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April 20, 2012

Doris Lefkowitz, Reports Clearance Officer
Agency for Healthcare Research and Quality (AHRQ)
Submitted via email: doris.lefkowitz@AHRQ.hhs.gov

Dear Ms. Lefkowitz:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22 million AHA and ASA volunteers and supporters, we appreciate the opportunity to submit our comments in response to the Agency for Health Research and Quality's comment request for its proposed information collection, entitled "American Recovery and Reinvestment Act Developing a Registry of Registries."

The Mission of the American Heart Association/American Stroke Association (AHA/ASA) is *Building healthier lives free of cardiovascular disease and stroke*, with a 2020 impact goal to improve the cardiovascular health of all Americans by 20%, while reducing deaths from CVD and stroke by 20%. One of the AHA/ASA's approaches to achieving its mission is to continually raise the bar on quality patient care by advocating for and creating systems, programs, and partnerships that ensure evidence-based medical guidelines are effectively translated into standard patient care. The flagship of these efforts is the Get With The Guidelines® (GWTG) suite of inpatient quality improvement programs which have impacted the care of more than 3 million patients and resulted in over 4 million patient records being entered in their supporting registries. The GWTG programs include in-hospital modules for myocardial infarction, heart failure, stroke, and resuscitation. In 2010, the AHA launched an outpatient program, The Guideline Advantage™ (TGA) that supports consistent use of evidence-based guidelines for prevention and disease management through existing health care technology.

All of these quality improvement programs use a patient registry as the primary data collection tool to facilitate data aggregation and analysis, as well as feedback reporting to providers and hospitals. It is the over ten years of experience developing, refining, and expanding these programs and their associated registries that allows us to provide the input below.

It is this same ten years of experience that makes AHRQ's potential information collection "Registry of Patient Registries (RoPR)" project very exciting to us as an organization. The American Heart Association/American Stroke Association supports AHRQ's overall goal in proposing RoPR, as we believe the creation of such a database could greatly increase the awareness, accessibility, use, and

impact of patient registries. Additionally, the AHA/ASA is particularly supportive of the investigator-led research that such a project could foster.

The Federal Register notice outlining the initial details of the program, however, is very general and leaves many unanswered questions. While we understand and appreciate AHRQ's request for input at the early conceptualization of the project, we also believe that more details are needed in order for responders to understand the project's impact and assess the willingness of their organizations, including ours, in participating. Additionally, without this additional information and detail, it is difficult for us to realistically identify potential pitfalls that the project could encounter. Below we highlight our main questions regarding the project.

What information, specifically, will AHRQ request of those participating?

The Federal Register notice does not provide any detail as to what information AHRQ has in mind to collect from each registry owner. It provides some indication of the quantity of data in the annualized burden section that estimates 45 minutes for initial data entry and an additional 15 minutes each year to update that information. These approximations suggest that the extent of information that AHRQ intends to collect is not that great and would change minimally from year to year. To this end, we would be interested in the specific data elements that AHRQ intends to request. While we recognize that the data burden should not be too large that it creates a barrier to broad participation in RoPR, at the same time, we would encourage AHRQ to make sure that the information requested is sufficient to be meaningful as to what it can present about the registries contained in the database and how meaningful a search of the database would be for a user.

Does AHRQ intend to make recommendations regarding what the specific common data fields should be?

AHRQ lists one of the RoPR's project objectives as to "facilitate the use of common data fields and definitions in similar health conditions." The notice, however, does not indicate whether it is AHRQ's intention to make recommendations as to what those common data fields and definitions would be. We would be interested in whether AHRQ plans to make these recommendations, and, if so, how it would go about generating the recommendations. For example, would AHRQ create standards at the beginning of the project that it would suggest participating registries use? Or would it wait for a period of time after which registry owners have entered information to identify consistencies across registries? Conversely, does AHRQ have no intention of generating recommendations, but instead is anticipating that the sharing of information across registry owners, on its own, will result in the coalescence of participants around particular recommendations? Or, as another alternative, does AHRQ intend to use the registry owners as participants in a recommendation process by which the project would generate recommendations? If so, what would the process look like? The AHA/ASA could see pros and cons to each approach and is interested in hearing more about AHRQ's plans.

What does AHRQ intend to include as part for searchable summary results?

We would like more information on the third objective listed in the Federal Register, related to the specific information that AHRQ is hoping to include in the summary results, as well as how the information contained in the summary result would be generated. For example, would the registry owner provide that synopsis or would it be generated based on information pulled from other data fields for the particular registry?

Can AHRQ provide more information related to its parenthetical comment that the searchable summary results could “includ[e] results from registries that have not yet been published in the peer-reviewed literature”?

We understand that the ability for the RoPR to provide summary results based on registry data holds the potential for a huge impact on research and the dissemination of results. At the same time, we are concerned by the parenthetical statement that indicates results would be provided in the RoPR prior to publication. We believe that using this venue as a method to announce and disseminate “results” prior to publication bypasses the peer review process critical to the validation of study results. For this reason, we encourage AHRQ to provide more information on this important element of the RoPR project and solicit specific feedback to that information release from potential participating organizations to further assess and refine the approach taken.

Thank you very much for the opportunity to provide comment on this exciting project. We look forward to hearing more soon.

Sincerely,

A handwritten signature in blue ink, appearing to read 'G. Tomaselli', with a long horizontal flourish extending to the right.

Gordon F. Tomaselli, MD, FAHA
President, American Heart Association