ABSTRACT: Increasing Precision of Real-World Data Estimates: The Importance of a Step-Wise Process to Limit Data Collection Errors and Data Incompleteness

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Objectives:

For both prospective and retrospective observational study designs, data collection errors and missing data are inherent challenges. Our purpose was to outline principal challenges for either methodology and propose solutions aiming to increase overall quality of study data and improved precision of study results.

Methods:

We evaluated factors that could lead to data collection errors and missing data as part of study design and throughout conduct/data cleaning/quality control phases of two retrospective chart reviews and two prospective time and motion (T&M) studies completed during 2014. This resulted in a step-wise process, suitable for both study designs.

Results:

During study design conceptualization, study variables should unequivocally be defined with terminology/semantics matching the source document (e.g. medical chart) or what is observed in real-world. Across-country differences need to be considered. For chart reviews, training using real-time demo of electronic data collection (EDC) tool using examples of de-identified patient data is recommended. For T&M studies, observers must be thoroughly trained on accurate data measurement and recording. For a chart review design using an EDC tool, logic and edit checks should be built into the
EDC tool to limit data errors and incomplete data at entry. For a T&M design, speed of data transmission and fast quality control is essential to allow recall by the data observer/interviewee. In case of missing data or queries for outliers, queries should be phrased objectively, adequately describing the required data clarification.

**Conclusions:**

Limiting data collection errors and data incompleteness starts at study concept/design. Essential components of a step-wise process, aiming to prevent overlooking key factors, include appropriate variable selection and description (terminology/semantics), thorough appropriate training, and quality control mechanisms. If such steps are followed, data collected would result in a more accurate dataset, therefore improving the overall quality of study results.