



GUEST EDITORIAL

Health Services Research

Opportunities for Pathology

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Health services research (HSR) is a rapidly growing area of research and training, with significant applications to patients, providers, and society, that offers tremendous opportunities for pathologists to affect the health of our community. The limited involvement of anatomical and clinical pathologists in HSR largely reflects the historical focus of pathology research on the mechanisms and manifestations of disease. However, HSR provides extraordinary potential for pathologists to study the direct impact of their clinical research and diagnostic services on health care outcomes, access, and cost.

Health Services Research

What actually is HSR? Although HSR has a variety of definitions, they all focus on the study of health care quality (eg, outcomes, safety, and satisfaction), access, and cost. Academy Health, the largest professional HSR society, provided a detailed definition and description of HSR in 2000 (<http://www.academyhealth.org/About/content.cfm?ItemNumber=831&navItemNumber=514>, last accessed July 22, 2014) with the simple summary that HSR is the scientific study of health care delivery asking what works, for whom, at what cost, and under what circumstances. The Agency for Healthcare Research and Quality defined the goals of HSR in 2002 as finding “the most effective ways to organize, manage, finance, and deliver high-quality care; reduce medical errors; and improve patient safety” (<http://archive.ahrq.gov/about/whatis.htm>, last accessed July 22, 2014).

Several types of research significantly overlap or are components of HSR. These include comparative effectiveness research, which studies the impact of an intervention at a population level; implementation-dissemination science, which studies how evidence-based practices are adopted by

appropriate populations; and delivery system research, which studies the effectiveness and efficiency of health care providers. A major characteristic of HSR is its multidisciplinary nature. Whether at the level of prevention, diagnosis, or treatment, HSR usually involves one or more health science disciplines. Because HSR often includes other factors, such as social determinants, environment, personal behaviors, economics, regulations/policy, work processes, human resources, or technology, it may also involve disciplines in the social sciences, humanities, business, law, and engineering.

With the increasing emphasis on translational research by the NIH (Bethesda, MD) and others, a shorthand nomenclature has been developed by a variety of organizations and authors, unfortunately yielding inconsistent definitions, especially as related to HSR. Some define two categories of translational research: T1 (basic to clinical) and T2 (clinical to population) (NIH—Behavioral and Social Sciences Research, http://obssr.od.nih.gov/scientific_areas/translation/index.aspx, last accessed July 22, 2014). Others use T1, T2, and T3 to represent transitions between basic-patient, patient-population, and basic-population research,¹ whereas others use five categories, including T0 (basic biomedical research), T1 (clinical translation), T2 (demonstrating efficacy), T3 (translation to practice), and T4 (translation to populations)² (Institute of Translational Health Sciences, <https://www.iths.org/about/translational>, last accessed July 22, 2014). Thus, HSR may represent T2 in the first scheme, T2 and T3 in the second scheme, or T3 and T4 in the third scheme, which is becoming most widely accepted.

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The importance of HSR has increased dramatically during the past few years, largely as a result of public attention and demands to address the well-recognized, complex, and interdependent problems of US health care cost, quality, and access.^{3,4} The socioeconomic-political debates about health care delivery in the United States have, if nothing else, made it clear that effective solutions must be based more on evidence than rhetoric. Adding to the urgency of HSR studies is the rapid transition underway toward delivery models based on population health, which are significantly affected by many confounding factors, of which the impact on specific cohorts in various settings is poorly understood. These include the multidisciplinary parameters mentioned above, as well as the nature of health plans and provider systems. Rigorous population-based HSR studies provide many challenges, including the need to develop larger and more complex big data repositories that include the necessary social and biomedical covariates, as well as appropriate and sometimes novel biostatistical and informatics approaches for analysis of the questions under study.⁵

As the field of HSR has expanded in scope, scale, and public importance, the attention and support from government agencies and other organizations have also increased. The NIH generated the HSR Information Central in 2005 to provide information on HSR topics of activity and funding opportunities across all government agencies, which recently has been combined with information on public health (<http://www.nlm.nih.gov/hsrph.html>, last accessed July 22, 2014). This site also provides General Resources information on HSR data, tools, meetings, legislation, organizations, and publications. More recently, the generation of the National Center for Advancing Translational Sciences, by NIH, to advance translational science has HSR as one of its pillars. The US Department of Veterans Affairs now has >20 Health Services Research and Development Centers across the country. In addition, as part of the Patient Protection and Affordable Care Act, the Centers for Medicare and Medicaid Services Center for Medicare and Medicaid Innovation and the independent Patient-Centered Outcomes Research Institute were generated to support HSR with new and significant funding streams (Centers for Medicare and Medicaid Services, <http://innovation.cms.gov/initiatives/Health-Care-Innovation-Awards/Round-2.html>; Patient-Centered Outcomes Research Institute, <http://www.pcori.org/funding-opportunities/funding-center>, last accessed July 22, 2014). There also is increasing federal support to train scientists in HSR; for example, 18 institutions have T32 grants supporting predoctoral and post-doctoral HSR Training Programs, 60 institutions with Clinical and Translational Science Award grants have clinical research training programs, and the US Department of Veterans Affairs Health Services Research and Development supports 15 HSR Fellowship programs. Funding and/or support of HSR and training is also the major emphasis of numerous private foundations, professional societies, and research and patient advocacy organizations.

With this growth of interest, organizations, and funding has come a concomitant growth in publications with a focus

on HSR. Most general medical journals, such as the *The New England Journal of Medicine* and *The Journal of the American Medical Association*, as well as clinically oriented medical specialty journals, including those in pathology, have a long history of publishing HSR studies. However, an increasing number of professional journals are becoming devoted to HSR and its subspecialties, including *Health Affairs*, *Health Services Research*, *Health Services Management Research*, *Health Services Research and Policy*, *Implementation Science*, *Medical Care*, and *Medical Care Research and Review*.

Opportunities for Pathology

Research in pathology is largely focused on the biomedical mechanisms and *in vitro* manifestations of disease, and although some pathology subspecialties, such as transfusion medicine and cytopathology, provide direct interactions with patients, most pathology diagnostic services do not. Nevertheless, the interest of pathologists in population health and HSR goes back to the impact both Rudolf Virchow and William Welch had in developing public health systems in their respective countries. As the father of modern pathology, Virchow was also a scientific and political force in developing public health projects throughout Germany and was noted as one of the founders of social medicine.⁶ After establishing the pathology department and medical school at Johns Hopkins University, Welch generated and served as initial dean of the first school of public health in the United States, which has become widely recognized for its HSR (<http://www.nasonline.org/publications/biographical-memoirs/memoir-pdfs/welch-william.pdf>, last accessed July 22, 2014).

More recently, pathologists have extended their basic and diagnostic research activities in pathology to clinical and population health settings. A striking example is the work of J. Brooks Jackson and colleagues (reviewed by Anderson⁷), who translated their molecular pathology studies in HIV to develop diagnostics, therapeutics, and rigorous HSR studies in Uganda, China, and the United States that established population-based, cost-effective methods of preventing neonatal HIV transmission and that have saved thousands of lives.

Many HSR opportunities exist within the scope of diagnostic anatomical and clinical pathology, especially related

Table 1 HSR Opportunities in Pathology

Diagnostic services:	Comparative effectiveness, safety
anatomical and clinical	Use, access, cost
pathology	Delivery models, method
Technology: analytic,	Analytic performance
information,	Use, access, cost
communications	Population data repositories
Decision support:	Test selection
providers, payers,	Interpretation
patients	Clinical application

to the delivery of services and use of technology (Table 1). The most evident area for HSR studies in pathology center around the outcome, safety, efficacy, access, and cost of diagnostic services. Comparative effectiveness research examining sensitivity, specificity, predictive value, and cost effectiveness is a core HSR question, especially when applied to population health. The appropriate use of tests for screening versus diagnosis in specific patient cohorts has become more controversial in the public dialogue on health care delivery. Whether the discussion is about the use of prostate-specific antigen testing and prostate biopsy specimens or molecular genetic testing and breast biopsy specimens, pathologists can and should be key figures in the design and implementation of studies that provide evidence-based answers to questions of the safety, efficacy, and cost of diagnostic tests. In addition to the clinical parameters involved in assessing diagnostic effectiveness and efficiency are the analytic parameters tied to the technology used, providing another area for HSR studies that can be led by pathologists.

The information accumulated by pathology services also provides extensive opportunities for HSR, especially in developing effective methods to recognize population health trends. The pathologist has access to a wealth of diagnostic data from the patient community that could rapidly identify an impending infectious epidemic or toxic environmental issue, as well as to track the development of more insidious population health problems, manifested by data from the laboratory, surgical pathology, or the autopsy service. Translating these data to information that leads to effective interventions is an area of HSR that is of high priority to public health services at the local, state, and federal levels.

Perhaps the greatest area of HSR impact for pathology is in the development of diagnostic decision support algorithms and tools for providers, payers, and patients. Studies to define appropriate diagnostic test order sets for specific patient populations has substantial impact on outcomes and cost, as does the determination of appropriate follow-up tests and the need for second opinions on tests involving interpretation. Likewise, HSR to identify the most effective means of determining, transmitting, and implementing test results for specific patients is increasing in importance as the number and complexity of diagnostic tools expand.

An emerging area of decision support HSR in pathology is in direct patient interactions. With regulatory changes providing greater ease of direct access by patients to their own test results, the importance of providing timely and accurate interpretation and advice directly to patients is

likely to increase dramatically. HSR studies will be important to identify the most effective approaches for translating test results to useful knowledge and appropriate action by patients seeking help. Likewise, HSR studies on the analytic aspects of direct-to-patient diagnostic testing, especially regarding informatics and technology, will have a major bearing on access and cost as well as outcomes.

As detailed above, there are a wide range of potential funding sources for pathology-related HSR, as well as many venues for publication of results. For many pathology departments without the experience or infrastructure to support HSR, the NIH website (<http://www.nlm.nih.gov/hsrph.html>, last accessed July 22, 2014) can be a valuable resource, along with *An Organizational Guide to Building Health Services Research Capacity*, published by the Agency for Healthcare Research and Quality.⁸

In summary, there are extensive opportunities for HSR across the sub-specialties of pathology and laboratory medicine that can quickly and significantly affect the outcomes, access, and cost of health care. Driving these increased opportunities has been increased public awareness and demand for improved health care services, making it incumbent on pathology as a discipline and pathologists in research to focus greater effort in HSR and the training of future HSR investigators.

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