Clinical Lipidology: A Subspecialty Whose Time Has Come

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Goals of Today’s Presentation

• To define the subspecialty of Clinical Lipidology
• To identify major ongoing clinical controversies in our field
• To define the scope of knowledge required for excellence in clinical lipidology consultation as defined by the NLA Core Curriculum
• To discuss the educational initiatives designed by the NLA to enhance the knowledge base of clinical lipidology consultants
• To explore the steps that have been taken by the ABCL and ACCL to document academic proficiency in Clinical Lipidology
• To review current obstacles to the recognition of clinical lipidologists as subspecialists and suggest solutions
• To define the steps that are being taken by the NLA to achieve external recognition of Clinical Lipidology as a subspeciality
Definition of Clinical Lipidology

• An academic discipline focused primarily on knowledge of the pathophysiology, diagnosis and management of lipid and lipoprotein disorders to reduce or prevent detrimental clinical consequences

• Primary focus on ASCVD prevention, but also on prevention and treatment of triglyceride-related complications (pancreatitis, hepatosplenomegaly, xanthomas); and of disorders due to severely compromised lipid transport (fat soluble vitamin deficiencies, central and peripheral neuropathy and growth retardation).
Which Health Professionals are Involved?

• Basic and clinical researchers
• Academic and practicing primary and subspecialty care physicians
• Pharmacists
• Registered dietitian-nutritionists
• Exercise physiologists
• Nurses
• Nurse educators
• Health behavior professionals
Multidisciplinary Membership

NLA MEMBERSHIP

PHYSICIAN & ALLIED HEALTH

Data as of June 2015
Some Current Controversies in the Domain of the Clinical Lipidiologist

• Which guidelines should be used and when?
• Should the main focus be on statin adherence or on reduction of atherogenic cholesterol?
• Is statin dosage titration proven and useful?
• Should we set lipid/lipoprotein goals?
• How often and with what objective(s) should lipid/lipoprotein monitoring be performed?
• Can we support the viewpoint that “lower is better”?
• When should ezetimibe, resins, fibrates and niacin be used?
• What approach should be taken to the patient with statin intolerance?
• When should population-based versus individualized lipid management be used?
More Lipidology Controversies

- How is ASCVD risk best estimated?
- Is risk factor counting of value?
- Are risk calculators of value, and if so, when and which one?
- Is long-term risk defined enough to be of value?
- When should blood biomarkers and/or subclinical atherosclerosis testing be done?
- When, at what level, and how should TG be addressed?
- Who should be prescribed PCSK9 inhibitors and how and by whom is the process of getting approval best handled?
- What is the best strategy for lipid management in special populations?
Special Populations

- Children and adolescents
- Older patients
- Women throughout the lifespan
- Ethnic groups: African-Americans, Hispanics, south Asian Indians, American Indians/Alaska natives, others
- Patients with chronic inflammatory states
- HIV patients
- Patients with progressive ASCVD despite evidence-based therapy
Key Drivers of Clinical Lipidology Education in the U.S.

- The National Cholesterol Education Program Adult Treatment Panels I, II and III
- The American College of Cardiology/ American Heart Association
- The National Lipid Association
The Role of the NLA in Clinical Lipidology Education
History of the NLA

1997: Southeast Lipid Association (SEL) was established by a group of pioneering lipid researchers and clinicians

2000: SELA BOD voted to formulate a national association to promote the specialization of Clinical Lipidology

2002: NLA officially incorporated in Florida as a 501(c)6 non-profit professional membership organization

Today…

• 5 Regional Chapters: Southeast, Northeast, Midwest, Southwest, Pacific
• 3,000+ members
• Regularly issues recommendations, position statements, consensus statements, clinical practice tools, patient education materials…
NLA Core Curriculum (Updated July 2015)

• A collated outline developed by a committee of NLA academicians that enumerates and classifies a series of topics, the working knowledge of which serves as a basis for expertise in the management of lipid disorders and facilitates
  – High quality patient care
  – Educational activities to enhance provider knowledge
  – The identification of core competencies of individuals involved in lipid management
NLA Clinical Lipidology Core Curriculum

• Classification, measurement and metabolism of lipids and lipoproteins
• Pathophysiology and vascular biology of atherosclerosis
• Pathophysiology and diagnosis of genetic dyslipidemias
• Evidence-based medicine and clinically applicable statistical methods
• Identification and clinical significance of dyslipidemia-related risk factors, risk assessment tools, novel risk markers and subclinical atherosclerosis testing
• The appropriate use of national and international lipid management recommendations
NLA Clinical Lipidology Core Curriculum

- Dietary, exercise and behavioral interventions for dyslipidemia prevention and treatment
- Pharmacologic lipid therapy, including knowledge of drug metabolism, interactions and management of drug-related side effects, and the use of drugs for rare lipid disorders
- An understanding of indications for, expected benefits of, and patient safety issues related to LDL apheresis
- Dyslipidemia management in patients with other ASCVD risk factors and other complicating medical conditions
- Management of lipid disorders in special populations
NLA Educational Activities to Promote Clinical Lipidology

- NLA Annual Meeting and regional Clinical Lipid Updates
- NLA enduring materials (JCL, Lipid Spin)
- NLA self-assessment programs
- Web-based education (Lipid Insights; LipidEducation.com; NLA slide sets)
- Masters in Lipidology
- Lipid Academy
- Lipid Insights
- JCL Annual Summary of Clinical Lipidology
The Journal of Clinical Lipidology

- First edition 2007
- Bimonthly Elsevier journal
- Focuses on science and practice of Clinical Lipidology
- Available in print, web or as iOS/Android app

Editor in Chief: W. Virgil Brown, MD, FNLA
The Journal of Clinical Lipidology

- Included in Medline and PubMed
- 2014 impact factor 3.904 (83rd %-ile of 254 journals in pharmacy and pharmacology)
- Average monthly article downloads: 6, 615
LipidSpin

- Quarterly magazine
- Each issue sponsored by a regional chapter
- 9 - 12 articles per issue
  - Clinical reviews
  - Practical articles
  - Editorials
NLA Self Assessment Program-Volume 3

- Volume 1: The science of Clinical Lipidology
- Volume 2: Cardiometabolic risk assessment and management
- Volume 3: Therapeutic lifestyle change
- Volume 4: Pharmacologic management of dyslipidemia
- Volume 5: Consultative issues in Clinical Lipidology

525 multiple choice questions
150 CME hours
170 ABIM MOC credit hours
Available in print or on-line
CLM-SAP 17: Guidelines in Clinical Lipidology – Concepts and Controversies
Available on web at: www.lipid.org/education/clmsap

CLM-SAP App available on:
All of the following except for which one are basic tenets of the National Lipid Association Recommendations for the Patient-Centered Management of Dyslipidemia?

- A) An elevated level of cholesterol carried by circulating apolipoprotein B-containing lipoproteins (non-HDL-C and LDL-C, termed atherogenic cholesterol) is a root cause of atherosclerosis, the key underlying process contributing to most clinical ASCVD events.

- B) Reducing elevated levels of atherogenic cholesterol will lower ASCVD risk in proportion to the extent that atherogenic cholesterol is reduced. This benefit is presumed to result from atherogenic cholesterol lowering through multiple modalities, including lifestyle and drug therapies.

- C) For patients in whom lipid-lowering drug therapy is indicated, the identification of statin benefit groups and treatment based upon such identification is the optimal method for reducing ASCVD risk.

- D) The intensity of risk-reduction therapy should generally be adjusted to the patient’s absolute risk for an ASCVD event.

- E) Atherosclerosis is a process that often begins early in life and progresses for decades before resulting in a clinical ASCVD event. Therefore, both intermediate-term and long-term/lifetime risk should be considered when assessing the potential benefits and hazards of risk-reduction therapies.
Correct! The answer is C) For patients in whom lipid-lowering drug therapy is indicated, the identification of statin benefit groups and treatment based upon such identification is the optimal method for reducing ASCVD risk.

Options A, B, D and E described in this question are basic tenets of the 2014 NLA Recommendations for the Patient-Centered Management of Dyslipidemia. Option C, the correct answer, is the only incorrect statement. While the NLA Expert Panel recognized the importance of identifying those patients who would most likely benefit from lipid-lowering therapy and initiating and maintaining such therapy, their approach to ASCVD prevention is based on the initiation and maintenance of patient-specific lipid and lipoprotein goal-directed reduction in atherogenic cholesterol (non-HDL-C and LDL-C). Such reduction is accomplished by lifestyle therapy, often with supplemental moderate- or high-statin, and if necessary, non-statin therapy, the intensity of which depends upon the patient’s estimated absolute ASCVD risk.
• Offers an in-depth review of the core curriculum in Clinical Lipidology for healthcare professionals who desire to practice at an advanced level within the field and/or are pursuing ABCL certification

• Available formats: Live or web-based

• Live activity supplemented with Q and A sessions using an audience response system to facilitate interactive learning

• Access to resource page containing downloadable resources and additional self-study materials
Curriculum:

- Lipoprotein Metabolism, Genetics and Familial Lipid Disorders
- Vascular Biology and Atherosclerosis Pathogenesis
- Evidence-Based Medicine, Cardiovascular Risk Assessment and Guidelines
- Cardiovascular Biomarkers, Atherosclerosis Imaging and Evidence-based Practice
- Obesity, Metabolic Syndrome and Diabetes Mellitus
- Nutrition and Non-Pharmacologic Therapy
- Pharmacology Part I: Lipid Lowering Drugs, Drug Interactions and Drug Safety
- Pharmacology Part II: Randomized Controlled Trials, Evidence-Based Treatment and Combination Therapy
- Complex Cases and Consultative Lipidology
• Offers an introduction to applied lipid science
• Open to all healthcare professionals interested in developing a core competency in the diagnosis and treatment of dyslipidemia.
• Serves as a preparatory course for other advanced lipid training.
• Available formats: Live or web-based
• Live activity includes interactive group discussions on literature evaluation and patient cases
Curriculum:

• Lipids, Lipoproteins and Atherosclerosis
• Clinical Trials
• Primary Literature Evaluation and Discussion
• Dyslipidemia Diagnosis and Risk Assessment
• Pharmacologic Therapies
• Therapeutic Lifestyle Changes
• Overview of Clinical Guidelines in Lipid Management
• Challenging Patient Cases
LipidEducation.com

- Provides online adaptation of the NLA's live training courses
- Slide-audio presentations recorded by expert faculty
- Evidence-based lecture notes and references
- Embedded assessment questions
• Multimedia slide lecture modules (with downloadable PDFs of slide-audio presentation modules with evidence-based notes and references)
• Learning reinforcement test questions and answers
• A complete pre- and post-test to determine your achievement of the educational objectives for the program
• A personalized learning dashboard containing your assignments, transcript and assessment scores
• Glossaries of common terms, common abbreviations and key clinical studies
• A complete list of references per module
• Links to additional educational resources
Nicole's Master's in Lipidology Course Curriculum

Estimated Total Time for Completion: 12.5 hours

PRE-TEST

Masters in Lipidology Pre-Test

You have already completed the Pre-Test.

PRE-COURSE

Pre-Course Reading Materials

Prior to completing the course modules, it is recommended that you review the materials presented here. The "NLA Recommendations for Patient-Centered Management of Dyslipidemia" provides a detailed overview of available clinical practice guidelines and recommendations related to lipid management to reduce atherosclerotic cardiovascular risk. This resource may be used to provide an updated knowledge base before beginning the activity or may serve as a reference to which clinicians may refer when taking the program. The NLA Annual Summary of Clinical Lipidology 2016 provides updates based on emerging science, clinical considerations, and new NLA position and consensus statements.

After reviewing these materials, you should proceed to the modules of the course.

MODULE 1

Lipoprotein Metabolism: Genetics, and Familial Lipid Disorders

You have already completed this module.

MODULE 2

Vascular Biology and Atherosclerosis Pathogenesis

You have already completed this module.

MODULE 3

Evidence Based Medicine, Cardiovascular Risk Assessment, and Practice Guidelines

You have already completed this module.
**Objectives**

- To define and identify characteristics of an optimal atherosclerotic cardiovascular disease (ASCVD) biomarker
- To review the clinical utility of subclinical atherosclerosis testing, inflammatory biomarkers and widely used advanced lipoprotein testing
- To review the recommendations of current guidelines on the clinical use of biomarkers

Seamlessly move backwards and forward

View notes related to specific slides

Search for specific terms
• 60-minute interactive CME Webcast with Q&A
• Intended to encourage critical appraisal skills, impact clinical practice and encourage regular literature review
• Available both to NLA members and non-members
• Offered quarterly
• CME/CE accredited
Previous Webcast Topics:

- A Case Study in Dyslipidemia Management - Incorporating the NLA Recommendations into Practice
- Lysosomal Acid Lipase (LAL) Deficiency
- New Therapies for HoFH
- The Role of Omega-3's in Cardiovascular Disease
- CETP Inhibition - An Important Potential Strategy in Reducing Cardiovascular Events
- The Effects of Statin Therapy on Diabetes Incidence and Glycemic Control
Annual Summary of Clinical Lipidology

- First Annual Summary of Clinical Lipidology published as supplement to 2014 Nov/Dec issue of JCL

- “Living document” founded on principles of evidence-based medicine and based on emerging science, clinical considerations, and new NLA position and consensus statements

- Open access (available to NLA members and non-members)
How to Utilize Annual Summary

• **Online version** hyperlinks to information (tables, figures, journal articles, appendix etc.) so users can easily navigate and retrieve data

• Provides a central directory of tables and figures useful for both medical science as well as the day-to-day management of patients with dyslipidemia

• Available on [www.lipid.org](http://www.lipid.org)
FDA Approves Alirocumab (Praluent) for Certain Patients with Hypercholesterolemia

Following a June 2015 recommendation by the U.S Food and Drug Administration’s (FDA) Endocrinology and Metabolic Drugs Advisory Committee, the FDA has approved alirocumab for patients on maximally tolerated statin therapy with heterozygous familial hypercholesterolemia (HeFH) or with clinical... read more
NL A and AHA/ACC Slide Review Panel

Carl E. Orringer, MD (Chair)
Reviewers
Harold E. Bays, MD
Mary R. Dicklin, PhD
Matthew K. Ito, PharmD
Terry A. Jacobson, MD
Peter H. Jones, MD
Kevin C. Maki, PhD
James M. McKenney, PharmD

www.lipid.org
Click Recommendations
Click “View” or “Download this slide deck”
## Central Focus of Guideline

<table>
<thead>
<tr>
<th>ACC/AHA</th>
<th>NLA</th>
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</thead>
<tbody>
<tr>
<td>• Identification of statin benefit groups</td>
<td>• Identification of an individual patient’s ASCVD risk based on clinical</td>
</tr>
<tr>
<td>• Initiation and maintenance of high- or moderate-intensity statin</td>
<td>parameters and risk factors</td>
</tr>
<tr>
<td>therapy</td>
<td>• Initiation of ASCVD risk-based lipid-lowering therapy</td>
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<tr>
<td>• No recommendation for or against lipid goals</td>
<td>• Maintenance of lipid goals to assess effective reduction of atherogenic</td>
</tr>
<tr>
<td>• Recommendation against non-statin therapy because of less favorable</td>
<td>lipoproteins and enhance adherence</td>
</tr>
<tr>
<td>net benefit</td>
<td>• Use of high- or moderate-intensity statins, ± non-statins, if necessary,</td>
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Recognition of Clinical Lipidology as a Legitimate Subspecialty
Who is the ABIM?

• The AMA and the ACP formed the ABIM in 1936 to ensure uniform high standards for new physicians.
• A non-profit, independent evaluation organization that is physician-run, but is independent of any physician societies or membership organizations.
• Certifies 1 out of every 4 practicing physicians in the United States.
• Accountable to both the profession of medicine and to the public.
History of ABIM Recognition of New Subspecialties

• With the evolution of subspecialties, The American Board of Internal Medicine (ABIM) has introduced Certification exams in:
  – CVD, Clinical Cardiac Electrophysiology, Interventional Cardiology, Advanced Heart Failure and Transplant Cardiology and Adult Congenital Heart Disease
• Physician certification in CVD has evolved outside the more traditional ABIM pathways, and derivative boards have been established and recognized

“We must promote actual accountability based on standards set unimpeachably high. That is how we will show the public that we take their trust in us seriously.” – Douglas Zipes, MD (2001 ACC President)
ABIM Criteria for Recognition of a New Subspecialty

- Must have a unique body of knowledge that cannot be fully incorporated into the “parent” discipline.
- Must have clinical applicability to be practiced in a form that is distinct from the “parent” discipline.
- Must contribute to the scholarly generation of new information and must advance research in the field.
- Must be an important social need for the discipline and evidence that practice of the discipline improves patient care.
- The positive value of certification in the new discipline must outweigh any negative impact on the practice of general internal medicine or an existing subspecialty or on the basic education in the core competencies of internal medicine.
Clinical Lipidology Fellowships

NYU Langone Medical Center Lipids/Obesity Fellowship [med.nyu.edu](http://med.nyu.edu)
In-patient and outpatient consultation, academic conferences, apheresis, research

Baylor College of Medicine Lipid and Atherosclerosis Fellowship [bcm.edu](http://bcm.edu)
In-patient and outpatient consultation, clinical/translational research; basic research may be elected

Medical University of South Carolina [musc.edu](http://musc.edu)
Outpatient consultation, education in obesity, core curriculum 20 topic lecture series, research
Steps in the Right Direction

- **Clinical Lipidology fellowships**
  - Next steps:
    - Standardization of application of NLA Core Curriculum among current fellowship programs
    - Formation of more fellowships
    - Accreditation Council for Graduate Medical Education (ACGME) accreditation

- **Establishment and maintenance of certification boards in Clinical Lipidology**
  - American Board of Clinical Lipidology (ABCL)
  - Accreditation Council for Clinical Lipidology (ACCL)
Certification

Although independent from each other, the NLA, ABCL and ACCL work closely together to ensure adequate educational opportunities for lipid professionals.

COMMON GOAL: Recognition of Clinical Lipidology as a legitimate subspecialty of medicine.
American Board of Clinical Lipidology

• The only certification program for physicians specializing in Clinical Lipidology
• Documents and validates the specialized knowledge and advanced training required to practice in the field
• Enacts standards that mirror ABIM and other ABMS member boards
  – Undergoes yearly review and psychometric process
    – Current ABCL exam to be updated in 2015
  – Maintenance of Certification created in 2015
  – The NLA and ABCL anticipate that ABIM recognition of the specialty will improve reimbursement of clinical lipidologists
Pathway Toward ABIM Recognition

- Phone conference between NLA leadership and Furman MacDonald, MD, VP for Graduate Medical Education, ABIM 6/3/15
- The ABIM will not be considering applications for new subspecialty recognition until, the earliest, late 2016 or early 2017
- The NLA’s current educational programming is favorably viewed by the ABIM, including ABCL examination process and ABCL’s MOC process
- Maintaining these programs is an important step in a positive review by the ABIM
- The pathway for application for ABIM recognition is outlined in a document, “Final Report of the Committee on Recognizing New and Emerging Disciplines in Internal Medicine (NEDIM)-2
- The Presidents of the NLA and ABCL met on 8/1/15 and developed plans to convene a joint committee to facilitate the process
ABIM Diplomates Who Are ABCL Certified

- Internal Medicine: 532
- Cardiovascular Disease: 205
- Endocrinology and Metabolism: 9
- Interventional Cardiology: 2
- Geriatrics: 1
- Nephrology: 1
- Gastroenterology: 30
- Infectious Disease: 70
- Pulmonary Disease: 20

N=870
Accreditation Council for Clinical Lipidology

• Provides recognition and distinction in the field for the following healthcare professionals:
  ♦ Pharmacists ♦ Nurses ♦ Physician Assistants ♦ Dietitians ♦
  ♦ Exercise Specialists ♦ Physicians* ♦ PhDs

• Provides benefits to both the practitioner and the profession by:
  – Improving the quality of patient care
  – Setting benchmarks of clinical competency for lipid specialists
  – Enhancing the credibility of the health care professionals and the specialty of Clinical Lipidology in the medical community

• 2 levels of certification offered:
  – Advanced: Clinical Lipid Specialist (CLS)
  – Core: Basic Competency in Clinical Lipidology (BCCL)

*Those not wishing to or not ready to pursue ABCL certification
Breakdown of CLS Diplomates

- 50 Pharmcists
- 54 Nurse Practitioner
- 20 Nurse
- 19 Dietitian
- 25 Physician Assistant
- 3 Exercise Specialist
- 2 PhD
- 1 MD

N=174
Pathway Towards ACCL Recognition

• National Commission for Certifying Agencies (NCCA)
• NCCA accreditation demonstrates compliance with its *Standards for the Accreditation of Certification Programs*
  – Enables credentialing organizations to demonstrate to the profession it represents, and to the general public, that the program has met the stringent standards set by the credentialing community
  – Enhances a program's credibility and legitimacy by providing impartial, third party oversight of a conformity assessment system
Current Obstacles Toward Recognition of Clinical Lipidologists as Subspecialists

• Non-lipidologists can prescribe high-intensity statins, the most evidence-based ASCVD risk reduction therapy
• Non-lipidologists can prescribe adjunctive non-statin therapies
• Cardiologists and endocrinologists may believe that clinical lipidology is their domain
• Subspecialists may be hesitant to refer to primary care providers with clinical lipidology expertise
• Primary care providers may hesitate to refer to other primary care providers with clinical lipidology expertise
The NLA’s Role in Addressing the Obstacles

- Produce scientific statements and educational activities that enhance the role of the NLA as a significant source for evidence-based lipid-related education
- Sanction and promote the work of the ABCL and ACCL, which work to demonstrate mastery of the knowledge base defined by our core curriculum
- Promote the importance of demonstrated MOC, both to enhance patient care and to externally demonstrate our commitment to educational achievement
- Actively pursue ABIM, ACGME and NCCA accreditation
- Collaboration with other stakeholders to advance education, patient care and patient advocacy
FNLA

• **Mission:** To support patient and clinician educational, research and community outreach activities that enhance and support the initiatives of the NLA in its efforts to reduce CV events and deaths related to abnormalities of cholesterol metabolism.

• **Activities**
  – Clinician and patient education
  – Outreach programs
  – Grant opportunities

• **Supported by donor contributions**
2014 FNLA Initiatives

- NLA Events
- Triglyceride Public Awareness Campaign
- NLA Young Investigator Award
- Hunninghake Abstract Award
- New York Yankees FanFest
Summary

• Clinical Lipidology is a legitimate subspecialty with a well-defined knowledge base, the mastery of which qualifies clinicians to render high-quality patient care. Such knowledge provides the basis for engagement in lipidology-related educational and clinical research activities.

• The NLA serves the Clinical Lipidology community by providing a variety of educational activities, supporting the ABCL and ACCL, whose purpose is to certify educational achievement in the field.

• The NLA, ABCL and ACCL continue to collaborate to seek external recognition of the unique skills and services provided by certified clinical lipidologists and lipid specialists.