NATIONAL ASSOCIATION FOR CONTINUING EDUCATION

Alpha One Anti-trypsin Deficiency: Challenges in Diagnosis and Treatment

Final Outcome Report

Presented at:
Cleveland Clinic Florida
Weston, Florida
November 21, 2015

Report Date: January 5, 2016
Course Director

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Weston, FL

Course Accreditation

The National Association for Continuing Education is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The National Association for Continuing Education designates this live activity for a maximum of 8 AMA PRA Category 1 Credits™. Physicians should only claim the credit commensurate with the extent of their participation in the activity.

National Association for Continuing Education is approved as a provider of nurse practitioner continuing education by the American Association of Nurse Practitioners. AANP Provider Number 121222. This program has been approved for 8.0 contact hours of continuing education (which includes 1.25 hours of pharmacology).
Commercial Support

Challenges in Pulmonary and Critical Care: 2015 CME activity was supported through educational grants from the following companies:

Actelion
Baxalta
Boehringer Ingelheim Pharmaceuticals, Inc.
CSL Behring
Grifols
Mallinckrodt Pharmaceuticals
United Therapeutics Corporation
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
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<tbody>
<tr>
<td>7:00-7:45</td>
<td>Registration and Breakfast</td>
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<tr>
<td>7:45-8:00</td>
<td>Welcome Remarks: Franck Rahaghi, MD, MHS, FCCP</td>
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<tr>
<td>8:00-9:00</td>
<td>Pulmonary Hypertension: Goal Oriented Therapy: Abubakr Bajwa, MD</td>
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<tr>
<td>9:00-10:00</td>
<td>Idiopathic Pulmonary Fibrosis: How to Use our New Treatments: Felipe Martinez, MD</td>
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<tr>
<td>10:00-10:15</td>
<td>Break/Exhibits</td>
</tr>
<tr>
<td>10:15-11:15</td>
<td>Alpha One Anti-trypsin Deficiency: Challenges in Diagnosis and Treatment: Franck Rahaghi, MD, MHS, FCCP</td>
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<tr>
<td>11:15-12:15</td>
<td>Lung Cancer: Screening and the New Outlook: Jinesh Mehta, MD</td>
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<tr>
<td>12:15-1:00</td>
<td>Lunch and Exhibits</td>
</tr>
<tr>
<td>1:00-2:00</td>
<td>Identifying and Managing Patients with Sarcoidosis: Franck Rahaghi, MD, MHS, FCCP</td>
</tr>
<tr>
<td>2:00-3:00</td>
<td>Pathology of Pulmonary Diseases: COPD/Sarcoidosis/Idiopathic Pulmonary Fibrosis/Hypersensitivity Pneumonitis: Pablo A. Bejarano, MD</td>
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<tr>
<td>3:00-3:15</td>
<td>Break/Exhibits</td>
</tr>
<tr>
<td>3:15-4:15</td>
<td>COPD: Bridging the Gaps: Anas Hadeh, MD, FCCP</td>
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<tr>
<td>4:15-5:15</td>
<td>Palliative Care and Chronic Pulmonary Diseases: Nydia Martinez Galvis, MD</td>
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<tr>
<td>5:15-5:30</td>
<td>Concluding Remarks: Franck Rahaghi, MD, MHS, FCCP</td>
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Levels of Evaluation

Consistent with the policies of the ACCME, NACE evaluates the effectiveness of all CME activities using a systematic process based on the following model:

1. Participation
2. Satisfaction
3. Learning
   A. Declarative Knowledge
   B. Procedural Knowledge
4. Competence
5. Performance
6. Patient Health
7. Community Health

Level 1: Participation

- 156 attendees
- 43% Physicians; 25% NPs; 6% PAs; 5% RNs; 21% Other
- Over 36% in community-based practice
- 47% PCPs, 26% Pulmonology; 2% Cardiology; 1% Endocrinology
- 24% Other or did not respond

Did we reach the right audience? Yes!
Level 2: Satisfaction

- 99% rated the activity as very good to excellent
- 100% indicated the activity improved their knowledge
- 100% stated that they learned new strategies for patient care
- 83% said they would implement new strategies that they learned in their practice
- 100% said the program was fair-balanced and unbiased

Were our learners satisfied? Yes!
Level 2: Satisfaction

Upon completion of this activity, I can now –
Discuss the etiology of alpha one anti-trypsin deficiency (AATD); Explain the treatments for AATD; Discuss how to change your office flow to incorporate testing for AATD, utilization of ancillary staff, and the pulmonary function lab

Did learners indicate they achieved the learning objectives? Yes! 95% believed they did.
Outcome Study Methodology

Goal
To determine the effect this CME activity had on learners with respect to competence to apply critical knowledge, confidence in treating patients with diseases or conditions discussed, and change in practice behavior.

Dependent Variables

1. **Level 3-5: Knowledge, Competence, and Performance**
   Case-based vignettes and pre- and post-test knowledge questions were asked with each session in the CME activity. Identical questions were also asked to a sample of attendees 4 weeks after the program to assess retention of knowledge. Responses can demonstrate learning and competence in applying critical knowledge. The use of case vignettes for this purpose has considerable predictive value. Vignettes, or written case simulations, have been widely used as indicators of actual practice behavior. ¹

2. **Practitioner Confidence**
   Confidence with the information relates directly to the likeliness of actively using knowledge. Practitioner confidence in his/her ability to diagnose and treat a disease or condition can affect practice behavior patterns.

3. **Level 5: Self-Reported Change in Practice Behavior**
   Four weeks after CME activity, practitioners are asked if they changed practice behavior.

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4. Readiness to Change Behavior (Prochaska and DeClemente Model)

CME activities can motivate providers to move through different stages of change which can ultimately lead them to take action and modify their practice behavior in accordance with the objectives of the education. Movement through these stages of change is an important dependent variable to consider in evaluating the impact of CME. Participants were asked to evaluate their stage of change with respect to specific topics being presented.

- **Pre-contemplation stage**: I do not manage (Alpha One Deficiency), nor do I plan to this year.
- **Contemplation stage**: I did not manage (Alpha One Deficiency) before this course, but as a result of attending this course I'm thinking of managing it now.
- **Pre-contemplation/confirmation stage**: I do manage patients with (Alpha One Deficiency) and this course confirmed that I do not need to change my treatment methods.
- **Preparation for action stage**: I do manage patients with (Alpha One Deficiency) and this course helped me change my treatment methods.

Alpha One Anti-trypsin Deficiency: Challenges in Diagnosis and Treatment

Faculty
Franck Rahaghi, MD, MHS, FCCP
Director, Pulmonary Hypertension Clinic
Director, Pulmonary Education and Rehabilitation
Cleveland Clinic Florida
Weston, FL

Learning Objectives

• Discuss the etiology of alpha one anti-trypsin deficiency (AATD)
• Explain the treatments for AATD
• Discuss how to change your office flow to incorporate testing for AATD, utilization of ancillary staff, and the pulmonary function lab
## Key Findings

**Alpha One Anti-trypsin Deficiency: Challenges in Diagnosis and Treatment**

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge/Competence</td>
<td>Learners demonstrated improvement from pre to post-testing in their answers to three out of four of the case-based questions regarding Alpha One Anti-trypsin Deficiency.</td>
</tr>
<tr>
<td>Confidence</td>
<td>Whereas the majority of learners rated themselves as having very low confidence in their understanding of treating Alpha One Anti-trypsin Deficiency before the education some of the learners showed gains in confidence after the program.</td>
</tr>
<tr>
<td>Intent to Perform</td>
<td>As a result of this program, 32% of learners who did not manage patients with Alpha-1 before are considering doing so, while 34% indicated that they will change their treatment methods.</td>
</tr>
<tr>
<td>Change of Practice Behavior</td>
<td>88% of learners who responded to our four week survey indicated that they had changed their practice behavior to implement the learning objectives of this program within four weeks after they attended the activity.</td>
</tr>
</tbody>
</table>

*N=60*
Case Vignette Knowledge and Competence Assessment Questions presented before and after lecture. Boxed answer is correct

All of the following statements are true except:

- Alpha-1 Deficiency was discovered in 1963
- Elastase/Anti-elastase theory for AATD was proposed in 2000
- We have known since the 1960's that AAT is secreted in the liver
- AAT augmentation therapy was first offered in 1987
- The American Thoracic Society released their guidelines in 2003, recommending screening for AAT in all COPD patients

Pre N = 87
Post N = 92

P Value: >0.028 – Significant

Green highlight indicates significant difference between pre and post testing.
Case Vignette Knowledge and Competence Assessment Questions
(Presented before and after lecture. Boxed answer is correct.)

What is the likelihood that Jaime would have Alpha-1 Antitrypsin deficiency?

Pre N = 102
Post N = 106

Red highlight indicates no significant difference between pre and post testing.

P Value: <0.206 – Not Significant
Methods for identifying the majority of patients with AATD include all the following EXCEPT:

- Using spirometry as a way to identify patients
- Performing Point of Care testing using Kits
- Using reminders from PFT's or Electronic Medical Records to elicit testing

P Value: >0.035 – Significant

Pre N = 95
Post N = 100

Green highlight indicates significant difference between pre and post testing.
Case Vignette Knowledge and Competence Assessment Questions
(Presented before and after lecture. Boxed answer is correct.)

All of the following benefits have been shown in AATD replacement therapy (Registry or RCT) EXCEPT:

- Mortality Benefit of treatment in patient with lower FEV1
- Improvement in FEV1 Decline for FEV1<30%
- CT Densitometry Benefits
- Improvement in FEV1 Decline in FEV 35-65 range

Pre N = 85
Post N = 86

Green highlight indicates significant difference between pre and post testing.
Which of the statements below describes your approach to participating in the diagnosis and/or treatment of Alpha One Anti-trypsin Deficiency?

<table>
<thead>
<tr>
<th>Pre-Contemplation Stage</th>
<th>Contemplation Stage</th>
<th>Preparation for Action Stage</th>
<th>Pre-Contemplation/Confirmation Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>I do not participate in the diagnosis/and or treatment of Alpha One Anti-trypsin Deficiency, nor do I plan to this year.</td>
<td>I did not participate in the diagnosis/and or treatment of Alpha One Anti-trypsin Deficiency before this course, but as a result of attending this course I'm thinking of doing this now.</td>
<td>I do participate in diagnosis/and or treatment of Alpha One Anti-trypsin Deficiency and I now plan to change my treatment methods based on completing this course.</td>
<td>I do participate in the diagnosis/and or treatment of Alpha One Anti-trypsin Deficiency and this course confirmed that I don't need to change my methods.</td>
</tr>
</tbody>
</table>

N = 93
Changes in Confidence from Pre to Post-Testing
Alpha One Anti-trypsin Deficiency: Challenges in Diagnosis and Treatment

On a scale of 1 to 5, please rate how confident you would be in the diagnosis and/or treatment of Alpha One Anti-trypsin Deficiency:

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>Pre %</th>
<th>Post %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all confident</td>
<td>9%</td>
<td>9%</td>
</tr>
<tr>
<td>Slightly confident</td>
<td>31%</td>
<td>28%</td>
</tr>
<tr>
<td>Moderately confident</td>
<td>19%</td>
<td>38%</td>
</tr>
<tr>
<td>Pretty much confident</td>
<td>6%</td>
<td>18%</td>
</tr>
<tr>
<td>Very confident</td>
<td>7%</td>
<td>8%</td>
</tr>
</tbody>
</table>

Pre N = 102
Post N = 101
Intention to Change Practice Behavior and Implement Learning

- Very Likely: 58%
- Somewhat Likely: 22%
- Unlikely: 3%
- Not Applicable: 17%

N = 146
Discussion and Implications

Alpha One Anti-trypsin Deficiency: Challenges in Diagnosis and Treatment

Alpha One Antitrypsin Deficiency (AATD) is an under-diagnosed condition. The need for continued education in the area of AATD was established in a comprehensive needs assessment and gap analysis completed prior to the symposia. We tasked to increase awareness in the etiology and prevalence of AATD, to suggest ways to incorporate testing in daily practice and to communicate the efficacy of available treatments for AATD.

Knowledge/Competence: Attendee knowledge was assessed at two points for this activity: prior to the activity and immediately following the activity using the case vignettes and knowledge questions listed above. The results indicated improvement in knowledge in all of the areas tested as measured by positive changes in pre to post-test scores (three out of four areas in a statistically significant manner)

Readiness to Change: Thirty-four percent of attendees noted that they currently screen or test patients for AATD and that this course provided information that would lead to further changes in their care of patients with AATD. Thirty-two percent indicated that they did not screen or test patients for AATD prior to participating in this activity, but would consider doing so after having been exposed to the information taught.

Confidence: Participants indicated a strong overall increase in self-reported confidence levels in assessing patients for AATD. Attendees who reported that they felt moderately or fairly confident rose from 25% to 56% by the end of the activity.

Intention for Practice Change: Fifty eight percent of the attendees indicated that they were very likely to change their practice with respect to caring for patients who may have AATD after the activity, and 22% suggested that they would be likely to do so.

This activity was successful in the goal of improving understanding of AATD to primary care providers and pulmonologists and had a positive impact in terms of self-reported likelihood of practice change. There appears to be a need for further education on this topic with respect to understanding of AATD and screening patients who may have risk factors for this condition.