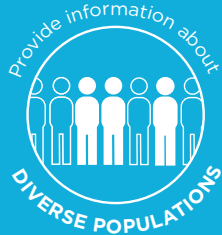


ASSESSING OBSERVATIONAL STUDIES

Observational studies follow patients over time and can evaluate the effect of interventions on health outcomes

STRENGTHS OF OBSERVATIONAL STUDIES



There is growing demand for comparative effectiveness research (CER) and how interventions work in the real world. Yet there is debate about whether and when observational studies are good enough to support decision-making.

LIMITATIONS OF OBSERVATIONAL STUDIES



A HELPFUL TOOL

When done correctly, observational studies can provide meaningful information; when done poorly, misinterpretations are possible. The Good ReseArch for Comparative Effectiveness (GRACE) Checklist was developed as a guide to assess the quality of observational studies and to help ensure that the information used is credible and reliable.

GRACE CHECKLIST*

DATA

- ✓ Treatment details adequately recorded?
- ✓ Primary outcomes adequately recorded?
- ✓ Primary clinical outcomes measured objectively?
- ✓ Primary outcomes valid?
- ✓ Primary outcome measured or identified equally between treatment and comparison groups?
- ✓ Differences between study groups captured?

METHODS

- ✓ Study population restricted to new users of medications?
- ✓ Comparative data collected for same time period?
- ✓ Differences between study groups taken into account?
- ✓ Outcomes of interest captured for all treatment groups?
- ✓ Sensitivity of conclusions to key assumptions analyzed?

*This is an abridged version of questions in the GRACE checklist. For more information, check out the March 2014 *Journal of Managed Care & Specialty Pharmacy*.

Source: Dreyer NA, Velentgas P, Westrich K, Dubois RW. The GRACE Checklist for Rating the Quality of Observational Studies of Comparative Effectiveness: A Tale of Hope and Caution. *J Manag Care Pharm*. 2014;20(3):1-12.