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A cross-sectional study to evaluate the validity of a novel patient-reported outcome measure of medication adherence in Type 2 Diabetes.

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## Introduction

The average medication adherence (MA) among patients in developed countries living with a chronic disease is estimated to be roughly 50%. (1) Non-adherence is multi-factorial, owing to socio-economic and clinical factors, as well as arguably the most important factor, patients' health beliefs and experiences. Patient Reported Outcome Measures (PROMs) are often uni-dimensional in their assessment of drivers of MA. This study has evaluated a novel PROM as part of a wider international research initiative focused on Type 2 Diabetes (T2D) which assesses four key factors of MA referred to as Social (S), Psychological (P), Usage (U) and Rationale (R), in short SPUR<sup>®</sup>.

## Aim

To compare the validity of SPUR<sup>®</sup> against previously validated PROMs in patients with T2D.

## Methods

This South London cross-sectional study surveyed adult participants with a confirmed diagnosis of T2D prescribed a minimum of one anti-hyperglycaemic medicine. Surveys were administered face-to-face by community pharmacists using a convenience sampling method based on interactions with pharmacy patients. The survey consisted of questions relating to socio-demographic and clinical data, the SPUR<sup>®</sup> tool and three previously validated PROMs (BeMQ-General<sup>®</sup>, MARS-10<sup>®</sup> and BeMQ-Specific<sup>®</sup>) as comparators to evaluate factors P, U and R respectively. The Medication Possession Ratio (MPR), a measure of a patient's pill count in a given time period, was used as an objective comparator of adherence. Pearson's correlation coefficients ( $r$ ) were calculated to determine the strength of association between the validated PROMs and SPUR<sup>®</sup>, with  $T$  tests used as a measure of significance ( $p < 0.05$ ) as an evaluation of validity for SPUR<sup>®</sup>.

## Results

The survey response rate was 21.6% ( $n=149/690$ ). The modal age range for participants was 60-69 years of age (40.1%,  $n=60$ ). Participants were predominantly educated to degree level (29.5%,  $n=44$ ), White (48.3%,  $n=72$ ) and retired (28.9%,  $n=43$ ). Overall, 47.6% ( $n=71$ ) of participants identified as female. Body Mass Index (BMI) data were available for 88.6% ( $n=132$ ) of the sample with 42.4% ( $n=56/132$ ) reporting a BMI  $>30$ . In ascending order, moderate to strong positive correlations were observed between SPUR<sup>®</sup> and the comparative PROMs for factors P ( $r=0.464$ ,  $p < 0.0001$ ), U ( $r=0.595$ ,  $p < 0.0001$ ) and R ( $r=0.719$ ,  $p < 0.0001$ ), indicating SPUR<sup>®</sup> to be a reliable measure of those MA factors. When assessing MA objectively, SPUR<sup>®</sup> demonstrated the strongest correlation ( $r=0.281$ ,  $p < 0.0001$ ) to MPR compared with the validated tools, with MARS-10<sup>®</sup> as the closest comparator ( $r=0.266$ ,  $p=0.001$ ). Despite this, SPUR<sup>®</sup> did not overestimate MA, 83.8% ( $n=125$ ) of the sample was identified as adherent based on MPR compared to 53% ( $n=79$ ) with SPUR<sup>®</sup>. The latter more closely reflecting HbA1c data which identified 55.4% ( $n=31/56$ ) as adherent.

## Discussion/Conclusion

Study strengths include the implementation of validated PROMs and two objective MA measures; however, the study sample size was limited. SPUR<sup>®</sup> has demonstrated its validity against validated PROMs whilst predicting adherence levels without exaggeration, which is often attributed to crude objective measures such as MPR. (2) SPUR<sup>®</sup> may therefore holistically identify the multiple factors linked to non-adherence, thus supporting the design of individualised interventions.. Such

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interventions are deemed by the World Health Organisation as potentially more impactful than developing new treatments.(1)

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