NAMDRC

WASHINGTON WATCHLINE

PHYSICIAN ADVOCACY FOR EXCELLENCE IN THE DELIVERY OF PULMONARY AND CRITICAL CARE

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The Impact of Comparative Effectiveness Research

With passage of The American Recovery and Reinvestment Act of 2009 (ARRA 2009) Congress authorized the Administration to spend $1.1 billion to develop a federally directed Comparative Effectiveness Research (CER) program. The majority of the initial expenditures were directed toward improving the capacity to conduct comparative effectiveness research through the establishment of a nationwide research architecture. In 2013, self-sustaining support for CER, in the form of a flat tax on health insurance and self insured health plans, began to fund the Patient Centered Outcomes Research institute (PCORI). The Affordable Care Act imposed a tax of $2 per year for each covered individual under a health care policy to be paid by the insurer. Starting this year, the Institute embarked on a three-year period of major research allocations of approximately $500 million annually developing and synthesizing comparative effectiveness evidence. Like any other investors, our legislators are expecting to see a significant return on this financial commitment in the form of a reduction in spending on Medicare and Medicaid services. The motivating factor behind this policy is the belief that reducing variations in care and eliminating ineffective care will result in a reduction in Medicare spending well in excess of the initial investment. The information generated from CER about the costs, risks, and benefits of different treatment options, combined with financial and other incentives based on that information, will impact the way in which medicine is practiced.

Prior to 2009, health services research accounted for approximately 1.5% of total biomedical research expenditures and 0.1% of total U.S. expenditures on health care. With a shift in focus toward population health and chronic disease management, the Department of Health and Human Services and the Congress

The WASHINGTON WATCHLINE is published monthly and provides timely information to NAMDRC members on pending legislative and regulatory issues that impact directly on the practice of pulmonary medicine

NAMDRC's primary mission is to improve access to quality care for patients with respiratory disease by removing regulatory and legislative barriers to appropriate treatment.

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NAMDRC 38th Annual Meeting and Educational Conference will be held:
March 12-14, 2015
FireSky, a Kimpton Hotel
Scottsdale, AZ

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have embraced comparative effectiveness research as a key strategy to control resource use and cost and reduce variations in care. A comprehensive comparative effectiveness research program has been a major goal of the Department of Health and Human Services (HHS) for several decades. After a failed attempt to establish an internal clinical guideline program within the Agency for Healthcare Research and Quality (AHRQ) in the 1990's, the focus was shifted to reviewing guidelines and recommendations issued by professional societies and academic centers. In 1997, AHRQ created the Evidence-based Practice Centers to perform in depth reviews of these products. In 2003, the Medicare Prescription Drug Improvement and Modernization Act established the AHRQ Effective Health Care Program. That legislation authorized AHRQ to conduct and support research with a focus on comparing the outcomes and effectiveness of different treatments and clinical approaches. In 2005, The Developing Evidence to Inform Decisions about Effectiveness Network (DEcIDE) was established by AHRQ. In 2008, Congress signaled its commitment to the DEcIDE policy by doubling AHRQ's Effective Health Care Program budget to $30 million. Senators Max Baucus (D–MT) and Kent Conrad (D–ND) first introduced the Comparative Effectiveness Research Act in 2008. That proposal was amended and incorporated into the ARRA 2009.

The American Recovery and Reinvestment Act established the Federal Coordinating Council for Comparative Effectiveness Research. The charge was to develop a framework for the CER program. The Affordable Care Act of 2010 replaced the Federal Coordinating council with The Patient Centered Outcomes Research Institute (PCORI) and assigned AHRQ and NIH as the chief thought partners. The assigned mission of PCORI is to identify national research priorities, establish and execute a research agenda, and communicate research findings to policy makers.

In addition to establishing funding for CER, The American Recovery and Reinvestment Act called on the Institute of Medicine to recommend a list of priority topics to be the initial focus of the national investment. The IOM's recommendations were published in a 2009 report:

http://iom.edu/Reports/2009/ComparativeEffectivenessResearchPriorities.aspx

Included in the report, *100 Initial Priority Topics for Comparative Effectiveness Research* were the following topics that touch on our practice domain:

Compare the effectiveness of comprehensive care coordination programs, such as the medical home, and usual care in managing children and adults with severe chronic disease, especially in populations with known health disparities.

Compare the effectiveness (including resource utilization, workforce needs, net health care expenditures, and requirements for large-scale deployment) of new remote patient monitoring and management technologies (e.g., telemedicine, Internet, remote sensing) and usual care in managing chronic disease, especially in rural settings.

Compare the effectiveness of accountable care systems and usual care on costs, processes of care, and outcomes for geographically defined populations of patients with one or more chronic diseases.

Compare the effectiveness of different benefit design, utilization management, and cost-sharing strategies in improving health care access and quality in patients with chronic diseases.

Compare the effectiveness of care coordination with and without clinical decision supports (e.g., electronic health records) in producing good health outcomes in chronically ill patients

Compare the effectiveness of traditional behavioral interventions versus economic incentives in motivating behavior changes (e.g., weight loss, smoking cessation, avoiding alcohol and substance abuse) in children and adults

Compare the effectiveness of alternative redesign strategies—using decision support capabilities, electronic health records, and personal health records—for increasing health professionals' compliance with evidence based guidelines and patients' adherence to guideline-based regimens for chronic disease care.

The PCORI was convened in 2011 and in May, 2012 the Institute released its first report:

National Priorities for Research and Research Agenda

The report presented the five priorities which were developed in light of PCORI's statutory requirements and its working definition of patient-centered outcomes research.
They are:

Assessment of Prevention, Diagnosis, and Treatment Options - Comparing the effectiveness and safety of alternative prevention, diagnosis, and treatment options to see which ones work best for different people with a particular health problem.

Improving Healthcare Systems - Comparing health system-level approaches to improving access, supporting patient self-care, innovative use of health information technology, coordinating care for complex conditions, and deploying workforce effectively.

Communication and Dissemination Research - Comparing approaches to providing comparative effectiveness research information, empowering people to ask for and use the information, and supporting shared decision-making between patients and their providers.

Addressing Disparities - Identifying potential differences in prevention, diagnosis or treatment effectiveness, or preferred clinical outcomes across patient populations and the healthcare required to achieve best outcomes in each population.

Accelerating Patient-Centered Outcomes Research and Methodological Research - Improving the nation's capacity to conduct patient-centered outcomes research, by building data infrastructure, improving analytic methods, and training researchers, patients and other stakeholders to participate in this research.

The first research awards were announced in 2012 and PCORI has approved a total of 313 awards to date. Funding for research related to our practice domain was first awarded in 2013 and a list of those projects is available at the end of this document.

In 2012 PCORI began to build out the framework for CER by establishing the National Patient-Centered Clinical Research Network (NPCCRN). This oversight group will supervise two major divisions, The Clinical Data Research Network (CDRN) and the Patient Powered Research Network (PPRN). CDRN's are composed of two or more health systems, covering a large population, with data interoperability and data standardization that would allow sharing of individual or aggregate data across systems. PPRN's are comprised of a patient community or group who are motivated to play an active role in comparative effectiveness research. The NPCCRN Board announced that they would fund up to $56 million to support up to eight CDRNs that could develop the capacity to conduct randomized comparative effectiveness studies using data from clinical practice and up to $12 million to support 18 PPRNs and their progression toward a sustainable research network. The Board of Governors subsequently established a Coordinating Center, led by the Harvard Pilgrim Health Care Institute and The Duke Clinical Research Institute, to provide technical and logistical support to the data networks and assist in program evaluation. The Coordinating Center will provide technical and logistical support to the CDRNs and PPRNs and will be responsible for executing the recommendations and policies of the governing bodies of the national network. In addition, the Board has recently approved $93.5 million to support 29 health data networks that link together a network of millions of patients' medical records. This entity, an ambitious "network of networks", will be known as PCORnet.

PCORnet, the National Patient-Centered Clinical Research Network.

Return on Investment

By the end of this year the Administration will have invested almost $2 billion in the CER project. In Washington, success will be measured by the degree of financial impact. A panel of the Institute of Medicine estimated in a September 2012 report that $690 billion was wasted in US health care annually, not including fraud. Examining regional variations in Medicare spending, researchers at the Dartmouth Institute for Health Policy and Clinical Practice have estimated that 30 percent of all Medicare clinical care spending could be avoided without worsening health outcomes. This amount represents about $700 billion in savings when extrapolated to total US health care spending, according to the Congressional Budget Office. A study by former Centers for Medicare and Medicaid Services (CMS) administrator Donald M. Berwick and RAND Corporation analyst Andrew D. Hackbarth, published in April 2012, estimated that five categories of waste consumed $476 billion to $992 billion, or 18 percent to 37 percent of the approximately $2.6 trillion annual total of all health spending in 2011. Obviously the target for this project is large and the return on investment could be significant in financial terms. The Institute will select issues to be studied using cost and frequency data from CMS.

Innovation

Comparative effectiveness research can either serve as a complement to the creation and introduction of new treatments or as a strong deterrent. Which becomes the reality will depend on how the research findings are applied to the practice of medicine. The studies that focus on determining the most effective processes of care delivery for patients with multiple medical problems are most likely to have a positive effect on both quality and cost. Studies that focus on comparing one form of treatment to another or one drug or one device to another may be more problematic. On the positive side, results could identify therapies or devices that are somewhat superior but could be improved upon opening paths for further research and resulting in advances in technology. However, using research results comparing one existing therapy to another to guide provider payment or make coverage decisions would have repercussions extending far beyond the bedside. Focusing on existing treatments for which data are available stacks the deck against evolving technologies and discourages investment in research and development by the pharmaceutical and device industries. This reactionary approach would discourage innovation. A move toward inflexible policies of top-down cost containment in health care spending could jeopardize the country's ability to produce new treatments and make them available to patients

Dissemination into clinical practice

The Affordable Care Act emphasizes evidence-based medicine as a crucial tool for reigning in the escalating costs of diagnosis and treatment. The policy presumption is that the compilation of sufficient evidence will allow for noncontroversial, rational coverage decisions. For many proponents of health reform, cost containment requires nothing more than a long hard look at the evidence to forge consensus about what to cover. However, the faith that some policy makers in the United States have in the sufficiency of evidence obtained through CER remains unproven. Prudent application of the results of CER will almost certainly yield benefits; however, policy makers will need to realize that oversimplification of the clinical process can occur. Comparing available treatment options could certainly be beneficial by informing patients and physicians of the trade-offs of alternative options for treating a certain condition. But, to improve quality of care for an individual patient, CER findings must be considered just one part of decision making. CER must not edge out other crucial factors guiding medical decisions, including a physician's training and experience combined with a patient's values and preferences. In countries with nationalized health care, such as the United

Kingdom, comparative and cost-effectiveness information is used to inform mandatory coverage and payment decisions and this has limited access to therapies that could be effective for certain sub-populations. The absence of personalized medicine (genotype) considerations in CER could be suboptimal for patient interests, particularly to the extent that CER findings are used to support gate-keeping or other authoritative functions, such as product labeling, clinical practice guidelines, coverage policies, and quality measures and criteria.

When and how will the results of this effort begin to affect medical practice in the United States? To reduce health care spending, the results of comparative effectiveness analyses would have to change both current medical practice and improve patient compliance. Analysts who have been following this issue believe it will probably be a decade or more before new research on comparative effectiveness had the potential to reduce health care spending in a substantial way, however, the impact on practice will be felt sooner through a variety of incentives. The dynamics that govern healthcare systems policies, physician practice patterns and patient compliance are complex.

The CMS administration clearly realizes that the financial investment in comparative effectiveness research will not yield real improvements and cost savings unless the results are integrated into clinical practice by health care organizations and providers sooner rather than later. The legislation establishing the PCORI contained some initial restrictions in the financial applications of the research. However, language was clearly included that, in conjunction with the unprecedented authority given to the Secretary of HHS through the Center for Medicare and Medicaid Innovation, could allow findings from CER to influence coverage and payment for services. In a review of the program, the Heritage Foundation recommended that Congress award HHS the legislative authority to allow the program to consider relative benefits and costs in a more extensive way and to modify the financial incentives facing doctors and enrollees.

Medicare could choose not to cover treatments that were less effective or less cost-effective or it could exclude noncompliant providers from participating in the program altogether. Once they have a set of protocols in hand, will CMS follow the example of the for profit insurers and adopt a policy of preauthorization for services that are high cost or judged to be high frequency? CMS has begun to develop lists of these services for each specialty.

AHRQ has indicated its hope that professional organizations will participate in the process and that the results of the research will be incorporated into their educational products. Furthermore, it is anticipated that the results of CER will become embedded into clinical decision support tools in the electronic medical record. For example, the stage 1 EHR Meaningful Use requirements included implementation of one clinical decision support rule relevant to specialty along with the ability to track compliance with that rule. Stage 2 Meaningful Use increased the requirement to implementing five clinical decision support interventions related to four or more clinical quality measures for the entire EHR reporting period.

As the CER project evolves and steps are taken to implement the results through multiple incentives and disincentives NAMDRC will welcome comments and observations from the membership.

PCORI Research Awards

While traditional CER has compared one medical intervention with an alternative in a defined patent population the current program is much more complex. The focus of most of the funded research to date has been on comparing different processes of care particularly as applied to managing populations with chronic disease. It is anticipated that the results will be used to establish uniform processes of care delivery for those populations.

The 2013 Awards included:

An Integrative Multilevel Study for Improving Patient-Centered Care Delivery among Patients with Chronic Obstructive Pulmonary Disease
Principal Investigator: Hanan J. Aboumatar, MD, MPH; Johns Hopkins University

The COPD Patient-Powered Research Network
Principal Investigator: Richard Mularski, MD, MS; COPD Foundation, Inc.

Clinic-Based vs. Home-Based Support to Improve Care and Outcomes for Older Asthmatics
Principal Investigator: Alex Federman, MD, MPH; Icahn School of Medicine at Mount Sinai

Imperial County Asthma Comparative Effectiveness Research Project
Principal Investigator: John Elder, MPH, PhD; San Diego State University Research Foundation

Parent-Centered Innovations to Improve Adherence in At-Risk Youth with Asthma
Principal Investigator: Stephen J. Teach, MD, MPH; Children's Research Institute

Puget Sound Asthma Coalition: A Community, Clinical, and Academic Partnership
Principal Investigator: Julie Postma, PhD; Puget Sound Asthma Coalition

The Coordinated Healthcare Interventions for Childhood Asthma Gaps in Outcomes (CHICAGO) Trial
Principal Investigator: Jerry A. Krishnan, MD, PhD; University of Illinois at Chicago

The Hispanic Family Asthma Outcomes Research Network
Principal Investigator: Jorge Otero; Nuestra Salud, LLC

Using Information Technology to Improve Access, Communication and Asthma in African American and Hispanic /Latino Adults
Principal Investigator: Andrea J. Apter, MD, MA, MSc; University of Pennsylvania

Empowering Patients and Their Families to Improve Outcomes That Are Most Important to Them after Lung Cancer Surgery
Principal Investigator: David Tom Cooke, MD; UC Davis Medical Center, Section of General Thoracic Surgery

Patient-Defined Treatment Success and Preferences in Stage IV Lung Cancer Patients
Principal Investigator: KM Islam, MBBS, PhD; University of Nebraska Medical Center

Comparative Effectiveness of Peer-Led Supplemental O2 Infoline for Patients and Caregivers (PELICAN)
Principal Investigator: Jerry A. Krishnan, MD, PhD; University of Illinois at Chicago

Patient Participation Program for Pulmonary Fibrosis: Assessing the Effects of Supplemental Oxygen
Principal Investigator: Jeffrey Swigris, DO, MS; National Jewish Health

Preventing Venous Thromboembolism: Empowering Patients and Enabling Patient-Centered Care via Health Information Technology
Principal Investigator: Elliott Haut, MD, PhD; Johns Hopkins University

Sleep Apnea Patient Centered Outcomes Network (SAPCON)
Principal Investigator: Susan Redline, MD, MPH; American Sleep Apnea Association

Smoking Cessation Versus Long-Term Nicotine Replacement among High-Risk Smokers
Principal Investigator: Edward Ellerbeck, MD, MPH; University of Kansas Medical Center

Included in the 2014 Awards:

Informing Tobacco-Treatment Guidelines for African American Non-Daily Smokers
Principal Investigator: Nikki Nollen, PhD; University of Kansas Medical Center Research Institute, Inc.

PRODUCT AND TECHNOLOGY NEWS!

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- Monthly publication of the Washington Watchline, providing timely information for practicing physicians;
- Publication of Current Controversies focusing on one specific Pulmonary/Critical Care Issue in each publication;
- Regulatory updates;
- Discounted Annual Meeting registration fees;
- The Executive Office Staff as a resource on a wide range of clinical and management issues; and
- The knowledge that NAMDRC is an advocate for you and your profession.

http://www.namdrc.org/issue-advocacy

One of **NAMDRC**'s primary reasons for existence is to provide both clinicians and patients with the most up-to-date information regarding pulmonary medicine. Bookmark this page!

The complexity of our nation's health care system in general, and Medicare in particular, create a true challenge for physicians and their office staffs. One of **NAMDRC**'s key strengths is to offer assistance on a myriad of coding, coverage and payment issues.

In fact, **NAMDRC** members indicate that their #1 reason for belonging to and continuing membership in the Association is its voice before regulatory agencies and legislators. That effective voice is translated into providing members with timely information, identifying important Federal Register announcements, pertinent statements and notices by the Centers for Medicare and Medicaid Services, the Durable Medical Equipment Regional Carriers, and local medical review policies.

ABOUT NAMDRC:

Established over three decades ago, the National Association for Medical Direction of Respiratory Care (NAMDRC) is a national organization of physicians whose mission is to educate its members and address regulatory, legislative and payment issues that relate to the delivery of healthcare to patients with respiratory disorders.

NAMDRC members, all physicians, work in close to 2,000 hospitals nationwide, primarily in respiratory care departments and critical/intensive care units. They also have responsibilities for sleep labs, management of blood gas laboratories, pulmonary rehabilitation services, and other respiratory related services.

NAMDRC MEMBERSHIP APPLICATION

TWO EASY WAYS TO BECOME A NAMDRC MEMBER

1. Go to www.namdrc.org and register for membership online.

2. Mail this application to:

   NAMDRC
   8618 Westwood Center Drive, Suite 210
   Vienna, VA 22182-2222

Please print clearly or type:

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NAME (LAST) (FIRST) (MIDDLE INITIAL)

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TELEPHONE FAX

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E-MAIL

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FACILITIES WITH WHICH YOU ARE AFFILIATED

Please indicate the areas that apply to your practice:

❒ Respiratory Care Management

❒ Hyperbaric Oxygen Therapy

❒ Anesthesiology

❒ Critical Care

❒ Sleep Disorders Pulmonary

❒ Home Health Services

❒ Pulmonary Rehabilitation

❒ Physiology Assessments

❒ Skilled Nursing Facility

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Includes groups of up to 6. Please include contact information for all members.

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National Association for Medical Direction of Respiratory Care

Physician Advocacy for Excellence in the Delivery of Pulmonary, Critical Care, and Sleep Medicine