

## Penn Study Shows How Electronic Medical Records Can Be Used to Test Drug Efficacy

Implications for circumventing studies too costly or unethical for clinical trial. For years controversy has surrounded whether electronic medical records (EMR) would lead to increased patient safety, cut medical errors, and reduce healthcare costs. Now, researchers at the University of Pennsylvania School of Medicine have discovered a way to get another bonus from the implementation of electronic medical records: testing the efficacy of treatments for disease. In the first study of its kind, Richard Tannen, M.D., Professor of Medicine at the University of Pennsylvania School of Medicine, led a team of researchers to find out if patient data, as captured by EMR databases, could be used to obtain vital information as effectively as randomized clinical trials, when evaluating drug therapies. The study appeared online last week in the British Medical Journal. Our findings show that if you do studies using EMR databases and you conduct analyses using new biostatistical methods we developed, we get results that are valid," Tannen says. "That's the real message of our paper — this can work. In January 2009, President Barack Obama unveiled plans to implement electronic medical records nationwide within five years, arguing that such a plan was crucial in the fight against rising health care costs. Of the nearly \$900 billion in Obama's planned stimulus package currently before the United States Senate, \$20 billion is proposed for electronic health records. Tannen says he and his group recognized that the large EMR databases containing compiled medical information could potentially give researchers the ability to study groups reflective of the total population, not just those who participate in clinical trials, and circumvent studies too costly or unethical for clinical trials. However, such databases contain observational information, which critics argue do not offer the same level of control as randomized trials. "Our study cautiously, yet strongly, suggests that enormous amounts of information within electronic medical records can be used to expand evidence of how we should or shouldn't manage healthcare," Tannen says. To address criticisms of observational studies, Tannen's group had to first determine a way to use EMR databases for insights on therapy efficacy and then prove the results they found were valid. Beginning six years ago, Tannen's team selected six previously performed randomized trials with 17 measured outcomes and compared them to study data from an electronic database -- the UK general practice research database (GPRD), which included the medical records of roughly 8 million patients. Treatment efficacy was determined by the prevalence of cardiovascular outcomes, such as stroke, heart attack and death. After using standard biostatistical methods to adjust for differences in the treated and untreated groups in the analysis of the database information, Tannen found that there were no differences in the database outcomes compared to randomized clinical trials in nine out of 17 outcomes. In the other eight outcomes, Tannen's group used an additional new biostatistical approach they discovered that controlled for differences between the treated and untreated groups prior to the time the study began. By using the new biostatistical method instead of the standard approach, the researchers showed there were no differences between the outcomes in the EMR database study compared to the randomized clinical trials. Though Tannen warns the ability to use EMR databases from the United States to measure the efficacy of therapies will take more than 10 years of national data, he says the results of his study should serve as a catalyst for more researchers to explore the accuracy of the information that can be obtained using EMR database studies. "An appropriately configured EMR database could offer an invaluable tool, but we need to get to work now on how to configure it properly," Tannen says. "If we don't worry about this issue right now and promote a higher investment in the area of EMR research, we'll lose an opportunity, an enormous health opportunity." Mark Wiener and Dawei Xie from Penn are co-authors on this study. This research was funded by a grant from the National Institutes of Health.

### About the Author

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