Texas Association for Clinical Laboratory Science **May 2003**

TACLS News

Congress Set to Mandate 20% Medicare Co-pay

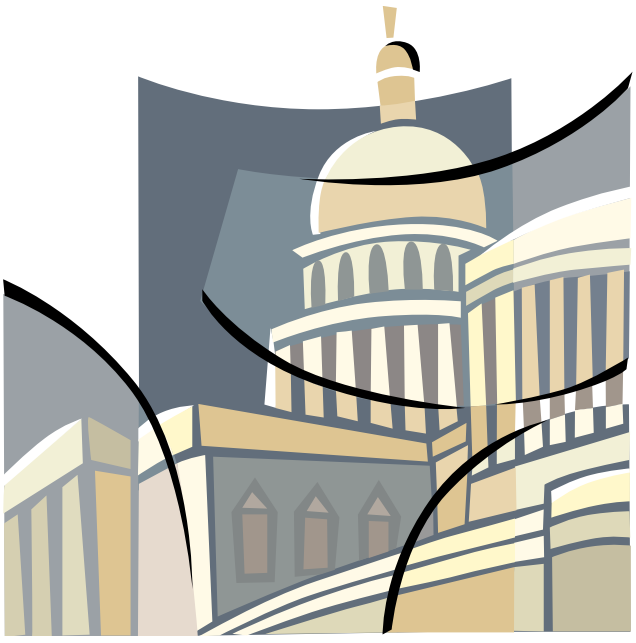
John Wentz

The issue of co-payments for laboratory services seems to surface every other year in Congress, but this time the timing may be right for passage of this misguided portion of Medicare reform. Senate bill S.1054 the "Job and Economic Growth Reconciliation Act" includes a provision that mandates a 20% copayment for Medicare laboratory services. Passage of this legislation will mean Medicare recipients will pay an additional $13.4 billion and clinical laboratories themselves will bear an even greater burden over ten years.

Under CMS rules, laboratories cannot simply decide to absorb the cost of these copayments, they must bill recipients of services. For a $35 billable test this means trying to collect $7 from the patient. Cost shifting is the operative term here. Before ASCLS and ten other laboratory groups formed the Clinical Laboratory Coalition (CLC), clinical labs were passive targets when Congress needed to fund something related to health care. Now (today) is the time to get on the Internet and let your Congressional representative and Senators Hutchison and Cornyn know that you are part of the CLC, and ask them to not support the provision in S.1054 "Application of Coinsurance and Deductible for Clinical Diagnostic Laboratory Tests."

Since they have first-hand knowledge of the problems with a 20% co-pay, laboratory managers and directors should definitely contact their representatives. You can find your congressperson's own web page at www.house.gov and your senator's web page at www.senate.gov . Click on "How to Contact", or "Contact", and you will be able to send an email message or fax a letter directly to their Washington D.C. office. For a sample message see page 2.

Regular mail to Congress can take weeks or months to reach the member since the terrorist attacks, so don't bother with regular posted letters. So if someone asks you "why should they become a member of their professional society?" Here's another reason.



Congress Set to Mandate 20% Medicare Co-pay

DRAFT E-MAIL FOR YOUR REPRESENTATIVE OR SENATOR

Dear Representative/Senator :

I am writing today to urge your opposition of the *Application of Coinsurance and Deductible for Clinical Diagnostic Laboratory Tests* provision in S. 1054, the "Job and Economic Growth Reconciliation Act."

The effect of this provision is an immediate 20 percent reduction to each Medicare beneficiary's entitlement, at a time when seniors across the country are faced with increasing health care costs. This provision imposes a 20 percent out-of-pocket co-payment and deductible requirement for lab tests that will create a serious impediment to access to quality health care for seniors who rely on Medicare, by discouraging seniors from seeking vital tests their physicians order.

The clinical diagnostic laboratory provision will translate into a $13.4 billion cost shift to seniors over the next ten years. Moreover, payments to clinical diagnostic laboratories will sustain an immediate 20 percent reduction in Medicare payments as laboratories are forced to spend more of their resources collecting co-payments from beneficiaries who have less to spend on health care costs. In many instances the cost of collecting the co-payments will cost more than the actual beneficiary cost which providers are required under law to pursue.

A 2000 Institute of Medicine (IOM) report on Medicare laboratory payment policy requested by Congress, recommends against beneficiary cost-sharing: The IOM report recommends that the current policy of not requiring beneficiary cost-sharing for Medicare outpatient clinical laboratory services should continue. Cost-sharing is unlikely to significantly reduce overuse or increase the detection of fraud and abuse; it could create barriers to access for the most vulnerable Medicare beneficiaries; and it would be financially and administratively burdensome for laboratories, patients, and the Medicare program depending on its design.

The clinical diagnostic laboratory offset provision will be devastating to beneficiaries and to community laboratories across this country. While there are many positive provisions included in S. 1054, the Medicare offsets such as the one proposed for clinical diagnostic laboratories be removed from this legislation.

Sincerely,

Your name, job title, and address

ASCLS Annual Meeting

Shirlyn B. McKenzie, Ph.D., Region VII Director

What a deal! The full registration for the ASCLS meeting in Philadelphia (July22-26) is only $275 if you register by June 4. That includes all scientific sessions, governance, two social events (both with food), a box lunch on Friday, newcomers' reception, and unlimited admission to the largest laboratory exhibit in the world. . In addition, there will be joint sessions with AACC. The intangible benefits are unlimited but the one I find the most valuable is the networking. You will meet people from all over the world with interests similar to yours. You can obtain almost all your CE PACE credits for NCA renewal at this meeting. You will be up to date on the cutting edge of what is happening in the clinical laboratory science world.

The social events include a welcome reception on Wednesday evening. This is always popular and fun. There is food, music and a silent auction. If you've never been to a silent auction, you need to attend this one. There are items from each state donated by members and state societies. The proceeds benefit the Education and Research Fund. This fund awards scholarships and grants for research that benefits our professions. On Thursday evening there is the TnT social. This event is sponsored by the Texas and Tennessee Societies. It is reminiscent of the previous Texas Tea. There is country-western music with lots of line dancing, as well as an assortment of other music. There is something to satisfy almost everyone.

I promise that if you attend this meeting, you will feel energized and renewed.

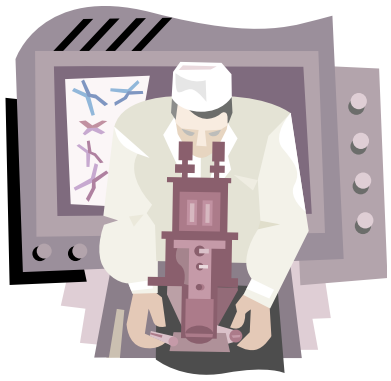
My hope is that you will attend and pass on this positive energy to those you work with. Talk to your employer and see if they will help with your expenses or at least pay you for the time you are gone. Make a deal to

share the information you bring back with your coworkers so they can benefit from your attendance too. One recent CLS graduate in San Antonio (lowest seniority of the group) asked to go to the meeting and was fully paid to go because she was the only one who asked and wanted to go. Many individuals come early or leave later so they can vacation in the area. Of course, Philadelphia is a city with much historical significance so it would be a great place to sightsee. If you need a roommate, contact one of your state's Board members or me and we will help you find a compatible roomie. Hope to see you in Philly!

ASCLS Governance Meetings

The following table shows the governance sessions that State Presidents, President-elects and delegates should attend. Anyone else who is interested may also attend the Board of Directors meeting (good way to find out about the issues) and committee meetings. Everyone should attend a Scientific Assembly meeting of their choice on Friday at 12:30 pm. Lunch is provided free to those who indicate they will attend this session on their registration form. Early registration ends on June 4. All the times during which delegates to the House of Delegates can be credentialed are listed. Once you are credentialed you can ignore all the other credentialing dates/times. You must be credentialed by Friday to vote. All delegates need to vote.

Date	Time	Session	President	President-Elect	Delegates
7/22, Tuesday	8:30am-noon	ASCLS Board of Directors	X	X	X
	12-1 pm	Credentials	X	X	X
	2:45-4:15 pm	Presidents' seminar	X		
	4:30-6:00 pm	Credentials	X	X	X
7/23, Wednesday	4-5:15 pm	Credentials	X	X	X
	5:45-7:45 pm	President's Council & Issues	X	X	X
7/24, Thursday	8:30-10:30 am	Leadership development	X	X	X
	10:30am-noon	Meet the Candidates	X	X	X
	10;30-11:30 AM	Credentials	X	X	X
	1:30-4:45 pm	President-elect seminar		X	
	3:15-4:45	Membership development	X		X
7/25, Friday	7:30-8:45am	Region VII caucus	X	X	X
	11-11:45 am	Credentials	X	X	X
	12:15-12:45PM	Elections	X	X	X
7/26, Saturday	9-9:30 am	Credentials	X	X	X
	10-12:30	House of Delegates	X	X	X



Case Study

Wendy Sivilay, CLS Student, Southwest Texas State University

The patient was a 66 year old male who was admitted with a diagnosis of deep vein thrombosis.

Laboratory Results: On day of admission

Complete Metabolic Profile: Unremarkable, except for Decreased sodium and chloride and Low ALT.

CBC:	Result	Reference range
WBC	**12.5**	4.8-10.8 x10^3/uL
RBC	4.6	4.7-6.1 x10^3/uL
Hemoglobin	14.0	14.0-18.0 g/dL
Hematocrit	41.6	42.0-52.0 %

Red cell indices, platelet count, and WBC differential were normal.

D-dimer	**>1000**	0-500 ng/mL
aPTT	34.6	25.6-33.2 seconds

Coagulation Tests: run every day during the patient's stay.

Day	aPTT	PT/INR
1	34.6	14.5/1.39
2	49.4	14.1/1.31
	45.2	
	45.3	13.7/1.14
3	50.3	
4	47.9	13.3/1.14
	49.9	
	54.0	13.4/1.16
5	57.6	13.4/1.16
6	50.5	13.6/1.21
7	50.8	13.5/1.19

Questions

1. What is deep vein thrombosis and what complications can it lead to?

2. What are the causes/risk factors involved with DVT?

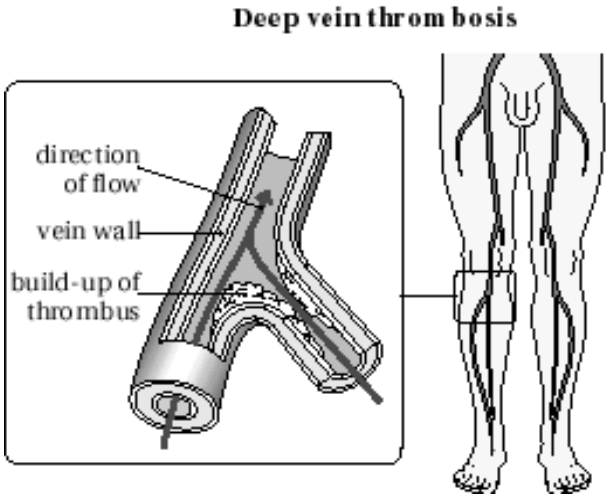
3. What are some of the symptoms of DVT? How is it diagnosed?

4. How is DVT treated?

What is deep vein thrombosis (DVT) and what complication can it lead to?

"Deep vein thrombosis is the formation of an obstructing blood clot in the deep veins of the muscle, usually in the lower leg and sometimes abdomen or groin." [6] It is a common complication among hospital inpatients and contributes to longer hospital stay, morbidity, and mortality."[11] In the United States, it affects about 500,000 people annually.[7]

Figure 1



British United Provident Association Limited

First of all, DVT can cause permanent damage to the affected vein.[6] The most serious complication, however, is the development of a pulmonary embolism. This occurs when the clot, or part of the clot, breaks off the endothelium of the blood vessel and travels to the lungs. This is a potentially fatal condition. "1-5% of patients with DVT will develop fatal pulmonary embolism."[11] Deep vein thrombosis and pulmonary embolism is sometimes seen as part of the same disease process and is termed collectively as venous thromboembolism."[2,10] Lastly, the patient might experience tissue

necrosis due to decreased blood flow; however, this is rare.[11]

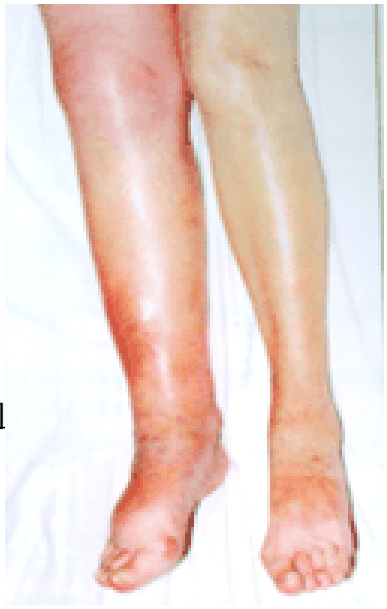
What are the causes/risk factors involved with DVT?

Anything that can cause abnormalities in blood flow or venous stasis can potentially cause DVT; it is also believed to be partially due to heredity.[6] Injury to blood vessels, infection, diseases, such as SLE, and malignancy can increase the risk for DVT. Congenital disorders can lead to DVT, and should be ruled out in recurrent incidents. Patients with Factor V Leiden, one such disorder, have an increased risk for developing DVT. "Heterozygosity increases risk to 0.6% compared to the risk of 0.16% in the general population."[1] Prolonged inactivity and bed rest can also play a part in DVT development. Airplane travel has been implicated in DVT. It is sometimes referred to as the "economy-class syndrome" because of the smaller leg space available in economy class promotes greater immobility.[8] Other risk factors include: smoking, obesity, oral contraceptive use, pregnancy, high blood pressure, and age greater than forty.[5,6,11,12]

What are some of the symptoms of DVT? How is it diagnosed?

There are often no symptoms of DVT; in fact, "only about one-half of patients with DVT show any symptoms."[6] In those cases, it is not diagnosed until the patient shows symptoms of pulmonary embolism, which include: rapid heart rate, shortness of breath, chest pain, blood-tinged coughing.[6] If symptoms of DVT do present themselves, the patient could experience pain, redness, swelling, and tenderness in the affected area, and sometimes have a fever.[12] Figure #2 shows a patient with right ileofemoral deep vein thrombosis. The patient's right leg is noticeably swollen and red.

Figure 2 [12]



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Diagnosis includes getting the patient's medical history; if the patient has already had an occurrence of DVT, they are more likely to develop it again.[9] If the clinician suspects DVT, then "compression ultrasound is the non-invasive tool of choice."[11] The procedure is about 95% percent accurate in detecting blockage of the vein.[6] Other options in diagnosis include the venogram, plesthysmogram, and MRI. The venogram is the "gold standard" but, unlike the compression ultrasound, it is an invasive procedure. The plethysmogram is less precise than the venogram; it is sometimes useful in diagnosing DVT in pregnant women.

The D-dimer test measures the amount of cross-linked fibrin fragments that have be created through the actions of plasmin. There are two methods used to measure the D-dimer: latex agglutination and ELISA. ELISA is more sensitive than latex agglutination, with a sensitivity of 90%.[7] It also has a negative predictive value of 90%, so if a patient has a negative result and a negative ultrasound, DVT can be ruled out. D-dimers are not normally

used alone in diagnosis, but in conjunction with ultrasound.[2] This patient had a value >1000 ng/mL, which is greater than the reference range of 0-500ng/mL. The method used to detect this was ELISA and the instrument used only measured up to 1000 ng/mL, so any value over 1000 is not quantitated but given the value >1000.

How is DVT treated?

Therapy is primarily aimed at anticoagulating the patient initially using concurrent doses of heparin and warfarin. Heparin binds to antithrombin III, increasing its activity, and thereby inhibiting Factor Xa. Two kinds of heparin may be used: unfractionated and low-molecular-weight (LMWH). Unfractionated heparin is given intravenously and needs to be monitored closely.[5] If unfractionated heparin is used it is recommended that the patient's aPTT be checked every 6 hours during the first twenty-four hours of administration and daily thereafter.[12] Low-molecular-weight heparin can be given as an injection, and it does not require monitoring as does unfractionated heparin.

The anticoagulant effects of warfarin take longer to be seen than heparin, usually about 5-7 days. Warfarin affects the recycling of the vitamin K-dependent factors: II, VII, IX, and X, thereby causing the production of defective factors.[5] It is monitored by the PT/INR. Due to the variability of the thromboplastin reagents, the International Normalized Ratio (INR) is the more important value than the PT result.[5,12] The INR target value for a patient taking warfarin is 2-3; once this value is reached, heparin therapy can be discontinued.[5] Warfarin is continued for at least another three months. This treatment method can be suspected in the patient because of the number and patterns of coagulation tests, PT and aPTT, he had while in the hospital.

Drugs are also available to help speed up the breakdown of the clot. Streptokinase and urokinase act by directly converting plasminogen to plasmin.[5] In some situations, it is necessary to insert a vena cava filter that traps the clot preventing it from traveling in the bloodstream.[12] This is an invasive procedure, and therefore only reserved for those patients in whom anticoagulation is contraindicated.[12]

Prevention:

Prevention of DVT involves eliminating any possible risk factors. Maintaining a healthy body weight, avoiding smoking, and regular exercise to promote good circulation are three of the risk factors that are within the patient's control. If bedridden, daily exercises should be used to improve circulation.[6] For at risk patients going in to surgery, prophylactic use of anticoagulants might be deemed beneficial, and compression stockings worn afterward may also help to protect the patient from developing DVT. A new study proposes that there is a possible benefit to long-term use of a low dose warfarin; it was shown to help reduce the risk of recurrent DVT between 76% and 81%.[9] Reducing the risks of causing any abnormalities in blood flow can reduce the patient's risk of developing deep vein thrombosis.

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