# **Research: Care Delivery**

# Development and validation of the Diabetes Medication System Rating Questionnaire-Short Form

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Accepted 21 March 2014

# Abstract

**Aims** To develop and validate a short form of the 54-item Diabetes Medication System Rating Questionnaire that maintains the domains and performance characteristics of the long-form questionnaire.

**Methods** Data from the Diabetes Medication System Rating Questionnaire validation study were analysed to select items representing the nine scales (convenience, negative events, interference, self-monitoring of blood glucose burden, efficacy, social burden, psychological well-being, treatment satisfaction and treatment preference). The resulting 20-item Diabetes Medication System Rating Questionnaire Short-Form was administered online, with validated criterion measures of treatment satisfaction and medication adherence, with a retest within 2 weeks. Participants were US adults (N = 413) with Type 2 diabetes using oral agents alone; insulin by syringe and/or pen with or without oral agents; or glucagon-like peptide-1 agents. Most participants (82%) completed the retest.

**Results** The median inter-item agreement of scales was 0.76 and the total composite (mean of all items except treatment preference) was 0.88. The median test-retest reliability of scales was 0.86, and of the total composite was 0.95. All statistically significant correlations between Diabetes Medication System Rating Questionnaire Short-Form scales and criterion measures of treatment satisfaction and adherence were in the expected direction. The median correlation of the Diabetes Medication System Rating Questionnaire Short-Form with corresponding criterion measures of treatment satisfaction of the same Diabetes Medication System Rating Questionnaire Short-Form measures with adherence was 0.42. The Diabetes Medication System Rating Questionnaire Short-Form scales were more powerful predictors of adherence than were the criterion measures of treatment satisfaction. The Diabetes Medication System Rating Questionnaire Short-Form scales differentiated between those taking different medications and between those using different insulin delivery devices.

**Conclusions** This study suggests that the Diabetes Medication System Rating Questionnaire Short-Form provides a comprehensive set of measures with acceptable reliability and validity and a reduced burden of administration.

Diabet. Med. 31, 1237-1244 (2014)

# Introduction

Diabetes medications and medication delivery systems have proliferated in recent years [1–4], and awareness of the critical role of patient satisfaction with these medications and medication adherence, medication persistence, and consequent clinical outcomes, including glycaemic control and complications [5–8]; thus, there is a need for a valid, reliable tool assessing a broad range of specific aspects of treatment satisfaction for use in patients who use any available diabetes medications and medication delivery systems. Until recently, diabetes treatment satisfaction questionnaires assessed the patient's overall diabetes treatment regimen without distinguishing specific components of this (medication, diet, exercise, glucose monitoring) [9] or they assessed specific medication systems (type of medication and means of delivery) [10–12]. We developed the 54-item Diabetes

delivery systems has grown. Patient satisfaction predicts

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Portions of the data described in the development of the Diabetes Medication System Rating Questionnaire Short-Form were reported in abstract form (see reference 14).

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# What's new?

- This study reports the development and validation of a short form of the Diabetes Medication System Rating Questionnaire (DMSRQ) that maintains the domains and performance of the long-form questionnaire.
- Like the Diabetes Medication System Rating Questionnaire, the Diabetes Medication System Rating Questionnaire-Short Form (DMSRQ-SF) has good reliability and enhanced validity relative to other comparable measures.
- The DMSRQ-SF has a lower burden of administration than the DMSRQ, which makes it suitable for use in clinical settings as well as research.
- Each of the DMSRQ-SF therapy perception items was chosen to have unique validity and applicability as a single-item measure, i.e. to assess an independent aspect of treatment satisfaction that discriminates treatments and drives global assessments of treatments.

Medication System Rating Questionnaire (DMSRQ) to provide a comprehensive measure of diabetes medication treatment satisfaction with acceptable reliability and validity [13]. The aim of the present study was to report the development and validation of a short form of the DMSRQ, designed to reduce respondent burden and be short enough for use in clinical practice and research. The DMSRQ-Short Form (DMSRQ-SF) was designed to incorporate all of the key DMSRQ items that are the basis of the DMSRQ's validity.

# **Patients and methods**

# Item selection

The DMSRQ items to be used in the DMSRQ-SF were selected based on analysis of data from the original DMSRQ validation study [13]. Measures of self-monitoring of blood glucose burden (one item), treatment satisfaction (three items) and treatment preference (one item) were unchanged; 13 items were chosen for six shortened DMSRQ-SF scales representing the original DMSRQ measures of convenience, negative events, interference, efficacy, social burden and psychological well-being. Items for each shortened DMSRQ-SF scale were chosen by assessing which original DMSRQ items were more strongly correlated with overall treatment satisfaction and which original DMSRQ items distinguished between the six study medication treatment groups (oral agents without insulin, oral agents with insulin by vial and syringe, oral agents with insulin by pen, insulin only by vial and syringe, insulin only by pen and glucagon-like peptide-1 agents). The selection procedure was designed to minimize the number of items by privileging validity and comprehensiveness over reliability, selecting items to maximize breadth of coverage (item heterogeneity) as opposed to selecting items to maximize inter-item correlation (item homogeneity), i.e. highly correlated items that measured the same construct were not included even though they would increase a scale's  $\alpha$  reliability. Each item in the DMSRQ-SF was chosen to have unique validity and applicability as a single-item measure, i.e. to assess an independent aspect of treatment satisfaction that discriminates treatments and drives global assessments of treatments.

The median correlation between the nine short-form scales and the nine long-form scales was 0.88. The median test-retest reliability (intraclass correlation) of short-form scales was 0.82 compared with 0.86 for the long form. Regression using the six shortened DMSRQ-SF scales accounted for 49% (first administration) and 50% (second administration) of variance in treatment satisfaction, compared with 51% and 54% for the corresponding long-form scales. The six shortened DMSRQ-SF scales each significantly differentiated among the six treatment groups [14].

Two additional items were added to the negative events measure to capture the degree to which the patient's diabetes medication system inhibits self-care. Previous research had indicated that this dimension, while correlated with convenience, was distinct from convenience and more strongly related to therapy initiation [15,16]. Cognitive debriefing interviews with patients (conducted by EPI-Q, Inc., Oak Brook, IL, USA) indicated that the new items were well understood.

# Participants

The participants in the DMSRQ-SF validation study comprised 413 adults with Type 2 diabetes recruited from a panel of individuals who participate in surveys administered by Harris Interactive Company (http://www.harrisinteractive. com/). Individuals who indicated they had diabetes were sent an email invitation to participate in the study. Those who logged on to the survey website completed screening questions to determine their study eligibility.

Eligible participants included US residents aged 40–80 years who had been diagnosed with Type 2 diabetes by a physician at least 12 months before, and who had been receiving treatment with their current diabetes medication system for at least the previous 3 months. Potential participants were not eligible for the study if they were using more than one injectable diabetes medication or had used inhaled insulin or an insulin pump.

The final study population was distributed across the following treatment groups: oral diabetes medication only (n = 111); glucagon-like peptide-1 agonists (n = 101; 64 exenatide users, 37 liraglutide users) and insulin injections with or without oral diabetes medication (n = 201). Insulin injectors used vial and syringe only (n = 115), pen only (n = 64) and both vial and syringe and pen (n = 22).

Study questionnaires were administered to eligible participants until quotas were met. Respondents who completed the initial questionnaires were reminded 7–14 days later to re-access the survey website and complete a retest consisting of only the DMSRQ-SF. Of the 413 participants who completed the first survey, 339 (82%) completed the retest.

The present research conformed with the Helsinki Declaration and was approved by an independent ethical review board.

#### Measures

The participants completed the DMSRQ-SF and measures of treatment satisfaction and medication adherence. Participants also completed a screening questionnaire assessing information about their demographics and their condition and treatment characteristics.

Diabetes Medication System Rating Questionnaire Short-Form The DMSRQ-SF (Appendix S1) contains five scales measuring specific aspects of the medication system (convenience satisfaction [two items], negative events [six items], interference [one item], self-monitoring of blood glucose burden [one item], efficacy [three items]), two scales measuring factors likely to be affected by the participant's medication system (social burden [one item], psychological well-being [two items]) and two scales representing global judgments of the medication system (treatment satisfaction [three items] and treatment preference if the respondent previously used another diabetes medication regimen [one item]). We also calculated a total composite score for all 19 items (excluding treatment preference, which was available only for a minority of respondents who had used a different medication system previously). All items were scored from 0 to 100, with equal increments between responses (e.g. 0-33-67-100 or 0-25-50-75-100); higher scores indicated greater levels of the construct measured (reverse scored as relevant). Scores were calculated as means of completed items.

# Treatment Satisfaction Questionnaire for Medication Version

The Treatment Satisfaction Questionnaire for Medication Version II (TSQM-II) [17] assesses four components of satisfaction with medications of any type for any condition: treatment efficacy, side effects, convenience and overall satisfaction. Measures were scored according to developers' instructions, with higher scores indicating higher satisfaction.

# Modified Morisky Medication Adherence Scale

The eight-item Modified Morisky Medication Adherence Scale (MMAS-8) [18] is a self-report measure of adherence to medications of any type for any condition. The single composite measure was scored according to developers' instructions, with higher scores indicating higher adherence.

#### Statistical analysis

The analysis (using all cases available for each analysis) assessed scale response characteristics (mean, standard deviation, floor/ceiling effects) for both administrations of the DMSRQ-SF. Inter-item agreement for both administrations of the DMSRQ-SF was assessed by Cronbach's  $\alpha$ . Test-retest reliability was assessed by the intra-class correlation coefficient and correlated t-test for shift in mean response over time.

Criterion and convergent/discriminant validity were assessed by correlations between baseline scores on the DMSRQ-SF and the criterion instruments (TSQM-II, MMAS-8). The primary hypotheses were that DMSRQ-SF measures would be significantly correlated with TSQM-II and MMAS-8 measures in the expected direction (see below), and that the correlations between corresponding DMSRQ-SF and TSQM-II measures would be higher than those between DMSRQ-SF and TSQM-II measures that do not directly correspond with each other. Positive correlations were expected between DMSRQ-SF measures of convenience, efficacy, well-being, treatment satisfaction, treatment preference and all criterion measures. Negative correlations were expected between DMSRQ-SF measures of negative events, interference, self-monitoring of blood glucose burden, social burden and all criterion measures. ANCOVA models, controlling for age, sex, race/ethnicity, geographic region, education and duration of diabetes, assessed the variance in MMAS-8 adherence accounted for by the three domain-specific TSQM-II measures and the seven domain-specific DMSRQ-SF scales using the shrunken or adjusted *r*-squared to compensate for the different number of variables in the two models.

'Known group' validity was assessed by examining differences in DMSRQ-SF scale scores between respondents using different treatment regimens who were expected to differ on these scores. Between-group differences in DMSRQ-SF scale scores were assessed by ANCOVA controlling for age, sex, race/ ethnicity, geographic region, education and duration of diabetes. Two sets of tests were performed: one comparing the three medication groups (oral agents only, glucagon-like peptide-1, insulin with or without oral agents) and the other comparing insulin delivery devices (insulin by vial and syringe alone and insulin by pen alone; this analysis excluded participants who used both types of device and controlled also for the use of oral agents, since this differed by insulin delivery device). We expected the treatment experience to be rated most positively among those taking oral medication only and least positively among those taking insulin, and more positively among those using a pen than among those using a vial and syringe.

# Results

### Sample characteristics

Of the 413 study respondents (Table 1), 59.1% were men, 57.9% were aged  $\leq 65$  years, 49.6% had been diagnosed

Table 1 Baseline demographic and clinical characteristics

| Characteristic                            |                 |
|---|-----------------|
| Mean $\pm$ sD age, years,                 | 64.5 ± 7.59     |
| Mean $\pm$ sD duration of diabetes, years | $11.7 \pm 6.43$ |
| Men, <i>n</i> (%)                         | 244 (59.1)      |
| Education, n (%)                          |                 |
| No college                                | 122 (29.5)      |
| Some college                              | 166 (40.2)      |
| College graduate                          | 125 (30.3)      |
| Race/ethnicity, n (%)                     |                 |
| White, non-Hispanic                       | 320 (77.5)      |
| Black, non-Hispanic                       | 43 (10.4)       |
| Hispanic                                  | 18 (4.4)        |
| Asian/Pacific Islander                    | 5 (1.2)         |
| American Indian/Alaska native             | 3 (0.7)         |
| Other                                     | 25 (5.8)        |
| Geographic region, n (%)                  |                 |
| Northeast                                 | 93 (22.5)       |
| Midwest                                   | 93 (22.5)       |
| South                                     | 136 (32.9)      |
| West                                      | 91 (22.0)       |
| Treatment group, $n$ (%)                  |                 |
| Oral medication only                      | 111 (26.9)      |
| Glucagon-like peptide-1                   | 101 (24.5)      |
| Insulin                                   | 201 (48.6)      |
| by vial/syringe only                      | 115 (27.9)      |
| by vial/syringe and pen                   | 22 (5.3)        |
| by pen only                               | 64 (15.5)       |

with Type 2 diabetes for > 10 years, 70.5% had attended college, and the majority (77.5%) were of non-Hispanic white ethnicity.

#### **Descriptive analysis**

Descriptive statistics at both timepoints were obtained for all DMSRQ-SF measures (Table 2). The percentage of scale scores that were the minimum possible (floor) value ranged from 0.3 to 74.9%; the percentage for all multi-item measures was < 25%. The percentage of scale scores that were the maximum possible (ceiling) value ranged from 0 to 51.3%; the percentage for all multi-item measures was < 37%. The single-item measures exhibited larger floor and ceiling effects because they consisted of only one item with a restricted number of response categories. For the 19-item total composite score, minimum scores were non-existent and maximum scores were 1.2%.

#### **Reliability analysis**

The results in Table 2 show that reliability (inter-item agreement) for the DMSRQ-SF multi-item measures ranged from 0.68 to 0.81 (median = 0.76). Reliability for the 19-item total composite measure was 0.89/0.91 (first and second administrations).

Test-retest correlations for the scales ranged from 0.73 to  $0.90 \pmod{200}$  (median = 0.86) and 0.95 for the 19-item total composite measure. Two of the nine scales showed signifi-

 Table 2 Diabetes Medication System Rating Questionnaire scale

 statistics

| Measure (number          | -               | D                | -            |
|--------------------------|-----------------|------------------|--------------|
| of items)                | Test            | Retest           | Test-retes   |
| Convenience satisf       | action (two)    |                  |              |
| Mean*                    | 72.2            | 67.2             | P < 0.001    |
| SD                       | 26.5            | 27.2             |              |
| % min,% max              | 1.5, 36.4       | 1.8, 28.1        |              |
| Reliability <sup>†</sup> | 0.78            | 0.81             | 0.86         |
| Negative events (si      | x)              |                  |              |
| Mean*                    | 15.2            | 17.2             | P = 0.003    |
| SD                       | 14.4            | 14.4             |              |
| % min.% max              | 24.0. 0         | 17.8. 0          |              |
| Reliability <sup>†</sup> | 0.76            | 0.76             | 0.90         |
| Interference (one)       | 0.70            | 0.70             | 0.20         |
| Mean*                    | 25.4            | 28.0             | P = 0.436    |
| sp.                      | 29.1            | 29.5             | 1 0.150      |
| % min % max              | 48741           | 44.2 4.1         |              |
| 70 IIIII, 70 IIIAX       | 40./, 4.1       | 44.2, 4.1        | 0.02         |
| Kenability               | INA<br>1.1      | INA<br>Ina (ina) | 0.82         |
| Self-monitoring of       | blood glucose b | urden (one)      | D 0.55       |
| Mean*                    | 17.2            | 15.8             | $P = 0.55^2$ |
| SD O                     | 29.7            | 29.5             |              |
| % min,% max              | /1./, 6.3       | /4.9, 6.5        |              |
| Reliability              | NA              | NA               | 0.82         |
| Efficacy (three)         |                 |                  |              |
| Mean*                    | 57.8            | 57.2             | P = 0.639    |
| SD                       | 22.3            | 22.7             |              |
| % min,% max              | 0.5, 8.3        | 0.3, 8.8         |              |
| Reliability <sup>†</sup> | 0.71            | 0.74             | 0.86         |
| Social burden (one       | :)              |                  |              |
| Mean*                    | 9.6             | 10.2             | P = 0.765    |
| SD                       | 19.6            | 19.0             |              |
| % min,% max              | 73.8, 1.7       | 58.4, 1.2        |              |
| Reliability <sup>†</sup> | NA              | NA               | 0.73         |
| Well-being (two)         |                 |                  |              |
| Mean*                    | 69.1            | 68.5             | P = 0.969    |
| SD                       | 24.4            | 25.5             |              |
| % min % max              | 1.5. 19.6       | 1.2. 19.2        |              |
| Reliability <sup>†</sup> | 0.68            | 0.78             | 0.86         |
| Treatment satisfac       | tion (three)    | 0.70             | 0.00         |
| Mean*                    | 66 0            | 64.8             | P = 0.283    |
| ivicali                  | 10.0            | 20.2             | 1 - 0.200    |
| SD<br>9/                 | 19.9            | 20.5             |              |
| 70 mm, 70 max            | 0.5, 9.0        | 0.5, 8.5         | 0.00         |
| Kenability               | 0.73            | 0.//             | 0.90         |
| I reatment preferei      | nce (one)       | 76.0             | D 0.01/      |
| Mean*                    | /8.0            | /6.9             | P = 0.913    |
| SD                       | 27.3            | 28.3             |              |
| % min,% max              | 2.0, 51.3       | 2.8, 50.3        |              |
| Reliability'             | NA              | NA               | 0.80         |
| Total composite (1       | 19)             |                  |              |
| Mean*                    | 73.8            | 72.7             | P < 0.001    |
| SD                       | 14.8            | 15.5             |              |
| % min,% max              | 0, 1.2          | 0, 1.2           |              |
| B 11 1 11 1              | 0.00            | 0.01             | 0.05         |

\*Test-retest is the *P*-value for paired *t*-test of difference in means across administrations.

<sup>†</sup>Reliability for each administration is Cronbach's  $\alpha$  (NA = not applicable); Test-retest reliability is the intraclass correlation coefficient.

cant (P < 0.05) shifts in means over time; convenience decreased and negative events increased. Neither of the changes represented a minimum detectable difference of 0.5 standard deviations [19]; all were 'small' differences, < 0.2 standard deviations [20]. The significant (P < 0.001) decrease in the mean of the 19-item total composite score was < 0.1 standard deviations. These small differences would not be regarded as meaningful.

#### Validity analysis

Pearson correlations between the DMSRQ-SF scales and the criterion measures are shown in Table 3. Most (46/50) correlations were significant, and all were in the expected direction. Correlations between DMSRO-SF scales and criterion measures of treatment satisfaction ranged from 0.02 to 0.73 (absolute values; interpolated median = 0.36). The two instruments have four measures that correspond directly (DMSRQ-SF convenience with TSQM-II convenience, DMSRQ-SF efficacy with TSQM-II effectiveness, DMSRQ-SF negative events with TSQM-II side effects and DMSRQ-SF treatment satisfaction with TSQM-II overall). Correlations between DMSRQ-SF and TSQM-II scales that directly corresponded (0.31 to 0.67, absolute values; interpolated median = 0.59) were stronger than between other scales that did not correspond directly, indicating convergent validity.

Correlations between DMSRQ-SF scales and adherence ranged from 0.14 to 0.59 (absolute values; interpolated median = 0.35). Correlations of adherence with the four DMSRQ-SF measures that correspond to the four TSQM-II measures (convenience, negative events, efficacy and treatment satisfaction) ranged from 0.35 to 0.59 (absolute values; interpolated median = 0.37). In comparison, correlations of adherence with the four corresponding TSQM-II measures ranged from 0.19 to 0.46 (absolute values; interpolated median = 0.35; data not shown in table). ANCOVA analyses of the adherence measure indicated that the DMSRQ-SF model explained 16.3% more of the total variance in adherence than the TSQM-II model (40.2 vs 23.9%, data not shown).

We used known group analysis to examine the differences in DMSRQ-SF scale scores between respondents who were expected to differ on these scores, i.e. those using different medications and medication delivery systems. Adjusted means and significance levels are shown in Table 4. All DMSRQ-SF scales differentiated between the medication groups, with insulin users consistently having fewer positive scores than one or both of the other medication groups. Compared with users of oral agents only, glucagon-like peptide-1 users scored significantly higher on negative events, interference and efficacy, and significantly lower on self-monitoring of blood glucose burden. Among insulin users, those using pens gave significantly more positive ratings for negative events, interference and treatment satisfaction.

The seven treatment perception scales were added to the earlier ANCOVA model of treatment satisfaction to determine whether the differences among the treatment groups in DMSRQ-SF overall treatment satisfaction were a function of differences in participant ratings on the specific DMSRQ-SF dimensions (data not shown). In this analysis there were no significant differences among the treatment groups in treatment satisfaction after adjustment for the specific measures, demonstrating that the dimensions assessed by the DMSRQ-SF adequately account for differences in overall satisfaction with the different medication systems used by study participants. The treatment perception scales accounted for an additional 43.6% of the variance in treatment satisfaction over the baseline model (treatment groups and control variables listed in Table 4). Significant independent predictors among the seven treatment perception scales (in order of strength of association) were convenience, efficacy, well-being and self-monitoring of blood glucose burden.

# Discussion

Like the long form of the DMSRQ, the DMSRQ-SF incorporates a broader range of measures than other medication satisfaction questionnaires. The reliability

| Table   | 3 | Association  | of 1 | Diabetes | Medication | Syste | m Rat     | ting ( | Duestionn | aire-Sh | ort Form  | measures | with    | criterion | measures | at | basel | line |
|---------|---|--------------|------|----------|------------|-------|-----------|--------|-----------|---------|-----------|----------|---------|-----------|----------|----|-------|------|
| 1 albic | - | 110000101011 | 01.  | Diabetes | meanon     | 0,000 | III I CUU |        | 2 acouomn | une om  | ort r orm | measures | ** 1011 | criterion | measures | uu | Duser | anc  |

| DMSRQ-SF                 | MMAS adherence    | TSQM-II effectiveness | TSQM-II side effects | TSQM-II convenience | TSQM-II overall    |  |  |
|--------------------------|-------------------|-----------------------|----------------------|---------------------|--------------------|--|--|
| Convenience satisfaction | 0.347             | 0.416                 | 0.271                | 0.654               | 0.576              |  |  |
| Negative events          | -0.590            | -0.291                | -0.314               | -0.544              | -0.413             |  |  |
| Interference             | -0.386            | -0.249                | -0.249               | -0.496              | -0.374             |  |  |
| Self-monitoring of blood | -0.341            | -0.237                | -0.231               | -0.387              | -0.345             |  |  |
| glucose burden           |                   |                       |                      |                     |                    |  |  |
| Efficacy                 | 0.348             | 0.528                 | 0.245                | 0.457               | 0.519              |  |  |
| Social burden            | -0.135*           | $-0.021^{\dagger}$    | -0.104*              | -0.108*             | $-0.078^{\dagger}$ |  |  |
| Well-being               | 0.356             | 0.406                 | 0.374                | 0.512               | 0.496              |  |  |
| Treatment satisfaction   | 0.389             | 0.572                 | 0.332                | 0.648               | 0.669              |  |  |
| Treatment preference     | $0.158^{\dagger}$ | 0.184*                | $0.105^{\dagger}$    | 0.187*              | 0.246*             |  |  |
| Total composite          | 0.565             | 0.541                 | 0.402                | 0.732               | 0.673              |  |  |

DMSRQ-SF, Diabetes Medication System Rating Questionnaire-Short Form; MMAS, Morisky Medication Adherence Scale; TSQM-II, Treatment Satisfaction Questionnaire for Medication Version II.

Cell entries are Pearson correlations. All correlations P < 0.001, except \* $P \le 0.01$ ; <sup>†</sup>No significant association. All TSQM-II measures are scored so that higher scores indicate higher satisfaction.

| DMSRQ-SF measure                 | Oral only $(N = 111)$ | Insulin $(N = 201)$ | Glucagon-like<br>peptide-1 (N = 101) | Insulin V+S ( $N = 115$ ) | Insulin pen $(N = 64)$ |
|----------------------------------|-----------------------|---------------------|--------------------------------------|---------------------------|------------------------|
| Convenience                      | 81.6                  | 63.0                | 74.7                                 | 63.7                      | 68.6                   |
| Satisfaction                     | В                     | A,C                 | В                                    |                           |                        |
| Negative                         | 7.0                   | 17.4                | 15.1                                 | 17.9                      | 13.1                   |
| Events                           | B,C                   | А                   | А                                    | E                         | D                      |
| Interference                     | 10.3                  | 25.8                | 21.6                                 | 28.0                      | 18.3                   |
|                                  | B,C                   | А                   | А                                    | E                         | D                      |
| Self-monitoring of blood glucose | 11.5                  | 22.9                | 2.5                                  | 21.9                      | 15.9                   |
| Burden                           | B,C                   | A,C                 | A,B                                  |                           |                        |
| Efficacy                         | 59.4                  | 52.9                | 67.9                                 | 51.5                      | 53.3                   |
|                                  | B,C                   | A,C                 | A,B                                  |                           |                        |
| Social                           | 5.9                   | 12.0                | 7.1                                  | 12.4                      | 9.9                    |
| Burden                           | В                     | А                   |                                      |                           |                        |
| Well-being                       | 76.6                  | 66.4                | 77.5                                 | 64.1                      | 71.1                   |
| 0                                | В                     | A.C                 | В                                    |                           |                        |
| Treatment                        | 72.1                  | 61.8                | 73.1                                 | 61.4                      | 68.7                   |
| satisfaction                     | В                     | A.C                 | В                                    | E                         | D                      |
| Treatment                        | 72.9                  | 75.3                | 87.9                                 | 74.0                      | 75.5                   |
| preference                       |                       | С                   | В                                    |                           |                        |
| Total                            | 81.2                  | 70.4                | 79.3                                 | 69.8                      | 74.9                   |
| composite                        | В                     | A,C                 | В                                    | E                         | D                      |

Table 4 Diabetes Medication System Rating Questionnaire-Short Form treatment group differences

DMSRQ-SF, Diabetes Medication System Rating Questionnaire-Short Form.

Cell entries are least square mean scores from ANCOVA adjusted for age, sex, race/ethnicity, education, residential region and duration of diabetes. Separate ANCOVA performed to compare medication groups and to compare device user groups. Means for insulin vial + syringe (V+S) and insulin pen are also adjusted for use of oral agents; 22 participants who used both V+S and pen are not included in this analysis. *P*-levels are for contrasts from ANCOVA.

A, mean significantly (P < 0.05) different from oral group mean.

B, mean significantly (P < 0.05) different from insulin group mean.

C, mean significantly (P < 0.05) different from glucagon-like peptide-1 group mean.

D, mean significantly (P < 0.05) different from insulin V+S group mean.

E, mean significantly (P < 0.05) different from insulin pen group mean.

(inter-item agreement) of DMSRQ-SF multi-item measures was acceptable, and test-retest reliability was good for all DMSRQ-SF measures. The few statistically significant shifts in mean scores over time were small in size.

Floor and ceiling effects were small to modest for multi-item measures, but were substantial for single-item measures. Floor effects were pronounced for the single-item measures of interference, self-monitoring of blood glucose burden and social burden, and ceiling effects were pronounced for treatment preference. The floor effects reflect intrinsic limits; it is not possible to have negative amounts of the measured characteristics. Nevertheless, these measures do have substantial explanatory power in differentiating treatments and/or accounting for overall treatment satisfaction, which was the rationale for choosing these items over those that might have less skew. The ceiling effect for treatment preference reflects the fact that most people prefer their current regimen over their previous one. This may reflect the fact that the changes patients make in their treatment regimens are made in response to the belief that a new regimen is superior to a previous one (and, if it is not superior, they may discontinue or make another change). This ceiling effect may be smaller when the measure is used in a setting in which patients do not have control over their medication regimens (e.g. in a clinical trial).

The validity of DMSRQ-SF measures was supported. Correlations with corresponding criterion measures were all significant and in the expected direction (criterion validity). Importantly, adherence was more strongly related to the DMSRQ-SF measures than to the criterion measure of medication satisfaction. DMSRQ-SF measures correlated more strongly with corresponding criterion measures of treatment satisfaction than with other measures that did not correspond directly (convergent validity). DMSRQ-SF measures distinguished different treatment groups in ways that were generally consistent with known differences among these groups, especially in terms of treatment burden [4,21]. This burden is lowest in patients treated with oral antidiabetic medications only and highest in those treated with insulin. The DMSRQ-SF distinguished not only between groups taking different diabetes medications, but also the more subtle differences between groups using different injection methods (i.e. pen vs vial and syringe). Finally, the DMSRQ-SF appears to provide a comprehensive assessment of factors influencing overall diabetes medication system treatment satisfaction; specific DMSRQ-SF measures were adequate to account for treatment group differences in overall satisfaction.

The strengths of the present study include its large study population, with participants who used a variety of diabetes medications and medication delivery systems, and the use of validated criterion measures. Limitations of the study include the fact that the sample was derived from a consumer panel and there was attrition for the re-test, with a potential lack of representativeness and generalizability. In addition, we could not assess sensitivity to change or predictive validity. Finally, the DMSRQ-SF was not validated among persons using insulin pumps or inhaled insulin, or among those with Type 1 or gestational diabetes.

The DMSRQ-SF was designed so that individual items from the seven therapy perception domains could be used as separate measures. For example, the three efficacy items (avoidance of hyperglycaemia, hypoglycaemia and weight gain) are three separate dimensions and vary independently; a medication that is superior in avoiding hyperglycaemia may be inferior in avoiding hypoglycaemia or weight gain. Disaggregating the multi-item scales may increase explanatory power. Moreover, this strategy for using the DMSRQ-SF may be ideal for application in routine clinical practice, when considering or evaluating a change in medication regimen. Assessment of patient perceptions and judgments about the medication system(s) may be helpful in identifying barriers to adherence and strategies for addressing them.

Future research should assess: 1) the validity of the DMSRQ-SF in other populations, including persons with Type 1 or gestational diabetes and those using inhaled insulin or insulin pumps; 2) the responsiveness of the DMSRQ-SF to change in medications and medication delivery systems; and 3) the prospective predictive validity of the DMSRQ-SF measures relative to key behavioural outcomes (e.g. medication adherence and persistence).

In summary, the present study suggests that, like the DMSRQ from which it was derived, the DMSRQ-SF has acceptable reliability and validity, allows assessment of diabetes medications and medication delivery systems, and provides a more comprehensive set of measures than existing medication satisfaction questionnaires. Moreover, the DMSRQ-SF has a substantially lower burden of administration, which should make it easier to use in clinical trials of diabetes therapies and routine clinical practice.

#### **Funding sources**

This research was supported by funding from Genentech, who also provided access to the data.

### **Competing interests**

M.P. and R.R.R. have received research funds and consulting fees from Genentech. Y.X. is an employee of Genentech.

### Acknowledgements

This research was supported by funding from Genentech, who also provided access to the data. Alicia Shillington and

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# **Supporting Information**

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Diabetes Medication System Rating Questionnaire-Short Form.