ABSTRAcT

Comparative Effectiveness Research in the United States: Implications for Publication Planners

OBJECTIVE: Government-sponsored comparative effectiveness research (CER) is established in Europe and is gaining prominence in the United States, raising concern that CER might be used to restrict access to branded products. 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 documents included in the AHRQ’s Comparative Effectiveness Review (CER) program were analyzed. Categories of documents include executive summaries for many interventions and therapeutic classes. Although subtly conveyed, CER reports include arguments that support restricted access to newer or branded products. Publication planners should be aware of CER in development and consider strategies to clarify data and provide context.

Background

• Comparative effectiveness research (CER) is designed to inform health care decision making by providing evidence on the effectiveness, benefits, and harms of treatment options from research studies that compare drugs, medical devices, tests, surgeries, or ways to deliver health care.

• Government-sponsored CER is currently established in European countries such as England, Denmark, Germany, and France, and is used to inform choices between treatment options and to make reimbursement decisions.

• In the United States, CER has been gaining a prominence as a result of $1.1 billion allocated to CER research under the American Recovery and Reinvestment Act of 2009. The health care system agencies conduct CER, notably The Agency for Healthcare Research and Quality (AHRQ).2

Objectives

• To describe the process of CER generation in terms of public health care decisions by providing evidence on the effectiveness, benefits, and harms of treatment options from research studies that compare drugs, medical devices, tests, surgeries, or ways to deliver health care.

• To provide specific drug/treatment recommendations with cost implications.

• To qualitatively analyze the information provided in the reports for specific recommendations about drug choice with regard to efficacy or cost.

Research Design and Methods

A search was conducted using the AHRQ search engine for all CER documents generated from 2005 to January 12, 2011. The following parameters were used to search:

• All conditions
• All research reviews and reports
• All stages of development (In Progress, Draft, Final)

The majority of documents were in the protocol/draft stages. 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. The current number of protocols and the available evidence suggests that the CERE landscape will change dramatically in the coming years.

Survey

Do you feel that the increasing role of CER will affect the way you plan publications?

• Has CER already changed the way you design and report studies?

• If CER has impacted your publication planning, have you employed the following strategies:
  a. Earlier timing of head-to-head studies
  b. Reactively addressed this by defenses publications
  c. Have you been involved in formulating a response during formal comment periods?

References