Novel Pharmacologic Advances for the Treatment of Hypercholesterolemia to Reduce LDL Levels in Patients Who Are Responsive and Refractory to Statin Therapy

Final Outcome Report
for Six Cities

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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

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Cities and Dates

Emerging Challenges in Primary Care: Update 2014-2015
Conference Schedule

October 25, 2014
San Diego, CA

November 1, 2014
Tampa, FL

November 8, 2014
Birmingham, AL

November 15, 2014
Nashville, TN

May 2, 2015
Miami, FL

May 9, 2015
Baltimore, MD
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

- 876 attendees in 6 cities
- 66% Physicians; 29% NPs or PAs; 4% RNs; 1% Other
- 58% in community-based practice, 8% Hospital, 8% Walk-in/Free standing clinic, 2% Academic, 14% Government, 10% Other
- 80% PCPs, 1% Endocrinology; 2% Cardiology; 17% Other or did not respond
- 92% provide direct patient care

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

• 99% rated the activity as excellent
• 100% indicated the activity improved their knowledge
• 97% stated that they learned new and useful strategies for patient care
• 93% said they would implement new strategies that they learned in their practice
• 98% said the program was fair-balanced and unbiased

Were our learners satisfied? Yes!
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Patients seen each week in a clinical setting regarding treating a patient with Hypercholesterolemia:

Sample Size: N = approximately 876
Did Learners Say They Achieved Learning Objective?

Upon completion of this activity, I can now identify concepts of residual cardiovascular risk despite statin therapy; review the role of genetics in statin efficacy; understand identification of minority populations that would benefit from lipid lowering therapy; and discuss the role of novel therapies to lower LDL and treat other lipid disorders:

Yes! 98% 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.

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Learning Objectives:

1. Identify concepts of residual cardiovascular risk despite statin therapy.
2. Review the role of genetics in statin efficacy.
3. Understand identification of minority populations that would benefit from lipid lowering therapy.
4. Discuss the role of novel therapies to lower LDL and treat other lipid disorders.
# Key Findings

**Novel Pharmacologic Advances for the Treatment of Hypercholesterolemia to Reduce LDL Levels in Patients Who Are Responsive and Refractory to Statin Therapy**

<table>
<thead>
<tr>
<th>Knowledge/Competence</th>
<th>Learners demonstrated significant improvement from pre to post-testing in their answers to <em>four</em> out of <em>four</em> of the case-based questions regarding treating Hypercholesterolemia.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confidence</td>
<td>Whereas the majority of learners rated themselves as having very low confidence in their understanding of treating Hypercholesterolemia in patients 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 71% indicated that they will change their treatment methods.</td>
</tr>
<tr>
<td>Change of Practice Behavior</td>
<td>90% 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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</tbody>
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4 Weeks Post N= 46
In randomized, controlled trials of statins vs. placebo, statins have consistently shown cardiovascular risk reduction of approximately:  (Learning Objective 1)

P Value: <0.001 – Significant

Pre N = 434    Post N = 503

Green highlight indicates significant difference between pre and post testing.
Which of the following patients would be expected to respond less well to statins: (Learning Objective 2)

A patient with a PCSK9 gain of function mutation
A patient with a PCSK9 loss of function mutation
A patient with apo E2 genotype
Unsure

Pre N = 461    Post N = 497

P Value: <0.001 – Significant

Green highlight indicates significant difference between pre and post testing.
Which of the following classes of medications would NOT provide additional LDL-C lowering when added to statin therapy? (Learning Objective 4)

P Value: <0.001 – Significant

Green highlight indicates significant difference between pre and post testing.
Which of the following statements is TRUE? (Learning Objective 3)

- **Hispanic Americans have the highest coronary heart disease rates in the US.**
- **Heart disease is the leading cause of death for African American women, but breast cancer is the leading cause of death for White women.**
- **The leading cause of death among Asian Americans is cardiovascular disease.**
- **Hispanic Americans have higher coronary heart disease mortality rates than African Americans.**

Pre N = 428  Post N = 476

Green highlight indicates significant difference between pre and post testing. P Value: <0.001 – Significant
Which of the statements below describes your approach to treating Hypercholesterolemia?

- Pre-Contemplation Stage
- Contemplation Stage
- Preparation for Action Stage
- Pre-Contemplation/Confirmation Stage

4 Weeks Post N= 44

I do not treat Hypercholesterolemia, nor do I plan to this year. 9%
I did not treat Hypercholesterolemia, but as a result of attending this course I'm thinking of doing this now. 8%
I do treat Hypercholesterolemia and this course helped me change my methods. 71%
I do treat Hypercholesterolemia and this course confirmed that I don't need to change my methods. 12%
In randomized, controlled trials of statins vs. placebo, statins have consistently shown cardiovascular risk reduction of approximately: (Learning Objective 1)
Which of the following patients would be expected to respond less well to statins:
(Learning Objective 2)

- A Patient with a PCSK9 gain of function mutation
- A patient with PCSK9 loss of function mutation
- A patient with apo E2 genotype
- Unsure

Green highlight indicates significant difference between pre and post testing.
Which of the following classes of medications would NOT provide additional LDL-C lowering when added to statin therapy? (Learning Objective 4)

- MTP inhibitors
- PCSK9 inhibitors
- Apo B antisense oligonucleotides
- Thrombin inhibitors
- Unsure

Green highlight indicates significant difference between pre and post testing.
Which of the following statements is TRUE? (Learning Objective 3)

Hispanic Americans have the highest coronary heart disease rate in the US.

Heart disease is the leading cause of death for African American women, but breast cancer is the leading cause of death for White women.

The leading cause of death among Asian Americans is cardiovascular disease.

Hispanic Americans have higher coronary heart disease mortality rates than African Americans.

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?

![Confidence Level Bar Chart]

Pre N= 448    Post N= 491
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Describe/list any other educational activities that you attended in the last month concerning the treatment of hypercholesterolemia?

- None: 54%
- Live Conferences: 26%
- Enduring webcasts or monographs: 9%
- Journal activities: 11%

4 Weeks Post  N= 44
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What specific skills or practice behaviors have you implemented for patients with hypercholesterolemia since this CME activity? (Comments received from attendees at 4 week follow up)

• Using increased dose of statins
• Using high potency statin in the highest-risk patients
• Close monitoring, early liver functions, avoiding polypharmacy
• Following the guidelines
• Moderate dose statins in all patients at risk
• I have used a higher dose statin to provide optimal CV risk protection with the statin and have used the AHA/ACC calculator to assess the need for treatment in young females with borderline LDL to gauge risk % and feel comfortable on starting therapy
• Providing patient education regarding use of statins
• Recommending diet, statin use, exercise programs
• Starting statin treatment based on calculated cardiovascular risk
What specific barriers have you encountered that may have prevented you from successfully implementing strategies for patients with hypercholesterolemia since this CME activity? (Comments received from attendees at 4 week follow up)

- Compliance, dietary, understanding issues
- Price of medication not covered by insurance plan
- Patient compliance
- Lack of time to spend with patients for education whenever I have a busy schedule
- Cost of some medications
- The biggest barrier are patient's who cannot tolerate statin therapy
- Patient non-adherence
- Lack of experience
- Getting patients to lose weight when their BMI is over 30
- Lack of time
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. The results indicated a statistically significant improvement in knowledge in all 4 of the areas tested. Specifically, as a result of this lecture, participants: are more aware that statin therapy provides a cardiovascular risk reduction of approximately 25%; understand that a patient with a PCKS9 gain of function mutation will not respond as well to statin therapy; recognize that MTP inhibitors, PCKS9 inhibitors and Apo B Antisense oligonucleotides all will provide additional LDL lowering when added to statin therapy but Thrombin inhibitors will not; and are aware that cardiovascular disease is the leading cause of death across all ethnic groups. After the conference, 92% of participants indicated that they were somewhat or very likely to utilize strategies learned from this program in their practice. 25% of participants reported managing hypercholesterolemia in over 25 patients weekly. This indicates a significant number of patients impacted by this program.

Data obtained from participants 4 weeks after the program demonstrated some decline in learning from the post-test scores but still significant improvement from the pre-test scores. Persistent gaps in knowledge exist: 46% of participants are still unaware that statins only reduce cardiovascular risk by 25%; 57% of learners are still not clear that patients with a PCSK9 gain of function mutation will respond less well to statin therapy; 43% are still unclear on the emerging therapies for to lower LDL when added to statin therapy; and finally 63% of learners are still not clear that cardiovascular disease is the leading cause of death among all Americans. These results suggest that all of the learning objectives for this activity were effectively addressed with attendees.
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 71% who do manage hypercholesterolemia, indicated that they will change their treatment methods as a result of this program. After the program, 93% of participants indicated that they are likely to utilize information learned from this presentation in their practice and 90% indicated that they had made changes 4 weeks after the program. 50% of participants report seeing 16 or more patients every week with hypercholesterolemia indicating a large number of patients being impacted by this program.

Attendees indicated multiple new, specific, practice behaviors they implemented as a result of this program that included increased use of high potency statins, closer attention to recent guidelines, use of the ACC/AHA calculator for assessing cardiovascular risk, and recommending lifestyle changes more often. 54% of attendees had no other exposure to educational materials on this topic 1 month after this program.

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 lipid lowering therapies to improve cardiovascular risk; the role of currently available and emerging therapies to augment the role of statin-based treatments; and addressing treatment strategies across different populations.