

DEFINING HIGH-QUALITY OBSERVATIONAL STUDIES

Observational Studies Can Inform Health Decisions—When Done Correctly



TO IMPROVE HEALTH CARE QUALITY

&



REDUCE HEALTH CARE COSTS

THERE IS A GROWING DEMAND FOR AND SUPPLY OF



OBSERVATIONAL STUDIES*

*Sometimes called real-world evidence or evidence from clinical experience

OBSERVATIONAL STUDIES HAVE SEVERAL STRENGTHS



Provide information about
DIVERSE POPULATIONS



Improve understanding of
PATIENT-CENTERED OUTCOMES



Tell us how treatments work in
REAL-WORLD SETTINGS



Can be conducted more quickly for
TIMELY RESULTS

BUT ALSO HAVE LIMITATIONS THAT NEED TO BE ACCOUNTED FOR



Many factors drive
TREATMENT DECISIONS



Real-world patients can have
COMPLEX CLINICAL CONDITIONS



Some studies must address
UNBALANCED GROUPS, DIFFERENTIAL FOLLOW-UP, AND MISSING DATA

WHAT MAKES OBSERVATIONAL STUDIES HIGH QUALITY?

New research gives us an idea.

RESEARCHERS

EVALUATED

9 standards and guidelines for observational studies

COMPARED

23 items that observational studies should include



WHAT DID THEY FIND?

2 items are addressed and have agreement across standards and guidelines

- » Defining study objectives and research questions
- » Including details on data sources

12 items are addressed but disagree across standards and guidelines, such as

- » Describing study limitations
- » Handling missing data
- » Addressing bias

9 items are addressed by some but not all standards and guidelines, such as

- » Reviewing prior research
- » Involving stakeholders in research
- » Assessing heterogeneity of treatment effects

LACK OF COMMON STANDARDS FOR HIGH-QUALITY OBSERVATIONAL STUDIES CAN IMPACT



What Studies **FUNDERS** Support



What Methods **RESEARCHERS** Apply



What Studies **JOURNAL EDITORS** Publish



What Evidence **PATIENTS, PROVIDERS** and **PAYERS** Use

HOW DO WE AGREE ON WHAT “GOOD” LOOKS LIKE?

AUTHORS RECOMMEND 4 STEPS

1

GAIN ALIGNMENT

Perspectives may differ, but what items are included should not

2

AGREE ON LEVEL OF CONSENSUS

Minimum standards rather than best practices are most achievable

3

GARNER CONSENSUS

Stakeholders should convene in an iterative process to gain consensus

4

ENCOURAGE CONSENSUS

Voluntary adoption is most likely for success