Comparative Effectiveness Research: A Global View for Publication Planners

OBJECTIVE: Government-sponsored comparative effectiveness research (CER) is established in Europe and is gaining prominence in the United States. We analyzed CER summaries from the US Agency for Healthcare Research and Quality (AHRQ) to determine therapy areas of interest and implications for publication planning. METHODS: CER summaries in the AHRQ database were categorized by therapeutic area. Summaries in the most frequent categories were evaluated. RESULTS: 63 CER documents, including reports, protocols and drafts, were available. The most common therapy areas were cardiovascular disease (CVD) (14 CERs including drafts/protocols), haematology/oncology (10), psychiatry (6), and endocrinology (5). The reports utilised publicly available data, emphasising primary literature obtained through PubMed. Where available, data were meta-analysed. The seven final CVD reports were analysed qualitatively. An illustrative example compared angiotensin-converting enzyme inhibitors (an antihypertensive class with many generic options) with angiotensin II receptor blocker (an antihypertensive class with many branded members), concluding no difference in efficacy. A difference in adverse events in favour of ARBs was acknowledged; in contrast to European CER, relative cost was not explicitly mentioned.

RESULTS: AHRQ reports include comprehensive data summaries for many interventions and therapeutic classes. Although subtly conveyed, CER reports include arguments supporting restricted access to newer or branded products. Furthermore, these reports are public and could be adapted by payors in the United States or other countries to incorporate explicit cost analyses.

Background

- Comparative effectiveness research (CER) is designed to inform health care decisions by providing evidence on the effectiveness, benefits and harms of treatment options from research studies that compare drugs, medical devices, tests, surgery or ways to care for people with similar conditions.
- Government-sponsored CER is currently established in European countries such as Denmark, England, France and Germany and is used to inform choices between treatment options and to make reimbursement decisions.
- In the United States, CER has been gaining prominence as a result of $1.1 billion allocated to CER research under the American Recovery and Reinvestment Act of 2009. Several government agencies conduct CER, notably The Agency for Healthcare Research and Quality (AHRQ) [1].

The AHRQ's CER research is encompassed in the general Effective Health Care Program, which was instated in 2005 [2].

Objectives

- To describe the process of CER generation in terms of publication planning.
- To quantify CER documents by broad therapeutic areas and by AHRQ described areas of interest.
- To qualitatively analyse the information provided in the reports for specific recommendations about drug choice with regard to efficacy or cost.
- To assess the public impact of the reports.
- To describe the process of CER generation in terms of publication planning.

Research Design and Methods

- A search was conducted using the AHRQ search engine for all CER documents generated from 2005 to 12 January 2011.

The following parameters were used to search:

- Title: "Comparative Effectiveness of Management Strategies for Renal Artery Stenosis.
- Description of CER documents (goals of therapy, outcomes, etc.)
- Number of reports per therapy area

The number of CER documents varied by therapy area from 30% (haematology/oncology) to 67% (cardiovascular disease). The majority of documents were in the protocol/draft stages. The top 5 areas are depicted in the graph. The 14 AHRQ priority conditions are: diabetes mellitus, arthritis, cardiovascular disease, depression, and end-stage renal disease. The 14 CER documents included were classified into broad therapeutic areas. These areas were then reclassified to match the 14 AHRQ priority conditions. The process of CER review generation in the United States allows for the input of various stakeholders.

Of the top 14 priority conditions identified by the AHRQ, cardiovascular disease is the area that is most commonly researched and reported.

CER executive summaries and full reports present a descriptive summary of the current literature landscape (including potential data gaps) and comprehensive data summaries for many interventions and therapeutic classes.

CER reports present arguments regarding efficacy and safety that could support reimbursement decisions that are adverse to the interests of branded pharmaceuticals. Because these reports are public, they could have far-reaching impact beyond the United States.

The current number of protocols and drafts in progress suggests that the CERE landscape in the US will change dramatically in the coming years with potential impact on market access in other countries.