A Systematic Review of Patient-Reported Outcomes Measures to Assess Satisfaction with Drug Therapy in Clinical Trials

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WHAT DO WE KNOW ABOUT TREATMENT SATISFACTION ASSESSMENT IN CLINICAL TRIALS TO DATE?

When different stakeholders evaluate new medications, it is increasingly important to understand whether the medication is genuinely satisfying patient needs. The cost of eliciting a data point in a clinical trial makes most manufacturers focus on the most essential efficacy and safety endpoints. There is potentially more information to be gained, however, on the likely uptake of the medication by including treatment satisfaction instruments, particularly when new drugs are being evaluated against a standard of care. Manufacturers and payers currently benefit from learning about whether the treatment is effective at managing symptoms and health related quality of life but learning about the overall potential benefit, quality, and value of a pharmaceutical intervention for the patient – directly from the patient – may also be beneficial. This all the more so based on the mostly positive relationship identified in a recent review of treatment satisfaction’s relationship with adherence to treatment and treatment persistence [1] which may therefore help to predict future use. Another article outlined this theoretical link between treatment satisfaction and outcomes more generally, but also queried the quality of the development of such scales [2]. This article presents an effort to explore this issue further by conducting a systematic review of the literature for treatment satisfaction patient-reported outcomes (PRO) and their ability to evaluate treatment satisfaction in clinical trials.

HOW DID WE SEARCH THE LITERATURE?

The authors conducted a systematic review of the published literature using established biomedical literature databases (Medline and Embase), ClinicalTrials.gov as well as a PRO specific database (PROQOLID). The identified articles were screened according to specific inclusion and exclusion criteria. Included were articles that mentioned the development or use of PRO instruments of treatment satisfaction or preference as a sole concept of interest and/or at least two domains of treatment satisfaction or preference. Excluded were articles that: 1) evaluated treatment indirectly via surrogates – control of biomarkers (e.g. satisfaction with blood pressure or HbA1c control); 2) evaluated received care throughout a clinical trial or more broadly than pharmaceutical treatment; and 3) there were also three non-disease specific/generic instruments: The Treatment Satisfaction Questionnaire for Medication (TSQM) [5], Satisfaction with Medical Treatment-Questionnaire (SATMEDQ) [6], and the 1-item General Impression of Patient Satisfaction Scale [7].

We then classified the disease-specific satisfaction measures according to their therapeutic area and saw a preponderance of measures developed for primary care conditions including diabetes, pain, central nervous system, and respiratory conditions.

Using disease specific or treatment specific instruments allows manufacturers and other agencies to understand where their treatment fits in the overall therapeutic treatment option paradigm for a particular condition and in particular, what the strengths of a particular treatment are in relation to other treatments in that condition.

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to evaluate their content to measure the research question at hand (e.g. if convenience or ease of use or impact of side effects is important, the measure needs to assess these concepts).

This current systematic review of treatment satisfaction measures offers a range of options that manufacturers, prescribers, payers and other interested parties may be able to consider when making choices about how best to evaluate pharmaceutical treatments and whether the drug meets patient expectations. The list of 67 instruments and their associated development articles are found in Supplemental Materials at: http://www.ispor.org/News/Connections-outcomes-PROs-drug-therapy-supplemental-materials.PDF.

REFERENCES

Disclosure: KR, SP and TS are employees for Pfizer and undertook this research as part of their employment with Pfizer. IS and CP are employees for MAPI Research Trust who are contracted by Pfizer for standard and advanced literature searches.

WEB CONNECTIONS
Getting ready to include a resource utilization collection form in either a clinical trial or outcomes based study in order to conduct a health economic evaluation? You want the form to be complete without being over burdensome. The Medical Research Council Network of Hubs for Trial Methodology Research (MRC HTMR) has made your job much easier! MRC HTMR has compiled a database of instruments for resource use measurement (DIRUM). DIRUM provides a database of resource-use questionnaires. Currently there are 68 instruments available for review. Visit their website at: http://www.dirum.org/ where you can easily search the database.

Do you know of any websites that you would like to share with the ISPOR community? If so, contact Bonnie M. Korenblat Donato, PhD at: bonnie.donato@bms.com.