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From concept to policy: 10 years after the call for a US center for comparative effectiveness information

"Dr Wilensky described an emerging bipartisan interest on the need for 'objective, credible comparative clinical effectiveness information…'"

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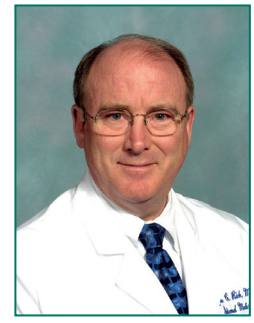

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In November 2006, Gail Wilensky, the noted health economist and former Centers for Medicare and Medicaid Services (CMS) administrator (under George HW Bush), published her proposal for a 'center for comparative effectiveness information'. In this widely circulated *Health Affairs* article, she described an emerging bipartisan interest on the need for "objective, credible comparative clinical effectiveness information… both by those who support competitive behavior in healthcare and by those who support administered pricing" [1]. In this piece, she reviewed options for the US federal government to establish and finance such a center devoted to comparative effectiveness research (CER).

In her article, Wilensky described the advantages and disadvantages of four alternative approaches to 'placement' of the CER effort relative to US Federal government support. Her first option was placement within the Agency for Healthcare Research and Quality (AHRQ), the federal research agency already supporting systematic reviews of the clinical literature and other relevant evidence production as part of its 'Effective Care Program'. The second option was placement elsewhere within the US Department of Health and Human Services (HHS), as a new government entity or within a different existing agency (like the NIH). Option three was placement within a 'quasi-governmental entity'; the article noted several such quasi-governmental structures that had been used previously to support funding or conduct of research initiatives, including the approach developed during the Second World War of the Federally Funded Research and Development Center. The last option she discussed was federal funding of a private sector entity to conduct CER.

Dr Wilensky noted the location within government of this US CER entity as an important policy challenge. "The placement of such a center should be judged by whether the data produced will be perceived as objective and credible, represent minimal or no conflict of interest, and be perceived as being insulated from stakeholder pressure." However, this 'placement' issue was resolved, her recommended approach to public funding of this effort was "a small charge or fee…" and she identified health plans as a potential payer of this fee since they might be anticipated to benefit (through lower spending on unneeded services) from additional information on comparative effectiveness.

This publication was followed by a burst of CER-related activity within the US federal government. In June 2007, the US House of Representatives held hearings on "Strategies to Increase Information on Comparative Clinical Effectiveness" featuring Wilensky as well as the Congressional Budget Office Director (and future Obama administration official), Peter Orszag and

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AHRQ Director, Carolyn Clancy [2]. In July of the same year, the House passed legislation employing Wilensky's 'placement option' of a CER Center at AHRQ, to be funded by a fee paid by health insurers [3]. Disagreements with the Executive branch (under the President George W Bush) over other elements of this legislation (specifically how to fund reform of Medicare physician payment) prevented a House-Senate compromise from becoming law in December 2007.

However, 14 months later under the newly installed Obama administration, Congress enacted the American Recovery and Reinvestment Act of 2009 (ARRA) [4]. This 'economic stimulus' legislation included an unprecedented US$1.1 billion investment in CER. The ARRA allocated substantial funds to both the AHRQ and the Office of the Director of the NIH to build their capabilities for supporting CER (US$300 and US$400 million, respectively). US$400 million was appropriated for the Office of the Secretary of HHS "to accelerate the development and dissemination of research assessing the comparative effectiveness of health care treatments and strategies." HHS agencies used the total US$1.1 billion in funds to award more than 400 grants and contracts, as described in a November 2014 special issue of the journal [5].

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As described in that special issue, the goal of the CER investment under ARRA was to enhance the national capacity for conducting CER (while meeting the needs of stimulus of the US economy and initiating promising projects to generate new clinical effectiveness information). Because of the diverse mix of funding approaches used under ARRA, and the fact that many projects received continuing support through subsequent non-ARRA sources, it may not be easy to tie all the succeeding research publications back to their ARRA funding origins. However, a cursory look at PubMed citations suggests a dramatic change in the volume of CER work since the publication of Dr Wilensky's *Health Affairs* article. Before November 2006, a PubMeD search yielded only 200 clinical studies published in English featuring the phrase 'comparative effectiveness'. Over 4200 have followed in the last 10 years (with 3100 of these since the founding of the *Journal of Comparative Effectiveness Research* in January 2012 [PubMed search by author, 23 September 2016, 'comparative effectiveness', limited to clinical studies published in English]).

As had been recounted, elsewhere the passage of ARRA and the debates about US healthcare reform led to intense political backlash over the notion of public investments in comparative effectiveness information. Indeed the bipartisan consensus noted by Wilensky in 2006 seemed to be breaking down by the spring of 2009. Despite these difficulties, during the 2009 healthcare-reform debate, the House of Representatives retained the model proposed in 2007 (and the phrase CER) [6]. However, Republican opponents of CER began referring to it as 'cost–effectiveness research' arguing that such publicly funded studies would provide the basis for government mandated 'rationing' of healthcare services [7]. In June 2009, the US Senate Finance Committee chair proposed an alternative terminology and approach to CER [8]. Perhaps to underscore the 'patient centered' aspect of this information as well as to distance the policy from the conflation of 'comparative effectiveness' with 'cost–effectiveness', Chairman Baucus proposed to establish a 'patient-centered outcomes research (PCOR)' institute outside of US federal agencies. The model described was a variation of Wilensky's 'Option three' – placement within a 'quasi-governmental entity' a nonprofit corporation governed by a board appointed by the Comptroller General and largely supported by the House-proposed approach of a tax on health insurance.

As has been extensively documented elsewhere, the process of final passage of the Affordable Care Act was complex. Relative to CER, the widely anticipated opportunity to negotiate a compromise between the House and Senate visions for supporting a center for comparative effectiveness information were brought to a halt by the loss of the needed Senates votes to pass additional healthcare reform legislation [9]. Thus, a substantial new funding mechanism was established in 2010 for the related concept of PCOR as well as 'comparative clinical effectiveness research' also included in Patient-Centered Outcomes Research Institute's (PCORI) mandate. Accordingly, a PubMed search shows 241 clinical studies in English published featuring the term 'patient centered outcomes research', all but two following the passage of the Affordable Care Act (ACA), (PubMed search by author, 23 September 2016, 'patient centered outcomes research' [limited to clinical studies published in English]).

PCORI still has a number of years of support until a congressionally mandated evaluation and reauthorization are required. In the contentious world of Washington, DC, USA, political discourse circa 2016, the success of this version of a publicly supported

'Center For Comparative Effectiveness Information' remains a subject to debate. Of course the Republican-dominated US House of Representatives has in recent years passed numerous bills repealing the ACA (including PCORI). Other legislation has attempted to strip both federal research agencies and PCORI from authority to conduct CER and PCOR [10]. And some left-leaning US policy 'think tanks' have been critical of PCORI as well. In 2014, the Center for American Progress (CAP) noted that most of PCORI's funding had gone to "studies of communication tools, patient decision aids, methodological approaches, and the establishment of data infrastructure – rather than to actual CER studies of medical interventions." An updated CAP report in May 2016 was somewhat more positive: "From December 2013 through January 2016, PCORI dedicated 58% of its funding to CER, compared with 37% in the previous analysis" [11]. CAP has argued that ideally 80% of the US$1.7 billion to date should have been invested in CER. Nonetheless CAP estimates that PCORI has devoted the substantial sum of US$716 million to CER (PCORI argues this is an underestimate). Accordingly since mid-2009, the US taxpayer has invested nearly US$2 billion of new funds in CER through ARRA and the ACA. Thus, it is clear that the policy ideas described a decade ago in Wilensky's article have led to large US government investments, substantial scholarship and a lively discourse about 'what works best for whom' in US healthcare.

Financial & competing interests disclosure

The author has no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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