

The Importance of Interpreting the Study Data in a Meaningful Way

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Often is the case that researchers rely on just the statistical significance of the result in question to convey the study results to a broader audience, whether that is a publication or a presentation at a medical meeting. Ignored are the interpretation from the clinical perspective and the magnitude of the statistic in question.

A noticeable misstep is the interpretation of the correlation coefficient, often times the researcher interprets the p-value and leaves it at that. Not discussed is the degree of association, whether there is no, weak, moderate, or strong correlation.

The correlation coefficient measures the strength of association between two variables, or a single variable across time. There are many different ways to calculate the correlation coefficient depending on the distribution of the variables or the type of variable being analyzed. For example, the pearson correlation coefficient is calculated when the data are normal or the use of polychoric correlation to measure the strength of association between two ordinal variables.

The statistic generally ranges from -1 to 1 with the sign indicating the direction of the association. While there are many different ways that one can interpret the magnitude of the relationship, in general, a coefficient that is equal to 0 indicates no relationship, and a coefficient of 1 indicates a perfect relationship-that is the two variables in question are redundant, and if both are included in the analyses will introduce multicollinearity. The absolute value of the correlation coefficient indicates the strength of the relationship, with the following gradient: $|0|$ = none; $|0.1-0.3|$ is weak, $|0.3-0.5|$ is moderate, $|0.5-0.7|$ is strong and $|0.7-1.0|$ is very strong. The endpoints of each range are open, 0.299 will be considered as weak, and 0.30 would be considered moderate.

It is important when conveying the results of the study that both the magnitude and statistical significance is presented. The magnitude and statistical significance has an important place in understanding the clinical value of the relationship.

Another area where researchers often present just the statistical results is when presenting data on the minimum clinical important difference (also known as the minimum clinical threshold). This concept is important when presenting the results of any clinical outcome assessment (COA). COAs are defined as either CLINROS (a scale completed by the health-care provider after observing the patient); PROs (a measure about the patients' health status completed by the patient without any interpretation by others); PerFos (a measurement based on a standardized task and evaluated by a trained personnel) and an ObsRo (a measurement based on observable signs, events or behaviors related to the patients' health status). Caregivers usually provide such information. In trials of MDD, the FDA acknowledges the importance of PRO measures, suggesting that such information is useful in assessing benefits of treatment.

"MDD is primarily a subjective experience, with severity of symptoms directly related to the degree of impairment (Foley 2013). Therefore, the assessment of patient-perceived depressive symptoms is an essential endpoint for clinical studies, particularly where the use of clinical indicators will be limited" (<https://www.fda.gov/media/119243/download>).

Both the clinical and statistical interpretation of the MCID is important if PROs are to provide useful clinical information. Knowledge of just the statistical properties of the MCID is not enough because it does not convey whether the MCID is meaningful to patients. MCID is usually established when conducting the psychometric evaluation of the scale, as well as by eliciting what is important to the patient (or the relevant responder) via exit interviews, once the trial has concluded.

MCID are particular to the disease state being examined. For example, an MCID on a PRO measuring health status or symptoms will differ by disease state. For example when analyzing the MCID from the SF-8 health survey, a patient with chronic pain may have a different value of what is important to them relative to an asthmatic patient. It is important to establish the MCID for the disease that is under study.

An optimal way of presenting such data from a study is the MCID of 2.6 was statistically significant but was not clinically meaningful, or that it was not statistically significant but was clinically meaningful or that the MCID was both clinically meaningful and statistically significant.

Thus, whether a researcher is interpreting the degree of association or an MCID, it is good clinical practice to discuss the findings in terms of clinical relevance as well as statistical significance.

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