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

Despite improvements in the management of patients living with Type 2 Diabetes (T2D), a holistic understanding of the factors that contribute to medication adherence (MA) is still lacking. A number of methods have been proposed for the assessment of MA, namely Patient Reported Outcome Measures (PROMs), such as:

- MMAS[1]
- BeMQ[2]
- MARS[3]

Adherence reporting with PROMs is subject to moderate to high variability depending on the measure used due to their assessment of only one or two MA factors[4-8].

This study has evaluated a novel holistic PROM as part of a wider international research initiative focused on T2D which assesses four key factors of MA referred to as **Social (S), Psychological (P), Usage (U) and Rationale (R), in short SPUR.**

Aim

To compare the validity of **SPUR against previously validated PROMs** in patients with T2D.

SPUR / **BeMQ-General**
MARS-10
BeMQ-Specific

Methods

What:
- Prospective cross-sectional study
- Face-to-face survey using convenience sampling

Where:
- Community pharmacies in South London

Who:
- Patients living with T2D
- Minimum of one anti-glycaemic agent prescribed for 6 months

The survey consisted of questions relating to socio-demographic and clinical data, the SPUR tool and three previously validated PROMs (BeMQ-General®, MARS -10® and BeMQ-Specific®) as comparators to evaluate factors S, P, U and R respectively.

The **Medication Possession Ratio (MPR)**, a measure of a patient's pill count in a given time period, was calculated using **6 months of patient medication history** with respect to **anti-hyperglycaemic medicines only.** Self-reported HbA1c was also collected. Pearson's correlation coefficients (r) were calculated to determine the strength of association between the validated PROMs and SPUR, with T tests used as a measure of significance (p=<0.05) as an evaluation of validity for SPUR.

Results

The study demonstrated a moderate response rate with 21.6% (n=149/690) of participants approached in community pharmacies completing the survey. Demographic characteristics are reported in Table 1. 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.

Table 1 - Demographic Characteristics (n=149)

Gender		Ethnicity		Education		Age (Years)		Annual Income	
Male	78 (52,3%)	White	72 (48.3%)	Nil Formal	30 (20.1%)	18-29	3 (2,0%)	<£14,999	19 (12.8%)
Female	71 (47,6%)	Mixed/ Multiple ethnic groups	6 (4,0%)	GSCE or eq*	27 (18.1%)	30-39	3 (2,0%)	£15-£24,999	29 (19.5%)
Other	0	Asian/Asian British	52 (34,9%)	A-Level or eq*	27 (18.1%)	40-49	28 (18,8%)	£25-£34,999	19 (12.8%)
		Black/ African/ Caribbean/ Black British	1 (6,7%)	Bachelors or eq*	44 (29.5%)	50-59	32 (21,5%)	£35-£44,999	19 (12.8%)
		Other ethnic group	9 (6,1%)	Postgraduate or eq*	14 (9.4%)	60-69	60 (40,1%)	£45-£54,999	5 (3.4%)
				Other	7 (4.7%)	70-79	16 (10,7%)	£55-£64,999	5 (3.4%)
						>80	7 (4,7%)	£65-£74,999	0
								>£75,000	0
								Unemployed	10 (6.7%)
								Retired	43 (28.9%)

*or equivalent

In ascending order, moderate to strong positive correlations were observed between SPUR 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 to be a reliable measure of those MA factors. (Table 2)**

Table 2 - Comparison of Pearson's Correlation Coefficients for PROMs (r)

Tools		BeMQ-General	MARS	BeMQ-Specific
Social	*			
Psychographic		0.464 (p<0.0001)		
Usage			0.595 (p<0.0001)	
Rationale				0.719 (p<0.0001)

*No comparator available at this stage of the study

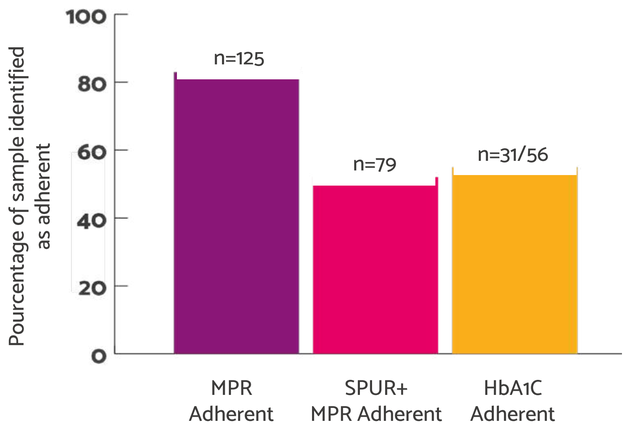

Figure - 1 - A comparison of objective MA measures vs SPUR

When assessing MA objectively, SPUR demonstrated the strongest correlation (r=0.281, p=<0.0001) to MPR compared with the validated tools, with MARS-10® as the closest comparator (r=0.266, p=0.001). Despite this, **SPUR did not overestimate MA**; 83.8% (n=125) of the sample were identified as adherent based on MPR compared to 53% (n=79) with SPUR. The latter more closely reflecting HbA1c data which identified 55.4% (n=31/56) as adherent. (Figure 1)

Conclusion

The study has demonstrated SPUR to be a reliable novel PROM when holistically assessing factors related to MA against previously validated tools in T2D.

The provision of a holistic measure such as SPUR can improve the design of personalised interventions which may prove to be more impactful in managing the burden of chronic disease than novel medical treatments, a notion shared by the WHO[9]. The study incorporated both validated PROMs and two objective measures of MA, however results should be treated cautiously owing to the limited study sample size. Further work will look to expand the study both in the UK and internationally as part of the wider SPUR research project in primary and secondary care settings.

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