At Last! Research Funds for Diagnostic Safety

Research findings have been an important component of the growing interest in diagnostic error. Early studies and expert opinion raised awareness that diagnosis is a patient safety issue and began to identify the need to define diagnostic error, assess incidence rates, identify contributing factors, examine economic impact, and evaluate improvement strategies. Despite limited funding, this early research has been fruitful, providing evidence on these points, as well as direction to address the many gaps that remain.

With the recent release of two Funding Opportunity Announcements (FOAs), investigators are now able to apply for federal research grants specifically focused on diagnostic safety. The grants are available from the Agency for Healthcare Research and Quality (AHRQ). (See sidebar on page 3 for details.)

AHRQ has encouraged diagnostic safety research in the past through special emphasis announcements, but the current FOAs represent the first time that dedicated funds have been allocated for this purpose.

With these grants, AHRQ indicates that diagnosis will have a prominent place in its patient safety portfolio. According to Kerm Henriksen, PhD, human factors advisor for patient safety in AHRQ’s Center for Quality Improvement and Patient Safety and program contact for the FOAs on diagnostic safety, the agency recognizes that interest in diagnosis has grown significantly and that related research has matured to a level that warrants dedicated funding (personal communication, June 18, 2015).

The concurrent FOAs acknowledge the need to work on different dimensions of diagnostic safety simultaneously. In AHRQ’s view, it is important to examine potential interventions for improvement—the R18 grant—while recognizing there is still much to learn about the incidence and causes of diagnostic failures in various settings—the R01 grant (K. Henriksen, personal communication, June 18, 2015).

System-Related Risks

In addition to learning more about the incidence of diagnostic failure, the rationale behind the R01 FOA is based on awareness that adverse diagnostic outcomes frequently are the result of multiple factors converging in a complex, dynamic, and fragmented system of care. Henriksen explains:

Going all the way back to the IOM’s To Err Is Human report, the underlying message is that the problem isn’t necessarily bad providers. The problem can be a number of factors or gaps in the healthcare systems that providers inherit. When these factors converge under uncertain conditions and align themselves in uncertain ways, they can lead to medical and diagnostic failures. Diagnostic failures, as well as successes, are the consequence of these

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converging system factors, made up of human and non-human components. That’s why we are interested in research that expands the depth and breadth of knowledge about contributing factors. In brief, the agency is casting a wide diagnostic net and welcomes innovative proposals seeking to understand and do something about improving safety (personal communication, June 18, 2015).

Beyond understanding system-related problems that diagnostic safety shares with other areas of healthcare, research is needed to learn more about contributing factors that are specific to diagnostic error. These issues have been explored by members of the Society to Improve Diagnosis in Medicine (SIDM), by its Research Committee, and participants at the invitational research summits held at the Diagnostic Error in Medicine conferences. Many questions persist, including:

- What is the definition of diagnostic error?
- Should those definitions be disease-specific?
- At what point should overdiagnosis be considered an error?
- What is the rate of diagnostic error in physician practices?
- How do complex systems reliably adapt to the changing shape of risk before diagnostic harm occurs?
- How should efforts to improve diagnosis (including research) be prioritized?

More research is also needed to understand why and how often diagnostic failures occur in different specialties and settings.

**Improvement Strategies**

The R18 grants are for “demonstration and dissemination” of improvement strategies, including interventions designed to improve the accuracy, timeliness, reliability, and safety of diagnosis and to prevent patient harm. The FOA lists the following examples of activities and tools consistent with the R18 grant: financial incentives, patient-based reporting systems, checklists, data visualization, debiasing techniques, decision support tools, and other education and training programs. In the FOA, AHRQ issues a challenge to the research community:

> Despite the abundance of ideas, recent reviews of the literature have found few efforts that actually operationalize the ideas and test them empirically whether in actual clinical or simulated settings. Clearly there is a need for innovative and disciplined approaches for the testing of these ideas.10

Laura Zwaan, PhD, postdoctoral researcher at the Institute for Medical Education Research Rotterdam, Erasmus MC, the Netherlands, and co-chair of SIDM’s Research Committee, concurs that research activity to date has focused more on the epidemiology and root causes of diagnostic error than on error reduction. Zwaan observes, “It has been very difficult to find funding to study diagnostic safety. Relatively few interventions have been tested. Some things have proven to be effective in small studies, but larger trials are needed in real world settings.”

**Scarcity of Research Funding**

The AHRQ research grant process is demanding, competition is vigorous, and there are not many other options for funding.

The National Patient Safety Foundation (NPSF) offered a Research Grants Program between 1998 and 2012. Among the projects that received NPSF funding were three that focused on diagnosis: “Diagnostic Errors in Internal Medicine” (Mark L. Graber, MD, FACP; 2001); “Error Detection and Recovery: Fixation vs. Adaptability” (William R. Torbert, PhD; and Jenny Rudolph, PhD; 2001); and “Identifying the Cognitive Dimensions of Failure to Rescue” (Alexa Doig, PhD, RN; 2009).11 NPSF welcomes new grant funders to assist in advancing research.

CRICO, the malpractice insurer for physicians and organizations affiliated with Harvard Medical School, offers research grants to its members. Diagnostic failure is a priority, according to Carol Keohane, MS, RN, CRICO’s vice president for patient safety, who oversees the grants program.

In addition to large projects, CRICO funds demonstration projects to test innovative solutions. Interventions that prove successful in pilot programs are disseminated across CRICO’s membership. Although funding is limited to members, Keohane emphasizes that sharing new learning and evidence widely (not just with members) is consistent with CRICO’s mission. CRICO Strategies has recently published a landmark study on claims in their database related to diagnostic error, which contains a wealth of information on where and why these errors arise.14

David Newman-Toker, MD, PhD, co-chair of SIDM’s Research Committee, has observed that one underlying reason why funding for research in diagnostic error has been so limited relates to the way research funding is organized by the
Understanding and Improving Diagnostic Safety in Ambulatory Care

Incidence and Contributing Factors (R01)
Recurring submission dates: October 5, February 5, June 5
Expiration date: November 6, 2018

Strategies and Interventions (R18)
Recurring submission dates: September 25, January 25, May 25
Expiration date: September 26, 2018

- Maximum funding per project will be $350,000 per year for up to five years.
- Funding is available to public and non-profit private organizations. Eligible entities may include applicant partners who are not eligible to apply on their own.
- AHRQ uses the National Institutes of Health’s online system, eRA Commons, for applications to submit and track the status of their grant applications.

Helping to facilitate funding for research is a long-term goal of SIDM’s Research Committee.

National Institutes of Health (NIH). The NIH funds the vast majority of biomedical research in the United States through its 27 institutes, which are dedicated to the study of individual diseases or body systems, such as the National Heart, Lung, and Blood Institute and the National Cancer Institute. Given that framework, finding funding for diagnostic improvement and other patient safety research, which spans specialties and diseases, is problematic.

SIDM’s president, Mark L. Graber, MD, points out the discrepancy between the harm related to diagnostic error and the research funding available. If current estimates are accurate, diagnostic error is a leading cause of death in the United States but receives very little funding for research.

Helping to facilitate funding for research is a long-term goal of SIDM’s Research Committee, which also plans to launch a mentoring program for new researchers in the near future. SIDM members may contact Robert El-Kareh, MD, about the mentoring program; Research Committee Co-chairs Laura Zwaan and David Newman-Toker with questions about performing research; and consult SIDM’s website for links to other resources (http://www.improvediagnosis.org/?page=DiagnosticResearch).

References
Grant Supports Development of Training Modules on Clinical Reasoning

By Mark L. Graber, MD, FACP
Founder & President
Society to Improve Diagnosis in Medicine

The Society to Improve Diagnosis in Medicine (SIDM) is proud to announce a new $200,000 grant from The Doctors Company Foundation (DCF), awarded to SIDM and our partner Med-U to improve diagnosis by providing novel training modules on clinical reasoning.

These scenario-based modules represent the first formal educational products to specifically address diagnostic error in the US. By taking advantage of the stature and scope of the Med-U educational platform, we have the opportunity to reach a substantial portion of US medical trainees. Each module will be incorporated into the Med-U educational platform and used across the country for 3rd and 4th year medical students. The modules will introduce the cognitive biases that lead to errors in clinical reasoning, how to avoid these pitfalls, and how to recognize and discuss diagnostic errors encountered in everyday patient care, all with the goal of improving diagnosis in practice.

The project will be directed by Drs Andrew Olsen, Gurpreet Dhaliwal, and Bob Trowbridge, in addition to members of the SIDM Education Committee, along with key staff from Med-U, including Drs Leslie Fall and Valerie Lang, national experts on developing state-of-the-art teaching modules.

I offer my thanks and appreciation to the project team. We are all looking forward to these first forays in developing the curriculum we need to improve diagnosis.

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Keynote Presenters

Sunday, 27 September
Tejal K. Gandhi, MD, MPH, CPPS, is President and Chief Executive Officer of the National Patient Safety Foundation. She is also a board certified internist, Associate Professor of Medicine at Harvard Medical School, and a certified professional in patient safety.

Monday, 28 September
Richard Kronick, PhD, is the director of AHRQ; his work, and that of the Office of Health Policy under his leadership, was integral to the implementation of the Affordable Care Act.

Tuesday, 29 September
Francis ‘Jay’ Crosson, MD, is a member of the Medicare Payment Advisory Commission. Previously, he was group vice president, American Medical Association, and prior to that, a physician and physician executive at Kaiser Permanente as well as senior fellow at the Kaiser Permanente Institute for Health Policy.

Early Bird Registration Discount Ends August 3

The Diagnostic Error in Medicine International Conference is the premier event for medical professionals and patients with specific interest in improving medical diagnosis. As a collaborative event, leaders and practitioners are invited to gather together for meaningful discussions driving potential solutions.

Visit DEMConference.org to learn more.

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