**Simple ways to measure and predict treatment response to type 1 diabetes immunotherapy suitable for routine use in the clinic.**

**Objective**

Baricitinib preserves beta cell function in people with recently-diagnosed type 1 diabetes. We aimed to determine if simple routine clinical measures could be used to assess beta cell preservation and predict treatment response.

**Research Designs and Method**

Measures of beta cell function derived from clinical and biochemical measures were

calculated using data from the BANDIT randomised trial of baricitinib in recent-onset type 1 diabetes. Measures that reported and predicted treatment efficacy were determined, respectively, using linear regression and receiver-operator characteristic analysis. Therapeutic predictors were validated using data from trials of rituximab, abatacept and anti-thymocyte globulin.

**Results**

Quantitative response score (QRS), fasting C-peptide and model-estimated C-peptide

(CPest) most reliably differentiated placebo- from baricitinib-treated participants at 24 and 48 weeks. Beta2 score, derived from fasting glucose, C-peptide, HbA1c and insulin dose at 12 weeks, was optimal for predicting beta cell preservation following one year of treatment with baricitinib and the other immunotherapies (areas under receiver-operator curve 0.864 and 0.765 respectively). A 6.2% decrease in Beta2 score at week 12 predicted significant improvement in HbA1c (-0.6% or -6 mmol/mol) and insulin use (-0.26 units/kg/day) in combined data from the rituximab, abatacept and anti-thymocyte globulin trials.

**Conclusions**

QRS, fasting C-peptide and CPest could be used as more efficient, less burdensome

primary outcome measures for future immunotherapy trials. The ability of Beta2 score to predict treatment responses could facilitate adaptive trial designs and help guide treatment decisions in the clinic.