

Point of Care Research

Point of Care Research (POC-R) is a new approach to study design that embeds trials into clinical care. It is uniquely positioned to pragmatically compare two or more approved treatment options or strategies that are considered to be equivalent (in equipoise).

Recruitment and randomization are accomplished at decision points in clinical care. Customized order-entry screens in the VA electronic medical record (EMR) allow for minimal disruption. A provider selecting between available treatments, who has no preference for one over the other, is prompted to learn more about the study. After reviewing a brief summary of the trial, the provider may give permission for the research team to approach the patient for consent to participate.

Those patients who consent to be randomized are assigned to a treatment arm, and orders for the assigned treatment appear in the EMR. At this point, care returns to the clinical provider, who continues to treat the patient without deviation from usual care or interruption by research staff. Patients who do not agree to randomization may choose to allow their clinical data to be utilized.

Study data collection is accomplished by automatically extracting information from the EMR, and includes clinical endpoints, deviations from treatment protocols, and patient compliance.

The expectation is that costs will be significantly reduced in comparison to a randomized controlled study, and results from these studies will be available sooner to inform clinical practice.

References

A point-of-care clinical trial comparing insulin administered using a sliding scale versus a weight-based regimen

Fiore LD, Brophy M, Ferguson RE, D'Avolio L, Hermos JA, Lew RA, Doros G, Conrad CH, O'Neil JA Jr, Sabin TP, Kaufman J, Swartz SL, Lawler E, Liang MH, Gaziano JM, Lavori PW. *Clin Trials*. 2011 Apr;8(2):183-95.

Implementation of the Department of Veterans Affairs' first point-of-care clinical trial

D'Avolio L, Ferguson R, Goryachev S, Woods P, Sabin T, O'Neil J, Conrad C, Gillon J, Escalera J, Brophy M, Lavori P, Fiore L. *J Am Med Inform Assoc*. 2012 Feb 24.