Ask the Experts: Current Considerations in Managing Hyponatremia in Hospitalized Patients

Presented as a Live Webinar
Tuesday, March 4, 2014
12:00 p.m. – 1:00 p.m. ET

Planned and conducted by ASHP Advantage and supported by an educational grant from Otsuka America Pharmaceutical, Inc.
Webinar Information

How do I register?
Go to http://www.ashpadvantagemedia.com/hyponatremiacases/webinar-experts.php 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?
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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 (Voice Over IP) 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.

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 Voice Over IP [VoIP] via your computer).

Webinar System Requirements
Be sure to view the webinar system requirements for Windows, Mac, iOS, and Android prior to the activity.
Ask the Experts: Current Considerations in Managing Hyponatremia in Hospitalized Patients

Activity Faculty

Joseph F. Dasta, M.S., FCCM, FCCP, Activity Chair
Professor Emeritus
The Ohio State University College of Pharmacy
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Austin, Texas

Joseph F. Dasta, M.S., FCCM, FCCP, is Professor Emeritus at The Ohio State University College of Pharmacy in Columbus and Adjunct Professor at The University of Texas College of Pharmacy in Austin. He retired from The Ohio State University (OSU) in 2007 after 31 years, and he currently lives in Austin. He serves as a health care consultant to pharmaceutical and device companies, and he provides pharmacy consulting services for the intensive care unit (ICU) at a local hospital.

Mr. Dasta earned his Bachelor of Science degree in pharmacy from West Virginia University School of Pharmacy. He began his academic career at OSU following completion of his Master of Science degree and residency in hospital pharmacy there in 1976. He developed one of the first practice sites and post-doctoral training programs in critical care pharmacy at OSU, through which he trained 11 residents and 9 fellows who are prominent practitioners, researchers, and leaders in the profession and pharmaceutical industry. He received OSU’s Jack L. Beal Post-baccalaureate Alumni Award in 2008.

Mr. Dasta was one of the first pharmacist members of the Society of Critical Care Medicine (SCCM), and he helped establish the role of pharmacists in this multidisciplinary society. He was a member of SCCM Council, the governing body of SCCM, from 2007-2010. SCCM honored him by creating the Joseph F. Dasta Critical Care Pharmacy Outcomes Research Grant in 2000. Ten years later, he was the first pharmacist to receive the SCCM Distinguished Investigator Award. Mr. Dasta’s contributions have also been recognized by other organizations. He received the Education Award from the American College of Clinical Pharmacy (ACCP) in 2002 and the Russel Miller award in 2013. Professor Dasta received the Sustained Contributions to the Literature Award from the American Society of Health-System Pharmacists in 2010. He serves on the editorial board of Critical Care Medicine and Annals of Pharmacotherapy.

Mr. Dasta is a fellow of ACCP and the American College of Critical Care Medicine. He has authored more than 200 peer-reviewed publications, abstracts, brief communications, and book chapters, and he has given over 250 lectures on topics related to critical care and health outcomes. Mr. Dasta’s research has focused on health economics and patient safety of acute care pharmaceuticals. Specific areas of interest include hyponatremia, acute pain, sedation, sepsis, acute kidney injury, acute heart failure, and hypertensive emergencies.
Ask the Experts: Current Considerations in Managing Hyponatremia in Hospitalized Patients

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Jodie L. Pepin, Pharm.D., is Director of Pharmacy at Seton Medical Center Williamson, an acute care facility that is part of a large health care network in the Austin Metro area called Seton Healthcare Family. She also is Clinical Assistant Professor of Health Outcomes and Pharmacy Practice for The University of Texas in Austin. She serves as a clinical pharmacist preceptor for Doctor of Pharmacy students, and her areas of clinical interest and practice include adult internal medicine, infectious disease, critical care, anticoagulation, patient safety, and pain management. As Director of Pharmacy, she has overseen the successful development and implementation of an oversedation and respiratory depression risk screening initiative that resulted in a 75-80% reduction in the use of reversal agents in the hospital.

Dr. Pepin earned her Bachelor of Science degree in pharmacy from Ohio Northern University in Ada, Ohio, and her Doctor of Pharmacy degree from The University of Texas in Austin. Since 1987 she has assumed a variety of practice and management roles, including home health care pharmacy, acute care adult medicine, critical care, clinical leadership, and pharmacy administration.

Dr. Pepin is a member of local and national pharmacy organizations, including the American Society of Health-System Pharmacists, American College of Clinical Pharmacists, and Society of Critical Care Medicine. She is certified in Anticoagulation Management and is a fellow of the Patient Safety Improvement Corps (PSIC) supported by the Agency for Healthcare Research and Quality (AHRQ) and U.S. Department of Veterans Affairs.

At Seton, Dr. Pepin has served as a team leader for TeamSTEPPS, which is an evidence-based teamwork system developed by AHRQ and the U.S. Department of Defense to improve patient safety and communication among health professionals. She has authored several publications and is currently involved in several patient safety initiatives, pain management, and clinical research projects.
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The following faculty and planners report no relationships pertinent to this activity:

- Jodie L. Pepin, Pharm.D.
- Amy L. Dzierba, Pharm.D., BCPS, FCCM
- Carla J. Brink, M.S., B.S.Pharm.
- Susan R. Dombrowski, M.S., B.S.Pharm.

ASHP staff has no relevant financial relationships to disclose.
Ask the Experts: Current Considerations in Managing Hyponatremia in Hospitalized Patients

Activity Overview

This activity will focus on current considerations related to the management of hyponatremia in hospitalized patients, including clinical and economic outcomes and suggestions for improving hyponatremia management in this patient population.

The content for this activity is based on questions raised by participants in a recent educational symposium on this topic.

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

Learning Objectives

At the conclusion of this application-based educational activity, participants should be able to

- Describe clinical and economic outcomes associated with hyponatremia in hospitalized patients.
- Develop a plan for improving the management of hyponatremia in hospitalized patients.

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 #0204-0000-14-466-L01-P).

Participants will process CE credit online at http://elearning.ashp.org/my-activities, with the option of printing a CE certificate. CPE credit will be reported directly to CPE Monitor.

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Additional Educational Opportunities on this Topic

- **On-demand activity**, “Optimal Management of Hospitalized Patients with Hyponatremia: Case Scenarios” based on January 29 webinar (1 hour CPE, available late March 2014)
  - Note: individuals who claim CPE credit for a live activity are ineligible to claim credit for the web-based activity)
- Informational **podcasts** featuring the faculty in a roundtable discussion
- **e-Newsletters** featuring updates on emerging information, as well as strategies for managing hyponatremia in hospitalized patients

http://www.ashpadvantage.com/hyponatremiacases
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Learning Objectives

At the conclusion of this activity, participants should be able to

• Describe clinical and economic outcomes associated with hyponatremia in hospitalized patients
• Develop a plan for improving the management of hyponatremia in hospitalized patients

Hyponatremia Definition

• Primarily defined using laboratory values
• Normal serum sodium range usually 135-145 mEq/L
• Hyponatremia commonly defined as serum sodium concentration <135 mEq/L
  – Cut-off values often vary by laboratory
• Symptoms vary with severity of hyponatremia

Issues Surrounding Hyponatremia

• Most common electrolyte disorder in hospitalized patients
  – 15-30% of general hospitalized patients
  – 11-30% in ICU patients
• Alterations in water homeostasis and osmolality
• Considerable amount of data reveal hyponatremia is “associated” with adverse clinical and economic outcomes
• Not established whether hyponatremia is a marker of disease severity or a mediator or cause of outcomes
  – Do patients die with or because of hyponatremia?

Overview of Clinical and Economic Data of Patients with Hyponatremia

• Large databases of patients with hyponatremia compared with matched patients without hyponatremia
  – Billing database (i.e., billing code for hyponatremia)
  – Admission serum sodium < 135 mEq/L
• Hyponatremia is an independent predictor of higher morbidity, longer LOS, more patients in ICU, more requiring ventilation, higher mortality, and higher costs
• Most studies do not report changes in sodium and adverse outcomes
• Well-established association of adverse outcomes of hyponatremia in patients with heart failure (HF) and liver disease

Serum [Na+] 130–135 mEq/L
- Asymptomatic
- Headache
- Nausea
- Vomiting
- Fatigue
- Confusion
- Anorexia
- Muscle cramps
- Depressed reflexes

Serum [Na+] 120–130 mEq/L
- Malaise
- Unsteadiness
- Headache
- Nausea
- Vomiting
- Fatigue
- Confusion
- Anorexia
- Muscle cramps

Serum [Na+] <120 mEq/L
- Headache
- Restlessness
- Lothargy
- Seizures
- Brainstem herniation
- Respiratory arrest
- Death

Annual Cost of Hyponatremia in the United States

• Cost-of-illness study
  – Included information from databases, published literature, and expert physician panel
• Results (estimates)
  – Prevalence: 3.2 to 6.1 million persons annually
  – Hospitalizations: 1 million annually with a principal or secondary diagnosis of hyponatremia
    • Of all inpatients with hyponatremia, 58-67% required a longer length of stay due to symptomatic hyponatremia
  – Direct costs: $1.6 to $3.6 billion annually


Outcomes of Patients with Hyponatremia*

<table>
<thead>
<tr>
<th>Variable**</th>
<th>Hyponatremia (n = 10,900)</th>
<th>No Hyponatremia (n = 187,400)</th>
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<tbody>
<tr>
<td>Hospital mortality (%)</td>
<td>5.9</td>
<td>3.0</td>
</tr>
<tr>
<td>Ventilated (%)</td>
<td>5.0</td>
<td>2.8</td>
</tr>
<tr>
<td>ICU (%)</td>
<td>17.3</td>
<td>10.9</td>
</tr>
<tr>
<td>Median LOS (days)</td>
<td>8.6</td>
<td>7.2</td>
</tr>
<tr>
<td>Hospital costs ($)</td>
<td>16,500</td>
<td>13,560</td>
</tr>
</tbody>
</table>

*From a database of 200,000 patients.
**All variables significantly different between groups at p < 0.001.
Adjusted incremental hospital cost = $2289

Effect of Declining Sodium Concentrations on Outcomes

• Database of 50,000 patients in one hospital
• Sodium <138 mEq/L on admission and further decline of at least 2 mEq/L over first 48 hours
  – This decline in sodium occurs in 6% of patients admitted with hyponatremia
• OR of in-hospital mortality
  – 2.30 (1.75-3.02) with decline
  – 1.46 (1.31-1.64) with no decline
• OR of prolonged LOS
  – 1.40 (1.32-1.49) with decline
  – 1.12 (1.10-1.15) with no decline

OR = odds ratio

Sodium Fluctuations and Outcomes in Surgical ICU Patients

• Evaluation of dysnatremia in 11,000 patients from 2004 to 2009 in one surgical intensive care unit (SICU)
• Median fluctuation of sodium during ICU stay is 5 mEq/L (IQR 2-7 mEq/L)
• Maximum fluctuation in sodium is associated with higher ICU and hospital mortality
• Sodium fluctuation > 6 mEq/L in normonatremia
  – Higher risk of hospital death OR 1.55 (IQR1.04-2.31)
  – Possible changes in osmolality in serum and brain
• First study to implicate serum sodium fluctuations as a contributor to adverse outcomes in SICU patients

IQR = interquartile range

Perceived Importance of Hyponatremia in the Clinical Setting

• “Hyponatremia is common in critical care units, and it can be deadly”
• However, hyponatremia often does not receive the attention it deserves and is often considered a benign situation
• “Give the patient some salt tablets and they will be fine”
• As such, treatment may be suboptimal


Optimal Treatment Based on Etiology and Symptomatology
Optimal Treatment Options

- Factors affecting optimal treatment options
  - Underlying etiology
  - Volume status of the patient
  - Time course of the decline in serum sodium concentration
  - Presence and severity of symptoms
- Urgency of treatment should be based on patient’s neurological status

Underlying Etiology

Classification of Hyponatremia

- **Dilutional Hyponatremia**
  - Total body water increased
  - Heart failure
  - Gastrointestinal losses
- **Hypovolemic (edema)**
  - Total body sodium increased
  - Nephrotic syndrome
- **Euvolemic**
  - Total body sodium unchanged
  - SIADH
- **Depletional Hyponatremia**
  - Total body sodium decreased
  - Hypothyroidism

SIADH = syndrome of inappropriate antidiuretic hormone

Symptoms Correlate with Severity and Rate of Decline in Serum Sodium

- Asymptomatic presentation common
- May present with mild, nonspecific symptoms
- Degree of symptomatology is surrogate for duration of hyponatremia
- Symptoms from underlying disease process also common

Acute versus Chronic Hyponatremia

<table>
<thead>
<tr>
<th>Acute (≤ 48 hr)</th>
<th>Chronic (&gt; 48 hr)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Symptoms</strong></td>
<td><strong>Symptoms</strong></td>
</tr>
<tr>
<td>• Cerebral edema</td>
<td>• Nausea and vomiting</td>
</tr>
<tr>
<td>• Seizures</td>
<td>• Confusion or personality changes</td>
</tr>
<tr>
<td>• Increased mortality risk</td>
<td>• Neurologic dysfunction</td>
</tr>
<tr>
<td>• Gait disturbances</td>
<td>• Seizures (with very low serum sodium levels)</td>
</tr>
<tr>
<td>Rapid correction reverses cerebral edema without sequelae</td>
<td>Rapid correction may cause brain dehydration and osmotic demyelination syndrome (ODS)</td>
</tr>
</tbody>
</table>

Potential Consequences of Uncorrected Hyponatremia

Falls: Common Symptom of Chronic “Asymptomatic” Hyponatremia

- Adjusted OR 67.4, 95% CI 7.5–607.4, p < 0.001
- Patients with chronic “asymptomatic” hyponatremia admitted for falls significantly more frequently than patients with normal serum sodium

References:
Hyponatremia Increases Fracture Risk

- Hyponatremia ([Na+] < 135 mmol/L) increased fracture risk in patients with chronic kidney disease independent of osteoporosis.
- Hyponatremia induces a 5-fold increase in osteoclasts compared with normonatremic controls.


Consider case scenario of 76-year-old woman who presents to ED after a fall.
- Complains of hip pain, nausea, and dizziness.
- Has felt “unsteady” recently. History of depression, hypertension, and hyperlipidemia.

What is often overlooked as contributing to falls in patients like this?
- a. High blood pressure
- b. Advanced age
- c. Medications
- d. Dementia

Treating Chronic Hyponatremia in Heart Failure

Key Points for Treating Hyponatremia in Heart Failure

- Consider volume status of patient with hypervolemia
  - Apply treatments that do not exacerbate condition
- Fluid restriction with diuretics may provide modest improvement in hyponatremia
- Hypertonic saline infusions plus high doses of loop diuretics have shown improved outcomes
  - Monitor serum sodium frequently

Vasopressin Receptor Antagonists

Indications
- Conivaptan - Treatment of euvolemic and hypervolemic hyponatremia in hospitalized patients
- Tolvaptan – Treatment of clinically significant hypervolemic and euvoletic hyponatremia (serum sodium < 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with HF, cirrhosis, and SIADH

Tolvaptan (Oral)
- Available in 15-mg and 30-mg tablets
- Dosing: 15 mg orally once daily
  - May increase at intervals >24 hr to maximum 60 mg once daily
- Limit therapy to 30 days
- Should only be initiated and re-initiated in hospital setting
  - Must review FDA-approved medication guide with every patient
- Contraindicated with potent CYP3A4 enzyme inhibitors
  - Examples: ketoconazole,itraconazole,indinavir
- Decreased bioavailability when administered via nasogastric tube

Safety Warning for Tolvaptan: Prescribing Information Revised
- Serious and potentially fatal liver injury
- Clinical trial, polycystic kidney disease (n = 1400)
  - Significant elevations in liver function tests
  - Reversible following tolvaptan discontinuation
  - Doses of 120 mg/day (higher than in hyponatremia)
- Liver damage not reported in hyponatremia trials
- Precautions
  - Limit use to 30 days
  - Avoid use in patients with underlying liver disease
  - Discontinue if symptoms of liver injury

Conivaptan (IV)
- Administer IV via large veins
  - Infusion-site reactions (63–73%), change infusion site every 24 hr
- Available as 20 mg/100 mL premixed in 5% dextrose
- Dosing: 20 mg IV loading dose over 30 min, then 20 mg as continuous infusion over 24 hr
  - Moderate liver impairment: initiate half of normal dose
- Duration of infusion limited to 4 days
- Limited data on IV drug–drug compatibility
- Contraindicated with potent CYP3A4 enzyme inhibitors
  - Examples: ketoconazole,itraconazole,indinavir

Conivaptan Mixed (V1a+V2) IV 5
- Induce highly hypotonic urine and aquareesis without substantially affecting electrolyte excretion
- Avoid concomitant use of fluid restriction

Tolvaptan V 2 Oral 12

<table>
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<tr>
<th>Agent</th>
<th>Receptor Selectivity</th>
<th>Formulation</th>
<th>Half-life, hr</th>
<th>Urine Volume</th>
<th>Urine Osmolality</th>
<th>FDA Approval Status</th>
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<td>12</td>
<td>↑</td>
<td>↓</td>
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Economic Issues Pertaining to Patients with Heart Failure

Heart Failure and Tolvaptan

- Recall etiology of hyponatremia in patients with heart failure
  - If treat underlying disease, then hyponatremia may not occur
- Consider costs
  - Third-party coverage
  - Cost to the patient
  - Need to restart tolvaptan in hospital, possibly readmit patient for re-evaluation
- HF patients have high rate of readmissions
  - If less than 30 days, then no reimbursement from CMS

CMS = Centers for Medicare and Medicaid Services

If you had a patient with HF and tolvaptan was used during hospitalization to treat hyponatremia, what would you recommend?

a. Discontinue tolvaptan 24 hours before discharge
b. Continue 30 days as outpatient if covered by insurance
c. Continue indefinitely if covered by insurance
d. Discourage outpatient use and recommend other options

Hyponatremia Treatment Protocols, Algorithms, and Standardized Order Sets

Hyponatremia Protocols

- Expert panel recommendations on the diagnosis, evaluation, and treatment of hyponatremia
  - October 2013 in American Journal of Medicine
- Closest thing available to help with treatment protocol development
- Algorithms help to stratify patients to determine appropriate treatment options

Treatment Pathways

- Hyponatremia algorithm is an example of a disease-based algorithm
- Consider complementing that with a therapy-based protocol, such as
  - Fluid restriction protocol
  - Vaptans protocol
  - Hypertonic saline protocol

Which of the following disease-based and therapy-based protocols or order sets do you have? Select all that apply.

a. Hyponatremia treatment algorithm
b. Fluid restriction protocol
c. Hypertonic saline protocol
d. Conivaptan protocol or order set
e. Tolvaptan protocol or order set

Treatment Protocol Development

- Choose a physician champion to facilitate its development
- Include as many of the following as part of an interdisciplinary team
  - Hospitalist
  - Nephrologist
  - Critical care specialist
  - Cardiologist
  - Neurologist
  - ED physician
  - Pharmacist
  - Nurse
- Develop and revise disease-based or therapy-based protocols based on new evidence and experience
- Educate relevant hospital staff on implementation and adherence to protocols

Conclusion

- Hyponatremia is associated with adverse clinical and economic consequences
- Management is complex
  - Treatment options influenced by sodium level and chronicity of hyponatremia
  - Patients with heart failure can be especially challenging
- While guidance is available, no national guidelines exist
- Pharmacists are in a unique leadership position to develop hospital-based hyponatremia protocol
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Algorithms for the Medical intensive Care Unit: Hyponatremia (Na < 135 meq/L).

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Selected References


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Self-assessment Questions

1. As demonstrated by Zilberberg et al. (2008) in an evaluation of a large database, hospitalized patients with hyponatremia had all of the following outcomes compared with patients without hyponatremia EXCEPT
   a. Increased hospital costs.
   b. Increased mortality.
   c. Lower percentage requiring mechanical ventilation.
   d. Higher percentage requiring intensive care.

2. In a study of patients in one surgical intensive care unit by Sakr et al. (2013), patients with normonatremia with sodium fluctuations of more than 6 mEq/L compared with patients without fluctuations have been associated with
   b. Lower risk of hospital death.
   c. Prolonged length of stay.
   d. Shorter length of stay.

3. A 75-year-old woman presents to the emergency department after a fall. She complains of hip pain, nausea, and dizziness. She has felt “unsteady” recently. A CT scan of the head is negative, and x-ray shows evidence of a hip fracture. She has a history of depression, hypertension, and hyperlipidemia. The patient is noted to have hyponatremia based on serum sodium concentration of 118 mEq/L. Based on her symptoms, the chronicity of this patient’s hyponatremia is most likely
   a. Acute.
   b. Chronic.
   c. Unable to be determined.

4. What is the primary value of having a disease-based algorithm for use within the hospital?
   a. Ensures that hyponatremia is treated only within intensive care units.
   b. Ensures that hyponatremia is treated only by nephrologists and intensivists.
   c. Helps stratify patients to determine appropriate treatment options.
   d. Serves as source of specific prescribing information for hyponatremia treatment options.

Answers
1. c
2. a
3. b
4. c
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Instructions for Processing CE Credit with Enrollment Code

Pharmacists and Technicians:
All ACPE accredited activities which are processed on the eLearning site will be reported directly to CPE Monitor. To claim pharmacy credit, you must have your NABP e-profile ID, birth month, and birth day. If you do not have an NABP e-Profile ID, go to www.MyCPEMonitor.net for information and application. Please follow the instructions below to process your CPE credit for this activity.

1. The ASHP eLearning site allows participants to obtain statements of continuing education conveniently and immediately using any computer with an internet connection. Type the following link into your web browser to access the e-Learning site: http://elearning.ashp.org/my-activities

2. If you already have an account registered with ASHP, log in using your username and password. If you have not logged in to any of the ASHP sites before and/or are not a member of ASHP, you will need to set up an account. Click on the Register link and follow the registration instructions.

3. Once logged in to the site, enter the enrollment code for this activity in the field provided and click Redeem.
   Note: The Enrollment Code was announced at the end of the live activity.
   Please record the Enrollment Code in the grid below for your records.

4. The title of this activity should now appear in a pop-up box on your screen. Click on the Go button or the activity title.

5. Complete all required elements. A green ✔ should appear as each required element is completed. You can now claim your credit.

6. Available credit(s) will appear beneath the completed required activities. Look for your profession in the list of available credits and click the appropriate Claim button. You might have to click to see more credit options if you don’t see your profession listed.

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7. Review the information for the credit you are claiming. If all information appears to be correct, check the box at the bottom and click Claim. You will see a message if there are any problems claiming your credit.

8. After successfully claiming credit, you may print your statement of credit by clicking on Print. If you require a reprint of a statement of credit, you can return here at any time to print a duplicate. Please note that for CPE credit, printed statements may not be necessary because your credit will be reported directly to CPE Monitor.

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