2017 | ACMG Annual Clinical Genetics Meeting

ACMG American College of Medical Genetics and Genomics
Translating Genes Into Health®

Toward Next-Generation Newborn Screening: Myth and Reality - R. Rodney Howell Symposium

Held in Phoenix, Arizona, March 21-25, 2017

Date of Release: April 3, 2017
Expiration Date: April 3, 2020 (CME, NSGC, P.A.C.E.®)
Estimate Time of Completion: 2 hours
Course must be completed by the expiration dates

COURSE DESCRIPTION

Recent advances in genomic technologies have brought tremendous success in the realm of clinical medicine, primarily as powerful diagnostic tools. The application of these same technologies to newborn screening holds exciting promises to better public health. However, we are stilling facing technical, economical, ethical, and psychological challenges. In this symposium, a panel of prominent leaders in the field with expertise in clinical genetics, laboratory genetics, public health, ethical and psychological sciences will explore new and emerging opportunities for promoting precision medicine at the public health level right from the newborn period throughout an individual's lifetime. Topics will span the full spectrum of public health genomic applications in newborn screening, focusing on emerging opportunities as well as challenges, both perceived and real, which must be addressed and overcome. Ample time will be afforded so that attendees have an opportunity to discuss the numerous technical, economical, ethical, and psychological issues that must be navigated as we begin to apply genomic technologies to newborn screening in order to realize the full promise of precision medicine in the public health setting.

Dr. Cynthia Morton (Next-generation Newborn Hearing Screening: The SEQaBOO Experience) declined to release her slides but you will be able to listen to her presentation.

LEARNING OBJECTIVES

At the conclusion of this course, participants should be able to:

- Review goals and principles of newborn screening and its great public health achievement
- Discuss technical, economical, ethical, and psychological issues involving newborn screening with regard to its impact on public health
- Recognize the pros and cons of genomic sequencing approaches to newborn screening for genetic diagnosis of disorders currently screened via conventional methods
- Identify appropriate approaches to the delivery of follow-up care and service to patients identified through genomic newborn screening and to their family members

TARGET AUDIENCE

All healthcare professionals interested in the diagnosis, management, treatment and prevention of genetic conditions and increasing their understanding of the genetic basis of common, chronic health problems affecting both children and adults will find the programming applicable to their practice. These select sessions from the ACMG Annual Meeting are targeted for the following professionals:

- Medical and clinical geneticists
- Physicians of all specialties with an interest in genetics, genomics and the genetic basis of disease
- Genetic counselors
- Laboratory geneticists, directors, technicians and technologists
- Researchers
- Pathologists
- Educators
- Nurses
- Dietitians
- Physician assistants
- Biotechnology and pharmaceutical development professionals
- Fellows, Trainees and Students
- Public health professionals
- Genetic/consumer advocates
- Others with an interest in the science and art of medical genetics and genomics

SESSIONS

- Newborn Screening: Past, Now, and Future- R. Rodney Howell, MD, FAAP, FACMG
- Newborn Screening and NexGen Sequencing from the Front Lines- Susan Berry, MD, FACMG, FAAP
- Next-generation Newborn Screening in Action: What We Have Learned from the BabySeq Project- Ingrid Holm, MD MPH, FACMG
- Next-generation Newborn Hearing Screening: The SEQaBOO Experience- Cynthia Morton, PhD
- NBSeq Dialogues & Dilemmas in the Public Health Setting: Ethical and Psychosocial Implications of Applying Genomic Technologies to Newborn Screening- Lynn Bush, PhD, MS, MA

Accreditation:

The American College of Medical Genetics and Genomics is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Credit Designation:

The American College of Medical Genetics and Genomics designates this activity for a maximum of 2 *AMA PRA Category 1 Credit*s™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Genetic Counselor Credit

The National Society of Genetic Counselors (NSGC) has authorized American College of Medical Genetics and Genomics to offer up to 2 Category 1 contact hours for this OnDemand course. The American Board of Genetic Counseling (ABGC) will accept CEUs earned for this course for the purposes of genetic counselor certification and recertification. Reporting of credits is sent to NSGC quarterly. Additional fee (~$25) applies for NSGC credit that is billed by NSGC.

P.A.C.E. CEUs – Laboratory Directors and Laboratory Personnel

ACMG is approved as a provider of continuing education programs in the clinical laboratory sciences by the American Society for Clinical Laboratory Science (ASCLS) Professional Acknowledgment for Continuing Education (P.A.C.E.®) Program. The American College of Medical Genetics and Genomics designates this course for a maximum of 2 contact hours. ACMG is approved by the Florida Board of Clinical Laboratory Personnel as CE Provider. ACMG is approved by the California Department of Health Services through the ASCLS P.A.C.E.® Program as CE Provider #275.

HIPAA Compliance

The ACMG supports medical information privacy. While the ACMG is not a "covered entity" under HIPAA 1996 and therefore is not required to meet these standards, ACMG wishes to take reasonable steps to ensure that the presentation of individually identifiable health information at ACMG-sponsored events has been properly authorized. All presenters have completed a form indicating whether they intend to present any form of individually identifiable healthcare information. If so, they were asked either to attest that a HIPAA-compliant consent form is on file at their institution, or to send ACMG a copy of the ACMG HIPAA compliance form. This information is on record at the ACMG Administrative Office and will be made available on request.

Content Validation

ACMG follows the ACCME policy on Content Validation for CME activities, which requires:

Content Validation and Fair Balance

1. ACMG follows the ACCME policy on Content Validation for CME activities, which requires:
   a) All recommendations involving clinical medicine must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.
   b) All scientific research referred to, reported or used in CME in support or justification of patient care recommendations must conform to the generally accepted standards of experimental design, data collection and analysis.

2. Activities that fall outside the definition of CME/CE; "Educational activities that serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession" (source: ACCME and AMA) will not be certified for credit. CME activities that promote recommendations, treatment, or manners of practicing medicine or pharmacy that are not within the definition of CME/CE or, are known to have risks or dangers that outweigh the benefits or, are known to be ineffective in the treatment of patients.
3. Presentations and CME/CE activity materials must give a balanced view of therapeutic options; use of generic names will contribute to this impartiality. If the CME/CE educational materials or content includes trade names, where available, trade names from several companies must be used.

Off-label Uses of Products

When an off-label use of a product, or an investigational use not yet approved for any purpose, is discussed during an educational activity, the accredited sponsor shall require the speaker to disclose that the product is not labeled

for the use under discussion, or that the product is still investigational. Discussions of such uses shall focus on those uses that have been subject of objective investigation.

Disclaimer: *ACMG educational programs are designed primarily as an educational tool for health care providers who wish to increase their understanding of the application of genomic technologies to patient care. The ACMG does not endorse, or recommend the use of this educational program to make patient diagnoses, particular by individuals not trained in medical genetics. Adherence to the information provided in these programs does not necessarily ensure a successful diagnostic outcome. The program should not be considered inclusive of all proper procedures and tests or exclusive of other procedures and tests that are reasonably directed at obtaining the same results. In determining the propriety of any specific procedure or test, a healthcare provider should apply his or her own professional judgment to the specific clinical circumstances presented by the individual patient or specimen.*

2017 ACMG Program and Education Committee Members Disclosures

Members of the ACMG Staff, Education and Program Committees involved in planning the 2017 ACMG Annual Clinical Genetics Meeting are required to disclose relevant relationships which could be perceived by some as a real or apparent conflict of interest in planning. All disclosures have been reviewed and conflicts of interest resolved by the Education Committee COI sub-committee or the Executive Director and CME Associate Director and conflicts of interest are disclosed. In the cases where a conflict existed then the committee member refrained from the discussion.

Following is a list of program and education committee members who have disclosed one or more such relationships and names of companies with which those relationships exist:

EC = Education Committee; PC = Program Committee; S = ACMG Staff

1. Major stockholder/ownership interest 2. Grant/Research Support (External) 3. Salary/Employment/Royalty(ies)/Honoraria 4. Consultant/consulting fees/other remuneration 5. Speakers' bureau	6. Non-remunerative positions of influence such as officer, board member, trustee, or public spokesperson (All Committee Members Below are on ACMG Committees –Members with other affiliations are listed) 7. Receipt of intellectual property 8. Other

Georgianne L. Arnold, MD, FACMG - Horizon, 2; Recordati, 2; Biomarin, 2; Actelion, 2; SIMD, 6; ACGME, 6; AAP, 6; ASHG, 6 (PC)
Karen W. Gripp, MD, FACMG – Wiley Publishing Inc., 3; FDNA, 4; Novartis, 4 (PC)
Fuki M. Hisama, MD, FACMG – Horizon Pharmaceuticals, 4; ABMGG, 6 (PC)
Christine A. Curtis, PhD, FACMG - CSI Laboratories, 3 (EC)
Thomas E. Mullen, PhD, MS, FACMG - Good Start Genetics Inc., 3 (EC)
Christian P. Schaaf, MD, PhD, FACMG - Springer Publishing Company, 3 (PC), (EC)
Katrina M. Dipple, MD, PhD, FACMG – ACGME, 6; AAP, 6; ASHG, 6; LA BioMed DSMB, 4; SIMD 6 (PC)

Following is a list of committee, education members and staff who have no relationships to disclose:

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Jennelle C. Hodge, PhD, FACMG (PC)
Jessica Smith, MD (PC)
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Penelope Freire, CMP (PC), (S)

SPEAKERS AND MODERATORS

Faculty Disclosures:

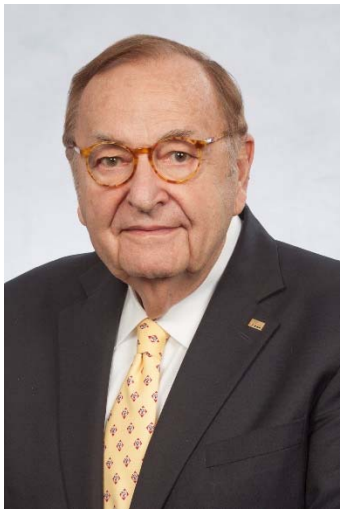
As a sponsor accredited by the ACCME, the American College of Medical Genetics and Genomics must ensure balance, independence, objectivity and scientific rigor in all its sponsored educational activities. All faculty participating in a CME-certified activity are expected to disclose to the audience any relevant financial interest(s) or other relationship(s) with the manufacturer(s) of any commercial product(s), provider(s) of commercial services or any commercial supporters, including diagnostic laboratories, of the activity discussed in an educational presentation. Relevant financial interest(s) or other relationship(s) can include such things as grants or research support, consultancy, major stock holder, etc. The intent of this disclosure is not to prevent a planner or speaker with a relevant financial or other relationship from course planning or making a presentation, but rather to provide learners with information on which they can make their own judgments. It remains for the audience to determine whether the speaker's interests or relationships may influence the presentation with regard to exposition or conclusion. All conflicts of interests have been reviewed and resolved by the education and CME subcommittee.

Moderator: Jun Shen, PhD, FACMG
Assistant Professor, Department of Pathology, Harvard Medical School, Harvard Medical School
No financial relationships to disclose.

Dr. Jun Shen is Assistant Professor in the Department of Pathology, Brigham and Women's Hospital, Harvard Medical School and Assistant Director of Laboratory for Molecular Medicine, Partners Personalized Medicine. She received her B.A. in Biochemistry and Molecular Biology / Computer Science from Dartmouth College and her Ph.D. in Neurobiology from Harvard University. She completed both a postdoctoral research fellowship in auditory neuroscience and a clinical molecular genetics fellowship at Harvard Medical School. Her research is focused on identifying the genetic etiology of diseases and developing innovative approaches to diagnosis, prevention and treatment of genetic disorders, particularly in the area of hereditary hearing loss. She serves on the Executive Committee of the Harvard Medical School Center for Hereditary Hearing Loss and chairs its Bioinformatics and Database Subcommittee. As Co-Principal Investigator of Hear-'n-SEQ: Sequencing Kids First For Hearing, part of the NIH Gabriella Miller Kids First Pediatric Research Program, she organizes the international consortium for genetic studies of childhood hearing loss. She volunteers on the ClinGen Hearing Loss Working Group, the NCC Newborn

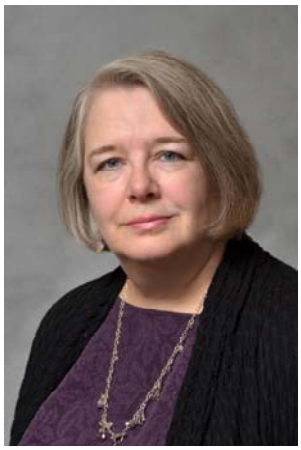
Screening Workgroup, and as an international collaborator in the Hearing and Sight Domain of the Genomics England Clinical Interpretation Partnership (GeCIP). She is a Clinical Molecular Geneticist certified by American Board of Medical Genetics and Genomics and a Fellow Member of the American College of Medical Genetics and Genomics. She currently serves on the ACMG Professional Practice and Guidelines Committee and its liaison to the Laboratory Quality Assurance Committee. She is also a Board Member and current Secretary of the Association of Chinese Geneticists in America.

Speaker: R. Rodney Howell, MD, FAAP, FACMG
University of Miami, Miller School of Medicine
No financial relationships to disclose.



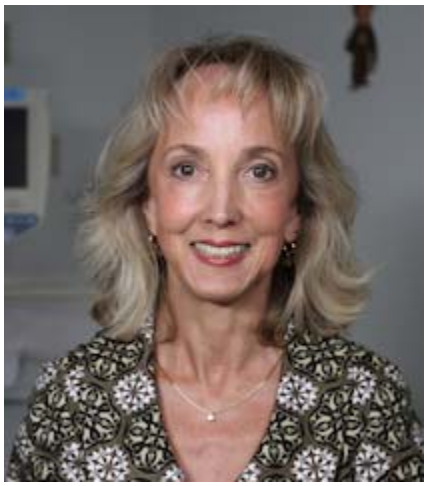
R. Rodney Howell, M. D. is Professor of Pediatrics and Chairman Emeritus, at the Miller School of Medicine of the University of Miami. He is certified by the American Board of Pediatrics, as well as by the American Board of Medical Genetics in the area of Clinical Biochemical Genetics. He has served as The Joseph P. Kennedy Jr. Scholar in Mental Retardation and Associate Professor of Pediatrics at the Johns Hopkins University School of Medicine, The David R. Park Professor and Chairman of Pediatrics at the University of Texas Medical School in Houston. He was recognized in 2007 with the Lifetime Achievement Award from the Duke University Medical Alumni Association, with the Lifetime Achievement Award of the American College of Medical Genetics Foundation in 2012, and the Harlan Sanders Lifetime Achievement Award in Genetics from the March of Dimes in 2013. To commemorate the 30th anniversary of the Federal Rare Disease Act, he was named one of the 30 Rare Disease Heroes by the U. S. FDA .In 2015, Dr. Howell was the first recipient of the Advocacy Award from the American Society of Human Genetics for his excellence and achievement in applications of human genetics for the common good. Dr. Howell was the Founding Chair (2004-2011) of the Secretary's Advisory Committee of Heritable Disorders in Newborns and Children, the congressionally-mandated Committee that advises the Secretary of HHS on issues concerning genetic testing in children. Dr. Howell has also been Chairman of the Muscular Dystrophy Association Board of Directors since 2007. He was elected President of the International Society of Neonatal Screening, based in The Netherlands in 2016.

Speaker: Susan Berry, MD, FACMG, FAAP
University of Minnesota
Financial relationships to disclose. (Self): Grant/Research from Horizon Pharma, Retrophin



Susan A. Berry, M.D. is Professor of Pediatrics and Genetics, Cell Biology and Development at the University of Minnesota. She is the Director of the Division of Genetics and Metabolism in the Department of Pediatrics. Like many genetics professionals, she sees adults and children with heritable conditions of all kinds. She has a particular interest in providing management for persons with inborn errors of metabolism and has a longstanding interest in improvement in their care through early diagnosis and treatment. Her research focuses on evaluation of long-term outcomes after newborn blood spot screening.

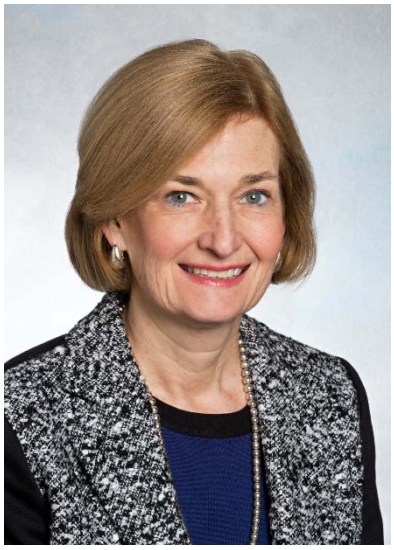
Speaker: Ingrid Holm, MD MPH, FACMG
Associate Professor, Department of Pediatrics, Harvard Medical School, Boston Children's Hospital and Harvard Medical School
No financial relationships to disclose.



Ingrid A. Holm, MD, MPH is faculty member of the Division of Genetics and Genomics at Boston Children's Hospital (BCH) and Associate Professor of Pediatrics at Harvard Medical School. She received her MD from the University of California, Los Angeles, and completed her residency in pediatrics, and fellowships in genetics and pediatric endocrinology, at BCH. In 2003 she completed the Harvard Pediatric Health Services Research Fellowship and received her MPH in Clinical Effectiveness from the Harvard School of Public Health. Dr. Holm's research is in the Ethical, Legal, and Social Implications (ELSI) of returning genomic information to children and parents. She developed a preference-setting model for participants to designate types of results to receive, and studied parental attitudes towards receiving results on their child. She developed a framework for ethical oversight of return of results at BCH, the Informed Cohort Oversight Board (ICOB). Dr. Holm is an investigator in the Electronic Medical Records and Genomics (eMERGE) Network. In eMERGE II she was co-PI of the Cincinnati Children's Hospital Medical

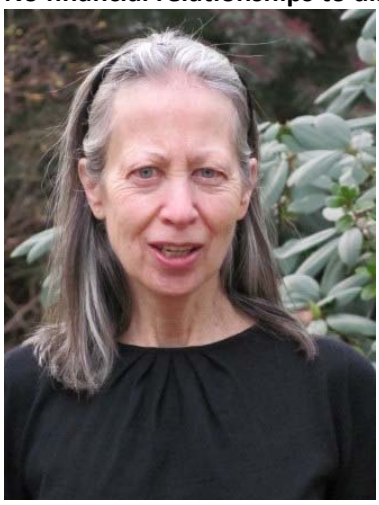
Center/BCH site, and she co-led the Consent, Education, Regulation, and Consultation (CERC) work group and supplement on patient perspectives on broad consent in biobanks. In eMERGE III she co-chairs the Return of Results-ELSI work group. Dr. Holm is co-investigator of the "Genomic Sequencing and Newborn Screening Disorders" U19. Dr. Holm's other research interest is in undiagnosed diseases. She is co-investigator of the Undiagnosed Diseases Network (UDN) Coordinating Center and the UDN Harvard Clinical site. Dr. Holm is co-investigator and leads the genetic studies for the Safe Passage Study, a large, prospective, international study of SIDS and prenatal alcohol exposure. Dr. Holm is a member of the Society for Pediatric Research, a Fellow in the American College of Medical Genetics, and a member of BCH IRB.

Speaker: Cynthia Morton, PhD, FACMG, Medical Genetics, Clinical Cytogenetics, Clinical Molecular Genetics
Professor, Departments of Ob/Gyn and Pathology, Brigham and Women's Hospital, Brigham and Women's Hospital
No financial relationships to disclose.



Cynthia Casson Morton received her B.S.in Biology from the College of William and Mary in Virginia and her Ph.D. in Human Genetics from the Medical College of Virginia in Richmond. She is the William Lambert Richardson Professor of Obstetrics, Gynecology and Reproductive Biology and Professor of Pathology at Harvard Medical School, and Kenneth J. Ryan, M.D. Distinguished Chair in Obstetrics and Gynecology, Director of Cytogenetics and Past Director of the Biomedical Research Institute at Brigham and Women's Hospital. She is an Institute Member of the Broad Institute. Dr. Morton is an adjunct faculty member of the University of Manchester where she holds a position as Chair in Auditory Genetics. Dr. Morton is certified by the American Board of Medical Genetics in Ph.D. Medical Genetics, Clinical Cytogenetics and Clinical Molecular Genetics. Her research interests are in molecular cytogenetics, hereditary deafness, genetics of uterine leiomyomata and human developmental disorders. She has published 290 original articles. Dr. Morton is a past member of the Board of Directors of the American Board of Medical Genetics where she served as Secretary, Treasurer and Chair of the Accreditation Committee. She was the Chair of the Molecular Genetic Pathology Policy and Exam Committees. She served as Member and Chair of the Board of Scientific Counselors of the National Institute of Deafness and Other Communication Disorders, and as Member and Chair of the Board of Regents of the National Library of Medicine. Dr. Morton is currently a member of the Counsel of Scientific Trustees of the Hearing Health Foundation, and Chair of the Veteran's Administration Genomic Medicine Program Advisory Committee. Dr. Morton is a past member of the Board of Directors of the American Society of Human Genetics and served as the 2014 President. She completed a six year tenure as Editor of The American Journal of Human Genetics and is currently Co-Editor of Human Genetics.

Moderator/Speaker: Lynn Bush, PhD, MS, MA
Faculty, Pediatric Clinical Genetics, Program Women & Children's Bioethics, Columbia University Medical Center, Columbia University Medical Center
No financial relationships to disclose.



Lynn Bush, PhD MS MA is on the faculty of Pediatric Clinical Genetics and faculty Program Women and Children's Bioethics at Columbia University Medical Center, a faculty associate at their Center for Bioethics, a member of the Clinical Ethics Committee Children's Hospital (CHONY), and ethicist for weekly Peds-MFM Genomic case conferences and PGM constitutional sign-outs. She also serves as an ethicist and liaison on MFM, pediatric and genomic advisory committees for numerous academic medical centers and professional organizations, incl ACMG SELI, Chair ACMG PH-SIG, NBSTRN, SMFM, SIMD, APHA, ASBH Peds. Dr. Bush has an interdisciplinary graduate background and fellowship training in clinical and developmental psychology, bioethics, genomics, public health, and neuroscience that informs her research, writing, and teaching on the ethical, psychological, and policy challenges of genomic diagnosis, screening, clinical care, and research involving embryos, fetuses, newborns, infants, and children. Her focus is on ethical dilemmas posed during the prenatal-neonatal period, especially with genetic-omic screens/tests as well as with pediatric inborn errors metabolism, unknown or rare diseases, and complex neurodevelopmental disorders. She co-authored The Drama of DNA: Narrative Genomics, Oxford UP 2014 with Karen Rothenberg and creates dramatic case vignette-plays as a pedagogical approach to bring to life these complex issues, enhance ethical reflection, and foster interdisciplinary discourse. Dr. Bush has given plenaries at ACMG, ASRM, NSGC; had recent Grand Rounds at Dartmouth and Einstein-Montefiore; and is frequently invited to present at the NIH, NHGRI, ACOG, ASHG, SMFM, SIMD, ASBH, HMS, and Baylor.

Participation Instructions

1. Participant logs into ondemand.acmg.net
2. Once logged in the participant will access the session they would like to view. They will be asked if they would like to claim credit for the meeting, or if they will not claim credit for the meeting. Then, this information (Course description) will appear, and participant will have to attest that they have read the information. They will then click Continue.
3. After that, the participant will be able to select the credit types to claim.
4. For each session with a post-test, the participant will need to mark and complete the matching pre-test.
5. Then the participant will watch the session presentations.
6. Participant will complete viewing all session content. "Check marks" indicate which presentations have been viewed.
7. After viewing all presentations within a session, participant will click the "Claim Credit for Session" button under the CME dropdown at the top of the page.
8. Participant should take and then successfully pass the post-test. If they do not pass with a score of 80% or higher, they will have unlimited tries to pass the post-test.

9. Participant will continue the steps above to earn credits for additional sessions.
10. If a session does not have a test attached, the participant will not need to take a pre- or posttest, but will have to complete a Concurrent or Plenary session-specific evaluation to claim credit.
11. To print their certificate, the participant will click the "Print Certificate" button under the CME dropdown at the top of the page. Participant must complete the meeting evaluation (one time only) before they can access their certificate. Participant will then choose their certificate(s). The certificate(s) will be automatically updated as they earn new credits.

Stream Requirements	
Network	For best results, use a hardwired network connection instead of wireless
Full Screen Viewing	If you would like to view the webcast full screen, display the tool bar at the bottom and click the double arrow in the far right corner. The screen will enlarge to the full screen of you system. To restore the size, press the "ESC" key
Refresh Browser Window	If the webcast freezes and does not recover in 3-4 seconds, refresh browser window
Freezing or Stuttering Issues	Adjust the amount of bandwidth needed by putting your mouse anywhere over the video window. A tool bar will appear at the bottom. On the right side you will see a "HD" button, click on that button and you will see a list of options. The top is "auto", with decreasing numbers below. Select a lower bandwidth (such as 360p) to see if your webcast improves
For Technical Support call	1-800-504-5379

Mobile Viewing Requirements	
Android Devices	Android 2.3+ with Adobe Flash Player 10.2 or better installed Install Flash Player
Apple Devices	iOS 4+

Online Viewing Requirements	
Bandwidth	512kbps
Required Hardware and Software	Screen resolution of 1024X768 or larger Sound card and speakers/headphones
Browser	Microsoft Internet Explorer 7.0 or better Mozilla Firefox 4 or better Safari 5 or better
Windows	Operating System: Windows 8 desktop mode, Windows 7; Windows Vista; Windows XP Service Pack 2 or 3 x86 or x64 (Browsers must be in 32-bit mode) 1.6-gigahertz (GHz) or higher processor 512MB of RAM
Mac OS	Operating System: Apple Mac OS X 10.4.8 or above Intel Core™ Duo 1.83GHz or faster processor 512MB of RAM

Registration and Fees

ondemand.acmg.net
ACMG Members and ACMG Trainees: ($50)
Non-members ($60)
Additional fee (~$25) applies for NSGC credit that is billed by NSGC.

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