

PRESS RELEASE

Renee Hurley
Outcome
(617) 715-6882
rhurley@outcome.com

Robert Stanislaro
FD
(212) 850-5657
robert.stanislaro@fd.com

OUTCOME ANNOUNCES COMMENTARY, CO-AUTHORED WITH NICE, ON REGISTRIES PUBLISHED IN THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION

-IMPORTANCE OF AND RECOMMENDATIONS FOR EVALUATING DATA FROM REGISTRIES DISCUSSED-

Cambridge, MA – AUGUST 18, 2009 – Outcome Sciences, Inc. (OUTCOME), the leading provider of patient registries, studies, and technologies for evaluating real-world outcomes, today announced that the August 19th issue of the *Journal of the American Medical Association* (JAMA) published an article entitled “Registries for Robust Evidence” by Nancy Dreyer, MPH, PhD, Chief of Scientific Affairs and Senior Vice President at Outcome, co-authored with Sarah Garner, PhD, Associate Director for Research and Development at the National Institute for Health and Clinical Excellence (NICE) in London. This commentary discusses the growing need for patient registries; shows how such data are already being used to support decision-making by physicians, regulatory authorities, and payers; and calls for greater clarity on how to evaluate the quality of registry studies.

“While randomized clinical trials are the standard for establishing efficacy, there is increasing evidence that they cannot address, in a timely fashion, the safety and efficacy associated with the wide variety of patient treatment options in real-world settings,” said Dr. Dreyer.

“Observational studies, including patient registries, have been identified as a way to fill these critical gaps and serve as a guide for helping to determine which products will be reimbursed by insurance companies based on the relative safety and efficacy of each treatment option. We hope this commentary in JAMA will provide healthcare stakeholders, including patients, physicians, payers and policy makers, with valuable information on observational studies, including how to further analyze and interpret information from these studies.”

Importance of Registries

Registries can be organized by specific diseases, procedures, as well drugs and devices, and used to determine reimbursement, risk factors and clinical events in a defined population.

Safety studies are increasingly being used by policy makers and regulatory bodies as part of postapproval requirements for biotechnology, pharmaceutical and medical device companies.

Recently, observational data were used to compare coronary artery bypass graft (CABG) surgery with percutaneous coronary intervention (PCI). Although it initially appeared that myocardial infarction and mortality were comparable for PCI and CABG among patients, registry data demonstrated a strong benefit in favor of CABG based on severity of disease.

Registry data has also been used by regulatory agencies for revising product labels and determining coverage for insurance purposes. Following safety data from the acyclovir (a treatment for infections caused by the herpes viruses) pregnancy registry, the U.S. Food and Drug Administration (FDA) changed its pregnancy label from category C (risk cannot be ruled out) to category B (no evidence of risk in humans). The Centers for Medicare and Medicaid Services (CMS) also recently expanded its coverage for positron emission tomography (PET) scans in diagnosing certain types of cancers, as a result of information derived from registries.

Evaluating Data from Registries

Evaluating data from registries requires an understanding about how the study was designed and conducted, including how well the researchers addressed various patient characteristics (e.g. disease severity, past treatments) and other factors that could have influenced the results (e.g. patients often receive new treatments because their disease is worsening, and “bad outcomes” could be due to their underlying disease, not to the new treatment). Additionally, research into what constitutes quality and determining the strengths and limitations associated with evidence from these studies, will help patients, health care providers and payers be able to make informed decisions based on studies derived from observational studies.

About Registries

As defined in the Agency for Healthcare Research and Quality (AHRQ) handbook “Registries for Evaluating Patient Outcomes: A User’s Guide”, a patient registry is “an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves a predetermined scientific, clinical, or policy purpose(s).”

About Outcome

Outcome is the leading provider of patient registries, studies, quality improvement programs, and integrated technologies for evaluating real-world outcomes. Outcome provides services and technologies focused on evaluating the safety, effectiveness, and quality of healthcare products and services. The company has designed, developed, and managed more than 150 patient registries, including many of the largest and most well-recognized programs for disease outcomes and patient safety. Outcome is a recognized leader in providing interoperability solutions linking electronic health record systems to research and quality reporting.

Outcome is also an AHRQ DEcIDE Research Center, a component of the “Effective Health Care” initiative sponsored by the U.S. Dept. of Health and Human Services. Outcome was selected by the Agency for Healthcare Research and Quality to lead the effort to create the patient registries handbook “Registries for Evaluating Patient Outcomes: A User’s Guide,” released in May 2007. For more information, please visit www.outcome.com.

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