The Diabetes Medication Satisfaction Tool (DMSAT): A Focus on Treatment Regimens.

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Research: Treatment complexity, side effects, and multiple medications are important in assessing diabetes treatment satisfaction.

Design and Methods: Survey items were developed from community clinic focus groups, pre-tested in patients with diabetes, and examined in two samples of treated patients.

Results: 16 items performed well in assessing treatment experiences: ease and convenience, lifestyle burdens, well-being, and medical control. Construct validity was supported by associations (p<0.05) with treatment complexity, self-rated glucose control, health worries, and HbA1c. Internal consistency ranged from .89 - .95.

Conclusion: The DMSAT offers a comprehensive assessment of patient acceptability with diabetes therapy useful to individualize therapeutic decision making.
Long-term glucose control is challenging to patients and clinicians alike.\textsuperscript{1,2} It is estimated that 30% of all primary care office visits for diabetes mellitus are for symptoms and complications (e.g., dizziness, exhaustion, vision and foot complaints), often involving three or more medications.\textsuperscript{3,4} Routine assessment of treatment satisfaction is an important step toward building and maintaining a therapeutic alliance among the patient and family, the physician and the other members of the health care team,\textsuperscript{1,4} to successfully tailor treatment regimens.\textsuperscript{5,6}

While the Diabetes Treatment Satisfaction Questionnaire (DTSQ)\textsuperscript{7} performs well in measuring patients' overall satisfaction with treatment, and blood glucose control, it, along with similar-purpose measures,\textsuperscript{8-10} does not conceptualize satisfaction in the context of multiple medications, where regimen complexity and treatment burden may become important. We developed and tested a brief instrument designed to measure patient diabetes medication treatment satisfaction (DMSAT) regimens, from simple to complex.

**DESIGN AND METHODS**

This study involved item generation, testing and refinement. Institutional Review Board approval was obtained from the Wake Forest University and informed consents were completed for all participants. Items for four concepts identified in the literature were ‘glucose control’, ‘wellbeing and side-effects’ ‘lifestyle burden’ and ‘treatment complexity and convenience’, and were evaluated in a series of focus groups (n=5) of 5 to 8 patients drawn from an evaluation study of community diabetes clinics in North Carolina.\textsuperscript{11} Participants were males and females, white and non-white, with simple and complex medication regimens and A1c levels that ranged from well-controlled to uncontrolled. The resulting 35-item prototype instrument was administered by mail to a convenience sample of 75 patients (‘exploratory sample’) treated with diabetes medications in our study community care sites, to assess item reliability, mean and distribution, redundancy or uniqueness, skewness, and construct validity. Also examined were item correlations with HbA1c level, the Multidimensional Diabetes Questionnaire (MDQ)\textsuperscript{12} lifestyle interference scale, the Medical Outcomes Studies (MOS) Health Worries Scale score,\textsuperscript{13} and global items assessing extent that blood sugar has been unacceptably ‘high’ or ‘low’. An item performance score was constructed (0= weak, 1= moderate, or 2 = ideal performance) to guide item retention. Fifty-five (73%) patients completed the survey, and 9 items were removed based on skewness, or redundancy (r > 0.75) with other items.

In the initial test sample, patients of a large family medicine practice treated for diabetes with a recent HbA1c value (last 3 months) were invited to complete the study survey packet (the “evaluation sample”) including revised 26-item instrument and validation instrument described above. Medication complexity was assessed using a score ‘0’ or ‘1’ (no/yes) for common diabetes medications, and ‘0’ or ‘2’ (no/yes) for insulin, a more demanding regimen. Self-reported adherence to medications was by recall of skipped or missed doses over the last 10 days. Packets were mailed to patients with instructions, with a voucher for a $25 gift certificate. Exploratory factor analysis (EFA) of the DMSAT items was conducted to assess whether the common factor model was appropriate\textsuperscript{14, 15} based on Kaiser’s sampling adequacy, Scree plot and model fit. An oblique rotation of the initial factor solution was performed to allow correlated factors. Discriminant validity of the DMSAT was examined by comparing means across levels of A1c (< 8%, ≥ 8%), treatment complexity...
(low/high), self-reported adherence, and MOS health worries.

In the final test sample, another sample of patients from our community diabetes care clinics and from an academic medical center was recruited to conduct and evaluate confirmatory factor analysis (CFA) of the DMSAT and confirm validity. Internal consistency reliability of the DMSAT scales and total score was also assessed.

RESULTS

In the evaluation sample, 194 (63%) of 307 eligible patients returned the survey packet; of these, n=140 had current medication use. Participants had a mean age of 63 years, most (77%) had completed high school, and were diagnosed with diabetes at least 5 years ago (61%). One-third (29 – 39%) were taking one, two or three medications for their diabetes, with 16% taking insulin; 14% had a recent A1c of > 8.0% and 19% rated their adherence to medication regimen in the last 10 days as less than complete. Ten items displayed high inter-item correlations (> .75) and were removed. Initial factor analysis of the reduced 16-item questionnaire identified a 4 factor structure consistent with our domains of life style, medical control, convenience and well-being, and explained 75% of the total variance. Kaiser’s measure (0.92) suggested a common factor model. Reliability estimates of the four DMSAT scales and total score were near (0.89) or above 0.90. Percentages at the ceiling of the scales was low (1.45% to 6.62%). As shown in Table 1 (upper), DMSAT scales and total score discriminated (p < 0.05) between ‘high’ and ‘low’ levels of treatment complexity, self-rated glucose control, MOS Health worries score, and clinical value for recent A1c (< 8% vs ≥ 8%) in the expected direction. Correlation of the DMSAT scores with continuous HbA1c values was -0.24 (p-value = 0.0049). In the final, the confirmatory sample, the DMSAT and survey packet was obtained on n=92 patients. Confirmatory factor analysis closely replicated the earlier 16-item structure (not shown). As shown in Table 1 (lower), DMSAT scales and total scores discriminated among validity groups as in the previous sample, and was highly correlated with the DTSQ (r = 0.68, p < .001). Unlike the DMSAT, the DTSQ total score did not discriminate between levels of treatment complexity and clinical A1c value.

CONCLUSION

The DMSAT is intended as a brief measure of diabetes medication treatment satisfaction regimen, and discriminates important correlates of patient management. It performed as well as the DTSQ in detecting self-rated glucose control and health worries, but showed superior properties in correspondence with treatment complexity and HcA1c. Note that appraisals of cost of medications or specific side-effects like those that may be impacted by diabetes or its treatment such as sexual functioning, bloating or weight gain are not separately assessed and may require assessment elsewhere. Longitudinal data are needed to examine responsiveness to interventions. In summary, we believe that the 16-item DMSAT offers a comprehensive assessment of satisfaction with diabetes therapy and may aid individualizing patient diabetes treatment.

DISCLOSURE

This study was funded by a grant to the Wake Forest University School of Medicine by Merck Inc, West Point, PA 2001-2003.
REFERENCES


Table 1. Final Model: Known Groups Validity: DMSAT Subscale and Total Score Means by Levels of Diabetes Treatment Characteristics, includes DTSQ (N=92).

<table>
<thead>
<tr>
<th></th>
<th># items</th>
<th>Treatment Complexity&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Self-Rated Glucose Control&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Perceived General Health&lt;sup&gt;c&lt;/sup&gt;</th>
<th>A1C</th>
<th>&gt; 8%</th>
<th>&lt;8%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>High</td>
<td>Low</td>
<td>Poor</td>
<td>Good</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>DMSAT&lt;sup&gt;d&lt;/sup&gt; Lifestyle</td>
<td>5</td>
<td>59.8</td>
<td>70.9 *</td>
<td>63.3</td>
<td>76.2**</td>
<td>79.8</td>
<td>62.3***</td>
</tr>
<tr>
<td>Convenience</td>
<td>3</td>
<td>68.4</td>
<td>77.7 *</td>
<td>71.1</td>
<td>82.6**</td>
<td>84.3</td>
<td>70.7**</td>
</tr>
<tr>
<td>Glucose Control</td>
<td>5</td>
<td>50.4</td>
<td>61.4*</td>
<td>51.0</td>
<td>74.1***</td>
<td>68.1</td>
<td>53.5**</td>
</tr>
<tr>
<td>Wellbeing</td>
<td>3</td>
<td>55.1</td>
<td>64.7</td>
<td>55.9</td>
<td>75.2***</td>
<td>76.9</td>
<td>55.5***</td>
</tr>
<tr>
<td>Total Score</td>
<td>16</td>
<td>59.9</td>
<td>70.1*</td>
<td>62.1</td>
<td>77.6***</td>
<td>78.4</td>
<td>62.0***</td>
</tr>
<tr>
<td>DTSQ&lt;sup&gt;e&lt;/sup&gt;</td>
<td>8</td>
<td>25.9</td>
<td>28.2</td>
<td>26.2</td>
<td>30.3**</td>
<td>30.9</td>
<td>26.1***</td>
</tr>
</tbody>
</table>

<sup>a</sup> Score of 0, 12 versus 3+
<sup>b</sup> Excellent or very good vs. good, fair or poor
<sup>c</sup> Excellent or very good vs. good, fair or poor
<sup>d</sup> Lower scores indicate less treatment satisfaction
<sup>e</sup> Used with permission of C. Bradley

* p < 0.05, ** p < 0.01, *** p < 0.001

A copy of instrument and full report can be accessed at:
http://www.hmc.psu.edu/diabetes/research.html