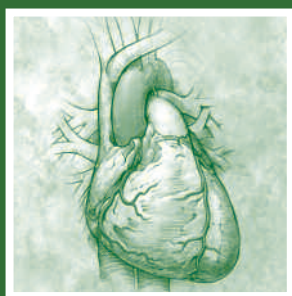


Advances in Anticoagulation

A Clinical Update for the Pharmacist

Part 1: New Insights into the Recognition and Management of Venous Thromboembolism



Part 2: New Insights into the Recognition and Management of Heparin-induced Thrombocytopenia



This program will be available from November 1, 2006 through November 1, 2007.

Sponsor:

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Intended Audience:

The activity was developed for pharmacists in clinical practice. It is certified for pharmacists. Please see inside for complete accreditation information.

This program is supported by an educational grant from GlaxoSmithKline.

Workbook

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Advances in Anticoagulation

A Clinical Update for the Pharmacist

Overview

Venous thromboembolism (VTE) is a highly prevalent disorder that is often asymptomatic and underdiagnosed. Both of its forms, deep vein thrombosis (DVT) and pulmonary embolism (PE), can manifest themselves through a number of medical conditions. Unfortunately, DVT and PE have been associated with preventable morbidity and mortality due to missed opportunities for prophylaxis, diagnosis, and treatment. Knowing when and how to implement aggressive anticoagulation therapy is vital to improving patient care. Conventional antithrombotic agents of the last few decades such as unfractionated heparin (UFH) and warfarin may no longer be the agents of choice for some patients, as low molecular weight heparins (LMWH), factor Xa inhibitors, and direct thrombin inhibitors have emerged as important treatment alternatives. Proper selection and utilization of anticoagulants are paramount to achieving better outcomes.

An important consideration in the management of VTE is an awareness of treatment complications, including heparin-induced thrombocytopenia (HIT). HIT is a potentially life-threatening complication of heparin therapy that occurs 4 to 14 days following heparin initiation. HIT may develop within 24 hours in patients with a history of recent heparin exposure. HIT can result in devastating thrombotic complications including acute thrombotic stroke, myocardial infarction, pulmonary embolism, and arterial limb occlusion requiring amputation. Although HIT is usually recognized by a characteristic drop in platelet count, new insights into the recognition of HIT have been gained over the past few years. Because heparin is prescribed in a variety of patient populations, clinicians should be able to recognize the atypical presentations of HIT. Early diagnosis, heparin cessation, and prompt initiation of appropriate alternative anticoagulants should assist in achieving optimal patient outcomes.

Part 1 of this program will discuss the epidemiology, risk factors, and clinical presentation of DVT and PE. Treatment options and guidelines will be reviewed in the context of recent clinical data. Part 2 will describe new insights into the clinical presentation of HIT, and provide recommendations for optimizing outcomes in HIT patients. Clinical trial data on the direct thrombin inhibitors will be reviewed and new therapeutic options will be discussed.

Part 1: New Insights into the Recognition and Management of Venous Thromboembolism

Part 2: New Insights into the Recognition and Management of Heparin-induced Thrombocytopenia

Educational Objectives

Following both parts of this audioconference, participants should be able to:

1. Cite the epidemiology, risk factors, and clinical presentation of deep vein thrombosis (DVT) and pulmonary embolism (PE).
 2. Identify current treatment options for the management of DVT and PE, and differentiate their potential benefits and limitations.
 3. Describe new insights into the clinical presentation of heparin-induced thrombocytopenia (HIT) and key recommendations for its management.
 4. Compare and contrast clinical trial data on HIT treatment agents and identify new therapies on the horizon.
-

Speakers

Robert Hallisey, MS Pharm, RPh, is a Drug Therapy Clinical Coordinator in the Department of Pharmacy at Massachusetts General Hospital, Boston, Massachusetts. He is also a Clinical Pharmacist for the International Medical-Surgical Response Team, Rockville, Maryland, and Assistant Professor of Pharmacy Practice (Massachusetts College of Pharmacy and Health Sciences), Clinical Pharmacy (Northeastern University), and Pharmacology (MGH Institute of Health Professions) in Boston, Massachusetts.

Mr. Hallisey received his Master of Science degree in hospital pharmacy administration and Bachelor of Science degree in pharmacy at the Massachusetts College of Pharmacy and Allied Health Sciences, Boston, Massachusetts.

Mr. Hallisey is also a member of the Massachusetts Society of Health Systems Pharmacists, the Massachusetts State Pharmaceutical Association, the American Society of Health Systems Pharmacists, and the American Pharmaceutical Association.

Faculty Disclosure:

Mr. Hallisey has made the following disclosure:

Advisory Board	Genentech, Cardinal Health
Consultant, Speaker	GlaxoSmithKline, OrthoBiotech

Mr. Hallisey's discussion will include the investigational use of fondaparinux.

Name: Robert Hallisey, MS Pharm, RPh **Date:** 2/27/2006

Maureen A. Smythe, PharmD, BCPS, FCCP, is a Professor of Pharmacy Practice at the Eugene Applebaum College of Pharmacy and Health Sciences, Wayne State University, Detroit, Michigan. She also holds a cross-appointment with the Department of Pharmaceutical Services at William Beaumont Hospital, Royal Oak, Michigan. She received her doctorate of pharmacy degree at Wayne State University and completed a critical care fellowship at Henry Ford Hospital, Detroit, Michigan.

Dr. Smythe teaches several pharmacy courses at Wayne State University including didactic as well as clinical clerkships. She is well published and has delivered presentations on both national and international levels.

Dr. Smythe is a Board Certified Pharmacotherapy Specialist (BCPS). She is a Fellow of the American College of Clinical Pharmacy and a member of the Society of Critical Care Medicine. Dr. Smythe is a reviewer for *Annals of Pharmacotherapy*, *Pharmacotherapy*, and *Critical Care Medicine*, and an abstract reviewer for *American College of Clinical Pharmacotherapy*. She serves as a member of the editorial board for *Annals of Pharmacotherapy*.

Faculty Disclosure:

Dr. Smythe has made the following disclosure:

Advisory Board	GlaxoSmithKline
Consultant, Speaker	The Medicines Company

Dr. Smythe's discussion will include the investigational use of bivalirudin and fondaparinux.

Name: Maureen A. Smythe, PharmD, BCPS, FCCP **Date:** 2/13/2006

Educational Objectives

- Review the epidemiology, risk factors, and clinical presentation of venous thromboembolism (VTE)
- Compare data from recent clinical trials of agents used to prevent and treat deep vein thrombosis (DVT) and pulmonary embolism (PE)
- Describe the potential benefits and limitations of current treatment options for DVT

Notes

Slide 1

Venous Thromboembolic Disease (VTE)

- Venous thrombus formation with or without subsequent intravascular migration
 - DVT
 - PE
- Complications
 - Acute
 - Recurrent VTE
 - Limb loss
 - Death
 - Long term
 - Recurrent VTE
 - Post-thrombotic syndrome
 - Pulmonary hypertension

Notes

Slide 2

Colman RW, et al., eds. *Hemostasis and Thrombosis. Basic Principles and Clinical Practice*. 3rd ed. Philadelphia, PA: Lippincott Williams & Wilkins;1994:1275; Cohen AT, et al. *Thromb Haemost*. 2001;85:940-941.

VTE: Lower Extremity Sites

- Calf
 - Lower risk for PE
 - 20% propagate proximally
- Proximal (popliteal, femoral, or iliac)
 - Approximately 60% embolize to the lungs if untreated
- Asymptomatic VTE
 - Important proxy for symptomatic DVT and PE
 - Significant correlation between asymptomatic and symptomatic events

Colman RW, et al., eds. *Hemostasis and Thrombosis. Basic Principles and Clinical Practice*. 3rd ed. Philadelphia, PA: Lippincott Williams & Wilkins;1994:1275; Cohen AT, et al. *Thromb Haemost.* 2001;85:940-941.

Notes

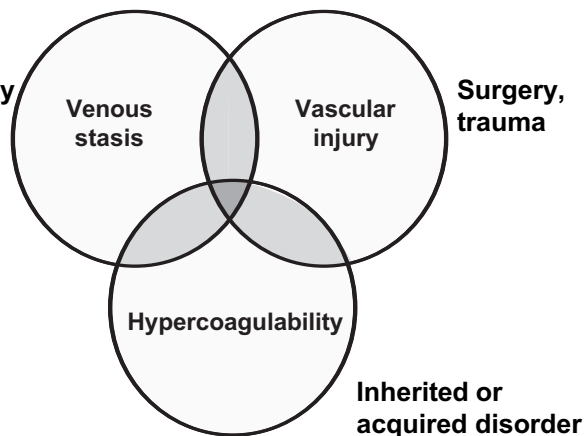
Slide 5

Pathogenesis of VTE: Virchow's Triad



Rudolf Virchow
1821–1902

Obesity,
immobility



Notes

Hirsh J, Hoak J. *Circulation.* 1996;93:2212-2245.

Slide 6

Groups at Risk for VTE

Stasis

- Age-related venous insufficiency
- Immobility (surgery, travel)
- Congestive heart failure
- Stroke
- Spinal cord injury/paralysis
- Polycythemia (hyperviscosity)
- Severe pulmonary disease
- Obesity

Hypercoagulable

- Cancer
- High estrogen states
- Inflammatory bowel
- Nephrotic syndrome
- Sepsis
- Thrombophilia

Endothelial damage

- Surgery
- Prior DVT
- Central lines
- Trauma

THRIFT Consensus Group. *Br Med J.* 1992;305:567-574.

Notes

Slide 7

Risk Factors for VTE: Hypercoagulability

- Inherited
 - Factor V Leiden (activated protein C resistance)
 - Prothrombin G20210A mutation
 - Deficiencies of
 - Antithrombin III
 - Protein C
 - Protein S
- Acquired or unknown
 - Antiphospholipid antibody syndrome
 - Elevated homocysteine levels
 - Elevated factor VIII levels

Haas S. *Semin Thromb Hemost.* 2003;29:17-21.

Notes

Slide 8

APOLLO: Efficacy and Safety Endpoints

Primary Efficacy Endpoint

- Incidence of VTE recorded up to day 10, determined by any of these VTE outcomes up to first venogram or day 10 (whichever came first)
 - Adjudicated mandatory venogram positive for DVT between day 5 and day 10
 - Adjudicated symptomatic DVT/PE

Primary Safety Endpoint

- Major bleeding during the treatment period (first injection to 2 days after last injection)
- Major bleeding up to day 32

Turpie AGG, et al. ASH 2005;106. Abstract 279.

Slide 25

Notes

Secondary Efficacy and Safety Endpoints

Secondary Efficacy Endpoint

- Incidence of any DVT, symptomatic VTE, any VTE, and all deaths up to day 10
- Incidence of adjudicated symptomatic VTE or VTE and all deaths recorded up to day 32

Secondary Safety Endpoint

- Minor bleeding during the treatment period and up to day 32
- All adjudicated (major and minor) bleeding, adverse event, transfusion need and total blood units transfused, changes from baseline parameters and deaths

Turpie AGG, et al. ASH 2005;106. Abstract 279.

Slide 26

Notes

VTE Prevention: Medical Patients

MEDENOX, 1999

- Age ≥ 40 years, expected hospital stay ≥ 6 days

and

- CHF (NYHA III/IV)
- Acute respiratory illness
- Infection or bone/joint or inflamed bowel
- Plus 1 risk factor

PREVENT, 2003

- Age ≥ 40 years, expected hospital stay ≥ 6 days

and

- CHF (NYHA III/IV)
- Acute respiratory failure
- Acute severe systemic disease
- Plus 1 risk factor

ARTEMIS, 2003

- Age ≥ 60 years, expected hospital stay ≥ 4 days

and

- CHF (NYHA III/IV)
- Acute or chronic lung disease
- Acute infectious or inflammatory disease
- No other risk factor analysis required

Samama MM, et al. *N Engl J Med.* 1999;341:793-800; Ridker PM, et al. *N Engl J Med.* 2003;348:1425-1434; Cohen AT, et al. *BMJ.* 2006;332:325-329.

Slide 29

Notes

Primary Efficacy and Safety Endpoints

MEDENOX, 1999

Efficacy

- Distal and proximal venographic DVT
- + Symptomatic VTE
- + Fatal PE

Safety

- Major bleeding
- Death at day 90

PREVENT, 2003

Efficacy

- Ultrasonographic proximal DVT
- + Symptomatic VTE
- + Fatal PE

Safety

- Major bleeding
- Death at day 90

ARTEMIS, 2003

Efficacy

- Distal and proximal venographic DVT
- + Symptomatic VTE
- + Fatal PE

Safety

- Major bleeding
- Death at day 30

Samama MM, et al. *N Engl J Med.* 1999;341:793-800; Ridker PM, et al. *N Engl J Med.* 2003;348:1425-1434; Cohen AT, et al. *J Thromb Haemost.* 2003;1(suppl 1):P2046.

Slide 30

Notes

ACCP VTE Prophylaxis Recommendations

Indication	Recommendation	ACCP Grade of Recommendation*
Medically ill	LMWH	1A
	UFH 5000 U SC (q12h vs q8h?)	1A
Total hip	LMWH	1A
	Fondaparinux	1A
	Warfarin INR 2-3	1A
Total hip (extended)	LMWH	1A
	Warfarin INR 2-3	1A
	Fondaparinux	1C+
Total knee	LMWH	1A
	Fondaparinux	1A
	Warfarin INR 2-3	1A
Hip fracture	Fondaparinux	1A
	LMWH	1C+
	Warfarin INR 2-3	2B
Hip fracture (extended)	Fondaparinux	1A
	LMWH	1C+
	Warfarin INR 2-3	1C+
Higher risk general surgery	LMWH	1A
	UFH 5000 U SC q8h	1A
Trauma	LMWH	1A
Abdominal surgery	LMWH	1A
	UFH 5000 U SC q8-12	1A

*From the Seventh American College of Chest Physicians Conference on Antithrombotic and Thrombolytic Therapy: Evidence-based Guidelines; Geerts WH, et al. *Chest*. 2004;126:338S-400S.

Notes

Slide 35

VTE Treatment

Notes

Slide 36

Objectives

- Discuss new insights into the clinical presentation of HIT
- Compare and contrast clinical trial data of lepirudin versus argatroban for HIT
- Discuss potential new therapies on the horizon for HIT
- Outline key recommendations from the new ACCP consensus guidelines for the management of HIT

Notes

Slide 1

Self-assessment Questions

- Can you develop HIT with thrombotic consequence from only low-dose SC heparin? Have you seen it?
- Would you recognize HIT? If so, how?
- An HIT patient on argatroban has an INR of 6.0 and an aPTT of 60 seconds; should the infusion be held?
- How often do your patients with a documented new diagnosis of HIT have heparin listed as an allergy in the medical record?

Notes

Slide 2

Case Presentation

- 68 yo male s/p falls on right hip, to OR on 9/2/04
- Heparin 5000 units SC preop x 1 then 3500 units q 8 h with daily warfarin
- 9/11/04 bilateral DVTs, IV heparin started
- 9/12/04 chest pain & ↓ O₂ sat: PE diagnosed
- 9/13 HIT suspected, argatroban started
- HPF4 antibody 0.97
- Warfarin restarted 9/14/04 and overlapped x 5 days

Date	Plat count	Date	Plat count
8/30/04	201	9/7/04	150
9/2/04	223	9/8/04	95
9/3/04	185	9/12/04	89
9/4/04	169	9/13/04	79
9/5/04	240	9/14/04	144
9/6/04	202	9/14/04	166

Should HIT have been suspected earlier?

Notes

Slide 15

Direct Thrombin Inhibitor Comparison

	Argatroban	Lepirudin	Bivalirudin
	Synthetic L-arginine derivative	Recombinant hirudin	Semisynthetic hirulog
Half-life in healthy subjects	39-51 min	0.8-1.7 hours	25-36 min
Elimination	Hepatic	Renal	20% Renal
Monitoring needed	aPTT, ACT	aPTT	aPTT, ACT
Thrombin binding*	Reversible	Irreversible	Partially reversible
Antidote	None	None	None

*Based on in vitro data.

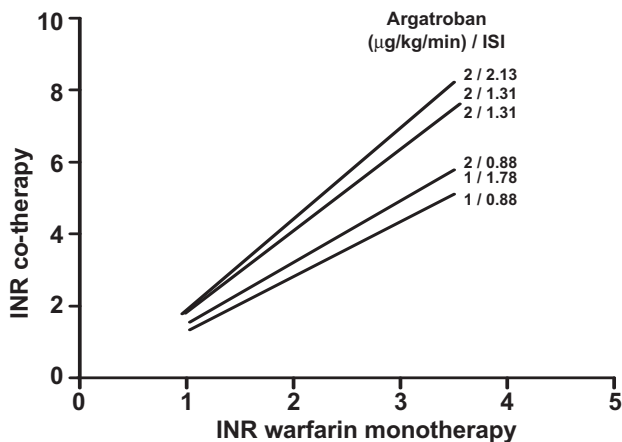
aPTT, activated partial thromboplastin time; ACT, activated clotting time.

Adapted from Chen L. *Heart Dis.* 2000;3:189-198; Warkentin TE, Greinacher A, eds. *Heparin-Induced Thrombocytopenia.* 3rd ed. New York, NY: Marcel Dekker, Inc; 2004. 339,441,479.

Notes

Slide 16

Effect of Argatroban Dose and ISI on INR



ISI, International Sensitivity Index; INR; international normalized ratio.
Seth SB, et al. *Thromb Haemost.* 2001;85:435-440.

Slide 25

Notes

Argatroban Dosing and Monitoring for HIT

- Initial infusion: 2 µg/kg/min
- Target aPTT 1.5-3 x baseline, monitor aPTT at least once daily to be therapeutic
- Median dose in ARG 911: 1.6 µg/kg/min, median incremental dose adjustment: 0.5 µg/kg/min
- ICU patients and those with hepatic impairment require lower initial dosing
- Pediatric patients (1 week to 16 years): doses range from 0.1-12 µg/kg/min

Verme-Giboney CN, Hursting MJ. *Ann Pharmacother.* 2003; 37:970-975; Reichert MG, et al. *Ann Pharmacother.* 2003;37:652-654; Williamson DR, et al. *Pharmacotherapy.* 2004;24: 409-414; Hursting MJ et al. *J Pediatr Oncol.* 2006; 28:4-10.

Slide 26

Notes

Lepirudin vs Argatroban: Major Bleeding Rate Comparison

Study	Drug	Rate (%)	Rate (%/day)
HAT-1	L	13	0.93
HAT-2	L	17	1.5
HAT-3	L	19.5	1.95
ARG 911	A	6.9	1.2
ARG 915	A	5.7	0.93*

*Based upon estimated duration of treatment of 6.1 days.

Lewis BE, et al. *Arch Intern Med.* 2003;163:1849-1856; Lewis BE, et al. *Circulation.* 2001;103:1838-1843; Greinacher A, et al. *Circulation.* 1999;99:73-80; Greinacher A, et al. *Circulation.* 1999;100:587-593; Lubenow N, et al. *J Thromb Haemost.* 2005;3:2428-2436.

Notes

Slide 27

DTI Dosing in Organ Failure

- Argatroban
 - Cardiothoracic ICU patients
 - 0.15-1.3 $\mu\text{g}/\text{kg}/\text{min}^1$
 - ICU with liver dysfunction on CRRT
 - 0.1-1.7 $\mu\text{g}/\text{kg}/\text{min}^{2,3}$
 - Renal function should be considered when selecting argatroban dose⁴
- Lepirudin
 - MODS: 0.001-0.024 $\text{mg}/\text{kg}/\text{h}^5$

MODS, Multiple Organ Dysfunction Syndrome.

1. Reichert MG, et al. *Ann Pharmacother.* 2003;37:652-654; 2. Williamson DR, et al. *Pharmacotherapy.* 2004;24: 409-414; 3. Reddy BV, et al. *Ann Pharmacother.* 2005;39:1601-1605; 4. Arpino PA, Hallisey RK. *Ann Pharmacother.* 2004;38:25-29; 5. Wester JPJ, et al. *Thromb Hemost.* 2003;1(suppl 1):P1907.

Notes

Slide 28

ACCP Recommendations: HIT Treatment

- Strongly suspected (or confirmed) HIT regardless of the presence of thrombosis
 - Lepirudin, 1C+
 - Argatroban, 1C
 - Bivalirudin, 2C
 - Danaparoid, 1B
- Strongly suspected (or confirmed) HIT whether or not there is clinical evidence of lower-limb DVT
 - Routine ultrasound of the lower-limb veins, 1C

Adapted from Warkentin TE, Greinacher A. *Chest.* 2004;126:311S-337S.

Slide 33

Notes

ACCP Recommendations: HIT Treatment (cont.)

- If HIT is strongly suspected or confirmed
 - Recommend against use of VKA until platelet count is at least 100,000 and preferably 150,000
 - Only administer VKA during overlapping alternate anticoagulation (minimum 5 days)
 - Begin VKA with low maintenance doses
 - Do not stop alternate anticoagulant therapy until the platelet count has reached a stable plateau and with at least 2 days with INR within target range

Warkentin TE, Greinacher A. *Chest.* 2004;126:311S-337S.

Slide 34

Notes

If you have participated in a recorded version of this presentation please complete this form.

CME on Demand

A CME on Demand Presentation of:

Advances in Anticoagulation: A Clinical Update for the Pharmacist

Part 1: New Insights into the Recognition and Management of Venous Thromboembolism

Presented by:

Robert Hallisey, MS, RPH

Assistant Professor, Clinical Pharmacy
Massachusetts College of Pharmacy
Clinical Director, Department of Pharmacy
Massachusetts General Hospital
Boston, Massachusetts

Part 2: New Insights into the Recognition and Management of Heparin-induced Thrombocytopenia

Presented by:

Maureen A. Smythe, PharmD

Department of Pharmaceutical Services
William Beaumont Hospital
Royal Oak, Michigan
Professor of Pharmacy Practice
Wayne State University
Detroit, Michigan

This program will be available from November 1, 2006 through November 1, 2007.

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NSB-212 (Hallisey/Smythe)
Course Code: 297-999-06-008-H01
(ACPE-AACME)

To receive credit, record your answers to this quiz on the following page and complete the form in its entirety (front and back).

SECTION A

Part 1 Quiz

- Delayed-onset HIT occurs _____.**
 - An average of 5 days after heparin is stopped
 - An average of 9 days after heparin is stopped
 - An average of 11 days after heparin is stopped
 - An average of 14 days after heparin is stopped
- Warfarin-associated venous limb gangrene is a common presentation of HIT.**
 - True
 - False
- With thrombosis of HIT, 15% of events occur with platelet counts _____.**
 - >50,000
 - >75,000
 - >100,000
 - >150,000
- Which of the following statements is true regarding citrated platelet-rich plasma assays?**
 - Moderate sensitivity, moderate-high specificity
 - High sensitivity, low specificity
 - Low sensitivity, moderate-high specificity
 - Moderate-high sensitivity, low specificity
- The half-life of argatroban in healthy subjects is _____.**
 - 15-30 minutes
 - 31-47 minutes
 - 39-51 minutes
 - 60-90 minutes

Part 2 Quiz

- Among people who develop VTE for the first time, _____ manifest as DVT alone.**
 - One quarter
 - One third
 - Two thirds
 - Three quarters
- If left untreated, what percentage of proximal VTE (femoral, popliteal, or iliac) embolizes to the lungs?**
 - ~25%
 - ~42%
 - ~50%
 - ~60%
- Risk factors for DVT include a deficiency of _____.**
 - Antithrombin III
 - Protein C
 - Protein S
 - All of the above
- Which of the following is *not* a clinical presentation of DVT?**
 - Hypotension
 - Erythema
 - Pain
 - Swelling
- In primary pharmacologic prevention of VTE, the use of aspirin is highly controversial.**
 - True
 - False

SECTION B

- To what extent did the activity meet or exceed your expectations?
- How current and relevant was the topic for your professional needs?
- To what extent were your professional knowledge and skills updated?
- Will your practice of medicine change as a result of participating in this activity? What changes will you make?
- How logically integrated and valuable were the audiovisuals and supplementary handouts as learning aids?
- How successful were the presentations in achieving fair balance?
- How knowledgeable were the speakers?
- How interested are you in seeing other activities on this topic?
- To what degree was the activity objective, balanced, and scientifically rigorous?

To what extent did Mr. Hallisey and Dr. Smythe prepare you to do the following:

- Cite the epidemiology, risk factors, and clinical presentation of deep vein thrombosis (DVT) and pulmonary embolism (PE).
- Identify current treatment options for the management of DVT and PE, and differentiate their potential benefits and limitations.
- Describe new insights into the clinical presentation of heparin-induced thrombocytopenia (HIT) and key recommendations for its management.
- Compare and contrast clinical trial data on HIT treatment agents and identify new therapies on the horizon.
- Please provide detailed comments and suggestions for future activities.

Please complete the front and back of this form.

SECTION A

	a	b	c	d		a	b	c	d
1.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	<input type="checkbox"/>	<input type="checkbox"/>			7.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10.	<input type="checkbox"/>	<input type="checkbox"/>		

SECTION B

	Not At All	Rarely	Moderately	Mostly	Completely
1.	1	2	3	4	5
2.	1	2	3	4	5
3.	1	2	3	4	5
4.	1	2	3	4	5
5.	1	2	3	4	5
6.	1	2	3	4	5
7.	1	2	3	4	5
8.	1	2	3	4	5
9.	1	2	3	4	5
10.	1	2	3	4	5
11.	1	2	3	4	5
12.	1	2	3	4	5
13.	1	2	3	4	5
14.					

CME on Demand
November 1, 2006 to November 1, 2007

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