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EDITORIAL

Comparative Effectiveness Research: Implications for Hospital Medicine

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The topic of comparative effectiveness research (CER) has recently gained prominence within the context of the national focus on health reform. This article provides a brief overview and history of CER, and discusses the implications of CER for hospitalists in each of four major career roles: research, clinical practice, education and training, and hospital leadership. Both medical journals and lay media have produced a flurry of articles recently on a variety of health reform subjects. One topic that has achieved prominence within this growing body of literature is comparative effectiveness research (CER). For many hospitalists, this particular brand of research may be unfamiliar. As discussions about CER priorities, the controversy surrounding CER, and even the definition of CER gain visibility, hospitalists may be left wondering, "What exactly is CER and what does it mean for me?"

Until recently no common definition for CER existed, and the very concept was identified only in relatively narrow policy and research circles. However, CER is not a new idea. Its ancestor is the notion of medical technology assessment (MTA), which garnered enthusiasm and support in the 1970s. In 1978, Congress established the National Center for Health Technology Assessment (which, over time, evolved into the Agency for Healthcare Research and Quality [AHRQ]), whose charge was to coordinate efforts within the government to assess the safety, efficacy, effectiveness, and cost-effectiveness of medical technologies. The recognition of a need for technology assessment at that time is mirrored by the widespread interest in CER seen today. Part of the reason that MTA did not take hold is that then, as now, this type of evaluation is challenging and time consuming, requiring large, well-designed effectiveness studies. These studies require rigorous methods, typically long-term follow-up, and acceptance via editors and the medical literature that effectiveness is as important as efficacy demonstrated in a randomized trial. With the spread of antiregulatory sentiment and the lack of an economic imperative to reduce costs, the national focus on technology assessment waned. The current economic crisis has refocused the government and private sector on the soaring cost of health care and the need to improve quality, and the stimulus package passed in February of 2009 placed CER once again in the forefront. The American Recovery and Reinvestment Act (ARRA) of 2009 allocated $1.1 billion for CER.[1] On June 30, 2009, 2 reports delineating the strategy and priorities for CER were released. The report from the ARRA-mandated Federal Coordinating Council (FCC) for CER includes a broad definition of CER and outlines a high-level strategic framework for priorities and investments in CER.[2] Simultaneously, the report from the Institute of Medicine (IOM) lists 100 priority research topics, and gives 10 general recommendations for the CER enterprise going forward.[3]

So what is CER and why is it important? How is it different from standard research that hospitalists use every day to inform their clinical decision-making? Unfortunately, patients and providers confront medical decisions daily that are not evidence based. All too frequently it is unclear what therapeutic option works best for which patient under which circumstances. For example, what is the best inpatient diabetes management strategy for an African American woman with multiple medical problems? What is the best discharge process for an elderly man with heart disease in order to prevent readmission? CER seeks to fill the gaps in evidence needed by patients and clinicians in order to make appropriate medical decisions. It differs from standard "efficacy" research in that it compares interventions or management strategies in real world settings, allows identification

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of effectiveness in patient subgroups, and is more patient-centered, focusing on the decisions confronting patients and their physicians. The following definition of CER was developed by the FCC for CER:

CER is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in "real world" settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs about which interventions are most effective for which patients under specific circumstances.

- To provide this information, CER must assess a comprehensive array of health-related outcomes for diverse patient populations and sub-groups.
- Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, diagnostic testing, behavioral change and delivery system strategies.
- This research necessitates the development, expansion and use of a variety of data sources and methods to assess comparative effectiveness and actively disseminate the results.

While CER is an evolving field requiring continued methodological development (such as enhancement of methods for "practical", or "pragmatic" trials and complex analyses of large, linked databases), examples of rigorous comparative studies do exist. The Veterans Administration (VA) COURAGE trial compared optimal medical therapy (OMT) with or without percutaneous coronary intervention (PCI) for patients with stable coronary disease, finding that PCI did not reduce the risk of death or cardiovascular events compared to OMT alone.[4] Another example is the Diabetes Prevention Program which compared placebo, metformin, and a lifestyle modification program to prevent or delay the onset of type 2 diabetes. This study famously showed that lifestyle modification was more effective than metformin or placebo in reducing the incidence of diabetes.[5]

CER holds the promise of significantly improving the health of Americans through the ability to target treatments and other interventions to individual patients. As noted by the FCC, CER can allow for the delivery of "the right treatment to the right patient at the right time"[2] even as the field continues to evolve. To quote Fineberg and Hiatt[6] in describing technology assessment in 1979, we cannot expect CER to "lead to perfect decisions," but we can expect "even imperfect methods to facilitate better informed decisions than would otherwise be possible."

CER has important implications for hospitalists in all roles and settings. As the field of hospital medicine has grown, hospitalists have increasingly assumed more responsibilities than just patient care. In academic and community hospitals, hospitalists take on leadership roles, particularly in quality improvement (QI) and patient safety, and educational roles in the training of housestaff, medical students, and physician extenders. The last several years have also seen a significant increase in hospitalists participating in research. The relevance of CER to each of these 4 major activities is described below and in the accompanying Table 1.

TABLE 1. The Primary Roles of Hospitalists and the Potential Implications of CER

Primary Role	Potential Implications of CER
Research	New availability of funds for hospital-based CER
	Enhanced data infrastructure to conduct CER
	Opportunity to apply CER to issues unique to hospital medicine
	Opportunity to develop methodologic skills
Clinical practice	End users of CER evidence
	Responsibility for translation of CER into practice
	Targets of Federal and non-Federal dissemination efforts
Education and training	Development of a workforce to conduct hospital-based CER
	Responsibility for teaching physician and nonphysician trainees about CER concepts and review of CER literature
Hospital leadership	Direct hospital-wide efforts to implement emerging CER evidence into practice through a multidisciplinary approach
	Education and empowerment of clinician and nonclinician staff to translate CER information into practice

Abbreviation: CER, comparative effectiveness research.

Hospitalists and Research

Many comparative effectiveness questions about clinical care, processes of care, and quality of care within the inpatient setting are in need of answers. Hospitalist researchers have the opportunity to make a significant impact on care by pursuing answers to questions that are unique to the field of hospital medicine. With the new availability of funds for CER, now is the time to address many of these questions head-on. For example, there is a lack of evidence about best practices for a large number of inpatient acute conditions. What is the best strategy to manage acute hospital delirium in an elderly patient? What is the best approach to treating acute pain in an elderly woman on multiple medications? Overwhelmingly the patients that hospitalists care for are elderly and/or have multiple chronic conditions, including children with special health care needs. Many are from racial or ethnic minority backgrounds. These subgroups of patients have been historically under-represented in clinical trials, yet represent exactly the priority populations that the Federal CER effort targets. The field of hospital medicine can be transformed with a substantial investment in research to address common inpatient clinical conditions in "real world" settings focused on the kinds of patients hospitalists actually care for.

One of the most vexing and frustrating care delivery issues for hospitalists, clinicians and researchers alike, is the

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discharge process. This problem received increased attention after a recent article highlighted the high rate of readmissions in the Medicare population.[7] Research on the discharge process has grown substantially in recent years, and has become an area of intense focus and attention for hospitalists, nurses, researchers, hospital administrators and policymakers. Without question, hospitalists are uniquely poised to conduct research on this critically important topic, and CER is an ideal vehicle for moving this field forward. In collaboration with nurses, primary care physicians, pharmacists, case managers and others, hospitalists should take advantage of the Federal investment in studying care delivery systems interventions, and develop innovative methods and strategies for studying and improving this crucial transition in care. CER is also applicable to other care transitions, including the admission process, transitions within the hospital, and discharge to nursing facilities. Other examples of comparative effectiveness topics that hospitalist researchers are particularly suited for include comparing methods for implementing inpatient treatment protocols or clinical pathways, comparison of health information technology (IT) systems to reduce medical error, and QI approaches.

What are the methodologies that hospitalists should use to conduct CER? While randomized pragmatic "real world" trials are appealing, this method may not always be practical. Other methodologies are available for rigorous use, including cohort studies, comparative QI interventions, clustered and factorial design, systematic reviews, and analysis of registries, administrative claims, or other databases. Databases currently available for analysis on priority populations and subgroups are limited, and include the VA and Medicare databases. To address this need, one of the primary Federal investments in CER is for the enhancement and expansion of data infrastructure. Data infrastructure tools that are likely to be available to hospitalist researchers for CER include expanded longitudinal administrative claims databases with linkages to electronic health records (EHRs), expanded patient registries with linkages to other forms of data, and distributed data networks that are populated by EHRs in provider and practice settings. Hospitalist researchers should take advantage of these resources as they become available, as they have tremendous potential to inform decision-making for providers and patients alike.

Hospitalists and Clinical Practice

As with all providers, hospitalists will be end-users of CER evidence, and will have the responsibility of translating new knowledge into practice. This process will not be easy. How are hospitalists to reliably access and incorporate new comparative effectiveness information into their daily practice? How should they deal with some of the potential unintended consequences of CER, such as information overload or conflicting evidence? While hospitalists have a professional responsibility to search for and apply CER findings, the future development of CER-based practice guidelines will encourage evidence translation. The development of a common platform for the dissemination of CER relevant to hospitalists would significantly enhance the uptake of new evidence by practicing hospitalists and other hospital-based providers such as physician assistants or nurse practitioners. Medical societies such as the Society of Hospital Medicine and the American Academy of Pediatrics should consider developing committees for CER and leading coordinated educational efforts specifically focused on CER results through publications and presentations at local, regional, and national meetings. In addition, other dissemination tools for CER will soon emerge and existing tools will be enhanced, such as the Effective Health Care Program and Eisenberg Center housed at the AHRQ. The coming years will see an expansion of these and other dissemination efforts to both providers and patients, and hospitalists must be vigilant about accessing these resources and integrating comparative effectiveness evidence into practice. As Federal dissemination efforts to consumers spread, patients will increasingly expect physicians to discuss comparative effectiveness evidence in describing options for their individual health needs. Finally, a key lever for translating CER into practice will be payment models that place accountability for performance on physicians and hospitals, with a significant proportion of payment based on the delivery of high quality, efficient care.

Education and Training

Investment in the training and development of a skilled workforce to conduct CER is an important priority. Hospitalist researchers should take advantage of education and training programs to support the development of methodologies and skills for conducting CER that will become available. These programs will enable hospitalists to learn such skills as the use of the newly enhanced data infrastructure discussed above. The national investment in human and scientific capital for CER can promote the training of a corps of hospitalist researchers focused on this research which, in turn, could support the growth of the academic hospitalist field. Hospitalists who have responsibilities in medical education and residency training programs should take the lead in teaching CER concepts that are relevant to inpatient care. They will need to train the next generation of medical students and residents to read and understand comparative effectiveness literature and its application in clinical practice. Hospitalist educators are also best positioned to teach medical trainees comparative effectiveness evidence about inpatient QI methods and care processes.

Hospital Leadership

As front-line providers and team leaders, hospitalists are well placed to direct the efforts within their hospitals to implement new CER evidence. For example, suppose new comparative effectiveness evidence about "best practices" for the discharge process for community-dwelling older

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adults with multiple chronic conditions were to emerge. Hospitalists could lead efforts within their hospital to establish a multidisciplinary team to address this development, create standard protocols for implementing the new discharge process that align with their hospital's unique systems and organizational structure, advocate for necessary resources for the team to accomplish the goal of safely discharging these patients, ensure a method to track outcomes such as readmissions once the new discharge process is implemented, and provide data feedback to the team, hospital staff, and administrative leadership of the hospital. All of these activities should include a variety of disciplines working together, but as physician leaders, hospitalists can take the initiative to spearhead these endeavors. The inpatient setting is one that requires teamwork and coordination, and as team leaders, hospitalists can strongly influence the spread and adoption of CER results. Similarly, hospitalists are in a position to affect this dissemination and translation process by actively educating and empowering other clinicians and hospital staff within their local environment. Finally, as hospitalists increasingly take on leadership roles in QI departments and as chief medical officers within both community and university-affiliated hospitals[8,] they are in a unique position to lead efforts to implement CER-based QI activities. These may range from the implementation of IT functions to reduce medical error to strategies to reduce hospital-acquired infections or falls.

Conclusion

As a result of the stimulus funds directed towards CER, the coming years will see a vast increase in the generation of comparative effectiveness evidence and the application of that evidence into practice.[9] The national CER endeavor is particularly germane to the field of hospital medicine, as uncertainty about "best" practices is common, and the patients hospitalists serve represent priority populations for CER investments. Hospitalists can play a central role in both generating CER and implementing its findings in settings in which patients are highly vulnerable, and existing information is insufficient. In addition to clinical questions, hospitalist researchers are particularly suited to answering important questions about quality of care and inpatient processes such as transitions of care and care coordination. Having evidence on the best practices for care transitions or strategies to reduce medical error, for example, could have a significant impact on patient outcomes, quality of life, and cost of care. However, none of this new evidence will be of any value if it is not used by front-line providers.[10] Practicing hospitalists should lead efforts within their hospital to disseminate new CER findings to their hospitalist and non-hospitalist colleagues, and to leverage their position as hospital and team leaders to implement inpatient-based CER findings. All of these combined efforts have the potential to significantly move the field of hospital medicine forward, with the end result being improved health and better outcomes for patients.

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