454S-545S.

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

## **EVIDENCE OVERVIEW**

### **Clinical background**

Blood clots or deep venous thrombosis (DVT) form in the lower extremities and can occur under a number of different circumstances. Temporary circumstances are prolonged immobility, recent surgery, trauma, pregnancy, or estrogen therapy. Longer term situations include people who have cancer, or people who have an inherited hypercoagulable tendency.

Deep vein thromboses can fragment and travel through the venous system to the lungs causing pulmonary embolism (PE). The major conduit of venous drainage from the lower half of the body is the inferior vena cava. Deep vein thromboses that extend into the thigh or pelvis are more likely to embolise than those that do not extend beyond the calf. Case series data indicate a rate between 27% to 60% for the risk of embolism if the clot is situated either within the inferior vena cava, the thigh, or pelvic veins.

The current treatment for pulmonary embolism is anticoagulation (heparin and vitamin K antagonists (warfarin, coumadin)). Infrequently, recurrent pulmonary emboli can occur despite therapeutic levels of anticoagulation; one suggested a rate is 3.8%.

### **Indications**

Filters are recommended for individuals who have a proximal DVT or pulmonary embolism, or both, where it is too dangerous for them to receive anticoagulation. There is controversy in the literature about whether other groups of people may potentially benefit from having a vena caval filter inserted.

### **Technology description**

Vena caval filters may be placed in the inferior or superior vena cava to mechanically trap emboli, interrupting their course before reaching the heart and lungs. These devices most commonly resemble an umbrella in appearance, are made from metal alloys, and can be inserted percutaneously. Once deployed, permanent filters are left in situ; they become endothelialised and are eventually incorporated within the blood vessel wall. Temporary or retrievable filters can be removed within a certain time interval (specified by the manufacturer) if their use is no longer required (up to approximately 12 weeks). There are currently approximately 12 filter designs, several of which are retrievable. Retrievable filters have potential advantages over the permanent filters; one is the opportunity for subsequent removal if no longer needed, thus avoiding longer term sequelae of DVT. Despite being called “retrievable”, these filters can become permanent implants if their subsequent removal becomes complicated due to endothelialisation, or if there is a significant amount of trapped thrombus within the filter such that the filter cannot be retracted back into its sheath.

## Evidence review

### Trusted sources

#### *Cochrane 2010*

Two trials met inclusion criteria for this systematic review. The PREPIC study was a randomized controlled trial of 400 participants with documented proximal DVT or PE who were also receiving vitamin K antagonists; this trial was followed for up to eight years. Four different permanent filter designs were employed. At two year follow-up, there was no significant difference in the incidence of symptomatic PE (OR = 0.50, 95% CI 0.19 to 1.33); however, the study lacked statistical power to detect a difference (power calculation required 800 participants to detect an expected 4% decrease in PE).

At eight years follow up, the PREPIC study demonstrated the efficacy of caval filters in preventing pulmonary embolism (hazard ratio 0.37, 95% CI 0.17 to 0.79 in favor of a filter). However, there was a significant increase in the rate of DVT in the filter group (hazard ratio 1.52, 95% CI 1.02 to 2.27). Post-thrombotic syndrome was a common complication (defined as the appearance or worsening of edema, varicose veins, trophic disorders, or ulcers) in both groups, affecting 68% to 70% of people in each study group. There also continued to be no significant difference between groups in mortality (HR = 0.97, 95% CI 0.74 to 1.28,  $p = 0.83$ ). No data were collected on filter-related complications.

Fullen (1973) was a quasi-randomized trial of 129 participants with a traumatic hip fracture who were followed approximately 33 days; neither group was anticoagulated. It demonstrated that caval filters were effective in reducing PE but not mortality. Mortality was 4/41 in the filter group and 14/59 in the control group (RR 0.41, 95%CI 0.15 to 1.16). Rate of pulmonary embolism in the filter group was 4/41, and 19/59 in the control group (RR 0.3, 95% CI 0.11 to 0.82). The incidence of short-term complications were reported to be similar in both groups, with the exception of PE, with both groups having similar incidences of infectious complications and phlebitis, although no statistical testing was done. No details about long term complication rates were given.

No recommendations can be drawn from the two studies. One study showed a reduction in PE rates but not mortality, but was subject to significant biases. The other study lacked statistical power to detect a reduction in PE in clinically significant time periods, and demonstrated that permanent IVC filters were associated with an increased risk of long term lower limb DVT.

There is a paucity of IVC filter outcome evidence when used within currently approved indications and a lack of trials on retrievable filters.

#### **AHRQ 2013**

Singh et al evaluated the efficacy and harms of IVC filters in patients with trauma, traumatic brain injury, burns, or liver disease; patients on antiplatelet therapy; and those undergoing obesity surgery.

## *Trauma*

The strength of evidence (SOE) is low that prophylactic IVC filter placement when compared with no filter use is associated with a lower incidence of PE and fatal PE in hospitalized patients with trauma, based on one RCT and 7 cohort studies (3 prospective, 1 retrospective, 3 using historical controls). Most of these included at least some patients who received anticoagulation. Two studies reported using venous compression devices alone, however both of these were excluded from the meta-analyses because the authors considered them to have fatal flaws. The RCT was a pilot study to determine feasibility of a larger trial, and reported one PE in the control group (n=16) and one DVT in the IVC filter group (n=18). No statistical testing was reported. Over 85% of participants were receiving pharmacologic prophylaxis on enrollment.

Meta-analysis of six studies showed a precise and consistent evidence of reduction in PE with IVC filters compared with no IVC filters without any evidence of statistical heterogeneity (RR:0.20, 95% CI:0.06-0.70;  $I^2=0\%$ ). Meta-analysis of four studies showed precise and consistent evidence of reduction in fatal PE with IVC filters compared with no IVC filters, without any evidence of statistical heterogeneity (RR, 0.09, 95% CI 0.01 to 0.81;  $I^2=0\%$ ) However, there was no statistically significant difference in mortality [three studies, RR 0.70 (0.40 to 1.23;  $I^2=6.7\%$ ), insufficient SOE].

There is insufficient evidence that prophylactic IVC filter placement is associated with an increased incidence of DVT in hospitalized patients with trauma when compared with no use of filters, based on three studies. Meta-analysis resulted in a RR of 1.76 (95% CI = 0.49 to 6.18;  $p=0.38$ ), and there was substantial statistical heterogeneity, with an  $I^2=56.8\%$ . The evidence was also insufficient to evaluate the comparative effectiveness and safety of various filter subtypes, or to evaluate the rates of other filter complications.

## *Bariatric Surgery*

There is a low SOE to support that IVC filters do not reduce the risk of PE in patients undergoing bariatric surgery, based on four cohort studies (RR = 0.91, 95% CI = 0.32 to 2.57;  $p=0.858$  ;  $I^2=16.3\%$ ). The evidence is insufficient to comment on the effectiveness of IVC filters for reducing fatal PE or VTE (one study each), or to support that IVC filters increase the incidence of DVTs, based on four cohort studies (RR = 2.77, 95% CI=0.87 to 8.85;  $p=0.086$  ;  $I^2=62.6\%$ ). There is low grade evidence to support that IVCFs are associated with increased mortality in patients undergoing bariatric surgery, based on 4 cohort studies (RR =3.63, 95% CI=1.99 to 6.61;  $p <0.05$ ;  $I^2=0.0\%$ ).

Complications of filter placement occasionally occur, some of which may be fatal (five cohort studies, two case reports). These include filter migration to the heart, nonfatal IVC thrombosis, fatal IVC thrombosis, errant placement of the filter into the common iliac vein, wrong positioning of the filter, pneumothorax, hemopericardium, and the inability to perform a transvenous ablation of a cardiac accessory pathway due to the filter. A subset of studies reported that physicians ultimately removed more than two thirds of the retrievable filters placed.

## *Other Populations*

The evidence is insufficient to evaluate the use of IVC filters in patients with traumatic brain injury, burns, liver disease, or patients taking antiplatelet therapy.

## AHRQ 2012

Sobieraj et al attempted to evaluate the efficacy and safety of prophylactic use of IVC filters in orthopedic surgery, but found no studies that met their inclusion criteria.

## Scottish Intercollegiate Guidelines Network 2010

The SIGN group developed a guideline on the prevention and management of venous thromboembolism. They recommend the following:

“Good Practice Point (expert opinion only): If a device is used, retrievable IVC filters should be used although successful retrieval cannot be guaranteed.

Grade D Recommendation (based on case reports, case series or expert opinion): Where IVC filters have been fitted because of an existing contraindication to anticoagulants at the time of presentation, anticoagulation may be introduced when the contraindication is resolved.”

The guideline provides the following rationale:

“Use of inferior vena cava (IVC) filters is rarely appropriate. No evidence was identified to support the routine placement of an IVC filter when a patient is able to be anticoagulated. If anticoagulation therapy is not possible for patients with acute deep vein thrombosis then placement of an IVC filter can lead to reduction in radiologically diagnosed PE but no difference in symptomatic PE and no overall mortality benefit. Once any contraindication to anticoagulation has passed, it should be reinstated. Whenever possible the filter should be retrieved. Filter insertion is not without complications and frequently filters cannot be retrieved.” (Based on expert opinion)

“There is no evidence to support or refute long term anticoagulation merely to prevent IVC filter thrombosis.”

“IVC filters significantly reduce the number of PEs suffered by patients who present with proximal DVT (1.1% v 4.8%, OR 0.22, 95% CI 0.05 to 0.90) but they are associated with an increase in the development of recurrent DVT (20.8% v 11.6%, OR 1.87, 95% CI 1.10 to 3.20) at two years follow up. This is the major complication of IVC filter insertion in patients with proximal DVT.” (Based on expert opinion and meta-analyses, systematic reviews, or RCTs with a high risk of bias)

Other complications are shown in the table below:

**Table 1. Complications of IVC Filter Insertion**

Immediate	
Misplacement	1.3%
Hematoma	0.6%
Pneumothorax	0.02%
Air embolism	0.2%
Carotid artery puncture	0.04%
Atrioventricular fistula	0.02%

<b>Early</b>	
Insertion site thrombosis	8.5%
Infection	Rare but documented
<b>Late</b>	
DVT	21%
IVC thrombosis	2-10%
Post-thrombotic syndrome	15-40%
IVC penetration	0.3%
Filter migration	0.3%
Entrapment of guidewires	Rare but documented
Filter tilting	Rare but documented
Fracture	Rare but documented

## EVIDENCE SUMMARY

There is a general consensus that IVC filters are indicated for patients who have proximal DVT or PE and cannot be anticoagulated. However, the evidence is insufficient to reach conclusions about the efficacy of IVC filters in this population, and there is evidence that IVC filters increase the risk of DVT (low SOE).

In hospitalized patients with trauma, the strength of evidence is low that IVC filter placement is associated with a lower incidence of pulmonary embolism and fatal pulmonary embolism compared with no IVC filter placement. However, there is no statistically significant impact on overall mortality.

In patients undergoing bariatric surgery, IVC filters are associated with increased mortality and do not decrease the risk of pulmonary embolism (low SOE).

## GRADE-INFORMED FRAMEWORK

The HERC develops recommendations by using the concepts of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are four elements that determine the strength of a recommendation, as listed in the table below. The HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Balance between desirable and undesirable effects, and quality of evidence, are derived from the evidence presented in this document, while estimated relative costs, values and preferences are assessments of the HERC members.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
IVC filter in hospitalized trauma patients	Decreased incidence of all PE and fatal PE, but no difference in overall mortality	Low	Moderate	High	IVC filters in some hospitalized trauma patients are recommended for coverage ( <i>weak recommendation</i> ).  Retrieval of removable filters is recommended for coverage if the benefits of removal outweigh harms ( <i>weak recommendation</i> )	There is evidence of less PE and fatal PE but no difference in mortality. High variability in preferences leads to a weak recommendation for coverage. Language was added to a box footnote describing the conditions that may indicate appropriateness such as prolonged immobilization.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
IVC filter in bariatric surgery patients	No decrease in PE, increase in mortality	Low	Moderate	Low	IVC filters are not recommended for coverage in bariatric surgery patients, but no explicit box recommendation was made for this subgroup.	Sufficient evidence demonstrates higher mortality and no benefit from IVC filters in bariatric surgery patients. However, after subcommittee deliberations it was felt that including a specific recommendation about the bariatric surgery subgroup did not make sense, as there are many other subgroups which have not been studied to the same extent which would be similarly inappropriate for coverage. The current box language indicates for which indications coverage is appropriate, but does not go into a list of all the indications for which coverage would be inappropriate.
IVC filter for populations with proximal DVT who are candidates for	Possible decrease in PE, increase in DVT	Very low	Moderate	Low	IVC filters are not recommended for coverage for patients with DVT	Insufficient evidence of effectiveness but more risk than no IVC filters.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
anticoagulation					who are candidates for anticoagulation ( <i>strong recommendation</i> )	
IVC filter in those with proximal DVT or PE and contraindication to anticoagulation	Unknown	Very low	Moderate	Low – many patients would be uncomfortabl e with a “time bomb” of a DVT which could cause fatal PE.	IVC filters are recommended for coverage in those with DVT/PE and contraindication to anticoagulation ( <i>strong recommendation</i> )  Retrieval of removable filters is recommended for coverage if the benefits of removal outweigh harms ( <i>weak recommendation</i> )	While there is insufficient evidence, it is very unlikely a study would be conducted (because of a lack of clinical equipoise). Many patients would choose to have this procedure to protect against fatal PE. It follows the coverage guidance development framework pathway IIb1a2 and is upgraded from a weak to a strong recommendation based on preferences and the low likelihood of additional evidence.

\*The Quality of Evidence rating was assigned by the primary evidence source, not the HERC Subcommittee

Note: GRADE framework elements are described in Appendix A

## POLICY LANDSCAPE

### Quality measures

No quality measures were identified when searching the [National Quality Measures Clearinghouse](#).

### Clinical practice guidelines

Because a primary evidence source for this document referenced a practice guideline in their background section, pertinent portions of the updated version of that guideline are extracted and presented here:

*Antithrombotic therapy for venous thromboembolic disease: American College of Chest Physicians Evidence-based Clinical Practice Guidelines (8th Edition)*<sup>1</sup>

#### Vena Caval Filters for the Initial Treatment of DVT

1.13.1. For patients with DVT, we recommend against the routine use of a vena cava filter in addition to anticoagulants (Grade 1A).

1.13.2. For patients with acute proximal DVT, if anticoagulant therapy is not possible because of the risk of bleeding, we recommend placement of an inferior vena cava (IVC) filter (Grade 1C).

1.13.3. For patients with acute DVT who have an IVC filter inserted as an alternative to anticoagulation, we recommend that they should subsequently receive a conventional course of anticoagulant therapy if their risk of bleeding resolves (Grade 1C).

Inferior vena caval (and rarely superior vena caval [SVC]) filters can be used instead of initial anticoagulation (eg, unacceptable risk of bleeding), or as an adjunct to anticoagulation, in patients with acute DVT. No randomized trial or prospective cohort study have evaluated IVC filters as sole therapy in patients with DVT (ie, without concurrent anticoagulation). Permanent IVC filter insertion as an adjunct to anticoagulant therapy has been evaluated in a single, large RCT of patients with acute DVT who were considered to be at high risk for PE (PREPIC study). The findings of that study, which were reported after 2 years and 8 years of follow-up, provide the strongest evidence to guide use of IVC filters in patients with acute VTE, and can be summarized as follows. First, routine insertion of filters in patients who are also anticoagulated does not alter the frequency of recurrent VTE (RR, 1.34 at 2 years; and RR, 1.03 at 8 years) or total mortality (RR, 1.08 at 2 years; and RR, 0.95 at 8 years). Second, filters reduce PE at 12 days (RR, 0.4; this estimate includes asymptomatic PE detected by routine lung scanning), 2

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<sup>1</sup> Evidence grading used by the ACCP in this document is as follows:

- Grade 1A: strong recommendation, high-quality evidence
- Grade 1B: strong recommendation, moderate-quality evidence
- Grade 1C: strong recommendation, low or very low-quality evidence
- Grade 2A: weak recommendation, high-quality evidence
- Grade 2B: weak recommendation, high-quality evidence
- Grade 2C: weak recommendation, high-quality evidence

years (RR, 0.54), and at 8 years (RR, 0.41). Third, filters increase DVT at 2 years (RR, 1.8) and at 8 years (RR, 1.3; hazard ratio, 1.5; 95% CI, 1.02 to 2.3 in the original report). Fourth, despite more frequent DVT during follow-up and frequent evidence of thrombosis at the filter site in those with recurrent VTE (43% of cases), filters were not associated with a higher frequency of post-thrombotic syndrome (PTS; defined as presence of at least one of edema, varicose veins, trophic disorders or ulcers) [hazard ratio, 0.87; 95% CI, 0.66 to 1.13]. Fifth, 2.5% (five patients) of the non-filter group and 1.0% (two patients) of the filter group died of PE during eight years of follow-up. Sixth, other complications of filter placement are rare (none were reported).

A comprehensive review of mostly retrospective case series of vena caval filter insertions (a total of 6,500 patients in 89 reports who had filters inserted for many different reasons) suggests that venous thrombosis at the site of filter insertion sites is common (e.g., approximately 10% of patients), that filters can be placed above the renal veins if necessary, and that it is feasible to place filters in the SVC. Epidemiologic data suggest that IVC filters are not associated with an increased risk of recurrent VTE in patients who present with DVT. If an IVC filter is being inserted in a patient with acute DVT or PE because anticoagulant therapy is temporarily contraindicated (e.g., active bleeding), there is the option of inserting a retrievable filter and removing the filter when it is safe to start anticoagulant therapy. However, the risks and benefits of using a retrievable filter compared with a permanent filter in this setting are uncertain.

#### Vena Caval Filters for the Initial Treatment of PE

4.6.1. For most patients with PE, we recommend against the routine use of a vena caval filter in addition to anticoagulants (Grade 1A).

4.6.2. In patients with acute PE, if anticoagulant therapy is not possible because of risk of bleeding, we recommend placement of an IVC filter (Grade 1C).

4.6.3. For patients with acute PE who have an IVC filter inserted as an alternative to anticoagulation, we recommend that they should subsequently receive a conventional course of anticoagulant therapy if their risk of bleeding resolves (Grade 1C).

As previously noted, vena caval filters can be used instead of initial anticoagulant therapy (e.g., unacceptable risk of bleeding) or as an adjunct to anticoagulation in patients with acute VTE. As for acute DVT, no randomized trials or prospective cohort studies have evaluated IVC filters as sole therapy for acute PE (i.e., without concurrent anticoagulation). The PREPIC study, which evaluated IVC filters as an adjunct to anticoagulation in 400 high-risk patients with proximal DVT, showed that filters reduced PE, increased DVT, and did not change overall frequency of VTE (DVT and/or PE combined). The PREPIC study included 145 patients (36% of total) with symptomatic PE and 52 patients (13% of total) with asymptomatic PE at enrollment in addition to proximal DVT. Multivariable analyses did not find an association between the presence of PE at entry and the frequency of PE at 2 years; however, such an association was present after eight years of follow-up.

There is uncertainty about the risk and benefits of inserting an IVC filter as an adjunct to anticoagulant and thrombolytic therapy in patients with massive PE. Among patients with hemodynamic compromise in the International Cooperative Pulmonary Embolism Registry, insertion of an IVC filter was associated with a reduction of early recurrent PE and death.

Epidemiologic data suggest that insertion of an IVC filter in patients who present with PE (with or without symptomatic DVT) is associated with about a doubling of the frequency of VTE during follow-up; most of this increase is due to a higher frequency of DVT (approximately 2.6-fold increase) rather than PE (approximately 1.3-fold increase).

#### Pulmonary Thromboendarterectomy, Vitamin K Antagonists (VKA), and Vena Cava Filter for the Treatment of Chronic Thromboembolic Pulmonary Hypertension (CTPH)

6.1.1. In selected patients with CTPH, such as those with central disease under the care of an experienced surgical/medical team, we recommend pulmonary thromboendarterectomy (Grade 1C).

6.1.2. For all patients with CTPH, we recommend life-long treatment with a VKA targeted to an INR of 2.0 to 3.0 (Grade 1C).

6.1.3. For patients with CTPH undergoing pulmonary thromboendarterectomy, we suggest the placement of a permanent vena caval filter before or at the time of the procedure (Grade 2C).

Primary therapy for CTPH is pulmonary thromboendarterectomy, which, if successful, can reduce and sometimes cure pulmonary hypertension. The operation requires a median sternotomy, institution of cardiopulmonary bypass, deep hypothermia with circulatory arrest periods, and exploration of both pulmonary arteries. Pulmonary thromboendarterectomy removes organized thrombus by establishing an endarterectomy plane in all involved vessels. At the most experienced centers, the mortality rate is < 5%. The most common postoperative problem is reperfusion pulmonary edema, generally managed with supportive care that requires several days of mechanical ventilation. When pulmonary thromboendarterectomy is successful, patients can usually resume normal daily activities and experience a greatly improved quality of life. Management usually includes insertion of a permanent vena cava filter before or during pulmonary endarterectomy and indefinite anticoagulant therapy with a target INR of 2.5-3.19 No randomized trials of CTPH therapy have been undertaken. Patients with CTPH who are not candidates for pulmonary endarterectomy because of comorbid disease or surgically inaccessible lesions may be candidates for pulmonary artery angioplasty.

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

## APPENDIX A. GRADE ELEMENT DESCRIPTIONS

Element	Description
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted

### Strong recommendation

**In Favor:** The subcommittee is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

**Against:** The subcommittee is confident that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

### Weak recommendation

**In Favor:** The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

**Against:** The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

### Quality or strength of evidence rating across studies for the treatment/outcome<sup>2</sup>

**High:** The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.

**Moderate:** The subcommittee is moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical sets of studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

**Low:** The subcommittee's confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

**Very low:** The subcommittee has very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

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<sup>2</sup> Includes risk of bias, precision, directness, consistency and publication bias

## APPENDIX B. APPLICABLE CODES

CODES	DESCRIPTION
<b>ICD-9 Diagnosis Codes</b>	
415.11	Iatrogenic pulmonary embolism and infarction
415.13	Saddle embolus of pulmonary artery
415.19	Other pulmonary embolism and infarction
451.11	Phlebitis and thrombophlebitis of femoral vein (Deep) (Superficial)
451.19	Phlebitis and thrombophlebitis of other
451.81	Phlebitis and thrombophlebitis of iliac vein
453.2	Other venous embolism and thrombosis of inferior vena cava
453.40	Acute venous embolism and thrombosis of unspecified deep vessels of lower extremity
453.41	Acute venous embolism and thrombosis of deep vessels of proximal lower extremity
453.42	Acute venous embolism and thrombosis of deep vessels of distal lower extremity
453.50	Chronic venous embolism and thrombosis of unspecified deep vessels of lower extremity
453.51	Chronic venous embolism and thrombosis of deep vessels of proximal lower extremity
453.52	Chronic venous embolism and thrombosis of deep vessels of distal lower extremity
671.3x	Deep phlebothrombosis, antepartum
671.4x	Deep phlebothrombosis, postpartum
671.5x	Other phlebitis and thrombosis complicating pregnancy and the puerperium
<b>ICD-10 Diagnosis Codes</b>	
I80.10	Phlebitis and thrombophlebitis of unspecified femoral vein
I80.209	Phlebitis and thrombophlebitis of unspecified deep vessels of unspecified lower extremity
I80.219	Phlebitis and thrombophlebitis of unspecified iliac vein
I82.220	Acute embolism and thrombosis of inferior vena cava
I82.221	Chronic embolism and thrombosis of inferior vena cava
I82.3	Embolism and thrombosis of renal vein
I82.409	Acute embolism and thrombosis of unspecified deep veins of unspecified lower extremity
I82.419	Acute embolism and thrombosis of unspecified femoral vein
I82.429	Acute embolism and thrombosis of unspecified iliac vein
I82.439	Acute embolism and thrombosis of unspecified popliteal vein
I82.4Y9	Acute embolism and thrombosis of unspecified deep veins of unspecified proximal lower
I82.449	Acute embolism and thrombosis of unspecified tibial vein
I82.499	Acute embolism and thrombosis of other specified deep vein of unspecified lower extremity
I82.4Z9	Acute embolism and thrombosis of unspecified deep veins of unspecified distal lower
I82.509	Chronic embolism and thrombosis of unspecified deep veins of unspecified lower extremity
I82.599	Chronic embolism and thrombosis of other specified deep vein of unspecified lower extremity
I82.519	Chronic embolism and thrombosis of unspecified femoral vein
I82.529	Chronic embolism and thrombosis of unspecified iliac vein
I82.539	Chronic embolism and thrombosis of unspecified popliteal vein
I82.5Y9	Chronic embolism and thrombosis of unspecified deep veins of unspecified proximal lower extremity
I82.549	Chronic embolism and thrombosis of unspecified tibial vein
I82.5Z9	Chronic embolism and thrombosis of unspecified deep veins of unspecified distal lower extremity
<b>ICD-9 Volume 3 (Procedure Codes)</b>	
	None
<b>CPT Codes</b>	
37191	Insertion of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural

	roadmapping, and imaging guidance (ultrasound and fluoroscopy, when preformed.
37192	Repositioning of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy, when preformed.
37193	Retrieval (removal) of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy, when preformed.
<b>HCPCS Level II Codes</b>	
C1880	Vena cava filter

Note: Inclusion on this list does not guarantee coverage

## APPENDIX C. HERC GUIDANCE DEVELOPMENT FRAMEWORK

### HERC Guidance Development Framework Principles

This framework was developed to assist with the decision making process for the Oregon policy-making body, the HERC and its subcommittees. It is a general guide, and must be used in the context of clinical judgment. It is not possible to include all possible scenarios and factors that may influence a policy decision in a graphic format. While this framework provides a general structure, factors that may influence decisions that are not captured on the framework include but are not limited to the following:

- Estimate of the level of risk associated with the treatment, or any alternatives;
- Which alternatives the treatment should most appropriately be compared to;
- Whether there is a discrete and clear diagnosis;
- The definition of clinical significance for a particular treatment, and the expected margin of benefit compared to alternatives;
- The relative balance of benefit compared to harm;
- The degree of benefit compared to cost; e.g., if the benefit is small and the cost is large, the committee may make a decision different than the algorithm suggests;
- Specific indications and contraindications that may determine appropriateness;
- Expected values and preferences of patients.

# IVC filter in hospitalized trauma patients



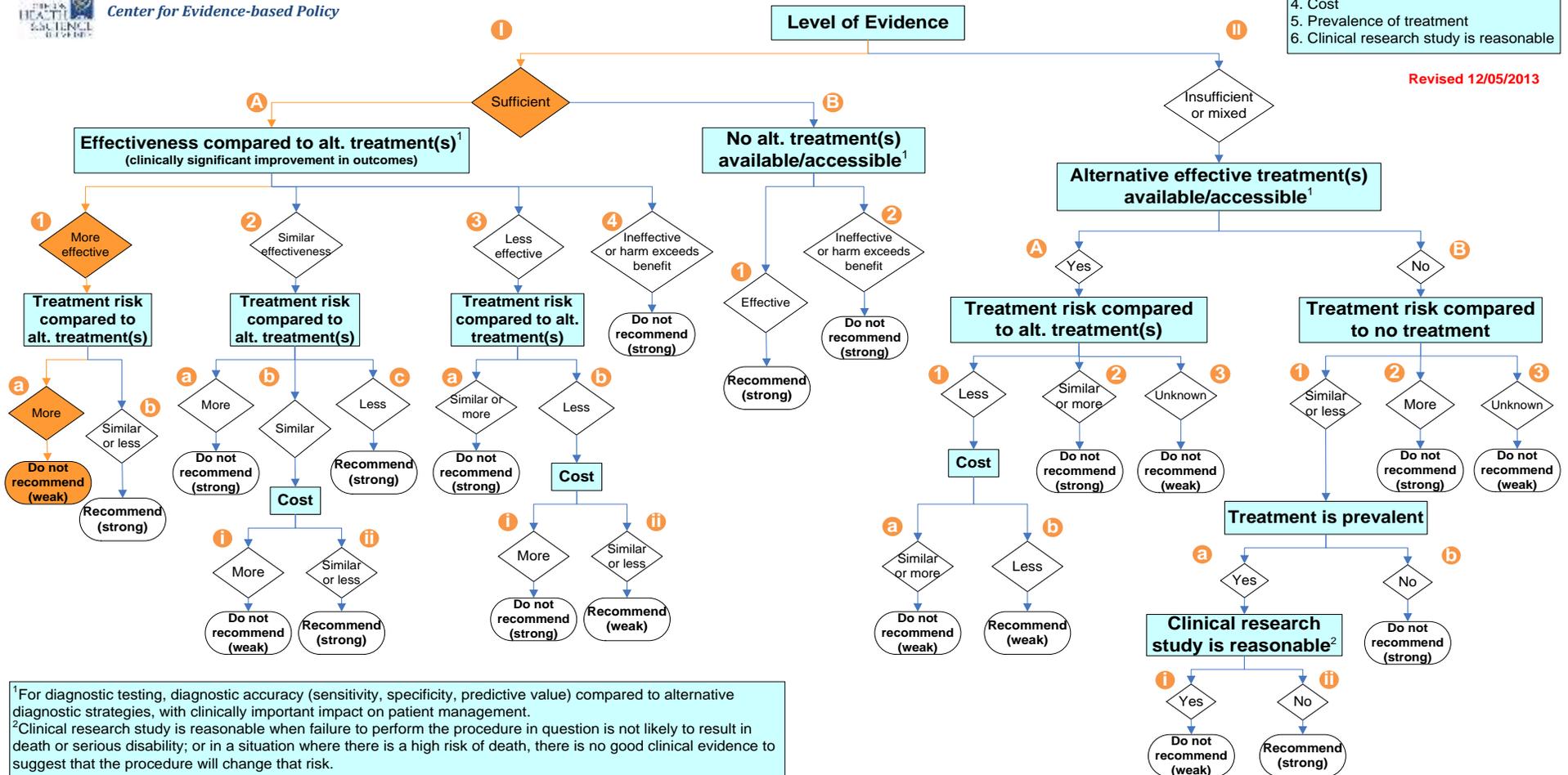
Center for Evidence-based Policy

## HERC Guidance Development Framework

Refer to *HERC Guidance Development Framework Principles* for additional considerations

- Decision Point Priorities**
1. Level of evidence
  2. Effectiveness & alternative treatments
  3. Harms and risk
  4. Cost
  5. Prevalence of treatment
  6. Clinical research study is reasonable

Revised 12/05/2013



# IVC filter in bariatric surgery patients



Center for Evidence-based Policy

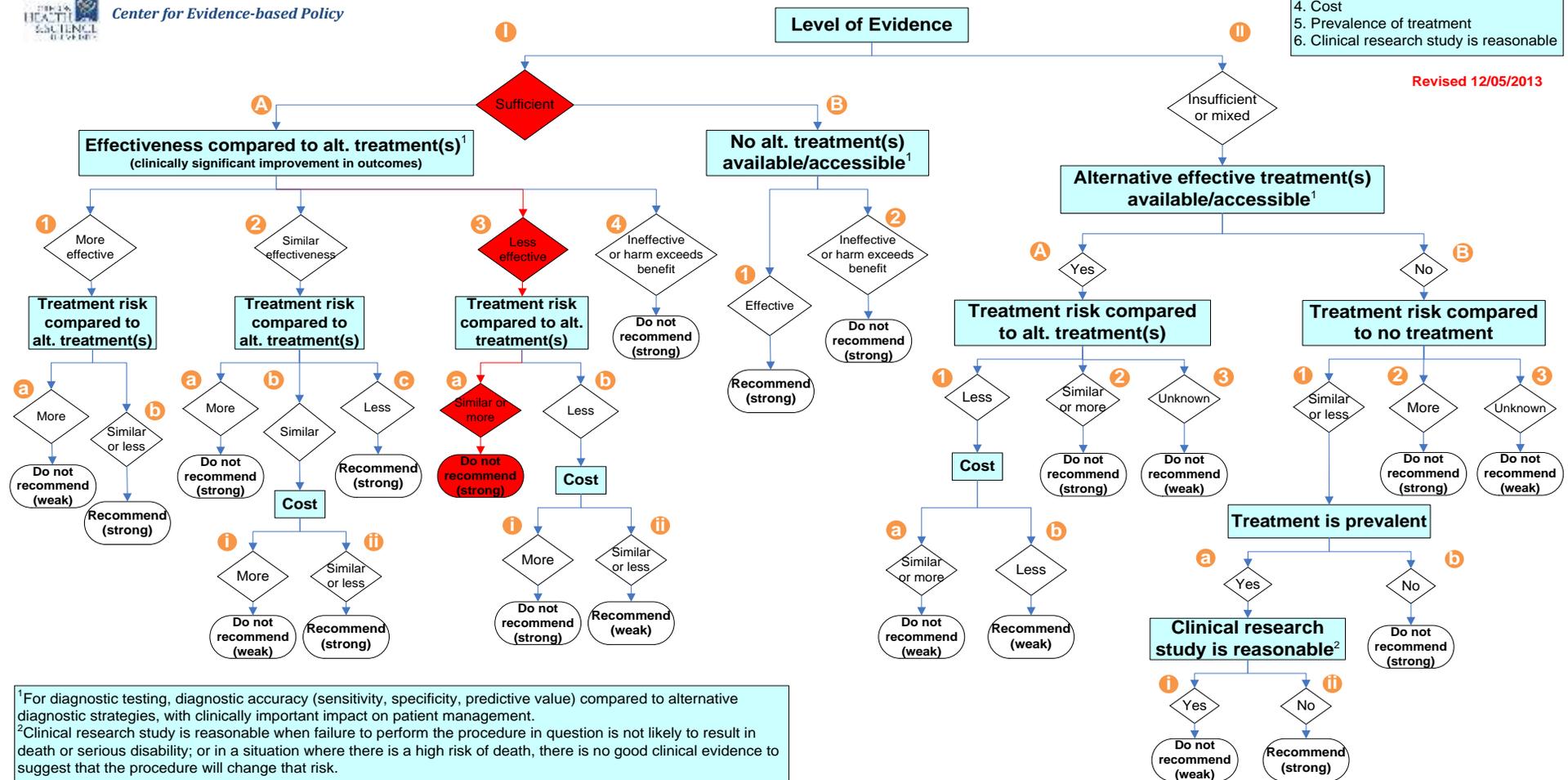
## HERC Guidance Development Framework

Refer to *HERC Guidance Development Framework Principles* for additional considerations

**Decision Point Priorities**

1. Level of evidence
2. Effectiveness & alternative treatments
3. Harms and risk
4. Cost
5. Prevalence of treatment
6. Clinical research study is reasonable

Revised 12/05/2013



# IVC filter in patients with proximal DVT who are candidates for anticoagulation

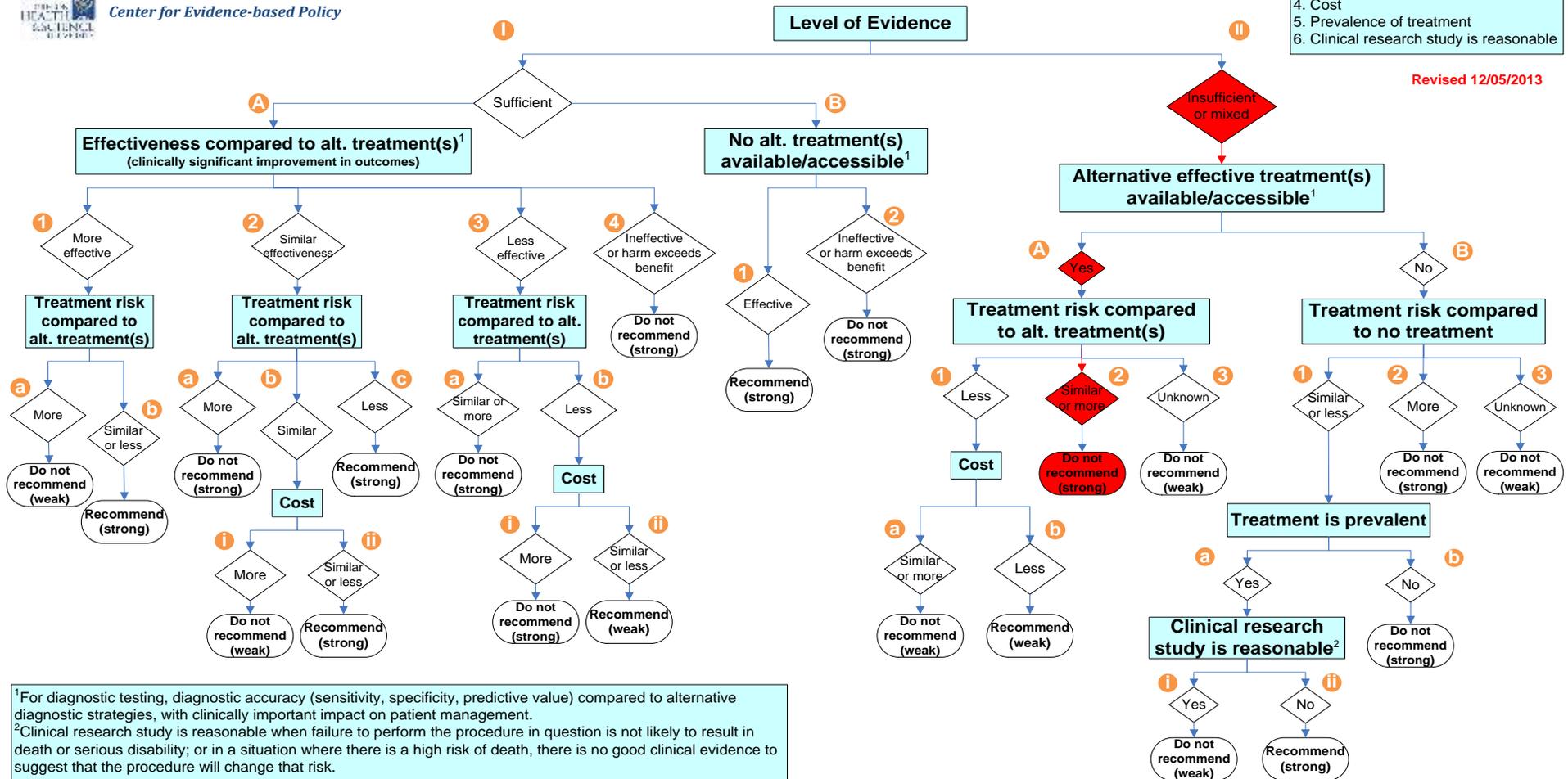


## HERC Guidance Development Framework

Refer to *HERC Guidance Development Framework Principles* for additional considerations

- Decision Point Priorities**
1. Level of evidence
  2. Effectiveness & alternative treatments
  3. Harms and risk
  4. Cost
  5. Prevalence of treatment
  6. Clinical research study is reasonable

Revised 12/05/2013



<sup>1</sup>For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.  
<sup>2</sup>Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

# IVC filter in those with proximal DVT or PE and contraindication to anticoagulation



Center for Evidence-based Policy

## HERC Guidance Development Framework

Refer to *HERC Guidance Development Framework Principles* for additional considerations

- Decision Point Priorities**
1. Level of evidence
  2. Effectiveness & alternative treatments
  3. Harms and risk
  4. Cost
  5. Prevalence of treatment
  6. Clinical research study is reasonable

Revised 12/05/2013

