Tools, methods of RCTs can be adapted to real-world settings

July 25 2018

(HealthDay)—Use of appropriate statistical methodology can allow for

the synthesis of data collected as part of traditional clinical trials with real-world data, according to an Ideas and Opinions piece published online July 24 in the *Annals of Internal Medicine*.

Michael J. Pencina, Ph.D., from the Duke University School of Medicine in Durham, N.C., and colleagues present three approaches to adapt tools and methods used in traditional randomized controlled trials (RCTs) to real-world settings.

The researchers note that embedding randomization within real-world data helps to make the trial-eligible population more representative of the actual clinical setting and is equally applicable to large trials and small experiments. Embedding randomization has a relatively low cost and consequently it should be the default approach for testing new methods of care delivery. If embedding is not feasible, translation of the results of an RCT to a population of interest can be done by fitting a model to the original trial data and applying it to a sample from the target population. Finally, comparative effectiveness research methods can help to design experiments that mimic RCTs. Techniques such as matching of fixed or time-varying variables in a longitudinal data setting, g-estimation, or parametric g-formula can mimic the randomized setting reasonably well.

"Clinical research will benefit greatly from an acceptance that data are complementary, which will result in a much larger universe of health questions to be asked and answered," the authors write.

More information: Abstract/Full Text (subscription or payment may be required)