DRIVING MILLIONS TO BETTER CHOLESTEROL MANAGEMENT

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Check. Change. Control. CHOLESTEROL™

Identifying Strategies to Address Gaps in Cholesterol Management in the U.S.

Cholesterol Summit Report

APRIL 11, 2017 | DALLAS, TEXAS

National Supporter

EXECUTIVE SUMMARY

BACKGROUND

High cholesterol is a major risk factor for cardiovascular diseases (CVD) and stroke, the No. 1 and No. 5 killers in the U.S. With support from Sanofi and Regeneron, the American Heart Association/American Stroke Association is launching a comprehensive initiative focused on improving cholesterol control. Check. Change. ***Control.*** Cholesterol™ (CCC Cholesterol) aims to improve awareness, detection, and management of high cholesterol. The initiative will accomplish this by educating and empowering consumers, healthcare professionals, and patients with evidence-based information and tools, while also improving quality of care for patients via the AHA's quality improvement programs.

The Cholesterol Summit was convened to gather healthcare professionals, organizations, and patients to discuss gaps and potential solutions in cholesterol management — from diagnosis to treatment to adherence.

MEETING SCOPE AND PURPOSE

The goal of the Cholesterol Summit was to develop tangible, actionable solutions for cholesterol management, aligning to AHA/ASA's 2020 Impact Goal to improve the cardiovascular health of all Americans by 20% by 2020. During the Summit, the participants:

- Discussed gaps and barrier in providing high-quality cholesterol management
- Identified innovative and actionable strategies to improve prevention, diagnosis, treatment, and coordination of care
- Understood the role of the healthcare system in supporting guidelines-based management
- Addressed the patient's role in self-management and how to offer support to address real-world barriers
- Helped prioritize activities/approaches to ensure patients receive optimal care

As an outcome of the summit, a CCC Cholesterol Action Plan was developed and will serve as a roadmap to AHA and other partner organizations. The priorities identified include:

Improving the patient experience and increasing patient empowerment by:

(1) Conducting public campaigns to raise awareness by translating risks so people can understand and act on changing these risks

(2) Improving patient-provider dialogue through shared decision-making tools

(3) Starting early with education and behavior change through youth programs

(4) Seeking peer-to-peer and social support moderated by health professionals and other influencers to increase patient empowerment

(5) Enlisting support from public and health organizations to elevate patient health issues

Advancing lifestyle recommendation compliance through the following priority solutions:

(1) Combating myths around cholesterol treatment with consistent messaging across multiple platforms

(2) Encouraging healthcare providers to incorporate dialogues about lifestyle as the standard of care, incorporate the family into discussions, and provide "prescriptions" to patients for specific diet and exercise recommendations

(3) Exploring social and local advocacy opportunities to advance healthy behaviors in communities

Increasing medication treatment and adherence through the following strategies:

(1) Increasing professional understanding of complex evidence-based guidelines by developing resources with brief, simple messaging

(2) Helping providers understand how to better focus on the patient and have a joint treatment plan discussion

(3) Encouraging multi-disciplinary management; possible area of focus on inpatient and outpatient pharmacists who can provide medication management and follow-up support

(4) Exploring relevant technology tools to bring practice guidelines "in the hands" of clinicians

(5) Exploring e-measurement and work with electronic health records (EHRs) to improve clinical process and measurement

(6) Exploring funding of novel research ideas

(7) Recognizing and rewarding exceling providers and practices through a recognition program

CHOLESTEROL SUMMIT BACKGROUND & OVERVIEW

The American Heart Association is a global leader in cardiovascular care and has a long history of advancing quality care, science, and public education in the United States. There are 94.6 million American adults (39.7%) who have total cholesterol of 200 mg/dL or higher.[1] According to a recent AHA study on patients with high LDL and total cholesterol levels, most with high total cholesterol understood the importance of cholesterol management.[2] However, many expressed being confused (39%), discouraged (44%), and not confident (45%) about their ability to do so. These numbers suggest an opportunity to better support and treat patients living with high cholesterol.

To address this problem, the American Heart Association/American Stroke Association convened the Cholesterol Summit in Dallas, Texas, on April 11, 2017. Experts from leading U.S. healthcare, patient, professional, government, and public organizations discussed the barriers to cholesterol management. The Summit format included keynote speakers from the Million Hearts Initiative and the National Forum for Heart Disease & Stroke Prevention (National Forum). Subject matter experts participated in panel discussions focusing on patient-centered care; lifestyle, evaluation, and counseling; and treatment and adherence. Presenters addressed these issues from clinical, patient, and public health perspectives. Each panel included a patient, healthcare providers, and researchers. Small-group discussions after each panel generated a priority list of activities addressing gaps and needs for the AHA and its partners to work on over the short and long term. Participants further narrowed down recommended solutions through an electronic voting process considering impact and effort (resources) over the next three years.

Key AHA leadership kicked off the summit by framing the importance of cholesterol management as one of the five priorities to accelerate AHA/ASA's progress to its 2020 Impact Goal of improving cardiovascular health by 20% and decreasing cardiovascular mortality by 20% in the United States. (Those priorities are cholesterol management, reduction of sugar sweetened beverages, reduction of tobacco use, reduction of sodium in food supply, and better control of high blood pressure.) The summit participants were charged with developing a robust actionable plan to support the "Check. Change. ***Control.*** Cholesterol" initiative. During the next three years, Check. Change. ***Control.*** Cholesterol, with support from Sanofi and Regeneron and with partner organizations, will improve adoption and utilization of the cholesterol treatment guidelines. The initiative will do this through professional education,

[1] NHANES 2013-2014
[2] AHA Cholesterol Research. March 2017.

quality improvement programs, and increased patient and public understanding of and adherence to evidence-based treatment plans.

Cholesterol Summit attendees were challenged to discuss gaps and potential solutions in cholesterol management, and arrive on recommended solutions by the end of the day.

Lessons learned from other programs, such as Million Hearts and National Forum, can inform the plan. The Million Hearts 1.0 Program is now transitioning to its second phase. Key lessons learned from the first phase included:

- An emphasis on partnerships to help drive broad change
- Focusing on a small number of high-impact measures that are broadly inserted into multiple areas
- Remaining nimble as the science and measures can both change rapidly
- Promoting evidence-based treatment protocols to standardize guideline-based care
- An understanding that change is often much slower than expected

The National Forum highlighted its pilot community-based program for mothers and their families in Austin, Texas. This program focused on providing relevant tips and education about high-cholesterol management. Key lessons learned included:

- The need to begin with focus groups to develop informed, clear, and relevant messaging to target audiences
- The fact that people do not fully understand the direct link between high cholesterol and risk for cardiovascular events
- Patients’ desire for a trusted, credible source to provide clear and unbiased information
- The need for toolkits to allow people and partner organizations to spread messaging quickly and efficiently
- The importance of bringing a face to the initiative by incorporating real-life stories of community members

From the panel presentations and small-group discussions, potential barriers to cholesterol management were identified (Table 1). Each panel also focused on a series of solutions to address these potential barriers.

Table 1: Potential Barriers to Cholesterol Management

KEY AUDIENCE	POTENTIAL BARRIERS IDENTIFIED
PATIENTS	**Knowledge** • Information overload so they do not know where to access the correct information • Confusion on what is good and bad cholesterol and why high cholesterol can be bad for one's health • Do not fully understand the risks of high cholesterol • Many adults lack adequate literacy and numeracy skills required to understand most commonly available medical resources • The fact that high cholesterol is a "silent killer" because there are no symptoms • Healthcare providers do not have enough time to fully explain the risks of high cholesterol and/or the benefits of treatment (medication and lifestyle change) • Misconception that high cholesterol can be "fixed" by a brief course of therapy **Medication** • Fear of taking medications, sometimes influenced by myths • Afraid of side effects *(e.g., statin intolerance)* • Cost *(e.g., PCSK9s are expensive and often not covered by insurance)* • Healthcare providers prescribe medications but do not explain why or what other options patients may have **Other Topics** • Social determinants of health supersede cholesterol management *(e.g., food insecurity, cost of fruits and vegetables, unsafe neighborhoods)* • Lack of peer-to-peer and social support

HEALTHCARE PROVIDERS

Knowledge

- Information overload; science is constantly changing, difficult to keep up
- Need for shorter, more consumable bite-sized information; guidelines and professional education materials are long and complex
- Difficult to decipher conflicting science
- Current guidelines not available in practical formats at the point of care; for example, mobile application or embedded into electronic health records

Interaction with the Patient

- Do not know what the lifestyle recommendations are and have not been trained in effective methods for behavioral counseling
- Lifestyle counseling is time-consuming, often not high-priority given other medical issues, and not reimbursable
- May not have sufficient time for the needed patient discussion
- May not have a clear understanding of the patient's biggest concerns
- Do not know if the patient is compliant on medications
- Need tools for shared decision-making with patients on risk assessing and treatment plans

HOSPITAL SYSTEMS

Providing Evidence-Based Care

- Clinical decision support is not readily available and accessible for providers
- No access to appropriate team members *(e.g. no readily available pharmacist, dietitian, or cardiac rehab support)*
- Confusion over who "owns" team-based cholesterol management; diffusion of responsibility *(e.g., someone else can discuss lifestyle modification)*
- Discharge planning does not include diet and lifestyle counseling
- Lost "teachable moments" when patients are in the hospital for cholesterol-related cardiovascular events *(e.g., heart attack, stroke)*
- Learning modules for newest guidelines not readily available or integrated uniformly into EHRs

OTHER TOPICS

Shared Patient/Healthcare Providers/Hospitals

- Barriers to communication in the usual healthcare encounter
- Difficult to understand risk as it applies to an individual patient
- Resources not culturally relevant or tailored
- Providers are not similar in culture or appearance, causing difficulty for patients to relate to their providers
- Mixed messages from many organizations working in this space

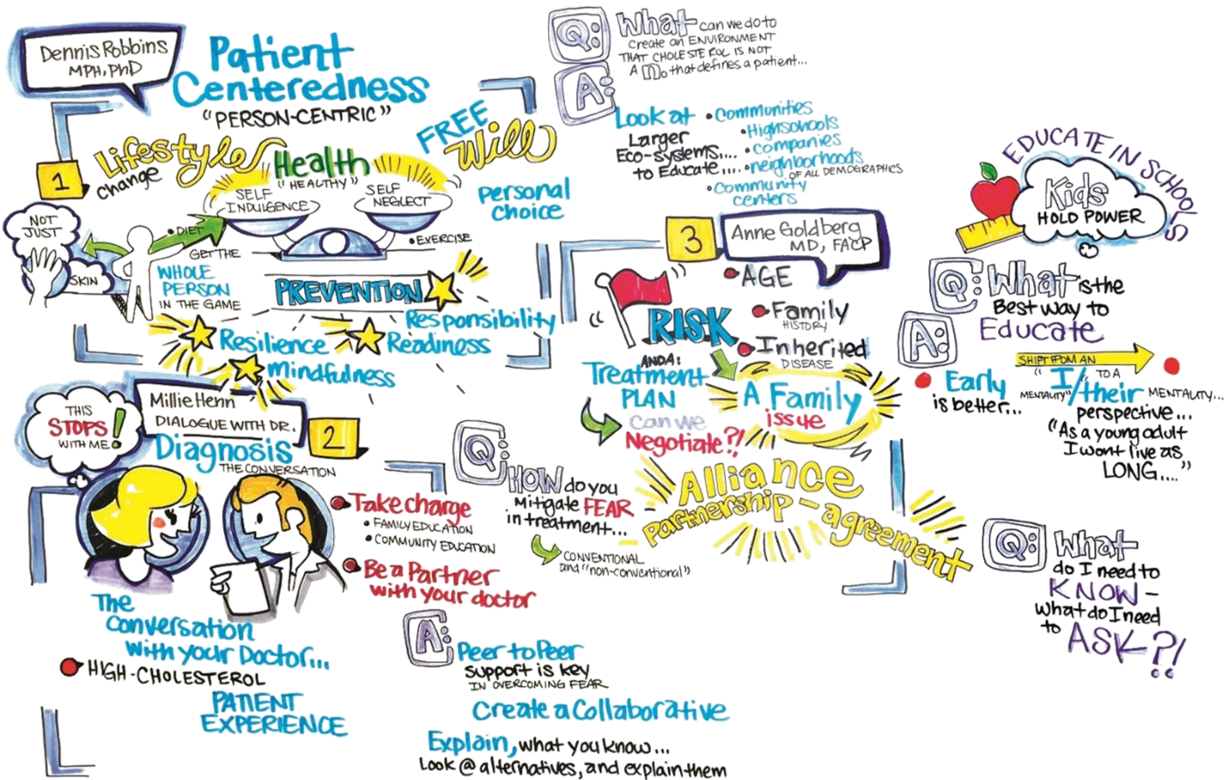
Research

- Measuring outcomes (what is considered “managed” cholesterol) is difficult
- Medication adherence is difficult to measure as there is very little data sharing between pharmacies, healthcare providers, and/or hospital systems
- Lack of research in practical solutions to help manage cholesterol
- Need for dedicated research in special populations not currently included in risk calculators and/or clinical trials

Familial Hypercholesterolemia

- Questions regarding who should be screened and when
- Unclear how and when to screen children
- Still underdiagnosed in the general population

PATIENT-CENTERED CARE PANEL



Panelists discussed moving from the concept of the patient being passive and vulnerable to the concept of the patient as the "person in charge" who, ultimately, can do anything to improve his or her health. This leads to a different dynamic in discussions with the clinician about improving health. By putting the patient at the center of this decision-making process, opportunities can be created for appropriate changes in behavior to improve health.

Current AHA guidelines ask healthcare providers to use the ASCVD Risk Calculator to calculate a 10-year risk of CVD, which is then used to determine appropriate prevention therapy and management. It is important for patients to understand this process and the meaning of risk for themselves. This includes understanding family history and how it contributes to personal risk. Often this concept is difficult for patients to comprehend because the concept of risk is derived from population-based studies/clinical trials but must be applied to an individual for clinical treatment decisions. It is imperative that this risk be communicated to patients in a way that is both understandable and actionable.

Finally, the healthcare provider should engage the patient in a discussion about the meaning of risk. The clinician should determine what the patient is most worried about. Is there an initial

understanding of the factors contributing to increased risk? What kinds of family and social support does the patient have? This involves active listening on the part of the healthcare provider to best understand the patient's concerns regarding the needed changes in lifestyle and the need for medication. For success, the clinician and patient must work together toward implementation of the treatment plan.

Key Solutions Identified to Increase Patient-Centered Care:

- Information
  - Increase reach and access to credible resources from the AHA Go where people are, with culturally relevant and culturally sensitive messaging *(e.g. school, work, places of worship)*
  - Translate risk so people understand
  - Use social media for dissemination
  - Simplify the message
  - Numbers/targets matter to people
- Healthcare providers should shift their attitudes toward the "person" not the patient and create treatment plans together with patients
- Peer-to-peer support, moderated by healthcare providers, is important
- Provider and patient shared decision-making on medications and lifestyle changes
- Incorporate the whole healthcare team into providing care with culturally competent and literacy-adjusted approaches
- Incorporate the family into discussions about cholesterol screening, treatment, and lifestyle change
- Incorporate cholesterol/lifestyle education into school curricula

LIFESTYLE, EVALUATION, & COUNSELING PANEL

Lifestyle modifications, such as diet and exercise, remain the first-line therapy for high cholesterol and are critical to maintain optimal cardiovascular health. Panelists discussed:

- A personal experience trying to manage life after a stroke
- The current state of diet-modification research
- Successful programs that have used culturally relevant and culturally sensitive approaches to make lifestyle modifications
- The importance of designing messaging that can be efficiently and effectively delivered to key audiences

Large randomized trial data show dietary interventions such as the DASH and DELTA diets can improve lipid profiles, [3] while the PREDIMED study demonstrated that a Mediterranean diet can

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[3] Eckel, RH et. al., Circulation 2014 June 24;129(25 Suppl 2):S76-99.

reduce CVD risk overall.[4] Yet how to disseminate this information to patients has been challenging. Our patient panelist encouraged healthcare providers to consider themselves "salespeople" for cardiovascular health, emphasizing persistence with patients and the potential benefits of frequent follow-up contacts. Healthcare provider coaching for patients has been shown to be an effective tool, both in person and remotely.

Other technological solutions such as mobile apps, meal delivery programs, and online support platforms may help improve delivery of dietary interventions. But not all people may benefit equally from currently available lifestyle interventions. Providers must be skilled at assessing and counseling the patient based on current lifestyle, ensuring a treatment plan can be individualized and tailored based on the patient's health and wellbeing.

Successful implementation of any lifestyle intervention requires participant engagement and motivation through effective education. Many adults lack adequate literacy and numeracy skills to understand most commonly available medical resources. Following best practices for educational material development such as large fonts, showing examples, visuals and using repetition can improve participant understanding. Techniques such as motivational interviewing by providers and tools for participant self-monitoring can also improve adherence and lead to long-term behavior change.

Importantly, ensuring interventions are culturally sensitive and available across diverse socioeconomic backgrounds is critical to improving health disparities. Many examples illustrate how to deliver culturally tailored lifestyle interventions, such as the BAILAMOS program, but lessons learned from individual programs may not be effectively disseminated to others. These programs have been evaluated for feasibility and also studied for cardiovascular outcomes, if being disseminated and promoted.

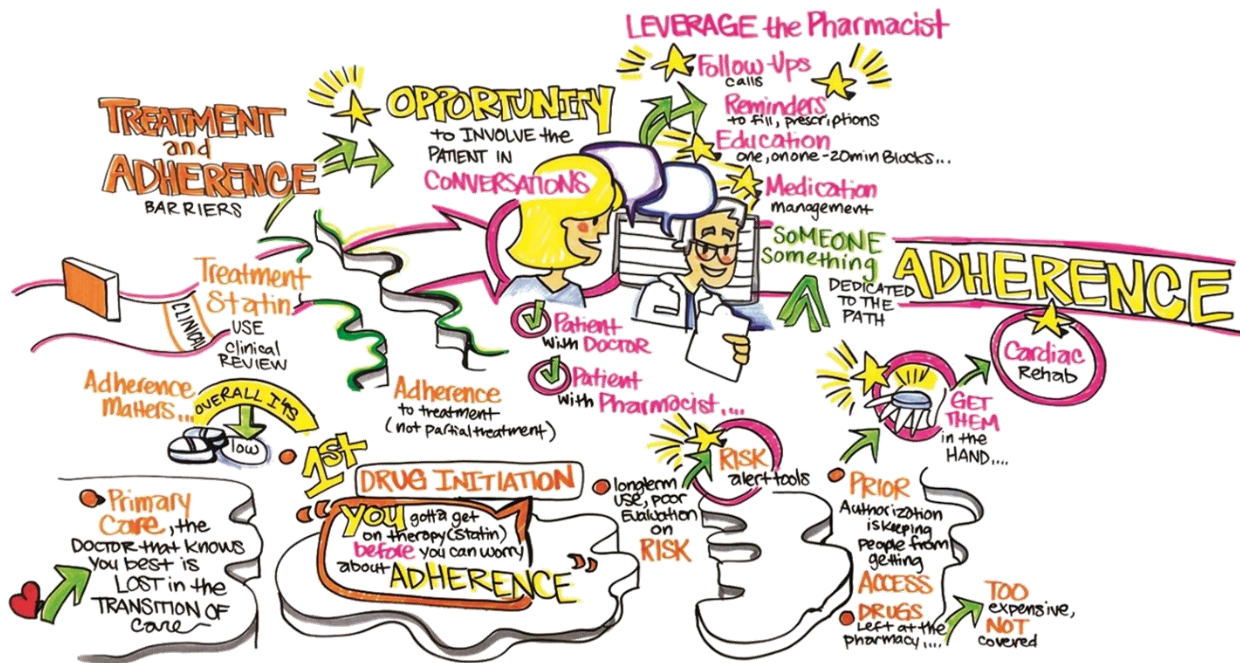
Key Solutions Identified for Lifestyle, Evaluation, and Counseling:

- Engage patients through social media, health portals and quick tips
- Take the individual and his or her family into account when counseling on lifestyle interventions
- Provide information:
  - Make messages more consistent and dynamic, multi-channel distribution
  - Integrate health education in schools, after-school programs, and PE
  - Bi-directional flow of information between schools and worksites *(e.g., students speak to company employees to teach them, and employees come to schools to teach students)*
  - Frame the message to individuals' value
  - Use a multigenerational and multicultural approach

[4] Estruch R, et al., N Engl J Med. 2013 April 4;368(14):1279-90

- Involve the healthcare system:
  - Providers to give lifestyle prescriptions
  - “Filling” your prescription makes the patient eligible for reimbursement, incentives, rebates
  - Need to educate providers on how to do discuss lifestyle interventions more effectively and efficiently
- Explore opportunities for social advocacy and policy change *(e.g., city councils, school boards)*
- Develop a peer-to-peer support network
- Disseminating information through four target channels: healthcare environment (inpatient and outpatient settings), community outreach, schools and formal wellness programs *(e.g., businesses)*

TREATMENT & ADHERENCE PANEL



Panelists discussed the current state of statin medication use, potential reasons for poor medication adherence, and successful models for increasing medication adherence, many of which used pharmacists in the inpatient and outpatient settings.

Overall, the use of statins for those who have experienced a heart attack has increased from 30% in 2011 to almost 60% in 2014.[5] However, at 60 months only 30% of patients are taking their statins,[6] increasing their chances of having another cardiovascular event or dying.[7]

The reasons for this poor adherence are varied and include cost, side effects or fear of them, misinformation, and provider resistance to prescribing statins. Treatment with PCSK9 medications, a new class of drugs for the treatment of high-risk patients, is limited by cumbersome authorization procedures with 79% of prescriptions rejected on day one.[8] Of the 53% that are ultimately approved, almost 35% are never picked up from the pharmacy.

Many techniques to improve patient adherence have been tried. A 2016 meta-analysis of 35 randomized controlled studies involving 925,000 patients indicated that reminder systems,

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[5] Rosenson, RS et. al., Poster presentation at European Society of Cardiology 2016. Paper in Press.
[6] Lin, I et. al., J Manag Care Spec Pharm 2016 June;22:685-98
[7] Bansilal, S et. al., J Am Coll Cardiol. 2016 Aug 23; 68:789-801
[8] Navar, AM et. al., Presentation at American College of Cardiology Scientific Sessions 2017

multidisciplinary educational activities, and pharmacist-led interventions consistently showed improvement.[9] Other interventions including decision-support systems, drug regimen simplification, complex behavioral approaches, administrative improvements, and large-scale automated telephone pharmacy interventions showed inconsistent results. A 2012 systematic review of 62 trials of interventions to improve medication adherence for chronic diseases *(e.g., cholesterol)* showed benefit when patient out-of-pocket expenses were reduced, case management used, and patient education with behavioral support instituted.[10] Overall, there are still many more ways in which medication adherence can be improved.

Key Solutions Identified for Increasing Treatment and Medication Adherence:

- Lower barriers to taking medication:
  - Discharge with medication
  - Create easy-to-follow and mutually agreed upon treatment plan
  - Amazon.com-like services for delivery of medications
  - Improved access to social services
- Educate
  - Shift the conversation from discussion about medication side effects to helping patients understand their risks in context of the potential benefits
  - Predict misinformation; provide a fact-checker to combat myths online
  - Better understand how the supplement industry disseminate its products widely despite no clinical trials or science to back up claims, and use this as a potential model to spread accurate data on clinically proven and effective medications
  - Integrate community health workers into the process
  - Provide training and education opportunities for community pharmacists to help address common myths and misconceptions
- Leverage technology
  - Improve communication between pharmacists and physicians
  - Leverage technology to lower barriers to medication adherence
- Conduct research targeted for special populations

[9] van Driel, ML et. al., Cochrane Database Syst Rev. 2016 Dec 21;12:CD004371
[10] Viswanathan, M et. al., Ann Intern Med. 2012 Dec 4;157:785-795

NEEDS UNCOVERED FOR THE CHOLESTEROL MEDICAL LANDSCAPE

Based on discussions through panels, needs were shared by patients, providers, and the "ecosystems" where they live, play, and work.

Figure 1: Needs by Target Audience

PATIENTS

- Simple messages
- Trusted source
- Shared decision-making
- Empowerment
- Engagement
- Understanding of risk
- Addressing barriers and identify individual solutions
- Lowering barriers to getting/taking medications
- Peer-to-peer support
- Involving the family
- Culturally relevant and sensitive materials and messages

PROVIDERS

- Resources to share with patients
- Time to discuss treatment options
- Incentivizing physician behaviors
- Simplifying the message
- Easy, quick ways to stay up to date on science
- Leveraging technology for clinical decision support and point of care
- Involving the healthcare team (moving beyond the 20-minute physician visit)

ECOSYSTEM

- Policies that make communities healthier *(i.e., making the default choice the healthy choice)*
- Leveraging technology for medication adherence tracking
- Making drugs affordable and easier to take
- Starting education starts early (youth) and involving the family
- Research/data on special populations

Moving Ahead: Advancing AHA's Check. Change. ***Control.*** Cholesterol Initiative

Identifying the needs of patients, providers, and the ecosystem were critical in defining a robust plan for Check. Change. ***Control.*** Cholesterol. The AHA and the leaders at the Cholesterol Summit created an agenda to advance cholesterol management in the U.S. The participants, patients, and organizations identified actions that can advance better cholesterol understanding and engagement in treatment plans through better lifestyle management and treatment adherence. Through a voting process to focus strategies and tactics, the participants identified core areas that will bring the greatest impact in the next three years. These recommendations reflect realistic, actionable strategies for the AHA and partners to support.

Improve the patient experience and increase patient empowerment by:

(1) Conducting public campaigns to increase awareness and translate CVD risks and help patients understand how to prevent a CVD event

(2) Improving patient-provider dialogue by providing tools that will support shared decision-making; focus on making tools culturally relevant and at basic level of health literacy

(3) Seeking peer-to-peer support moderated by health professionals and other influencers to improve treatment outcomes

(4) Starting early with education and behavior change through youth programs

(5) Enlisting support from public and health organizations to elevate these issues to constituents, government entities, and the public

Advance lifestyle recommendation compliance through the following priority solutions:

(1) Combating myths around cholesterol treatment by engaging patients and their families via social media and websites, sharing a consistent message across multiple platforms; clarifying what is bad cholesterol and why it is potentially harmful

(2) Encouraging healthcare providers to incorporate lifestyle/treatment plan dialogue as the standard of care, exploring “prescriptions” for diet and exercise recommendations, and considering the role of technology solutions

(3) Exploring social and local advocacy to advance healthy behaviors in communities, such as school boards regarding healthy school foods and physical activity in school

Increase medication treatment and adherence through the following strategies:

(1) Increasing professional understanding of evidence-based guidelines by providing a robust toolkit and/or resources to better treat and engage patients in their treatment plans; the toolkit must have relevant bite-sized guideline summaries, clinically usable case studies, shared decision-making tools, treatment discussion guides, and the ASCVD risk calculator.

(2) Encouraging multidisciplinary team engagement through targeted tools for pharmacists and healthcare providers who can influence patient compliance; incorporate inpatient and outpatient pharmacists to help with medication management and follow-up

(3) Exploring relevant technology tools to put practice guidelines “in the hands” of clinicians, either through training, on-hand clinical tools, or support of patient dialogues

(4) Support progress toward e-measurement through NQF/ Medicare for cholesterol management and high-risk groups, and work with EHR companies to improve clinical process and measurement

(5) Work with partner organizations to explore novel research ideas to improve cholesterol management

(6) Recognize successful providers or practices through a quality improvement or recognition program, similar to the Get With The Guidelines Recognition model

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