Comparative Clinical Effectiveness Research: Will it be a Sword against or a Shield for Physicians?

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On February 17, 2009, President Obama signed into law the American Recovery and Reinvestment Act of 2009 (Public Law 111-5). Leading up to his signing of this bill (hereafter ARRA of 2009), he made it abundantly clear during his Address to Congress that there could be no sustainable economic recovery without controlling the costs of healthcare. To accentuate his point, soon after signing this bill, the U.S. Department of Commerce projected that healthcare costs for 2009 would top $2.5 trillion and consume 17.6% of the entire Gross Domestic Product (GDP). The GDP percentage increase from 16.6% in 2008 to 17.6% in 2009 represented the first time in almost 50 years of tracking that healthcare’s percentage of the GDP had jumped a full point in just one year. Based on current trends and without any changes, the Congressional Budget Office (CBO) has projected that by 2025, the cost of healthcare alone will consume fully 25% of the GDP.

In an effort to alleviate the escalating costs of healthcare, which are crushing both businesses and individuals, while maintaining or improving the quality and safety of care, the ARRA of 2009 has appropriated a total of $1.1 billion to fund what is being termed comparative clinical effectiveness research. Of this $1.1 billion, $300 million will be administered by the Agency for Healthcare Research and Quality (AHRQ), $400 million by the National Institutes for Health (NIH) and $400 million by the Secretary of HHS.

The Act includes funds for a contract under which the Institute of Medicine (IOM) will make recommendations (to the Congress and Obama Administration by June 30, 2009) for ‘national priorities for comparative effectiveness research’. It establishes a Federal Coordinating Council for Comparative Effectiveness Research, which will be composed of up to 15 federal officials (at least half of whom are physicians or others with clinical expertise) and chaired by the Secretary of Health and Human Services (HHS). The council will be tasked with recommending and coordinating research, but will not be able to ‘mandate coverage, reimbursement, or other policies for any public or private payer’ (Steinbrook, R., Health Care and the American Recovery and Reinvestment Act at: http://content.nejm.org/cgi/content/full/NEJMp0900665).

The Commonwealth Fund Commission on a High Performance Health System, chaired by James Mongan, M.D., CEO of Partners HealthCare, concluded in a recent report that creation of a center for comparative effectiveness could save $634 billion between 2009 and 2020. The $634 billion question, however, is how strictly would the results of these studies need to be followed to achieve these savings? Would the results of these studies establish new standards of care, against which physicians’ actions will be evaluated?

How much will the results of comparative clinical effectiveness research influence physician reimbursement?

Fortunately for physicians, the Senate version of the ARRA of 2009 contained the previously mentioned non-coercive language in it:

The Federal Coordinating Council for Comparative Effectiveness Research will be tasked with recommending and coordinating research, but will not be able to mandate coverage, reimbursement, or other policies for any public or private payer (Cf. Steinbrook and the NEJM web link, above).

The House version of the ARRA of 2009 had no such restriction. The Council
has its first public meeting on April 14, 2009 in the D.C. area.

Nevertheless, just how much will this provision prevent either public or private payers from altering their reimbursement policies to “persuade” physicians to follow the recommendations deriving from these studies? The language above merely prevents the Council from mandating coverage, reimbursement or other policies for any public or private payer. That provision could not be read to prevent any public or private payer from using the results of the research to alter its coverage, reimbursement or other policies.

As both public and private payers continue to move toward some type of value-based purchasing reimbursement model, it certainly seems plausible, if not likely, that they will seriously consider various means of persuasion to get physicians to follow the recommendations deriving from the results of these studies. Their methods of persuasion could include:

- Providing something less than previous levels of reimbursement for following a course of action not supported by the results of comparative clinical effectiveness research (e.g. performance of a meniscectomy prior to a full course of physical therapy for a patient with chronic knee problems with or without previously diagnosed torn cartilage)
- Classifying as “non-preferred” or even “non-formulary” those medications being ordered for specific purposes (e.g. antibiotics for first time pediatric ear infections) that are not necessarily supported by clinical effectiveness research results
- Reimbursing at the same level any treatment (e.g. diuretics for hypertension) concluded by the results of studies to be at least as effective for patients with certain levels of high blood pressure as the more expensive treatments which may achieve comparable results
- Insurers may influence patients also by using the results of the research to:
  - Steer them toward certain treatments by lowering the copayment, coinsurance or deductible amounts associated with those deemed to be of higher value
  - Make it more difficult to obtain certain treatments (e.g. knee operations - see above) by making them complete a course of physical therapy before qualifying for the invasive (perhaps, more definitive) procedure
  - Reimbursing less of the costs of seeing certain practitioners known (through tracking) to be more likely not to follow the best evidence based practices deriving from the results of these comparative effectiveness studies

Reimbursement issues aside for the moment, what might be the potential liability implications of not following (or, in some cases, even following) these best practices? What defenses could physicians mount for not following them? What types of best practices could be determined to be credible and might even serve as a shield for physicians who follow them?

Potential liability and risk management implications

Many physicians may find it controversial enough that the results of comparative clinical effectiveness research (especially when the relative costs of different interventions are taken into account) may impact their future reimbursement. This controversy could intensify if the results of these studies could be taken into account in liability actions.

What potential legal weight might the results of these studies have in liability actions? What would these studies need to have taken into account in arriving at their conclusions for a physician to be able to use adherence to them as a shield? What would need to be taken into account to permit the other side to use them as a sword against physicians for not following them (or even for following them resulting in a bad outcome)?

A close cousin to comparative clinical effectiveness research (controlled clinical trials) has carried varying degrees of weight in medical liability actions in the past. As the standard of care has slowly evolved from local determinations of “what would a reasonable physician have done under similar circumstances” to what is the recognized best evidence based practice(s) to employ, the results of these studies have acquired more heft in liability actions.

Comparative clinical effectiveness research will likely be somewhat similar in its evolution and probable applications in medical liability actions. What may well turn out to be different about it are at least two things:

- Reimbursement (in whole or in part) may turn in the future upon proof of following the recommendations deriving from this research
- To get their results into the mainstream more quickly and cost effectively than the very expensive and time-consuming controlled clinical trials, comparative clinical effectiveness research may be conducted through the analysis of large electronic databases to link certain practice patterns with superior value (high quality, safety and efficiently produced) clinical outcomes

Especially regarding results of studies that are produced by the analysis of large clinical databases (often derived from the use of electronic medical records), there would need to be certain safeguards built in to ensure fairness and accuracy in using the fact of adherence or non-adherence with best practices as a basis for liability or exoneration. Some of the factors that would need to be taken into account during these studies when applied to demonstrate potential negligence (or lack thereof) for not following their recommendations would be:

- **Pre-treatment Severity of Illness:** Did the plaintiff in a particular action exhibit a comparable clinical condition and severity of illness to those in the study whose results are being introduced either as a sword by the plaintiff or a shield by the defense?
- **Statistically Significant Conclusions:** Were there enough patients in the samples comparing interventions to be able to conclude with an acceptable level of statistical significance that the variations in clinical outcomes were due to the differences in the interventions and not due to chance alone?
- **Impact of Other Clinical and Non-Clinical Factors:** Were there other countervailing factors occurring during the comparative effectiveness studies other than the interventions being evaluated (e.g. preventive measures, lifestyle changes, environmental influences, etc.) which were not sufficiently “teased out” of the analysis of the results so as to open to question the conclusions for recommending one specific intervention over another?

**Summary**

Of all of the initiatives in the ARRA of 2009, the fresh $1.1 billion appropriated for comparative clinical effectiveness research has probably generated the most controversy. The most immediate reason is the fear expressed by physicians (and some lawmakers) that the results of this

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research may start us on the slippery slope to cookbook medicine, rationed care and central government-driven medicine.

Other, more nuanced criticisms have questioned whether enough of the unique clinical attributes of individual patients can be taken into account to provide truly useful guidelines to physicians and their patients to promote better decisions resulting in higher quality, safer and more efficient care. Either way, there are still a lot of unanswered questions about the extent to which the results of this research may inform future reimbursement, much less the medical liability of physicians. Nevertheless, physicians need to be aware that this research is coming and be in a position to influence the course and results of the policy debates ahead.

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