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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, and Michael S. Lauer, MD

From the Office of the Director (GHG, GAM and SBS) of the National Heart, Lung, and Blood Institute (NHLBI); and the Office of the Director (MSL) of the Division of Cardiovascular Sciences (DCVS) of the NHLBI; all from the National Institutes of Health (NIH) of the United States Department of Health and Human Services.

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Please address all post-publication correspondence to:

Dr. Gary H. Gibbons  
Office of the Director, NHBLI  
31 Center Drive, Room 5A48, MSC 2486  
Bethesda, MD 20892-2486  
Phone: 301-496-5166  
Fax: 301-402-0818  
Email: [Gary.Gibbons@nih.gov](mailto:Gary.Gibbons@nih.gov)

Please address all pre-publication correspondence to:

Dr. Michael S. Lauer  
Office of the Director, DCVS, NHLBI  
6701 Rockledge Drive, Room 8128, MSC 7940  
Bethesda, MD 20817  
Phone: 301-435-0422  
Fax: 301-480-1864  
Email: [lauer@nhlbi.nih.gov](mailto:lauer@nhlbi.nih.gov)



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 sixty-five years, the National Heart, Lung, and Blood Institute’s (NHLBI) 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 US Department of Health, Education, and Welfare, announced the establishment of a “National Hypertension Program.”(3) The program planned a four-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 health care delivery. Richardson appointed *two* committees: one, the “Hypertension Information and Education Advisory Committee,” was to focus on the knowledge of hypertension and the communication of that knowledge, while the other, an “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 Blood Pressure Education Program, as well as from other similar efforts like 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 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 has 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 literally exploded, serious questions and controversies have arisen about how guidelines should be developed, implemented, and evaluated. Critics have aptly 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)

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 which 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 (MSL) helped write.(12,13) When multiple stakeholders work together collaboratively, 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 two reports, one 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 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 conflict 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 two separate reports, one on writing of systematic reviews and one on development of guidelines. The two activities are related, require careful intersection and coordination but nonetheless are distinct. In some respects this distinction reflects the composition and charges of the two 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 Healthcare Policy Research (AHCPR) 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, on the occasion of a public meeting with the NHLBI Advisory Council (NHLBAC), we report on our plans regarding current and future efforts of the NHLBI 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 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 an extensive process that included consultation with a number of internal and external stakeholders. This Working Group initiated the evaluation with five 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 performances of systematic reviews and the creation of practice guidelines. The NHLBAC Working Group has 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 five integrated 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 the responsibility for generating the systematic review dataset and evidence syntheses that other organizations will use to develop cardiovascular guidelines. While 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 six 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 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.

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