Statement

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Considerations in National Efforts for Comparative Effectiveness Research to be conducted under the American Recovery and Reinvestment Act of 2009

Submitted for the Record to the

Federal Coordinating Council for Comparative Effectiveness Research

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The Association of American Medical Colleges (AAMC) welcomes the opportunity to submit this statement for the record in conjunction with the April 14, 2009 listening session convened by the Federal Coordinating Council for Comparative Effectiveness Research. The AAMC applauds the Council for holding this public forum, underscoring the importance of input from a broad range of stakeholders relevant to coordinating federal efforts on comparative effectiveness research.

The AAMC is a not-for-profit association representing all 130 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 68 Department of Veterans Affairs medical centers; and 94 academic and scientific societies. Through these institutions and organizations, the AAMC represents 109,000 faculty members, 67,000 medical students, and 104,000 resident physicians. Our members play a significant role in the U.S. health care system not only by educating and training future physicians, and promoting discovery and innovation through biomedical, clinical, behavioral, and health services research, but through providing complex state-of-the-art treatment and life-saving care to millions of Americans. AAMC members account for one sixth of all Medicare physicians, 22 percent of all hospital discharges, and 41 percent of all charity care in the US

Accordingly, AAMC and its members recognize that the U.S. health care system faces a crisis of access, cost, and quality that must be addressed now. The Association of American Medical Colleges (AAMC) and its members believe that ensuring access to safe, high-quality, appropriate, and affordable patient-centered health care is, and should continue to be, the focal point of all health care reform discussions. Clearly research is essential to achieving this goal. Additional comparative effectiveness research is required to determine the most effective treatments to address the health care needs and concerns of specific patients. Also important is research that will clarify the best approaches to achieving timely, efficient, and effective provision of the services required by specific patient conditions.

The U.S. health care system is recognized for discovering and providing life-saving treatments for many of the most difficult diseases and conditions and for educating a highly skilled workforce of clinicians and scientists. In the last few decades, landmark developments in genetics, bioengineering, neuroscience, and molecular and structural biology have vastly increased our understanding of the causes of disease and raised new possibilities for treatment and prevention. However, there is a gap between the pace of scientific and technological advancements and the successful translation of this science into effective medical and health practices at the bedside, in the clinic, and in the community. Comparative effectiveness research (CER), and related research on knowledge translation, patient engagement, and health system transformation are key to converting biomedical discoveries into effective new approaches to the diagnosis, treatment, and prevention of human illnesses.

Recommendations

1. **The AAMC strongly supports investments to further develop research methods to support the national comparative effectiveness research enterprise.**

A host of different techniques and approaches have developed in the past 50 years after the emergence of the randomized controlled clinical trial as a standard of evidence. Of course, RCTs can not be the only form of evidence used to determine relative clinical effectiveness, given their many limitations, including cost, timeliness, and the challenge of applying evidence to clinically relevant subpopulations.. New sources of data offer important opportunities; for example, use of electronic health records is expanding, especially among teaching hospitals and faculty group practices. For many health plans, claims data are being linked to clinical information as part of Pay for Performance (P4P) programs, creating richer administrative data sets for research. Clinical registries are expanding for a variety of procedural interventions, devices and therapeutics. All of these trends lead to increased options for secondary data analysis relevant to CER. With these and other expanded data sources, increased numbers of observations, and greater richness of clinical detail, new analytic methods aiding valid inference from observational research should be a high priority. Moreover, every effort must be made to utilize these new sources of data while protecting the privacy of patient information.

2. **The AAMC identifies as another high priority robust, sustained investment in research training in the disciplines relevant to comparative effectiveness research to enhance the skill, supply and diversity of the research workforce**

Systematic development of the CER workforce will also be important. CER represents the fullest expression of the community application side of "translational research." Thus, there are many features of the discipline of CER that are relevant to the "discipline of clinical and translational science" fostered by the NIH and the "homes for clinical and translational research training" being developed in leading academic medical centers. Within the broad area of clinical and translation research, the skilled scholar of CER must have expertise not only in traditional clinical trial design, but also pragmatic/practical clinical trials and Bayesian modeling/ adaptive trial design, quasi-experimental/observational studies of clinical effectiveness, meta-analysis, clinical outcomes measurement and utility assessment..

3. **The AAMC strongly supports investments to develop and sustain the national research infrastructure for CER as among the highest priorities for developing the national comparative effectiveness research enterprise.**

In addition to the further development of the intellectual discipline and human resources for CER, investments will be required to develop and sustain key infrastructure relevant to efficient conduct of CER. One fundamental need is for expanded networks for evidence review, the fundamental building block for CER. With the rapid evolution of health information technology, and clinical data, there will be opportunities to augment existing networks of clinical data and to establish and sustain new clinical research databases that could encourage the timely conduct of CER projects. Many CER questions will need to address questions of effectiveness in patients with specific, multiple conditions, cared for in a variety of settings. Therefore CER studies will be facilitated by clinical research networks that are multidisciplinary, and can address multiple conditions, clinical circumstances, and practice settings. These must be able to quickly undertake large scale clinical trials, preferably using community-based clinical resources.

With the publication of the 2006 Report of its Task Force II on Clinical Research, AAMC has endorsed major investments by academic medicine in these areas. Among the prominent

recommendations of this report are that "academic medical institutions should establish collaborations with community healthcare providers and practice-based research networks to broaden the diversity and size of the population base for translational and clinical research and to increase opportunities for health services, epidemiological, and outcomes research.:" and that they "should explicitly recognize and vigorously promote translational and clinical research as a core mission." Accordingly, many leading academic medical centers have already made substantial initial investments in the kinds of interdisciplinary research teams and academic – community partnerships needed for efficient conduct of successful, clinically relevant CER.

4. **The AAMC strongly supports further research to inform clinical care delivery and the development of delivery system reforms.**

Physicians and others must treat patients on a daily basis for whom no relevant clinical trials exist that fully capture the conditions and preferences of single individuals. Further investment in clinical information useful to clinician and patient decision-making must be developed alongside the research which will inform the systems and processes which facilitate high quality patient-centered care. In addition to CER, research on knowledge translation, patient engagement, and health system transformation are key to converting biomedical discoveries into effective new approaches to the diagnosis, treatment, and prevention of human illnesses.

5. **The AAMC strongly supports developing and using CER through means that are synergistic with continued discovery of clinical innovations through biomedical science.**

In this exciting era of burgeoning discoveries in the health sciences (such as genomic medicine) it is essential to advancing the health of the public that we continue to apply the discoveries in biomedical science to enhance patient care. Simplistic applications of CER could stifle new discoveries and limit the benefits from ongoing US investments in biomedical science. A robust culture of discovery spanning all the health care sciences, including biomedical, translational, comparative effectiveness, and health services, will be needed to create a sustainable system that can advance the health of all Americans

Conclusion

The problems of cost and quality that beset our health care delivery system do not lend themselves to easy solution. The AAMC and its members believe that new investments in biomedical, comparative effectiveness, and health services research are key to discovering the answers to the nations' health care crisis. Such research, when integrated with the development of medical and health systems knowledge, is the keystone to a vibrant "learning" health care system. Medical schools and major teaching hospitals are uniquely situated to provide both the institutional support and the rigorous training necessary to conduct this research and to nurture physician-scientists equipped to exploit scientific opportunities.