VALIDATING A SURVEY INSTRUMENT USING NONPARAMETRIC ITEM RESPONSE THEORY—APPLICATION OF KERNEL REGRESSION
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OBJECTIVE: Psychometric analysis is often used in health outcomes research to evaluate the validity of survey instruments. The kernel regression approach is a nonparametric alternative to parametric item response theory (IRT) models, which assume that item responses follow a more restrictive, parametric distribution. The purpose of this study was to demonstrate the effectiveness of kernel regression for psychometric analysis of data arising from a small sample pilot study. METHODS: The kernel approach to IRT was applied to data obtained from 24 pharmacists who completed a 99-item questionnaire on herbal and dietary supplements. The questionnaire was designed to measure five different traits, two of which included knowledge and performance of patient counseling. Using visual plots, each item was analyzed by its estimated category response function (CRF), the probability that an item response category is endorsed as a function of ability (trait) level, i.e., total score. For categories that indicate an item score (a “correct” option in a multiple-choice [MC] item or an ordinal category in a rating scale item), CRF should increase with the level of ability. For illustrative purposes, we report the performances of two of 56-MC items that assessed pharmacists’ knowledge (knowledge1, knowledge2), and two of 11, 5-point rating scale items that examined pharmacists’ provision of patient counseling (counseling1, counseling2). RESULTS: The knowledge1 and counseling2 items fulfilled the psychometric criteria. Knowledge2 was removed from the survey because the CRF of the correct response option did not increase with level of ability, i.e., pharmacist knowledge. The counseling1 item was removed because CRFs revealed that the ordinal categories did not increase with pharmacists’ patient counseling ability. CONCLUSION: The kernel regression approach to IRT provides a flexible and informative approach to refine a survey instrument and evaluate its properties using pilot data.

USING VALUE OF INFORMATION METHODOLOGY TO DETERMINE THE SAMPLE SIZE FOR A RANDOMIZED CLINICAL TRIAL FROM AN INDUSTRY PERSPECTIVE
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To illustrate, with the use of an example, the application of value of information (VOI) methodology for determining optimal sample size in the design of a randomized clinical trial (RCT) from an industry perspective. Using a societal perspective, VOI methodology has been used previously to determine the sample size which maximizes the difference between the cost of an RCT and the value of the information it provides. From a societal perspective, the value of the information relates to the reduction in the expected opportunity loss provided by the trial data. The cost of the trial has an opportunity in addition to a financial component. From an industry perspective, the value of the information relates to the probability of regulatory approval and the effect this has on profits. The costs of the trial are solely financial. To determine optimal sample size from an industry perspective one must specify the profit per prescription, the incidence, the time horizon and the relationship between the strength of the evidence and the probability of approval. The methodology is applied to a specific example. It is demonstrated that for highly profitable trials (i.e. value greatly exceeds cost), the optimality is very robust to the specification of the profit per prescription, the incidence, the time horizon and the relationship between the strength of the evidence and the probability of approval. Robustness diminishes with the profitability of the trial. VOI methodology can be used to provide optimal robust sample size determinations for industry based RCTs.