Alpha-1 Antitrypsin Deficiency (AAT):
A Primary Care Opportunity for Patients with COPD

Final Outcome Report for Eight Cities

Clinical Updates for Nurse Practitioners and Physician Assistants: 2014

Report Date: 02/15/2015
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*This applies to the full day CME activity, Clinical Updates for Nurse Practitioners and Physician Assistants.
Commercial Support

The Clinical Updates for Nurse Practitioners and Physician Assistants: 2014 series of CME activities were supported through educational grants or donations from the following companies:

AbbVie
Grifols
Lilly
Salix

Alpha-1 Antitrypsin Deficiency (AAT): A Primary Care Opportunity for Patients with COPD was supported by an independent medical education grant from Grifols.
Cities and Dates

Clinical Updates for Nurse Practitioners and Physician Assistants: 2014 Conference Schedule

<table>
<thead>
<tr>
<th>Date</th>
<th>City</th>
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<th>City</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 27, 2014</td>
<td>Fairfax, Virginia</td>
<td>November 8, 2014</td>
<td>Orlando, Florida</td>
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<tr>
<td>October 18, 2014</td>
<td>*Columbia, South Carolina</td>
<td>December 6, 2014</td>
<td>Pittsburgh, Pennsylvania</td>
</tr>
<tr>
<td>October 25, 2014</td>
<td>Charlotte, North Carolina</td>
<td>December 13, 2014</td>
<td>*Dallas, Texas</td>
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* Live Activity and Simulcast
Titles of Presentations

Taking the Sting Out of Injectable Therapies for Diabetes: Improving Communication and Breaking Barriers
  • Part I: Rationale for Injectable Therapies for Diabetes – Breaking the Barrier
  • Part II: Intensifying Diabetes Therapy – Making Injectables Work for Your Patient: A Case Based Approach
Patricia Munz, MSN, APN, CDE or Gary Scheiner, MS, CDE or Mark Stolar, MD

Alpha-1 Antitrypsin Deficiency (AAT): A Primary Care Opportunity for Patients with COPD
Susan Collazo, RN, MSN, ARNP-BC or Franck Rahaghi, MD, MHS, FCCP

Psoriasis: Connecting Science and Practice
  • Part I: Psoriasis Here and Now: More than just a Skin Disease
  • Part II: Treatment of Psoriatic Disease: Current and Evolving Strategies
Brad P. Glick, DO, MPH, FAOCD or Paul S. Yamauchi, MD, PhD

Inflammatory Bowel Disease: Risk Stratification and Treatment Strategies
Kimberly Carter, MS, PA-C or Gerald W. Dryden, MD, MSPH, MSc, AGAF, FASGE
Levels of Evaluation

Consistent with the policies of the ACCME, NACE evaluates the effectiveness of all CME activities using a systematic process based on Moore’s model. This outcome study reaches Level 5.

- Level 1: Participation
- Level 2: Satisfaction
- Level 3: Declarative and Procedural Knowledge
- Level 4: Competence
- Level 5: Performance
- Level 6: Patient Health
- Level 7: Community Health

Level 1: Participation

- 519 attendees in 8 cities
- 60% NPs; 28% PAs; 4% Physicians; 3% RNs; 5% Other
- 56% in community-based practice
- 60% Primary Care; 2% Cardiology 3% Gastroenterology; 35% Other or did not respond
- 97% provide direct patient care

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

- 98% rated the activity as very good to excellent
- 100% indicated the activity improved their knowledge
- 97% stated that they learned new strategies for patient care
- 90% said they would implement new strategies that they learned in their practice
- 99% said the program was fair-balanced and unbiased

Sample Size: N = approximately 519

Were our learners satisfied? Yes! Data was collected across eight cities for the Clinical Updates for Nurse Practitioners and Physician Assistants program.
Patients seen each week in a clinical setting regarding diagnosis and management of a patient with Alpha-1 Antitrypsin deficiency:

Sample Size: N = approximately 519
Did Learners Say They Achieved Learning Objective?

Upon completion of this activity, I can now – Identify who and when to test for AAT deficiency; Describe the 50-year history of alpha1-antitrypsin (AAT) deficiency; Discuss how to incorporate testing for AAT deficiency into everyday practice; Describe the new insights into the efficacy of treatment for AAT deficiency.

Yes! 99% believed they did. Data was collected across eight cities for the Clinical Updates for Nurse Practitioners and Physician Assistants program.

Sample Size: N = approximately 519
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.  

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.

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 (XXX illness), nor do I plan to this year.
- **Contemplation stage**: I did not manage (XXX illness) 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 (XXX Illness) and this course confirmed that I do not need to change my treatment methods.
- **Preparation for action stage**: I do manage patients with (XXX illness) and this course helped me change my treatment methods.

Alpha-1 Antitrypsin Deficiency (AAT):
A Primary Care Opportunity for Patients with COPD

Faculty
Susan Collazo, RN, MSN, ARNP-BC
Franck Rahaghi, MD, MHS, FCCP

Learning Objectives
1. Identify who and when to test for AAT deficiency.
2. Describe the 50-year history of alpha1-antitrypsin (AAT) deficiency.
3. Discuss how to incorporate testing for AAT deficiency into everyday practice.
4. Describe the new insights into the efficacy of treatment for AAT deficiency.
**Key Findings**

**Alpha-1 Antitrypsin Deficiency (AAT): A Primary Care Opportunity for Patients with COPD**

<table>
<thead>
<tr>
<th>Knowledge/Competence</th>
<th>Learners demonstrated improvement from pre to post-testing in their answers to <em>three</em> out of <em>four</em> of the case-based questions regarding Alpha-1 Antitrypsin deficiency.</th>
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</thead>
<tbody>
<tr>
<td>Confidence</td>
<td>Whereas the majority of learners rated themselves as having very low confidence in their understanding of treating Alpha-1 Antitrypsin deficiency before the education most of the learners showed moderate gains in confidence after the program.</td>
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<tr>
<td>Intent to Perform</td>
<td>As a result of this program, 61% of learners who did not manage patients with Alpha-1 before are considering doing so, while 15% indicated that they will change their treatment methods.</td>
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<tr>
<td>Change of Practice Behavior</td>
<td>89% 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>
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*N= 42

*Four week case question survey is sent to one city per topic*
Case Vignette Knowledge and Competence Assessment Questions
(Presented before and after lecture. Boxed answer is correct.)

All of the following statements are true except: (Learning Objective 1)

- **P Value:** <0.001 - Significant

- **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= 197  Post N= 203

Green highlight indicates significant difference between pre and post testing.
Jaime is a 54 y/o male pilot who reveals a 30 pk year previous history of tobacco use. The spirometry shows very severe obstruction, non reversible with bronchodilators.

What is the likelihood that Jaime would have Alpha-1 Antitrypsin deficiency? (Learning Objective 2)

P Value: <0.001 - Significant
Jaime was known to have COPD for a few years, but no physician had tested him in the past, in spite of the fact that they thought it would be good idea to do so.

Methods for systematically identifying the MAJORITY of patients with AATD include all the following EXCEPT: (Learning Objectives 2 & 3)

- Using spirometry as a way to identify patients
- Performing Point of Care testing using Kits on all COPD patients
- Using reminders from PFT's or Electronic Medical Records to elicit testing on all COPD patients
- Making all efforts to test all young patients with emphysema

Red highlight indicates no significant difference between pre and post testing.
Case Vignette Knowledge and Competence Assessment Questions

(Presented before and after lecture. Boxed answer is correct.)

After being diagnosed as an AAT deficient patient with ZZ genotype, and a level of 30 mg/dL below the protective threshold of 90 mg/dL, his spirometry is now 30%. Jaime’s practitioner suggested that because of his low FEV1, he should not be given augmentation therapy because it was too late.

All of the following benefits have been shown in AATD replacement therapy (Registry or RCT) except: (Learning objective 4)

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

P Value: <0.001 - Significant

Green highlight indicates significant difference between pre and post testing.

Pre N= 192  Post N= 217
Change in Practice Behavior Question
(presented after the lecture)

Which of the statements below describes your approach to participating in diagnosing and treating Alpha -1 Antitrypsin deficiency?

1. I do not participate in the diagnosis and treatment of Alpha -1 Antitrypsin deficiency, nor do I plan to this year.
2. I did not participate in the diagnosis and treatment of Alpha -1 Antitrypsin deficiency before this course, but as a result of attending this course I'm thinking of doing this now.
3. I do participate in the diagnosis and treatment of Alpha -1 Antitrypsin deficiency and I now plan to change my treatment methods based on completing this course.
4. I do participate in the diagnosis and treatment of Alpha -1 Antitrypsin deficiency and this course confirmed that I don't need to change my methods.

N = 241
Four Week Case Study Questions

Key Findings

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= 197  Post N= 203  4 Weeks Post N= 42

*Four week case question survey is sent to one city per topic

Green highlight indicates significant difference between pre and post testing.
Jaime is a 54 y/o male pilot who reveals a 30 pk year previous history of tobacco use. The spirometry shows very severe obstruction, non reversible with bronchodilators.

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

Green highlight indicates significant difference between pre and post testing.

Pre N=171  Post N=200  4 Weeks Post N=42

*Four week case question survey is sent to one city per topic

Green highlight indicates significant difference between pre and post testing.
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Methods for systematically 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 on all COPD patients
- Using reminders from PFT's or Electronic Medical Records to elicit testing on all COPD patients
- Making all efforts to test all young patients with emphysema

Pre N = 198  Post N = 208  4 Weeks Post N = 42

Red highlight indicates no significant difference between pre and post testing.
After being diagnosed as an AAT deficient patient with ZZ genotype, and a level of 30 mg/dL below the protective threshold of 90 mg/dL, his spirometry is now 30%. Jaime’s practitioner suggested that because of his low FEV1, he should not be given augmentation therapy because it was too late.

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

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

Green highlight indicates significant difference between pre and post testing.
Intention to Change Practice Behavior and Implement Learning
Alpha-1 Antitrypsin Deficiency (AAT):
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Describe/list any other educational activities that you attended in the last month concerning the diagnosing and treatment of Alpha-1 Antitrypsin Deficiency.

- None: 84%
- Live Conferences: 9%
- Enduring webcasts or monographs: 3%
- Journal activities: 5%

4 Weeks Post  N= 42
What specific skills or practice behaviors have you implemented for patients with Alpha-1 Antitrypsin deficiency since this CME activity? (Comments received from attendees at 4 week follow up)

- Looking closer at patients with COPD
- Screening in primary care setting instead of letting pulmonology
- Testing/screening patients more frequently
- Asking patients if they have been screened for AATD
- Ordered kits to test all of our patients with a diagnosis of COPD
- Use some of the resources provided to develop a ATT deficiency testing protocol for the
- Increased awareness of possibility of AATD in COPD patients
- Better communication of options
- Considered screening younger patients with COPD for AAT
- Testing and referring heterozygotes with normal level to pulmonology
Intention to Change Practice Behavior and Implement Learning

Alpha-1 Antitrypsin Deficiency (AAT):
A Primary Care Opportunity for Patients with COPD

What specific barriers have you encountered that may have prevented you from successfully implementing strategies for patients with Alpha-1 Antitrypsin deficiency since this CME activity? (Comments received from attendees at 4 week follow up)

- Difficulty finding and ordering lab in current EHR
- Lack of knowledge of the disease and treatment
- Third party payers coverage and co pay - Lack of insurance
- Not able to identify any patients with AATD
- Time and getting reimbursement for testing
- It is a challenge to make testing for alpha 1 a habit especially because cardiovascular health is on the forefront of our minds. I really appreciated how the speaker made me realize to importance of screening for alpha1 since COPD is the 3rd biggest killer in our nation
- Having the test available - Need to get kits for practice
- Patients not wanting to be tested
Changes in Confidence from Pre to Post-Testing

Alpha-1 Antitrypsin Deficiency (AAT):
A Primary Care Opportunity for Patients with COPD

On a scale of 1 to 5, please rate how confident you would be in the diagnosis and management of a patient with Alpha-1 Antitrypsin deficiency:

Pre %  N= 194
Post % N= 189
Discussion and Implications
Alpha-1 Antitrypsin Deficiency (AAT): A Primary Care Opportunity for Patients with COPD

The need for continued education in the evaluation and management of patients with Alpha-1 Antitrypsin Deficiency (AAT) was demonstrated based on literature reviews and surveys completed prior to the conference series. Attendee knowledge was assessed at 3 points for this program: prior to the lecture, immediately following the lecture and again at 4 weeks after the conference using the case vignettes and knowledge questions listed above. The results indicated a statistically significant improvement in knowledge in 3 of the 4 areas tested. Specifically, as a result of this lecture, participants: are more aware that neutrophil elastase (NE) was discovered in 1967, and the elastase-anti-elastase hypothesis was proposed in the same year; realize that 1-3% of all emphysema patients have severe AATD; and recognize that AAT replacement therapy has shown mortality benefit, improvement in CT densitometry, and improved FEV1 decline for patients with FEV 35-65 range, but no improvement in FEV₁ decline for those patients with FEV₁ < 30%. Attendees were still not clear that only screening all young people with emphysema for AAT deficiency would still miss many patients. Since the presentations of AATD vary, it is important to screen all COPD patients using spirometry, point of care testing, and electronic reminders from EMR and PFT's.

Data obtained from participants 4 weeks after the program demonstrated some change in learning from the post-test scores, but still notable improvement from pre-test scores in 3 of the 4 areas. These results suggest that most of the learning objectives for this activity have been effectively addressed with attendees. Persistent gaps in knowledge were evident with the following findings: 57% of participants still don't realize that the theory for both Elastase/Anti-elastase and AATD were proposed in 1967; 40% of learners are still unaware that 1-3% of individuals with severe obstructive disease have Alpha-1 Antitrypsin deficiency; while 65% remain unclear on the effective strategies for identifying patients for AATD which should include all patient with non-reversible airway obstruction regardless of age; 43% were still unaware that AAT replacement therapy has not been shown to improve FEV₁ decline in patients with FEV₁ <30%.
Discussion and Implications
Alpha-1 Antitrypsin Deficiency (AAT): A Primary Care Opportunity for Patients with COPD

Moderate to very confident levels rose from 10% to 63% by the end of the program. As a result of this program, 61% of learners who did not manage patients with Alpha-1 before are considering doing so, while 15% indicated that they will change their treatment methods. 89% of learners who responded to our four week survey indicated that they actually had changed their practice behavior to implement the learning objectives of this program within four weeks after they attended the activity.

Many participants identified specific skills and behaviors that they learned from the program like: looking closer at patients with COPD, screening in primary care setting instead of letting pulmonology, testing/screening patients more frequently, asking patients if they have been screened for AATD, ordering kits to test all patients with a diagnosis of COPD, using some of the resources provided to develop a ATT deficiency testing protocol for the increased awareness of possibility of AATD in COPD patients, testing and referring heterozygotes with normal AAT levels to pulmonology.

Barriers identified include: difficulty finding and ordering lab in current EHR, lack of knowledge of the disease and treatment, third party payers coverage and co pay, lack of insurance, difficulty identifying patients with AATD, time and getting reimbursement for testing.

Nearly 84% of participants had no other exposure to an educational activity on this topic in the month after this conference.

The notable changes in post test scores signify a clear gap in knowledge and an unmet need among primary care clinicians. It continues to be an important area for future educational programs. Additional programming should continue to educate clinicians on AAT deficiency, recognizing the relationship between severe obstructive disease and incidence for Alpha-1 Antitrypsin disease, the importance of testing all COPD patients for AATD, and understanding the benefit and implementation of augmentation therapy.