patient-reported outcome (PRO) instruments in clinical trials, as recommended in the FDA draft guidance for industry. A systematic review of PROs assures that the best available instrument is used to measure the preferred endpoint. As systematic reviews are scientific exercises, they require the same rigour as other aspects of research, yet current methods used to conduct systematic reviews remain variable, meaning that the quality and comparability of such reviews is not assured. Our aim was to explore the comprehensiveness, understandability, and adaptability of two widely used methodologies in conducting and modifying a standard search.

METHODS: We compared the most common systematic review method (syntax search) and the Cochrane-collaboration recommended “Population-Intervention-Comparator-Outcome” (PICO) strategy. SCOPUS was searched using terms devised to answer the research question “which PROs have been used to date in islet cell transplantation?” The output resulting from each strategy was independently evaluated by two researchers and the methods critiqued. RESULTS: Both methods returned 6486 abstracts for review. Researchers were asked to identify ways in which to combine search terms to present a more manageable number for abstract screening. Both researchers agreed that PICO allowed for greater adaptability and targeted reviewing without compromising quality. Combining a priori search terms systematically according to [P and (I or C) and O], resulted in 359 abstracts.

CONCLUSIONS: The quality of a review depends on the extent to which scientific review methods are used to minimise the risk of error and bias, but also the extent to which the search strategy is replicable and flexible. The PICO method is comparable to the standard syntax search, but offers the added benefits of being easy to implement, and sufficiently versatile to allow further targeting according to subtle changes in the research question as desired.

THE C-STATISTIC AND THE EFFICIENCY OF THE PROPENSITY SCORES MODEL: EVIDENCE FROM SIMULATED DATA

Kiri VA1, Feudjo-Tepie M2

OBJECTIVES: Confounding is a common source of bias in outcome studies involving observational non-randomized data. The propensity scores methodology has been suggested as a good analytical approach for handling this problem without any indication on whether a threshold exists on its predictive ability. We investigate the usefulness of the C-statistic in this regard using simulated data.

METHODS: In each simulation, we generated 100 sets of 10,000 patients; each patient being assigned probabilities of being treated and of experiencing the outcome of interest. The process involved two logistic models, one that estimated the probabilities of being treated and of experiencing the outcome of interest, the other relating outcome to treatment and the same 10 covariates, of interest. The process involved two logistic models, one that estimated the probabilities of being treated and of experiencing the outcome of interest, the other relating outcome to treatment and the same 10 covariates, using Bernoulli distributions that assumed an odd ratio (OR) for treatment between 0.14 to 1.00 for each dataset. Propensity scores from each dataset were estimated and propensity scores matched analysis conducted using conditional logistic regression to estimate the OR and from the 100 sets, we obtained the mean, median and bias in the estimate. Bias was defined as the difference between actual and estimated ORs as a proportion of actual.

RESULTS: We found evidence of correlation between the levels of bias in the OR estimates and the C-statistics, with level often exceeding 300% when the C-statistic was less than 80%.

CONCLUSIONS: Where as an elevated value of the C-Statistic can not guarantee effective correction of confounding by the resultant propensity scores derived from a given data, our study indicates that a lower value does indicate a poor capability. We suggest the C-Statistic can be adopted as a simple reporting tool on the propensity scores model in respect of its efficiency.