FOCUS ON: Comparative Effectiveness Research

Health Reform's CER "Reality Check"

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Comparative Effectiveness Research (CER) has been a primary topic of both discussion and legislative debate for the past four Congressional sessions, with both House and Senate resolutions and bills drafted, debated, amended, and ultimately tabled as members tried to arrive at a meaningful way to cultivate the CER-derived evidence base within the U.S. As the recently passed health reform bills were considered, CER was once again added to the discussions and, this time, finally found the push necessary to become a reality.

The Patient-Centered Outcomes Research Institute

The Patient Protection and Affordable Care Act (H.R. 3590) has been described in many circles as the most sweeping health care legislation passed since the introduction of Medicare. Included within the over 900 pages of this legislation are 21 pages specifically dealing with comparative effectiveness research (Section 6301) by creating a freestanding, non-profit, center for CER, funded through a combination of public and private funds. The Patient-Centered Outcomes Research Institute has been put forward by Sen. Max Baucus, D-Mont., for several years as a complement to (and in some cases it appears a replacement of) the CER-related work currently being completed by the Agency for Healthcare Research and Quality (AHRQ). Introduced during previous Congressional sessions as an independent bill, its ultimate inclusion within the recently passed health reform legislation has finally turned Baucus' multi-year effort within this area into a reality.

Comprised of both a stakeholder steering committee, co-chaired by the Directors of AHRQ and the National Institutes of Health (NIH), and a methods committee, the Institute has been given a rather broad legislative mandate to, as needed:

- Facilitate the creation of new CER-based evidence;
- Facilitate the synthesis of existing evidence into secondary comparative analyses; and/or
- Pursue the development and application of new methods of evidence generation and review that could result in more appropriate evidence being delivered to the marketplace.

What seems less clear (and, indeed, it seems intentional at this point pending the establishment of the steering committee), is how this new Institute will eventually balance these multiple approaches to CER. The Institute will need to consider what is believed to be of highest value to a broad range of marketplace decision makers, as well as government entities with a stake in the decisions and the eventual outcomes (e.g., AHRQ, NIH, and CMS).

With the relatively high cost of planning, completing, and analyzing randomized controlled trials (RCTs), it seems unlikely that the Institute will pursue many, if any, studies of this type with its initially limited budget (the legislation provides for increasing budgets annually, with initial funding low compared to expected funding in later years). Despite budgetary limitations, the Institute is tasked with making operating decisions based on the perceived value of its activities to the marketplace, and in accordance with that mandate, must report to Congress on an annual basis regarding the impact the Institute's activities have had on some part(s) of the larger health care system. This combination makes it far more likely that the initial activities of the Institute will be methodologically focused, that is, developing novel methods for more efficient evidence development (e.g., Bayesian adaptive trials, prospective registry designs, etc.), while cultivating existing methods in a way that ensures ongoing improvement in research designs that are already becoming commonplace (e.g., mixed-treatment comparisons, meta-analytic techniques, etc.). If the Institute moves in this direction, at least

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initially, it will be able to show value during its initial years of existence while simultaneously laying the groundwork for even further success in future years when more money is available to undertake new trials and studies using these improved methods.

The Continued Importance of AHRQ

Despite the money and effort being put behind the new Patient-Centered Outcomes Research Institute, AHRQ will continue to play key roles in the development, utilization, and dissemination of CER-focused evidence within the U.S. health care system. Going beyond the fact that the director of AHRQ co-chairs the Institute's steering committee, a previous issue of *EvidenceMatters* (see "Health Care Reform is Dead! (Or is it?)" by Hunter in the March 2010 issue of *EvidenceMatters*) noted that the president's budget has called for a 150% increase in AHRQ's budget for FY2011, which is completely separate from the funding and structures created within the health reform bill. Given the uniquely positioned centers and programs ongoing within the Agency, it is highly unlikely that the new Institute could replace much (if any) of the value AHRQ adds to the research base, not only in terms of research produced, but even more so in the appropriate positioning and dissemination of that research to a wide range of stakeholders and decision makers.

Ultimately, the creation of the new Patient-Centered Outcomes Research Institute is likely to strengthen AHRQ's importance. Within the health reform legislation that created the center was a mandate that tasked AHRQ's Office of Communication and Knowledge Transfer (OCKT) with ensuring that all research and findings produced by the Institute are not only available, but translated into appropriately focused reports for various stakeholder groups of interest (e.g., providers, patients, researchers, etc.) and then disseminated for public use. Throughout the relevant legislative language, H.R. 3590 ensured that AHRQ would not only play a leading role in setting the direction of the Institute via the director's co-chair, but also remain an important gatekeeper of CER within the U.S. by ensuring that all resulting research is appropriately focused and communicated to the marketplace.

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