Lipid Management and Cardiovascular Risk Reduction: The Evolving Treatment Paradigm

Final Outcome Report for Sixteen Cities

Report Date: January 6, 2016

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Course Accreditation

The Association of Black Cardiologists, Inc. is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The Association of Black Cardiologists, Inc. designates this educational activity for a maximum of 1.0 *AMA PRA Category 1 Credit(s)™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Commercial Support

Lipid Management and Cardiovascular Risk Reduction: The Evolving Treatment Paradigm was supported by an educational donation provided by Amgen and by an educational grant from sanofi-aventis U.S. and Regeneron Pharmaceuticals.
## Cities and Dates

### Emerging Challenges in Primary Care: Update 2015

#### Conference Schedule

<table>
<thead>
<tr>
<th>May 2, 2015</th>
<th>June 20, 2015</th>
<th>September 19, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miami, FL</td>
<td>Columbus, OH</td>
<td>Sacramento, CA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>May 9, 2015</th>
<th>June 27, 2015</th>
<th>September 26, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baltimore, MD</td>
<td>Troy, MI</td>
<td>Ft. Lauderdale, FL</td>
</tr>
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| Tampa, FL | Denver, CO | San Antonio, TX |

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Atlanta, GA</td>
<td>St. Louis, MO</td>
<td>Uniondale, NY</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>June 6, 2015</th>
<th>August 29, 2015</th>
<th>October 17, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birmingham, AL</td>
<td>Houston, TX</td>
<td>San Diego, CA</td>
</tr>
</tbody>
</table>

| Raleigh, NC | Anaheim, CA | Nashville, TN |

*Simulcast and Live Conference

**BOLDED cities is where this lecture was given**
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 “self-reported”
- Level 6: Patient Health
- Level 7: Community Health

Level 1: Participation

• 3342 attendees in 16 cities
• 56% Physicians; 38% NPs or PAs; 4% RNs; 2% Other
• 53% in community-based practice, 10% Hospital, 9% Walk-in/Free standing clinic, 3% Academic, 14% Government, 12% Other
• 74% PCPs, 1% Endocrinology; 3% Cardiology; 22% Other or did not respond
• 91% provide direct patient care

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

- 98% rated the activity as excellent
- 99% indicated the activity improved their knowledge
- 96% stated that they learned new and useful strategies for patient care
- 88% said they would implement new strategies that they learned in their practice
- 99% said the program was fair-balanced and unbiased

Were our learners satisfied? Yes!

Sample Size: N = approximately 3342
Lipid Management and Cardiovascular Risk Reduction: The Evolving Treatment Paradigm

Patients seen each week in a clinical setting regarding treating a patient with Hypercholesterolemia:

Sample Size: N = approximately 3342
Did Learners Say They Achieved Learning Objective?

Upon completion of this activity, I can now - Discuss the benefits of LDL-C lowering with pharmacologic therapies that improve cardiovascular outcomes; recognize and understand the role of alternative or additional therapies in conjunction with statins; recognize the strengths and limitations of the 2013 ACC/AHA cholesterol guidelines and how to optimally implement the recommendations; recognize the potential role of emerging pharmacologic therapies to further lower LDL-C in those at high risk for cardiovascular disease; recognize and develop appropriate treatment strategies for special populations (women, elderly, ethnic minorities) that would benefit from lipid lowering therapy:

Yes! 99% of learners 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.

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.

Lipid Management and Cardiovascular Risk Reduction: The Evolving Treatment Paradigm

Learning Objectives:

1. Discuss the benefits of LDL-C lowering with pharmacologic therapies that improve cardiovascular outcomes.

2. Recognize and understand the role of alternative or additional therapies in conjunction with statins.

3. Recognize the strengths and limitations of the 2013 ACC/AHA cholesterol guidelines and how to optimally implement the recommendations.

4. Recognize the potential role of emerging pharmacologic therapies to further lower LDL-C in those at high risk for cardiovascular disease.

5. Recognize and develop appropriate treatment strategies for special populations (women, elderly, ethnic minorities) that would benefit from lipid lowering therapy.
Key Findings
Lipid Management and Cardiovascular Risk Reduction: The Evolving Treatment Paradigm

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge/Competence</td>
<td>Learners demonstrated significant improvement from pre to post-testing in their answers to five out of five of the case-based questions on the evolving lipid management treatment paradigm.</td>
</tr>
<tr>
<td>Confidence</td>
<td>Whereas the majority of learners rated themselves as having very low confidence in their understanding of the evolving lipid management treatment paradigm before the education, most of the learners showed very high gains in confidence after the program.</td>
</tr>
<tr>
<td>Intent to Perform</td>
<td>As a result of this program, 8% of learners who did not treat Hypercholesterolemia before are considering doing so, while 68% indicated that they will change their treatment methods.</td>
</tr>
<tr>
<td>Change of Practice Behavior</td>
<td>95% of learners who responded to our four week survey indicated that they had changed their practice patterns within four weeks after they attended the activity.</td>
</tr>
</tbody>
</table>

4 Weeks Post N= 42
MR, a 61-year-old male with an LDL-C of 130 mg/dL and diabetes has an ASCVD risk of 6.6% based on the new risk-calculator. What therapy should MR be started on according to the ACC/AHA 2013 guidelines? (Learning Objective 1)
Case Vignette Knowledge and Competence Assessment Questions
(presented before and after lecture—boxed answer is correct)

SJ, a 62 year old BF is hospitalized in the Coronary care unit following a non-ST segment MI and stent placement in a 95% right coronary lesion. Her admission lipids are LDL-C=90 mg/dl, HDL=35 mg/dL, triglycerides=160 mg/dl.

In addition to being placed on a statin, which of the following treatments has been shown to reduce her risk of major cardiovascular events? (Learning Objective 2)

Pre N = 1696   Post N = 1885

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)

Which of the following is NOT one of the 4 statin benefit groups according to the 2013 ACC/AHA Cholesterol Guideline to Reduce Atherosclerotic CV Disease? (Learning Objective 3)

- A patient with clinical ASCVD
- A patient with an LDL-C > 190 mg/dL
- A patient 56 years of age with diabetes and an LDL-C of 118 mg/dL
- A patient 67 years of age without diabetes or ASCVD with an LDL-C of 125 mg/dL and an estimated 10-year ASCVD risk of 7.5% or greater.
- A patient 28 years of age with an LDL-C of 145 mg/dL

P Value: <0.001 – Significant

Pre N = 1644  Post N = 1678

Green highlight indicates significant difference between pre and post testing.
Results to date with PCSK9 antibody use have demonstrated what effect? (Learning Objective 4)

P Value: <0.001 – Significant

### Case Vignette Knowledge and Competence Assessment Questions
(presented before and after lecture—boxed answer is correct)

- **Comparing lowering of LDL-C to high-intensity statins**
  - Pre N = 1525
  - Post N = 1757
  - Green highlight indicates significant difference between pre and post testing.

- **Significant reductions of LDL-C levels on top of statin therapy**
  - 13% (Pre) → 9% (Post)
  - 32% (Pre) → 30% (Post)

- **Regression of atherosclerotic disease as measured by carotid intimal medial thickness studies**
  - 6% (Pre) → 1% (Post)

- **Hepatic fibrosis at the phase 3 doses studied**
  - 9% (Pre) → 5% (Post)

- **None of the above**
  - 16% (Pre) → 5% (Post)
According to the 2013 ACC AHA Cholesterol guidelines, which of the following is recommended therapy for a 78 year old male who suffers an NSTEMI? (Learning Objective 5)

Case Vignette Knowledge and Competence Assessment Questions
(presented before and after lecture—boxed answer is correct)

![Bar chart showing the percentage of correct answers before and after the lecture. Pre N = 1719, Post N = 1747. Green highlight indicates significant difference between pre and post testing.]

P Value: <0.001 – Significant

- High intensity statin therapy
- High intensity statin therapy plus Ezetimibe
- Moderate Intensity statin therapy
- Moderate Intensity statin therapy plus Ezetimibe
- Ezetimibe alone

Pre % | Post %
--- | ---
High intensity statin therapy | 38% | 26%
High intensity statin therapy plus Ezetimibe | 15% | 16%
Moderate Intensity statin therapy | 25% | 38%
Moderate Intensity statin therapy plus Ezetimibe | 18% | 18%
Ezetimibe alone | 4% | 2%
Which of the statements below describes your approach to treating Hypercholesterolemia?

<table>
<thead>
<tr>
<th>Statement</th>
<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 treat Hypercholesterolemia, nor do I plan to this year.</td>
<td>14%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I did not treat Hypercholesterolemia, but as a result of attending this course I'm thinking of doing this now.</td>
<td>8%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I do treat Hypercholesterolemia and this course helped me change my methods.</td>
<td>68%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I do treat Hypercholesterolemia and this course confirmed that I don't need to change my methods</td>
<td>8%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

N= 1598
MR, a 61-year-old male with an LDL-C of 130 mg/dL and diabetes has an ASCVD risk of 6.6% based on the new risk-calculator. What therapy should MR be started on according to the ACC/AHA 2013 guidelines? (Learning Objective 1)

Four Week Case Study Questions

Key Findings

Green highlight indicates significant difference between pre and post testing.
SJ, a 62 year old BF is hospitalized in the Coronary care unit following a non-ST segment MI and stent placement in a 95% right coronary lesion. Her admission lipids are LDL-C=90 mg/dl, HDL=35 mg/dL, triglycerides=160 mg/dl.

In addition to being placed on a statin, which of the following treatments has been shown to reduce her risk of major cardiovascular events? (Learning Objective 2)

![Four Week Case Study Questions Key Findings](image_url)

Pre N = 1696  Post N = 1885  4 Weeks Post N = 42

Green highlight indicates significant difference between pre and post testing.
Which of the following is NOT one of the 4 statin benefit groups according to the 2013 ACC/AHA Cholesterol Guideline to Reduce Atherosclerotic CV Disease? (Learning Objective 3)

- A patient with clinical ASCVD
- A patient with an LDL-C > 190 mg/dL
- A patient 67 years of age without diabetes or ASCVD with an LDL-C of 125 mg/dL and an estimated 10-year ASCVD risk of 7.5% or greater.

A patient 28 years of age with an LDL-C of 145 mg/DL

Green highlight indicates significant difference between pre and post testing.
Four Week Case Study Questions

Key Findings

Results to date with PCSK9 antibody use have demonstrated what effect? (Learning Objective 4)

- Comparable lowering of LDL-C to high-intensity statins
- Significant reductions of LDL-C levels on top of statin therapy
- Regression of atherosclerotic disease as measured by carotid intimal medial thickness studies
- Hepatic fibrosis at the phase 3 doses studied
- None of the above

Pre N = 1525  Post N = 1757  4 Weeks Post N = 42

Green highlight indicates significant difference between pre and post testing.
According to the 2013 ACC AHA Cholesterol guidelines, which of the following is recommended therapy for a 78 year old male who suffers an NSTEMI? (Learning Objective 5)

![Graph showing treatment options](image)

- High intensity statin therapy
- High intensity statin therapy plus Ezetimibe
- Moderate Intensity statin therapy
- Moderate Intensity statin therapy plus ezetimibe
- Ezetimibe alone

Key Findings

- Pre N = 1009
- Post N = 1011
- 4 Weeks Post N = 42

Green highlight indicates significant difference between pre and post testing.
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On a scale of 1 to 5, please rate how confident you would be in treating Hypercholesterolemia in patients that are not achieving optimal goals or are refractory to statin therapy?

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>Pre Percentage</th>
<th>Post Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all confident</td>
<td>10%</td>
<td>2%</td>
</tr>
<tr>
<td>Slightly confident</td>
<td>12%</td>
<td>12%</td>
</tr>
<tr>
<td>Moderately confident</td>
<td>35%</td>
<td>36%</td>
</tr>
<tr>
<td>Pretty much confident</td>
<td>23%</td>
<td>35%</td>
</tr>
<tr>
<td>Very confident</td>
<td>7%</td>
<td>15%</td>
</tr>
</tbody>
</table>

Pre N= 1650  Post N= 1856
Describe/list any other educational activities that you attended in the last month concerning the treatment of Hypercholesterolemia in patients that are not achieving optimal goals or are refractory to statin therapy?

Lipid Management and Cardiovascular Risk Reduction: The Evolving Treatment Paradigm

- None: 69%
- Live Conferences: 14%
- Enduring webcasts or monographs: 2%
- Journal activities: 14%

4 Weeks Post  N= 42
Lipid Management and Cardiovascular Risk Reduction: The Evolving Treatment Paradigm

Content Reinforcement

• Every lecture developed for the Emerging Challenges Series is reinforced with a “Clinical Highlights” document (copy attached)
  • Faculty develop a 1-2 page document with the key teaching points or “clinical pearls” they feel the audience should learn as a result of this program.
  • Clinical Highlights are distributed to all participants the week after the program for download and printing. They can use this in their practice as a tool and reminder of the content presented.
  • There is no additional CME credit offered for this.
Lipid Management and Cardiovascular Risk Reduction: The Evolving Treatment Paradigm

What specific skills or practice behaviors have you implemented the treatment of Hypercholesterolemia in patients that are not achieving optimal goals or are refractory to statin therapy since this CME activity?
(Comments received from attendees at 4 week follow up)

- Implementing statin treatment on high risk patients
- Screening testing; f/u review of treatment plans based on guidelines
- Diet counseling
- Medication review and adjustments per guidelines
- Using PCSK9 therapies
- Using high intensity statin
- Aggressive treatments in high cholesterol patient with diabetes
- Advised a patient on the use of statin based on lipids level
- More tightly controlling LDL in high risk patient
- More efficient evaluation of patients and intense follow up
- Intensifying statins for CAD
- I am able to better recognize if a patient is on the best medical regimen in regards to dyslipidemia
- More aggressive intervention
- Better use of statins and other lipid reducing drugs in addition to diet and exercise
- Using combination therapy
- Using guidelines to change statins
Lipid Management and Cardiovascular Risk Reduction: The Evolving Treatment Paradigm

What specific barriers have you encountered that may have prevented you from successfully implementing strategies for treatment of Hypercholesterolemia in patients that are not achieving optimal goals or are refractory to statin therapy since this CME activity?
(Comments received from attendees at 4 week follow up)

- Cost of lipid lowering medications are still high
- Insurance coverage for medications
- Patients being able to afford medications and following their diet plan
- Lay press printing bad articles on statins which decreases patient compliance
- Resistance from patient to comply with therapy
- Inability of the patients to follow treatment regimen
- Cost to patients
- Patient misconceptions on statin therapy
- Patient resistance to therapy or not willing to take
- Patients' poor compliance
- Determining which patients need low, moderate and high intensity statin treatment remains confusing
Discussion and Implications

The need for continued education in the area of Hypercholesterolemia management 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 listed above. Data collected from 3342 clinicians 16 meetings indicated a statistically significant improvement in knowledge in all 5 of the areas tested. Specifically, as a result of this lecture, participants: are more aware that a male patient with an LDL-C of 130 mg/dL, diabetes and an ASCVD risk of 6.6% based on the new risk-calculator, should be started on moderate-intensity statin therapy; recognize that ezetimibe has been shown to reduce the risk of major cardiovascular events when added to statin therapy whereas fenofibrate, niacin and cholestyramine have not; know that a 28 y/o patient with an LDL of 145 mg/dL is not a candidate for statin therapy; understand that addition of PCSK9 antibodies to statin therapy has resulted in significant reductions in LDL-C levels; realize that a 78 year old male who suffered an NSTEM would be a candidate for moderate intensity statin therapy based on his age.

Data obtained from participants 4 weeks after the program demonstrated some decline in learning from the post-test scores in 4 areas, but continued improvement from post-test scores in 1 area concerning choosing appropriate statin intensity according to current guidelines. These results suggest that nearly all of the learning objectives for this activity were effectively addressed with attendees.

Persistent gaps in knowledge were evident with additional education needed in the following areas: selecting appropriate candidates for statin therapy and level of intensity based on current lipid guidelines, the role of non-statin therapy in addition to statins for patients at persistently elevated cardiovascular risk; and the mechanism of action and role of PCSK9 antibody therapy.
Discussion and Implications

After the conference, 96% stated that they learned new and useful strategies for patient care and 21% of participants reported managing hypercholesterolemia in over 25 patients weekly and 70% see 6 or more weekly. This indicates a significant number of patients impacted by this program. Moderate to very confident levels rose from 65% to 86% by the end of the program. In addition, 8% of learners who did not manage Hypercholesterolemia before the program are considering doing so, while 68% who do manage Hypercholesterolemia, indicated that they will change their treatment methods as a result of this program. The program content was reinforced to participants with a “Clinical Highlights” document containing key teaching points from the program. This is distributed 1 week after the meeting.

In a survey taken after 1 month, attendees indicated multiple new, specific, practice behaviors they implemented as a result of this program that included: more dietary counseling, greater use of guideline directed care to select and dose statin therapy for patients at risk of vascular disease, more aggressive statin therapy, use of PCSK9 antibodies, and greater use of combination therapy to optimize lipid profiles. 69% of participants reported no other exposure to education on the topic, indicating that their behavior changes were most likely the result of this activity. Barriers to care surrounded cost of medications, formulary coverage, patient misconception of statin therapy, patient compliance and resistance to therapy.

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.