

EMPACT

Thinking Critically About Enrollment Data

A presentation by the EMPACT consortium

Lisa M. Rogers, EMPACT
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First, Let us think about Data Collection Methods at the Patient Level

Self-report of Race / Ethnicity is the gold standard.

Intake-based methods are less desirable and accurate methods.

Intake-based methods include patient surname, primary language or need for interpreter, birthplace, or citizen vs. non-citizen status as well as determination by staff, often based on patient appearance.

On an institutional level, understand

...how is data collected? How often are data collected? Who collects and analyzes data? And how are these data verified?

Thinking critically about the data involves understanding race and ethnicity

Asian, Black, Hawaiian / Pacific Islander and White are racial categories.

While Hispanic / Latino and non-Hispanic / Latino are ethnicity categories.

These data are reported on the inclusion of women and minorities form. Important limitations of this form are

Category definitions are institute defined; Both therapeutic and non- therapeutic trials are included; And of course, data are only as accurate as the original source.

To think critically and Identify Potential Issues In Data Collection...

Examine how is each category defined, what subjects are excluded, and how are multi-racial subjects are categorized?

Let's look at a table of Category Definitions from Common Reference Databases

You can see definitions from databases such as SEER, the US Census, CTEP, and State registries, which vary widely in all categories.

Multiracial subjects may be excluded or classified as "other". Patients with unknown race or no answer for race may also be excluded. Most intake databases do not force an answer to race or ethnicity.

Regarding frequency of reporting

The CCSG required 5 year intervals *are not useful* when evaluating recruitment and retention interventions.

Try to balance frequency of reporting with sample size. Address staffing issues... are there enough staff to validate and analyze data? Is the period of data collection long enough to see trends? And is the period of collection long enough to yield enough subjects for significance?

In summary

Each institution may define its own catchment area; may choose how to collect patient race and ethnicity information; and may choose how to report patient race and ethnicity. It is important to know how your institution collects this information and the strengths and weaknesses of its processes.

This presentation has been brought to you by EMPACT, enhancing minority participation in clinical trials.