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# The CMS Ruling on Venous Thromboembolism After Total Knee or Hip Arthroplasty

## Weighing Risks and Benefits

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IN AUGUST 2008, THE US CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) added deep venous thrombosis and pulmonary embolism after total knee arthroplasty (TKA) and total hip arthroplasty (THA) to the list of *never events*.<sup>1</sup> If a patient experiences deep venous thrombosis or pulmonary embolism following one of these procedures, a portion of the payment made by CMS to hospitals is to be withheld. On the surface this decision seems to be a win-win for hospitals, clinicians, and patients. Venous thromboembolism (VTE) is a common cause of preventable harm,<sup>2</sup> yet many hospitalized patients fail to receive adequate VTE prophylaxis.<sup>3</sup> Accordingly, the strategy of using financial incentives to encourage better performance should result in fewer thrombotic events and consequently less morbidity and mortality related to VTE and its treatment.

The US health care system should reward high-quality care. However, the premise that this rule will result in less VTE-associated morbidity and mortality warrants additional scrutiny. The incidence of VTE and the risks and benefits of prophylaxis vary substantially among different populations of hospitalized patients. The currently recommended VTE prophylaxis options for patients after TKA and THA include low-molecular-weight heparin, fondaparinux, or warfarin (adjusted to an international normalized ratio of 2-3) for at least 10 days and for as many as 35 days following surgery.<sup>4</sup> Recent large randomized controlled trials (RCTs) of VTE prophylaxis in patients undergoing elective TKA or THA demonstrate that as many as 2.5% of patients will develop symptomatic VTE and as many as 1.8% will develop major bleeding despite receiving optimal prophylaxis<sup>5-12</sup> (TABLE).

These data highlight an important clinical reality: VTE prophylaxis is not perfect. The most effective currently available prophylactic regimens do not prevent all thrombotic events following TKA or THA. Yet the current CMS rule appears to be based on the false premise that VTE prophylaxis prevents all thrombotic events and is risk free. Therefore, under the current CMS rule, institutions will be financially penalized for at least 1% to 2.5% of patients undergoing elective TKA or THA, despite administering evidence-based prophylaxis.

Furthermore, it is likely that these estimates of VTE and major bleeding complications significantly underestimate the fre-

quency of these events in routine clinical care because clinical trial participants are typically healthier than general orthopedic patient populations. The Table outlines the detailed exclusion criteria that were used to select participants in the most recently published double-blind RCTs of VTE prophylaxis for TKA or THA. Review of these studies suggests that it is unlikely that the results obtained in published clinical trials will be achievable in real-world clinical settings. Higher rates of VTE and major bleeding complications are more likely to occur at tertiary care academic medical centers, where high-risk patients tend to be preferentially referred. Consequently, these institutions, which often already provide a disproportionate amount of medical care to needy and uninsured patients in the United States, are likely to bear a disproportionate amount of the financial penalties related to failure to comply with the CMS VTE rule.

The CMS VTE rule may have a number of unintended deleterious clinical consequences that could cause additional harm to patients undergoing TKA and THA.

First, the rule creates a significant disincentive for clinicians and institutions to provide services to high-risk patients (eg, obese patients and patients with thrombophilia, bleeding disorders, or renal insufficiency), thus limiting health care options for a significant segment of the population. It is likely these high-risk patients will be referred to tertiary care centers, which may be a considerable distance from their homes. It is also conceivable that geographic inaccessibility may force patients to postpone or forgo surgery as a result.

Second, the rule creates disincentives to perform total knee or total hip arthroplasty. Clinicians and institutions currently serving this population may shift the focus of their practice to other areas of orthopedic surgery (eg, orthopedic spine surgery and shoulder arthroplasty). Furthermore, some medical students may be dissuaded from pursuing orthopedic surgery as a profession given concern about possible built-in financial disincentives. The ultimate result could be a reduction in patient options and quality of care.

Third, the rule establishes a perverse disincentive for clinicians to pursue clinical suspicions of a thromboembolic

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event with objective radiologic testing, potentially resulting in delayed diagnoses of VTE with its attendant morbidity and mortality.

Fourth, the rule encourages clinicians to err on the side of overly aggressive prophylactic measures, increasing the risk of harm to patients in an attempt to prevent VTE. One plau-

**Table.** VTE Prophylaxis in Patients Undergoing Total Knee Arthroplasty or Total Hip Arthroplasty<sup>a</sup>

Source	Prophylaxis Regimen	Total No. of Patients	No. With Event/ No. in Group (%)		Exclusion Criteria
			Symptomatic VTE <sup>b</sup>	Major Bleeding	
<b>Total Knee Arthroplasty</b>					
Francis et al, <sup>5</sup> 2003	Ximelagatran	1526	18/1526 (1.2)	12/1526 (0.8)	Immobilization ( $\geq 3$ days); major surgery, MI, stroke, ulcer (<1 month); intracranial, intraocular, retroperitoneal, GI, or any bleeding disorder (<3 months); substance abuse (<6 months); active cancer, childbearing potential, uncontrolled hypertension, creatinine clearance (<30 mL/min), ALT or AST ( $> 2 \times$ normal), thrombocytopenia, traumatic epidural/lumbar puncture, use of thrombolytics, anticoagulants, or antiplatelets, weight (<40 kg or >136 kg)
	Warfarin (INR 1.8-3.0)	759	10/759 (1.3)	5/759 (0.7)	
Eriksson et al, <sup>6</sup> 2007	Dabigatran	1382	5/1371 (0.4)	19/1382 (1.4)	Liver function test results ( $> 2 \times$ normal) (<1 month); intracranial disease, hemorrhagic stroke, major surgery, trauma, uncontrolled hypertension, MI (<3 months); GI or GU bleeding, ulcer (<6 months); prior TKA, any bleeding disorder, severe liver disease, creatinine clearance (<30 mL/min/1.73 m <sup>2</sup> ), long-acting NSAIDs, active cancer, childbearing potential
	Enoxaparin	694	9/685 (1.3)	3/694 (1.3)	
Colwell et al, <sup>7</sup> 2003	Ximelagatran	1151	10/1151 (0.9)	12/1151 (1.0)	Immobilization ( $\geq 3$ days); major surgery, stroke, MI, ulcer (<1 month); intracranial, intraocular, retroperitoneal, GI, or any bleeding disorder (<3 months); substance abuse (<6 months); active cancer, childbearing potential, uncontrolled hypertension, creatinine clearance (<30 mL/min/1.73 m <sup>2</sup> ), ALT or AST ( $> 2 \times$ normal), thrombocytopenia, traumatic epidural/lumbar puncture, use of thrombolytics, anticoagulants, or antiplatelets, weight (<40 kg or >136 kg)
	Warfarin (INR 2-3)	1148	20/1148 (1.7)	5/1148 (0.4)	
Lassen et al, <sup>8</sup> 2008	Rivaroxaban	1220	8/1201 (0.7)	7/1220 (0.6)	Pregnancy, breastfeeding, liver disease, active or high risk of bleeding, contraindication to enoxaparin requiring dose adjustment, use of protease inhibitors, fibrinolytics, anticoagulants
	Enoxaparin	1239	24/1217 (2.0)	6/1239 (0.5)	
<b>Total Hip Arthroplasty</b>					
Colwell et al, <sup>9</sup> 2003	Ximelagatran	906	17/782 (2.2)	7/906 (0.8)	Immobilization ( $\geq 3$ days), use of thrombolytics, anticoagulants, antiplatelets (<1 week before surgery); major surgery, stroke, MI, ulcer (<1 month); intracranial, intraocular, retroperitoneal, GI, or any bleeding disorder (<3 months); substance abuse (<6 months); uncontrolled hypertension, revision of THA, active cancer, childbearing potential, creatinine clearance (<30 mL/min/1.73 m <sup>2</sup> ), ALT or AST ( $> 3 \times$ normal), platelet count (<100 $\times 10^3/\mu\text{L}$ ), traumatic epidural/lumbar puncture, weight (<40 kg or >125 kg)
	Enoxaparin	910	15/775 (1.9)	8/910 (0.9)	
Eriksson et al, <sup>10</sup> 2007	Dabigatran	2309	21/2293 (0.9)	38/2309 (1.7)	ALT or AST ( $> 2 \times$ normal) (<1 month); major surgery, trauma, uncontrolled hypertension, MI (<3 months); GI or GU bleeding, ulcer (<6 months); creatinine clearance (<30 mL/min/1.73 m <sup>2</sup> ), long-acting NSAIDs, childbearing potential, spinal or epidural anesthesia (requiring >3 attempts), indwelling anesthetic catheter; any history of a bleeding diathesis, acute intracranial disease, hemorrhagic stroke; severe liver disease, active cancer
	Enoxaparin	1154	4/1142 (0.4)	18/1154 (1.6)	
Eriksson et al, <sup>11</sup> 2008	Rivaroxaban	2209	7/2193 (0.3)	6/2209 (0.3)	Planned bilateral THA, pregnancy, breastfeeding, active or high risk of bleeding, contraindication to enoxaparin requiring dose adjustment, liver disease, creatinine clearance (<30 mL/min/1.73 m <sup>2</sup> ), use of protease inhibitors or anticoagulants
	Enoxaparin	2224	15/2206 (0.7)	2/2224 (0.1)	
Turpie et al, <sup>12</sup> 2002	Fondaparinux	1138	29/1138 (2.5)	20/1128 (1.8)	Serum creatinine ( $> 2.0$ mg/dL), platelet count (<100 $\times 10^3/\mu\text{L}$ ), anticoagulants, antiplatelets, or fibrinolytics (<2 days); hemorrhagic stroke, eye or neurosurgery (<3 months); planned bilateral THA, active or bleeding disorder, acute bacterial endocarditis, indwelling intrathecal or epidural catheter, contraindication to anticoagulants, addictive disorders, need for chronic anticoagulation
	Enoxaparin	1137	13/797 (1.1)	11/1129 (1)	

Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; GI, gastrointestinal; GU, genitourinary; HIV, human immunodeficiency virus; INR, international normalized ratio; MI, myocardial infarction; NSAID, nonsteroidal anti-inflammatory drug; RCT, randomized controlled trial; THA, total hip arthroplasty; TKA, total knee arthroplasty; and VTE, venous thromboembolism.

<sup>a</sup>Double-blind RCTs were identified using PubMed and the search terms *knee arthroplasty, venous thromboembolism, and prophylaxis; or hip arthroplasty, venous thromboembolism and prophylaxis* with the search limits of *randomized controlled trial, English*. The 4 most recently published RCTs that recruited only TKA or THA patients were selected.

<sup>b</sup>In some studies, the number of patients evaluated for VTE may differ from the total number of patients in that treatment group because of exclusion of patients with inadequate venographic or duplex studies for VTE.

sible scenario is that clinicians may use pharmacologic VTE prophylaxis in patients at high risk for bleeding (eg, patients with thrombocytopenia or underlying bleeding disorders), resulting in increased bleeding complications.

And fifth, the currently proposed Centers for Medicare & Medicaid Services rule is too limited in scope to significantly reduce preventable episodes of VTE. Orthopedic patients only constitute 8.6% of all patients who develop hospital-associated VTE.<sup>13</sup> Therefore, the currently proposed rule will not result in substantial improvements in VTE prevention because it focuses on a small group of physicians who care for a limited number of patients at risk.

Although attempts to align payment with quality of care are appropriate, quality metrics that focus on one measure (eg, door-to-balloon time) generally provide a myopic view of quality. Quality patient care involves balancing risks and benefits. Without balancing measures of risk, a well-intended quality improvement effort can have unintended consequences. For example, as hospitals improve door-to-balloon times, the number of patients without coronary artery disease who undergo unnecessary cardiac catheterization is likely to increase.<sup>14</sup>

How might these unintended consequences be avoided? One approach is by linking the use of prophylaxis (eg, the process measure CMS is seeking to improve) with patients who develop VTE (eg, the outcome measure CMS is seeking to reduce). The Joint Commission has recommended that hospitals adopt procedures to ensure that all patients receive risk-appropriate VTE prophylaxis within 24 hours of hospital admission or within 24 hours of transfer to the intensive care unit.<sup>15</sup> Use of process measures such as these will ensure that all patients are getting evidence-based prophylaxis, not only patients undergoing TKA or THA. In addition, this approach will not unjustly penalize select clinicians and institutions or encourage approaches to VTE prophylaxis that may result in unnecessary bleeding complications. By linking patients who develop VTE with those who failed to receive prophylaxis, CMS can identify preventable VTE in the patients for whom it is just to reduce reimbursement. Alternatively or in addition, CMS can also develop a measure for preventable bleeding from VTE, although such a measure would likely be complex.

CMS should reconsider its currently proposed rule on TKA- and THA-associated VTE and should consider adopting the reasoned approach of the Joint Commission, which focuses on the correct measures for all hospitalized patients and maintains a balance between both the bleeding and thrombotic risks faced by hospitalized patients. Such an approach would be both wise and just.

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#### REFERENCES

1. Deep vein thrombosis/pulmonary embolism. *Fed Regist*. 2008;73(161):48480-48482. <http://edocket.access.gpo.gov/2008/pdf/E8-17914.pdf>. Accessed February 13, 2009.
2. Cohen AT, Agnelli G, Anderson FA, et al; VTE Impact Assessment Group in Europe (VITAE). Venous thromboembolism (VTE) in Europe: the number of VTE events and associated morbidity and mortality. *Thromb Haemost*. 2007;98(4):756-764.
3. Cohen AT, Tapson VF, Bergmann JF, et al; ENDORSE Investigators. Venous thromboembolism risk and prophylaxis in the acute hospital care setting (ENDORSE study): a multinational cross-sectional study. *Lancet*. 2008;371(9610):387-394.
4. Geerts WH, Bergqvist D, Pineo GF, et al; American College of Chest Physicians. Prevention of venous thromboembolism: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th edition). *Chest*. 2008;133(6)(suppl):381S-453S.
5. Francis CW, Berkowitz SD, Comp PC, et al; EXULT A Study Group. Comparison of ximelagatran with warfarin for the prevention of venous thromboembolism after total knee replacement. *N Engl J Med*. 2003;349(18):1703-1712.
6. Eriksson BI, Dahl OE, Rosencher N, et al; RE-MODEL Study Group. Oral dabigatran etexilate vs subcutaneous enoxaparin for the prevention of venous thromboembolism after total knee replacement: the RE-MODEL randomized trial. *J Thromb Haemost*. 2007;5(11):2178-2185.
7. Colwell CW Jr, Berkowitz SD, Lieberman JR, et al; EXULT B Study Group. Oral direct thrombin inhibitor ximelagatran compared with warfarin for prevention of venous thromboembolism after total knee arthroplasty. *J Bone Joint Surg Am*. 2005;87(10):2169-2177.
8. Lassen MR, Ageno W, Borris LC, et al; RECORD3 Investigators. Rivaroxaban versus enoxaparin for thromboprophylaxis after total knee arthroplasty. *N Engl J Med*. 2008;358(26):2776-2786.
9. Colwell CW Jr, Berkowitz SD, Davidson BL, et al. Comparison of ximelagatran, an oral direct thrombin inhibitor, with enoxaparin for the prevention of venous thromboembolism following total hip replacement: a randomized, double-blind study. *J Thromb Haemost*. 2003;1(10):2119-2130.
10. Eriksson BI, Dahl OE, Rosencher N, et al; RE-NOVATE Study Group. Dabigatran etexilate versus enoxaparin for prevention of venous thromboembolism after total hip replacement: a randomised, double-blind, non-inferiority trial. *Lancet*. 2007;370(9591):949-956.
11. Eriksson BI, Borris LC, Friedman RJ, et al; RECORD1 Study Group. Rivaroxaban versus enoxaparin for thromboprophylaxis after hip arthroplasty. *N Engl J Med*. 2008;358(26):2765-2775.
12. Turpie AG, Bauer KA, Eriksson BI, Lassen MR; PENTATHALON 2000 Study Steering Committee. Postoperative fondaparinux versus postoperative enoxaparin for prevention of venous thromboembolism after elective hip-replacement surgery: a randomised double-blind trial. *Lancet*. 2002;359(9319):1721-1726.
13. Goldhaber SZ, Dunn K, MacDougall RC. New onset of venous thromboembolism among hospitalized patients at Brigham and Women's Hospital is caused more often by prophylaxis failure than by withholding treatment. *Chest*. 2000;118(6):1680-1684.
14. Larson DM, Menssen KM, Sharkey SW, et al. "False-positive" cardiac catheterization laboratory activation among patients with suspected ST-segment elevation myocardial infarction. *JAMA*. 2007;298(23):2754-2760.
15. Michota FA. Bridging the gap between evidence and practice in venous thromboembolism prophylaxis: the quality improvement process. *J Ger Intern Med*. 2007;22(12):1762-1770.