Evolving Landscape of Chronic Pain Pharmacotherapy: Meeting the Challenges

Presented as a Live Webinar
Monday, May 21, 2012
2:00 p.m. – 3:00 p.m. EDT

Planned and conducted by ASHP Advantage and supported by an educational grant from Purdue Pharma L.P.
WEBINAR INFORMATION

How do I register?
Go to http://ashpadvantage.com/chronicpain and click on the Register button. After you submit your information, you will be e-mailed computer and audio information.

What is a live webinar?
A live webinar brings the presentation to you – at your desk, in your home, through a staff in-service program. You listen to the speaker presentation in “real time” as you watch the slides on the screen. You will have the opportunity to ask the speaker questions at the end of the program. Please join the conference at least 5 minutes before the scheduled start time for important program announcements.

How do I process my continuing education (CE) credit?
After completion of the live webinar, you will process your CE online and print your statement of credit at the ASHP CE Center found at http://ce.ashp.org. To process your CE, you will need the Activity and Session Codes that will be announced at the end of the webinar. If you have questions about processing your CE online, please contact ASHP Advantage at support@ashpadvantage.com.

What do I need in order to participate in the webinar?
1. Computer with internet access and basic system requirements. When you register, the webinar system will assess your system to ensure compatibility.
2. Telephone to dial the toll-free number and listen to the presentation (if you choose not to use VoIP [Voice Over IP] via your computer).

Webinar System Requirements
PC-based attendees
Required: Windows® 7, Vista, XP, or 2003 server

Macintosh®-based attendees
Required: Mac OS® X 10.5 or newer

View complete list of webinar system requirements

What if I would like to arrange for my colleagues to participate in this webinar as a group?
One person serving as the group coordinator should register for the webinar. That group coordinator will receive an e-mail confirmation with instructions for joining the webinar. A few minutes before the webinar begins, the group coordinator should launch the webinar link. Once the webinar has been activated, the coordinator will have the option to open the audio via VoIP on the webinar toolbar or use a touch tone phone with the provided dial-in information. At the conclusion of the activity, the group coordinator will complete a brief online evaluation and report the number of participants at that site. Each participant will process his or her individual continuing education statement online at the ASHP CE Center.

How do I ask a question of the presenter?
Follow the instructions provided at the beginning of the activity for submitting text questions using the webinar tool. The speaker will answer as many questions as possible at the conclusion of the activity.
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Meeting the Challenges

ACTIVITY FACULTY

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Carla Rubingh, Pharm.D., is Assistant Professor of Pharmacy Practice in the College of Pharmacy at University of Nebraska Medical Center (UNMC) in Omaha, Nebraska.

Dr. Rubingh earned her Doctor of Pharmacy degree at the University of Nebraska Medical Center. She then completed a pharmacy practice residency with an emphasis on ambulatory care accredited by the American Society of Health-System Pharmacists at the University of Utah in Salt Lake City (SLC).

At UNMC, Dr. Rubingh lectures on pain-related topics for students in the pharmacy, dental, and physician assistant programs. She also serves as a preceptor for pharmacy practice residents and Doctor of Pharmacy students. Before returning to her alma mater, Dr. Rubingh was on the faculty at University of Utah College of Pharmacy. During the 2002 Winter Olympic Games and Paralympic Games in SLC, she served as Co-Manager for the Polyclinic Pharmacy.

Dr. Rubingh is involved in several state and national pharmacy organizations, as well as the American Pain Society, American Headache Society, and Omaha Pain Society.
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The faculty and planners report the following relationships:

**Carla Rubingh, Pharm.D.**

Dr. Rubingh declares that she has no relationships pertinent to this activity.

**Susan R. Dombrowski, M.S., B.S.Pharm.**

Ms. Dombrowski declares that she has no relationships pertinent to this activity.

**Carla Brink, M.S., B.S.Pharm.**

Ms. Brink declares that she has no relationships pertinent to this activity.

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CONTINUING EDUCATION ACCREDITATION

The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This activity provides 1.0 hour (0.1 CEU) of continuing pharmacy education credit (ACPE activity #0204-0000-12-418-L01-P).

Attendees must complete a Continuing Pharmacy Education Request online and may immediately print their official statements of continuing pharmacy education (CPE) credit at the ASHP CE Center at http://ce.ashp.org following the activity.

Complete instructions for processing CE can be found on the last page of this handout.

METHODS AND FORMAT

This is a live web-based activity consisting of audio, presentation slides, and an activity evaluation tool. Participants must participate in the entire presentation and complete the course evaluation to receive continuing pharmacy education credit. Participants may print their official statements of continuing pharmacy education credit immediately following the activity. This activity is provided free of charge.

TARGET AUDIENCE

This continuing pharmacy education activity was planned to meet the needs of pharmacists in all practice settings, and it would be especially beneficial for pharmacists, clinical specialists, managers, leaders, and educators who are interested in improving the care of patients with chronic pain.
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ACTIVITY OVERVIEW
This educational activity is designed to help health-system pharmacists, in concert with other members of the health care team, assess and manage patients with chronic pain. Factors to consider in the assessment of pain and therapy selection will be explained. Recently released guidelines and government actions and reports related to the treatment of pain will also be discussed.

Time for questions and answers will be provided at the end of the presentation.

LEARNING OBJECTIVES
At the conclusion of this knowledge-based educational activity, participants should be able to

- Outline a plan for assessing a patient’s pain and selecting appropriate therapy.
- Explain key recommendations in newly released guidelines and reports on the use of opioids in the management of chronic pain.
- Describe key components of the risk evaluation and mitigation strategy for opioids.

LIST OF ABBREVIATIONS
For a list of abbreviations used in this activity, please see page 17.

Available soon
www.ashpmedia.org/symposia/chronicpain

A web-based version of this educational activity is being developed, and it is approved for 1 hour of CPE. Encourage your pharmacist colleagues who were unable to attend today’s webinar to look for this free online educational activity in June 2012.

Please note that individuals who claim CPE credit for the live webinar are ineligible to claim credit for the web-based activity.
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Pain

“Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.”


Scope of the Problem

- 50% in some kind of pain
- 20-30% of U.S. population in serious pain
- 50 million Americans have disabling pain
- 165 million people plagued with chronic pain
  - Up to $635 billion spent in medical treatment and lost productivity per year

American Academy of Pain Medicine. AAPM facts and figures on pain (URL in ref list).

What percentage of your time is committed to pain management?

Types of Pain

- Acute pain
  - Surgery, trauma
- Chronic pain associated with malignant disease
  - Cancer, AIDS, MS, ALS (Lou Gehrig’s disease)
  - End-stage organ system failure
- Chronic pain not associated with malignant disease
  - Myofascial pain, fibromyalgia
  - Headache
  - Nerve injury pain


Classification

- Nociceptive pain
  - Somatic
  - Visceral
- Neuropathic pain
  - Peripheral
  - Central
Physiologic Effects of Pain

• Increased catabolic demands
• Increased risk of thromboembolic event
• Respiratory effects
• Increased sodium and water retention
• Decreased gastrointestinal motility
• Tachycardia and elevated BP
• Decreased immune response

Impact of Pain on the Dimensions of Quality of Life

Physical
• Functional ability
• Strength or fatigue
• Sleep and rest
• Nausea
• Appetite
• Constipation

Psychological
• Anxiety
• Depression
• Enjoyment and leisure
• Pain distress
• Happiness
• Fear
• Cognition and attention

Social
• Caregiver burden
• Roles and relationships
• Affection and sexual function
• Appearance

Spiritual
• Suffering
• Meaning of pain
• Religiosity


How familiar are you with the 2009 Clinical Guidelines for the Use of Chronic Opioid Therapy for Chronic Noncancer Pain?


Pain Assessment

• Always subjective
  – Objective observations useful but often absent in chronic pain
• NO chemical test that can measure pain
• Accept patient’s reports of pain

Pain Assessment Tools

• Numerical rating scale
• Visual analog scale
• Categorical scale
• Wong-Baker Faces scale


Pain Assessment Mnemonic

• Ask about pain regularly
• Assess pain systematically
• Believe the patient
• Choose appropriate patient-specific options
• Deliver interventions in a timely, logical, and coordinated way
• Empower patients and families
• Enable patients to control their lives as much as possible
Pain History: Description
- Location
- Physical areas involved (body map)
- Quality
- Intensity
- Exacerbating and remitting factors
- Time sequence

Pain History: Medication
- All medications used currently and in the past
- Nonprescription drug use
- Social drug use
- Nutritional supplements and diet
- What worked, what didn’t
- Sources and problems in getting and taking medications
- Adverse effects experienced

Nonpharmacologic and Other Pain Management Options
- Nonpharmacologic options
  - Physical therapy
  - Transcutaneous electrical nerve stimulation (TENS)
  - Massage
  - Acupuncture
  - Psychotherapy
    - Self hypnosis, biofeedback, relaxation therapy
- Other management strategies
  - Steroid injections, nerve blocks

Biochemical Management of Pain
- Modify at source of pain
- Interfere with transmission to central nervous system (CNS)
- Alter perception in the brain

Nonsteroidal Anti-inflammatory Drugs (NSAIDs)
- Anti-inflammatory and analgesic effects
- Increased efficacy when taken around the clock
- Useful as co-analgesic with opioid analgesics
- Efficacy varies from patient to patient and from site to site within specific patients
- Adverse effects
  - GI effects, hypersensitivity reactions, CNS effects, blood dyscrasias, renal problems, and fluid retention

NSAIDs
- Advantages
  - Non-addictive
  - Anti-inflammatory action
  - Topical products available
- Disadvantages
  - Risk of adverse effects (i.e., GI bleed, nephrotic syndrome)
  - Avoid in elderly patients
  - In advanced osteoarthritis (OA), inflammatory component no longer present
Muscle Relaxants

- Heterogenous
- Primarily work by sedating the CNS
- Advantages
  - Useful in acute musculoskeletal pain
- Disadvantages
  - Not useful for chronic pain (tolerance develops)
  - Many require monitoring liver function
    - Avoid in liver dysfunction
  - Avoid in patients at risk for falls
  - Lack of quality evidence


Muscle Relaxants in Clinical Treatment of Pain

- Baclofen
- Benzodiazepines
  - Diazepam, lorazepam
- Carisoprodol
- Chlorzoxazone
- Cyclobenzaprine
- Tizanidine
- Metaxalone
- Methocarbamol
- Orphenadrine

Tolerance does not occur

Glucosamine and Chondroitin

- Advantages
  - Some patients report benefit
    - Recommend 3-month trial
  - Adverse effect profile
    - Methyl sulfonyl methane (MSM)?
- Disadvantages
  - Avoid in patients with severe shellfish allergy
  - Increases anticoagulant effect
  - No product regulation
  - Expensive


Topical Anesthetics

- Lidocaine 5% patch
  - Distributes numbing agent into tissues
  - Applied for 12 hours, then removed
  - Can be cut to shape of area
- Advantages
  - Localized effect
  - First-line treatment for postherpetic neuralgia
- Disadvantages
  - Limited area
  - Expensive
  - Adhesive

Biochemical Management of Pain

- Modify at source of pain
- Interfere with transmission to CNS
- Alter perception in the brain

Adjuvant Analgesics

- Defined as drugs with other indications that may provide pain relief in specific circumstances
- Numerous drugs in various classes
- Sequential trials often needed
Antidepressants

- **Advantages**
  - Treat co-morbid depression
  - First-line treatment for neuropathic pain
  - Once daily dosing, inexpensive

- **Disadvantages**
  - Tricyclic antidepressants
    - Cause drowsiness, avoid in patients at risk for falls
    - Cause QT prolongation, avoid in patients with cardiac arrhythmias or on other meds that cause QT prolongation
  - Lower seizure threshold
  - SNRIs
    - Increase BP and insomnia
    - Serotonin syndrome, caution in bipolar disorder


Anticonvulsants

- **Advantages**
  - Tolerance to adverse effects
  - Second-line treatment for neuropathic pain

- **Disadvantages**
  - Cognitive effects, may increase risk for falls
  - Expensive
  - Multiple doses throughout day
  - Most require monitoring liver function
  - Gabapentin cleared renally
    - Decrease dose and extend interval


Capsaicin Cream

- Red pepper, cayenne pepper, chili pepper
- 0.025%-0.075%
- Depletes substance P
  - Controls transmission of pain messages from nerves to spinal cord
  - Requires repeated application

- **Advantages**
  - Localized effect
  - Available without prescription
  - Can dilute to increase tolerability

- **Disadvantages**
  - Burning sensation
  - Requires dedicated patient

Biochemical Management of Pain

- **Modify at source of pain**
- **Interfere with transmission to CNS**
- **Alter perception in the brain**

Traditional Analgesics

- **Non-opioids**
  - Acetaminophen
- Tramadol
- **Weak opioids**
  - Codeine, hydrocodone, combination products
- **Strong opioids**
  - Morphine, hydromorphone, oxycodone, fentanyl, methadone, buprenorphine

[WHO Three-Step Analgesic Ladder]

[Traditional Analgesics]
Acetaminophen

- Most widely used agent in the world
- Max dose in adults = 4 g/day
  - FDA action January 2011
  - 325-mg limit per prescription tablet or capsule
  - McNeil action July 2011
  - Extra strength OTC product maximum dose 3 g/day
- Single toxic dose in adult = 7 g
- Acetaminophen toxicity
  - Number one cause of hospital admission for liver failure in U.S.

U.S. FDA. New steps aimed at cutting risk from acetaminophen. 2011 Sept 9 (URL in ref list).

Tramadol

- MOA
  - Primary: serotonin reuptake inhibition
  - Secondary: mu opioid receptor agonist
- Indication
  - Moderate to moderately-severe pain
- Precautions
  - Hepatic and renal impairment
  - History of seizures
  - History of opioid addiction or dependence


Opiate Receptors

- Mu
  - Analgesia
  - Respiratory depression
- Delta
  - Analgesia
- Kappa
  - Analgesia
- Sigma
  - Dysphoria and psychomimetic effects

Opioid Classifications

- Full agonists
  - Maximal analgesia through receptor binding
- Partial agonists
  - Occupy only part of a mu receptor
- Mixed agonist-antagonists
  - Different activities at different receptors
- Antagonists
  - Displace agonists from receptors

Reasons for Undertreatment of Pain

- Use of acute pain principles in chronic pain
- Limited evidence for optimal dose and duration
- Fear of fostering tolerance
- Fear of inducing addiction
- Fear of respiratory depression
- Belief that oral opioids are poorly absorbed
- Belief that opioids should be saved for extreme pain
Tolerance, Dependence, Addiction

• Dependence
  – *Physiologic* phenomenon
  – Nearly universal among patients receiving repeated doses of opioids for > 7-10 days
• Tolerance
  – *Physiologic* phenomenon
• Addiction
  – *Psychologic* phenomenon

Distinct Types of Opioid Tolerance

• Tolerance to analgesia
  – May occur in first days to weeks of therapy; rare after pain relief achieved with consistent dosing without increasing or new pathology
• Tolerance to respiratory depression and sedation
  – Occurs predictably after 5-7 days of consistent opioid administration
• Tolerance to cognitive impairment, urinary retention, itching
  – Occurs usually after 7-14 days of consistent opioid administration
• Tolerance to constipation
  – Does not occur; scheduled stool softeners and stimulant laxatives indicated with regularly scheduled opioids

How familiar are you with FDA-mandated Risk Evaluation and Mitigation Strategies (REMS)?

Risk Evaluation and Mitigation Strategy (REMS)

• FDA-mandated requirements to minimize the risks associated with certain medications
• Can be mandated for any medication or class of medication
• Visit www.fda.gov for complete list of medications with REMS

Components of REMS

✓ Medication guide or patient package insert
  – Provided to patient at time drug is dispensed
• Communication plan
  – Letters to providers, professional education, communication with professional societies
✓ Elements to assure safe use
  – Special requirements or restrictions
• Implementation system
  – Monitor, evaluate, and improve elements
• Timetable for assessment

Opioid REMS

• Opioids associated with significant risks, including misuse, abuse, addiction, and overdose
  – Prescription opioids are second only to marijuana in abuse
  – “Overdoses of prescription painkillers have more than tripled in the past 20 years, leading to 14,800 deaths in the United States in 2008.”
  – Emergency department visits for prescription painkiller abuse or misuse have doubled in the past 5 years to nearly half a million annually.


CDC. Saving lives and protecting people. 2012 Jan 17 (URL in ref list).
Opioid Classification

• Long-acting opioids (LAOs)
  – Longer onset, longer duration of analgesia
  – Individual REMS, developing opioid class-wide REMS

• Short-acting opioids (SAOs)
  – Onset of 30–45 minutes, shorter duration of analgesia

• Rapid-onset opioids (ROOs)
  – Includes transmucosal immediate-release fentanyl (TIRF)
  – Onset of 15 minutes or less, shorter duration of analgesia
  – Shared-system REMS

U.S. FDA. Opioid drugs and REMS. 2012 Apr 5 (URL in ref list).

Opioid Dosing

• Initial treatment should be viewed as trial
• Start with low dose(s) and titrate slowly
• Understand pharmacokinetics and pharmacodynamics of medication being used
• Equianalgesic dosing charts vary and should only be used as starting point

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Informed Consent and Medical Agreement

• Informed consent
  – Goals and expectations
    • Unreasonable to expect to be pain free
    • Set goals
  – Risks and benefits
  – Alternatives

• Medical agreement
  – Lost prescriptions not replaced
  – No opioids ordered on nights or weekends
  – No illicit substances
  – One physician, one pharmacy
  – Urine drug screens

Opioid Monitoring

• Documentation
  – Pain intensity assessment
  – Level of functioning
  – Assessment of progress toward goals
  – Adverse events
  – Adherence to prescribed therapy

• Laboratory monitoring
  – Urine drug screening
  – Testosterone levels

Assessment of Response

• Did you experience pain relief?
• How much? (quantify as much as possible)
• Did the drug affect one particular quality of pain?
• Did you experience side effects?
• Did these side effects subside as you continued the medication?
• Were side effects tolerable or intolerable?

“We are appalled by the needless pain that plagues the people of the world – in rich and poor nations alike. By any reasonable code, freedom from pain should be a basic human right limited only by our ability to achieve it.”

Evolving Landscape of Chronic Pain Pharmacotherapy: Meeting the Challenges

SELECTED REFERENCES


17. Saarto T, Wiffen PJ. Antidepressants for neuropathic pain.  

18. U.S. Food and Drug Administration. New steps aimed at cutting risk from acetaminophen.  


SELF-ASSESSMENT QUESTIONS

1. Changes in which of the following is the most reliable measure for assessing chronic pain?
   a. Blood pressure.
   b. Respiratory rate.
   c. Patient report.
   d. Mood.

2. GS, a 45-year-old man, is being discharged after being hospitalized for 14 days following a motor vehicle accident and subsequent surgeries. GS has been on i.v. opioids during his hospital stay. You will be counseling him on the use of his two-week supply of oral opioid analgesic. From the following options, choose the correct statement that should be explained to GS.
   a. This medication will likely cause constipation, and a laxative or stool softener is often required to maintain regularity.
   b. This medication may slow your breathing, and you should not stay home alone.
   c. This medication loses effectiveness over time, requiring you to take more. When this happens, before taking more, you should call your doctor.
   d. This medication should be taken around the clock, regardless if you are experiencing pain.

3. Which of the following components of Risk Evaluation and Mitigation Strategies (REMS) are most relevant to providers?
   a. Medication guide and communication plan.
   b. Medication guide and elements to assure safe use.
   c. Medication guide and implementation system.
   d. Medication guide and timetable for assessment.

4. Which of the following laboratory test results should be monitored when patients are on long-term opioids?
   a. Thyroid levels.
   b. Hemoglobin A1C.
   c. Testosterone levels.
   d. Cholesterol levels.

Answers:

1. c
2. a
3. b
4. c
# LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AIDS</td>
<td>acquired immune deficiency syndrome</td>
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<tr>
<td>ALS</td>
<td>amyotrophic lateral sclerosis</td>
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<td>BP</td>
<td>blood pressure</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<tr>
<td>CNS</td>
<td>central nervous system</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>GI</td>
<td>gastrointestinal</td>
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<td>LAO</td>
<td>long-acting opioid</td>
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<td>MOA</td>
<td>mechanism of action</td>
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<td>MS</td>
<td>multiple sclerosis</td>
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<td>MSM</td>
<td>methyl sulfonyl methane</td>
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<td>NSAID</td>
<td>nonsteroidal anti-inflammatory drug</td>
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<td>OA</td>
<td>osteoarthritis</td>
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<td>OTC</td>
<td>over the counter</td>
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<tr>
<td>REMS</td>
<td>risk evaluation and mitigation strategy</td>
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<td>ROO</td>
<td>Rapid-onset opioid</td>
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<tr>
<td>SAO</td>
<td>short-acting opioid</td>
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<tr>
<td>SNRI</td>
<td>selective serotonin- and norepinephrine-reuptake inhibitor</td>
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<tr>
<td>TCA</td>
<td>tricyclic antidepressant</td>
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<tr>
<td>TENS</td>
<td>transcutaneous electrical nerve stimulation</td>
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Instructions for Processing Continuing Education (CE)

To obtain CE statements for live symposia, webinars, or webcasts, please visit the ASHP CE Center at http://ce.ashp.org.

1. Select Process Meeting CE from bottom left. Log in to the ASHP CE Center using your e-mail address and password.

If you have not logged in to the ASHP CE Center (launched August 2008) and are not a member of ASHP, you will need to set up an account by clicking on “Become a user” and follow the instructions.

2. Once logged in to the site, click on Process Meeting CE.

3. If this activity title does not appear in your meeting list, enter the 5-digit activity code in the box above the list and click submit. The Activity and Session Codes are announced at the end of the activity. Click Submit when prompted and then click on the Start link to the right of the activity title.

4. Enter the session code, which starts with the letter “A” and was announced during the activity, and select the number of hours equal to your participation in the activity. Participants should only claim credit for the amount of time they participate in an activity.

5. Click Submit to receive the attestation page.

6. Confirm your participation and click Submit.

7. Print and/or save your CE statement as appropriate.

8. Complete activity evaluation by selecting the My Account tab and continue to My Transcript.

9. Select the applicable year from the drop down menu and locate the activity.

10. Click Complete Evaluation under the Status column to be taken to the evaluation page.

11. Complete all evaluation questions and click Finish.

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NEED HELP? Contact ASHP Advantage at support@ashpadvantage.com.