

NHLBI ANNOUNCEMENT: CARDIOVASCULAR GUIDELINES

Refocusing the Agenda on Cardiovascular Guidelines

An Announcement From the National Heart, Lung, and Blood Institute

Gary H. Gibbons, MD,* Susan B. Shurin, MD,* George A. Mensah, MD,* Michael S. Lauer, MD†
Bethesda, Maryland

When he dedicated the new National Institutes of Health (NIH) Bethesda campus in October 1940, President Franklin D. Roosevelt declared, “We cannot be a strong nation unless we are a healthy nation. And so we must recruit knowledge and science in the service of national strength” (1). For more than 65 years, the National Heart, Lung, and Blood Institute’s (NHLBI’s) core mission has been, and continues to be, the generation and dissemination of knowledge and science with the goal of securing a healthy nation (2).

Thirty-two years after Roosevelt’s NIH dedication, on July 26, 1972, Elliot Richardson, the Secretary of the U.S. Department of Health, Education, and Welfare, announced the establishment of a “National Hypertension Program” (3). The program planned a 4-step approach to include agreement on standards and conditions for treatment, education of health workers, public dissemination of information, and research on the impact of the program on healthcare delivery. Richardson appointed 2 committees: one, the Hypertension Information and Education Advisory Committee, was to focus on the knowledge of hypertension and the communication of that knowledge, whereas the other, the Interagency Working Group, was to focus on exchange of information and coordination with the professional community.

In 1977, the NHLBI issued the first of a number of clinical practice guidelines (4) that would emerge from the National High Blood Pressure Education Program, as well as from other similar efforts such as the National Cholesterol Education Program. The NHLBI guidelines have covered a variety of topics, including, but not limited to, cholesterol, blood pressure, asthma, and von Willebrand disease (5). Over the years, these groundbreaking health education initiatives have successfully promoted marked increases in the public’s awareness of cardiovascular disease risk factors and contributed to the major reductions in coronary heart disease mortality observed during this period (6,7).

In the ensuing years, the landscapes surrounding the management of blood pressure and cholesterol disorders, as

well as the landscape of clinical practice guidelines, have undergone profound changes. Many more effective strategies are available for clinicians and patients to choose from, and orders of magnitude more clinical evidence information is available. The advent of the Internet and the proliferation of mass media outlets provide the lay public with direct-to-consumer access to a plethora of health information. Clinical research sophistication has grown, as the “mega-trial” has gone from being the exception to the norm. During this period, the number and scope of governmental entities engaged in providing guidance on clinical practice have also changed substantially. Meanwhile, numerous organizations outside government have developed expertise and experience in developing guidelines. Indeed, a special working group of the NHLBI’s Advisory Council (NHLBAC) (5) has noted that nearly all NIH institutes and centers have elected to limit engagement in guideline development to efforts involving close collaboration with professional societies or other external groups. In recent history, the NHLBI has been the lone exception to this general NIH practice.

The world of clinical practice guidelines has undergone, and continues to undergo, transformational changes since the NHLBI started issuing guidelines as an adjunct to its health education efforts over 35 years ago. As the number of available guidelines provided by a variety of sources has exploded, serious questions and controversies have arisen about how guidelines should be developed, implemented, and evaluated. Critics have noted that it is not a given that clinical practice guidelines benefit patients (8). Guideline developers have been criticized for failing to adequately control for conflicts of interest (9), for issuing guidelines of variable quality (10), and for issuing contradictory guidelines that leave clinicians feeling confused and vulnerable (11). Yet the development of clinical practice guidelines leads to invaluable benefits for patients and clinicians: improved outcomes due to better deployment of evidence-based strategies, improved consistency of care, empowering information for patients, improved public policy through attention drawn to areas of importance to public health, assistance to clinicians who aim to keep their practices up to date, and guidance for quality-improvement activities (8). Guidelines also help researchers and research funders identify important research gaps and set the stage for the iterative process of new knowledge generation and advances in patient care (8).

From the *Office of the Director of the National Heart, Lung, and Blood Institute, National Institutes of Health, U.S. Department of Health and Human Services, Bethesda, Maryland; and the †Office of the Director, Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute, National Institutes of Health, U.S. Department of Health and Human Services, Bethesda, Maryland.

There has also been debate about who should be in the driver's seat. Primary care generalists, specialists, and government agencies may each have limitations that impede their effectiveness in leading the development of guidelines (8). These concerns have led many organizations to actively reach out to many stakeholders, as was the case in a cardiovascular guideline on risk assessment that one of us (M.S.L.) helped write (12,13). When multiple stakeholders work together, there is a much greater likelihood of high-quality products, products that reflect diverse perspectives, philosophies, and expertise.

In response to these and other concerns, the Institute of Medicine (IOM) recently issued 2 reports, 1 on standards for systematic reviews (14) and the other on development of trustworthy guidelines (15). Reflecting the vastly increased growth and complexity of scientific literature and methods, the standards on systematic reviews cover a variety of domains, including: 1) assembling expert teams with the capacity to manage bias, conflicts of interest, and stakeholder input; 2) identifying pressing clinical needs while developing an optimal analytic framework; 3) developing and following rigorous protocols that cover the search for and assessment of evidence, as well as its synthesis; and 4) preparing structured, user-friendly, peer-reviewed final reports (14). The standards on guidelines include a similar focus on transparency, management of conflicts of interest, team composition, effective articulation of recommendations, external review, and updating. The IOM standards emphasize the importance of the intersection of guideline development and systematic reviews: specifically, "Clinical Practice Guideline developers should use systematic reviews that meet standards, [and should interact with] the systematic review team regarding the scope, approach, and output of both processes" (15).

It is noteworthy that the IOM issued 2 separate reports, 1 on writing of systematic reviews (14) and 1 on development of guidelines (15). The 2 activities are related, require careful intersection and coordination, but nonetheless, are distinct. In some respects, this distinction reflects the composition and charges of the 2 committees that Secretary Richardson appointed back in 1972. This important delineation between the writing of systematic reviews and the construction of clinical practice guidelines has been articulated by others. For example, Clifton Gaus, an administrator of the Agency for Health Care Policy and Research from 1994 to 1997, recalls that when he consulted stakeholders, "Almost unanimously they said, 'We don't use your guidelines per se, but the *synthesis of science you base them on is invaluable to us in writing our own guidelines*'" (16).

Today, June 19, 2013, after a public meeting of the NHLBAC, we report the NHLBI's plans in the domain of clinical practice guidelines. In recognition of the rapidly changing landscape and the need for periodic re-evaluation and updating of the Institute's health education portfolio, the NHLBI leadership appointed two special working groups of the NHLBAC to provide guidance on options

to optimize the Institute's unique contribution to the process of guideline development. The NHLBAC working groups, which included members of the NHLBI Advisory Council and Board of External Experts, engaged in extensive processes that included consultation with a number of internal and external stakeholders. The second working group initiated the evaluation with 5 pending cardiovascular disease-related documents focused on cholesterol, blood pressure, risk assessment, lifestyle interventions, and obesity.

The NHLBI is cognizant of the clear distinction between the processes underlying the performance of systematic reviews and the creation of practice guidelines. Both NHLBAC working groups facilitated our evaluation of the existing landscape and evolving best practices to define the best approach for the NHLBI to fulfill its leadership role in health education for the public. Accordingly, we plan to refocus our health education agenda on our core mission of knowledge generation and synthesis by supporting and producing rigorous systematic reviews that can then be used by other collaborating organizations to generate guideline products that serve the public interest. The NHLBI has decided that the 5 pending cardiovascular guideline products will be published as evidentiary reviews, and that the Institute will subsequently collaborate with other organizations to prepare and issue the related clinical practice guidelines.

We enthusiastically embrace this public service leadership role in promoting health education by taking responsibility for generating the systematic review dataset and evidence syntheses that other organizations will use to develop cardiovascular guidelines. Although the detailed elements of the new NHLBI model remain to be further refined, the overall framework is well aligned with the IOM approach, and our implementation plan will be governed by 6 operating principles:

1. Before taking on new evidence syntheses, the NHLBI will consult closely with external stakeholders to identify high-priority needs with compelling relevance to the NHLBI mission and the health of the nation.
2. Once those needs are identified, the NHLBI will work with external stakeholders to determine which critical questions are most crucial for their ability to generate guidelines that are reliable, robust, credible, relatively easy to implement, and likely to promote significant improvements in public health.
3. In supporting and generating evidence syntheses, the NHLBI will pay careful attention to the evolving standards on systematic reviews promulgated by the IOM and other credible sources (14).
4. In enabling partner organizations to generate their own guideline products, the NHLBI will continue to abide by the highest standards for developing trustworthy clinical practice guidelines and will continue to adapt as best practices and the landscape of stakeholders evolve (15).

5. The NHLBI will implement a process for internal evaluation and continuous improvement in line with our commitment to results-based accountability and stewardship of public resources (17).
6. The syntheses will identify evidence gaps, which can guide research investments in areas of importance to public health.

History has taught us that there are very few immutable practices in science or medicine; and the time has come for a change in the NHLBI practice of generating clinical guidelines. As we adapt to changing times and refine the focus of our health education efforts, we remain steadfastly committed to fulfilling our mission by facilitating the generation of rigorous systematic evidentiary reviews in support of the highest quality clinical practice guidelines worthy of the public trust. This new collaborative partnership model of guideline development will enable the NHLBI to “recruit knowledge and science in the service of national strength” as envisioned by President Roosevelt 73 years ago (1).

Acknowledgment

The NHLBI is profoundly grateful for the outstanding and tireless work of the expert panels that have reviewed evidence and developed clinical practice guidelines.

Reprint requests and correspondence: Dr. Gary H. Gibbons, Office of the Director, National Heart, Lung, and Blood Institute, 31 Center Drive, Room 5A48, MSC 2486, Bethesda, Maryland 20892-2486. E-mail: Gary.Gibbons@nih.gov.

REFERENCES

1. Varmus H. *The Art and Politics of Science*. 1st edition. New York, NY: W.W. Norton, 2009.
2. Lauer MS. Cardiovascular science in the service of national strength. *JAMA* 2011;306:2145-6.
3. National Institutes of Health. HEW News Release. July 26, 1972. Available at: <http://profiles.nlm.nih.gov/ps/retrieve/ResourceMetadata/XFBBKS>. Accessed June 3, 2013.
4. Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure. A cooperative study. *JAMA* 1977; 237:255-61.
5. Douglas P. VI. Report of the Council Working Group on Clinical Practice Guidelines. In: National Heart, Lung, and Blood Institute,

National Institutes of Health. Meeting Summary of the National Heart, Lung, and Blood Advisory Council. June 13, 2012. Available at: <http://www.nhlbi.nih.gov/meetings/nhlbac/june12sum.htm#6>. Accessed June 2, 2013.

6. Egan BM, Zhao Y, Axon RN. US trends in prevalence, awareness, treatment, and control of hypertension, 1988-2008. *JAMA* 2010;303: 2043-50.
7. Ford ES, Ajani UA, Croft JB, et al. Explaining the decrease in U.S. deaths from coronary disease, 1980-2000. *N Engl J Med* 2007;356: 2388-98.
8. Woolf SH, Grol R, Hutchinson A, Eccles M, Grimshaw J. Clinical guidelines: potential benefits, limitations, and harms of clinical guidelines. *BMJ* 1999;318:527-30.
9. Nissen SE. Can we trust cardiovascular practice guidelines?: comment on “Conflicts of interest in cardiovascular clinical practice guidelines”. *Arch Intern Med* 2011;171:584-5.
10. Qaseem A, Barry MJ, Denberg TD, Owens DK, Shekelle P, Clinical Guidelines Committee of the American College of Physicians. Screening for prostate cancer: a guidance statement from the Clinical Guidelines Committee of the American College of Physicians. *Ann Intern Med* 2013;158:761-9.
11. Kachalia A, Mello MM. Breast cancer screening: conflicting guidelines and medicolegal risk. *JAMA* 2013;309:2555-6.
12. Greenland P, Alpert JS, Beller GA, et al. 2010 ACCF/AHA guideline for assessment of cardiovascular risk in asymptomatic adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol* 2010;56:e50-103.
13. Greenland P, Alpert JS, Beller GA, et al. 2010 ACCF/AHA guideline for assessment of cardiovascular risk in asymptomatic adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation* 2010;122: e584-636.
14. Eden J, Levit L, Berg A, Morton S, editors. *Finding What Works in Health Care: Standards for Systematic Reviews*. Washington DC: National Academies Press, 2011. Available at: <http://www.iom.edu/Reports/2011/Finding-What-Works-in-Health-Care-Standards-for-Systematic-Reviews.aspx>. Accessed June 2, 2013.
15. Graham R, Mancher M, Wolman DM, Greenfield S, Steinberg E, editors. *Clinical Practice Guidelines We Can Trust*. Washington DC: National Academies Press, 2011. Available at: <http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx>. Accessed June 2, 2013.
16. Gaus CR. An insider's perspective on the near-death experience of AHCP. *Health Aff (Millwood)* 2003;Suppl Web Exclusives:W3-311-3.
17. Lauer MS. Thought exercises on accountability and performance measures at the National Heart, Lung, and Blood Institute (NHLBI): an invited commentary for circulation research. *Circ Res* 2011;108: 405-9.

Key Words: clinical practice guidelines ■ NHLBI ■ systematic evidence review.