

# Assessing Regimen Adherence of Adolescents With Type 1 Diabetes

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**OBJECTIVE** — The purpose of this study is to evaluate two updated measures of diabetes regimen adherence. The Diabetes Self-Management Profile (DSMP) is a widely used, structured interview. Limitations include a substantial interviewer and respondent time burden and the need for well-trained interviewers to use appropriate prompts and score the open-ended responses. The Diabetes Behavior Rating Scale (DBRS) is a self-administered, fixed-choice survey.

**RESEARCH DESIGN AND METHODS** — Both measures were administered to 146 youth with type 1 diabetes (aged 11–18 years) and their parents. Items were added to the DBRS to allow for both flexible and conventional regimens, and the DSMP was modified to use standardized wording across items, accommodate flexible regimens, and permit administration by nonmedical interviewers.

**RESULTS** — Both measures had good evidence of internal consistency (for the DSMP: parent 0.75 and youth 0.70; for the DBRS: parent 0.84 and youth 0.84). Scores on the DSMP and the DBRS were significantly related ( $r = 0.72$  for parents and  $0.74$  for youth). There was moderate agreement between parent and youth (DSMP,  $r = 0.51$ ; DBRS,  $r = 0.48$ ). The measures were correlated with HbA<sub>1c</sub> for both parent (DSMP,  $r = -0.35$ ; DBRS,  $r = -0.35$ ) and youth (DSMP,  $r = -0.36$ ; DBRS,  $r = -0.34$ ) reports.

**CONCLUSIONS** — Both measures exhibit good psychometric properties and good criterion validity but varied in terms of respondent and interviewer burden, issues that should be considered in selecting assessment procedures.

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Long-term complications of insulin-dependent diabetes (type 1 diabetes) include higher morbidity and mortality from retinopathy, nephropathy, neuropathy, and cardiovascular disease (1–4). There may be no minimum glycemic threshold for the reduction of long-term complications; long-term risk continues to decrease with HbA<sub>1c</sub> (A1C) <8% accompanied by a less-gradual increase in the risk of hypoglycemia (5). Successful management of type 1 diabetes has been shown to reduce the frequency and severity of these long-term consequences; however, although intensive therapy may improve glycemic control, few families are able to maintain metabolic control within the recommended guidelines (1–6), and control appears to decrease during the adolescent years (7–12). To reduce potential long-term health effects, Cefalu (13) argues for

lowering the pediatric glycemic goal <8% but recognizes that until we can improve diabetes management during adolescence, such a goal is meaningless.

Diabetes self-management includes a variety of skills that must be performed daily: monitoring blood glucose, administering insulin, regulating diet and physical activity, and calculating appropriate care based on the results of these activities (14,15). In addition, the process requires adaptation to changing adolescent physiology and shifting parent and youth responsibilities while recognizing that the goals of diabetes management may be changing at the same time (15). Reliable and valid measures of adherence are essential for clinicians to determine the extent to which adolescents and their families are following their prescriptions for diabetes management and for researchers to determine whether efforts to improve adherence are successful.

A review of measures suggested that none of the available measures include all of the essential components of self-management of type 1 diabetes (16). Two of the measures receiving a positive review are the Diabetes Self-Management Profile (DSMP) (17) and the Diabetes Behavior Rating Scale (DBRS) (18,19). Both of these measures cover a wide range of self-management behaviors and have been used with adolescents. One major weakness noted for the DSMP is the need for personnel trained in the use of this specific measure. A weakness noted for the DBRS is that it does not include questions appropriate for insulin pump regimens (16).

Another issue in the assessment of diabetes self-management is whether measures of adherence should assess frequency of performing elements of an ideal regimen or adherence to the specific regimen prescribed by the youth's physician (14,20). The DSMP and DBRS differ on this dimension. The DSMP measures the extent to which diabetes management practices approach an ideal regimen. Although many of the items in the DBRS assess frequency of elements of an ideal regimen, the DBRS includes items asking the respondent about the patient's recommended regimen, e.g., "How often were your meals planned according to the sys-

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**Abbreviations:** DBRS, Diabetes Behavior Rating Scale; DSMP, Diabetes Self-Management Profile.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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tem you use?" and "How often were blood glucose levels tested as recommended by the doctor?"

The present study compares a modified version of the DSMP to an updated version of the DBRS in adolescents aged 11–18 years and their parents. Problems observed in each measure were addressed in modifications of these measures, and both were then evaluated. Psychometric properties of each measure were examined and criterion validity evaluated by comparing the adherence scores to the adolescents' glycemic control.

## RESEARCH DESIGN AND METHODS

**Participants**— Participants were recruited for two studies. One study was a randomized clinical trial testing the efficacy of a behavioral intervention designed to improve management of type 1 diabetes, and the other study was a longitudinal study of developmental influences on management of type 1 diabetes. Both study designs included multiple assessments over time and used the DSMP as the primary measure of adherence. To evaluate and compare the modified DBRS, the 1-year assessment in both studies included both measures of adherence.

Youth-parent dyads were recruited from three urban medical center pediatric diabetes clinics to participate in two studies: the randomized clinical trial ( $n = 81$ ) and the observational study ( $n = 87$ ). At baseline, the sample included 168 dyads; 146 parents (89%) and 144 youth (86%) completed the 1-year assessment reported in this study. Eligibility criteria at baseline included 1) youth diagnosed for a minimum of 1 year with type 1 diabetes requiring insulin treatment and 2) youth aged 10–16 years. Exclusion criteria were 1) major chronic illness (except for well-controlled asthma or thyroid problems) and 2) non-English speaking/writing youth or parent.

Parents provided written informed consent, and youths provided written informed assent. All assessments were completed in the home or at another convenient location selected by the parent. Trained interviewers administered the adherence measures, separated by other measures, to the parent and child independently. At two of the sites, these measures were administered in person; the interviewers administering the DSMP offered to read the self-administered DBRS survey items. At one of the sites, these measures were administered over the telephone and the interviewer read all

assessment items. Each participant (parent and youth) was given an incentive of \$25 for completing the assessment. To evaluate test-retest reliability, the DBRS was administered twice, within 1 week, in a random sample of 32 youth and 31 parents. Institutional review board approval was obtained from all institutions involved.

## The DSMP

Both parent and youth completed a modified version of the DSMP (17) in structured interviews. A potential problem with the DSMP, particularly when administered to younger adolescents, is that responses to the interview questions may not fit the scoring system; standardized probes necessary to code the response are not provided. Furthermore, the coding scales for individual items vary from two-point scales to five-point scales, and the meaning and metric for these different scales is not uniform even when the scale is the same. In response, the DSMP was modified to standardize wording across items, permitting administration by non-medical interviewers, and to make the scoring less subjective. For example, the original question on hypoglycemia asks the single question "What do you do to treat your low blood glucose reactions?" Responses are assessed for whether the child takes carbohydrates, whether the child tests again after taking the carbohydrates, and the time frame for these responses. Most respondents will not spontaneously give all of these details and, though the original DSMP does not specify it, further prompts from the interviewer may be necessary. The modified DSMP elicits each of these elements with a series of simple questions contingent on the respondent's responses: "What do you usually do when you have a low blood glucose?" "Do you eat or drink something right away?" "What do you eat or drink?" "How much do you eat or drink?" "How many grams of carbs is that?" "Do you check your blood glucose afterward?" "How soon after you eat or drink do you check?" Unfortunately, the DSMP for youth on a flexible regimen (21) was not available for evaluation when these data were gathered; however, the modified DSMP included adjustments to make it more appropriate for intensive treatment regimens. Final revisions were made by a panel including a pediatric endocrinologist, a certified diabetes educator, two developmental psychologists, and a clinical psychologist.

The modified DSMP included 29 items assessing the following elements of diabetes management: insulin administration routine, adjustment of the routine in response to changes in the routine, dietary routine, blood glucose testing frequency, and exercise frequency. Responses to individual items were scored by the interviewer. An overall DSMP score was derived by averaging scores from the five elements and represents the proportion of adherence to an optimal diabetes regimen (possible scores of 0.00–1.00), with high scores reflecting greater adherence.

## The DBRS

The original DBRS was a 35-item, self-administered, fixed-choice survey (18,19). Limitations of the original scale included lack of items addressing insulin administration with the pump, the need for updating to current intensive regimens, and the need for adequate respondent reading skills. To address the first two limitations, items were revised to reflect current diabetes management practices and a pump version of the DBRS was developed, replacing insulin injection-specific items with items relevant to administration of insulin with an insulin pump. To address the reading skills requirement for self-administered in-person administration, interviewers offered to read all items; for approximately half of the sample, interviews were conducted by telephone and all items were read to both parents and youth. The new instrument was reviewed and modified by a pediatric endocrinologist, a certified diabetes educator, and a developmental psychologist. The revised measure was then administered to an independent sample of five parents and youth in the same geographic area. After a second revision, the measure was then administered by an independent investigator to five parents and youth in a different geographic area. Feedback from this administration produced the final instrument. The insulin injection version of the DBRS has 36 items, and the pump version has 37 items. To make the results comparable with the DSMP, scoring was calculated as a proportion of the maximum possible score (possible scores of 0.06–1.00), with high scores reflecting greater adherence.

Glycemic control was assessed with A1C assays obtained at the clinics. To obtain a more stable estimate A1C, the average of the assays conducted in the

Table 1—Sample age, A1C, and response to assessments of adherence

	Means $\pm$ SD (range)
<i>n</i>	146
Age (years)	14.8 $\pm$ 2.0 (11.0–18.2)
Youth-reported DSMP	0.63 $\pm$ 0.10 (0.31–0.82)
Parent-reported DSMP	0.63 $\pm$ 0.12 (0.23–0.91)
Youth-reported DBRS	0.75 $\pm$ 0.10 (0.39–0.94)
Parent-reported DBRS	0.75 $\pm$ 0.10 (0.39–0.95)
A1C (%)	8.7 $\pm$ 1.6 (6.3–14.2)

preceding year was used as an index of glycemic control. Demographic data were gathered during the parent interviews.

### Analysis plan

Internal consistency of the scales was examined with Cronbach's  $\alpha$ . The 1-week test-retest reliability of the DBRS and 6-month test-retest consistency of the DSMP were examined with intraclass correlations. Criterion validity was evaluated with correlations between parent and child report, correlations between the two measures by the same respondent, and zero-order and partial correlations with glycemic control as assessed with A1C.

## RESULTS

### Sample

Of 222 families who met the inclusion/exclusion criteria, 76% ( $n = 168$ ) consented to participate and completed the baseline assessments. The average time from baseline to the 1-year assessment was 14 months, with 87% ( $n = 146$ ) of the baseline sample remaining (81 girls and 65 boys). Data from the 1-year sample are reported here. The mean age of the sample was 14.8 years (range 11–18, SD 1.98), with an average of 8.3 years since diagnosis. The sample was 81.5% white, which is representative of the clinic populations from which it was drawn. Approximately 45% of the sample used insulin pumps, and 15% were on other basal-bolus regimens. At baseline, compared with 22 subjects who could not be followed to 1 year, the families that completed the 1-year assessment had more education ( $t = 3.73, P < 0.001$ ), were less likely to be Hispanic [ $\chi^2 (161) = 10.9, P = 0.001$ ], and the youth, but not the parent, reported better adherence to the diabetes regimen ( $t = 2.28, P < 0.05$ ). They did not differ with respect to age, sex, other aspects of race/ethnicity, adiposity, time since diagnosis, diabetes regimen, or A1C. Mean age, adherence scores, and A1C are presented in Table 1.

### Internal consistency

The internal consistency (Cronbach's  $\alpha$ ) for the DSMP was acceptable for parents (0.75) and youth (0.70). Internal consistency of the DBRS was good in both parent (0.84) and youth (0.84).

### Parent-youth agreement

T tests revealed no significant differences between the levels of adherence reported by parent and youth on either of these measures ( $P > 0.30$ ). Parent and youth reports were significantly related, but these correlations were moderate (for the DSMP,  $r = 0.51, P < 0.0001$ ; for the DBRS,  $r = 0.48, P < 0.0001$ ).

### Test-retest reliability and the effect of method of administration

The 1-week test-retest intraclass correlations for parent and youth responses on the DBRS reflected good reliability: 0.71 ( $P < 0.0001$ ) for parents and 0.71 ( $P < 0.0001$ ) for youth. The intraclass correlation for youth-reported DSMP at 6-month and 1-year assessments was 0.69 ( $P < 0.0001$ ); the intraclass correlation for parent-reported DSMP at 6 months and 1 year was 0.73 ( $P < 0.0001$ ). The method of administration varied by clinic. This prevented a direct comparison of method of administration across clinics for both the DSMP and the DBRS without having potential confounding of differences between clinic populations. However, in all clinics the method of administration of the DSMP at 12 months was different from the method of administration at 6 months. A within-subject comparison of scores across methods indicated that the DSMP scores of youth, but not of parents, were significantly higher when the DSMP was administered by telephone than in person [for youth-reported DSMP,  $t (144) = 4.91, P < 0.0001$ ; for parent-reported DSMP,  $t (144) = 0.55, P = \text{NS}$ ]. This effect remained significant when age, sex, ethnicity, and intervention group were controlled. Therefore, the method of

administration was controlled in subsequent analyses.

### Criterion validity

The DSMP and DBRS were significantly related to each other among parent ( $r = 0.72, P < 0.0001$ ) and youth ( $0.74, P < 0.0001$ ). Both measures were negatively related to age, which is consistent with studies showing a decline in diabetes management during the adolescent years (parent-reported DSMP,  $r = -0.26, P < 0.01$ ; parent-reported DBRS,  $r = -0.20, P < 0.05$ ; youth-reported DSMP,  $r = -0.29, P < 0.001$ ; youth-reported DBRS,  $r = -0.18, P < 0.05$ ). White youths reported significantly higher adherence on the DSMP ( $t = 3.27, P < 0.01$ ) and the DBRS ( $t = 2.64, P < 0.01$ ) than youths from minority backgrounds. Parent responses were not significantly related to minority status. There were no sex differences on either measure. Parent and youth responses to the DSMP were significantly related to the 1-year cumulative index of A1C ( $r = -0.35, P < 0.0001$  and  $-0.36, P < 0.0001$ , respectively). Parent and youth responses to the DBRS were significantly related to A1C as well ( $r = -0.35, P < 0.0001$  and  $-0.34, P < 0.001$ , respectively). These relationships did not change substantially for partial correlations controlling for age, clinic site, method of administration, and assignment to intervention or control groups (Table 2).

**CONCLUSIONS**— The study provides good evidence for criterion validity for the modified versions of the DSMP and the DBRS. Parent and youth responses to the two measures were correlated, and responses to both measures were significantly related to the index of glycemic control, i.e., average A1C values over the previous year. These findings were robust. The significant relationships to glycemic control were maintained when age, sex, clinic site, method of administration, and intervention condition were statistically controlled.

The structure, wording, and scoring of the original DSMP make it more suitable for use as a diagnostic tool in a clinical setting than as a standardized research tool. Administration of the original instrument requires well-trained interviewers (16). The original DSMP interview has open-ended questions, but necessary prompts for each question are not standardized. The interviewer is required to transform the response for most

Table 2—Zero-order and partial correlations with age and A1C

	Zero-order correlations		Partial correlations
	Age	A1C	A1C
Youth report			
DSMP	−0.29*	−0.36†	−0.24‡
DBRS	−0.18§	−0.34†	−0.24‡
Parent report			
DSMP	−0.26‡	−0.35†	−0.25§
DBRS	−0.20§	−0.35†	−0.25‡

Partial correlations control for age, sex, minority status, clinic site, method of administration, and random assignment to intervention or control groups. \* $P < 0.001$ ; † $P < 0.0001$ ; ‡ $P < 0.01$ ; § $P < 0.05$ .

of the questions to fit a scoring system that may not always correspond to the response. Standardized probes necessary to code the response are not provided. Furthermore, the coding scales for individual items vary, and the metric for these different scales is not uniform even when the scale is the same. Thus, while this may be an effective means for a well-trained clinician to identify problem areas for adherence, it is less appropriate for empirical analyses of individual differences in overall adherence. In addition, the instrument takes ~20 min to complete; thus, costs attributed to interviewer training, interviewer time, and subject burden make it less suitable for large research studies. In the original versions of the DSMP, simple sums are used to calculate total scores resulting in differential weight given to different areas. For example, in the flexible regimen DSMP, blood glucose monitoring had a maximum score of 30 versus hypoglycemia, exercise, insulin administration, and eating (maximum scores of 11, 12, 16, and 17, respectively) (21). Weighting of scores or standardization across areas of diabetes management should be explored. If used as a research instrument, standardized training of all interviewers across sites and standardized probes are essential.

The psychometric properties of the revised DSMP and its relationship with glycemic control are comparable or better than those previously reported for the original DSMP (17,21). The validation study for the original conventional-regimen DSMP reported a Cronbach's  $\alpha$  of 0.76 (17). In the evaluation study of the original flexible-regimen DSMP (21), baseline Cronbach's  $\alpha$  for the adolescents were poor (0.45), and those for parents were marginal (0.69); however, these improved slightly at a repeated assessment 6 months later (adolescents 0.65 and par-

ents 0.70). Six-month test-retest correlations of the original flexible-regimen DSMP were poorer for adolescents than for parents (usual-care group test-retest: parents 0.73 and adolescents 0.42; intervention group test-retest: parents 0.73 and adolescents 0.51). Consistent with the current study, there was no significant difference between parents' and adolescents' scores and their scores were correlated. Criterion validity of the original DSMP was good (correlation with A1C ranged from −0.20 to −0.28) (17,21). Overall, the revised DSMP presented in this study appears to improve on the psychometric properties of the original and provides standardized wording for interviewers without expertise in diabetes care.

The findings for the revised DBRS are consistent with previous studies. The original DBRS had good psychometric properties, with a Cronbach's  $\alpha$  of 0.86 (18), comparable with the values for the revised DBRS reported in the current study. These values are superior to the current and previously reported internal consistency for the DSMP. However, unlike the revised DBRS, the original DBRS was not validated against the current standard for glycemic control, A1C values. The revised DBRS updates the original DBRS to include insulin administered with a pump and has good evidence for criterion validity; it was significantly related to the DSMP, parent and youth scores were correlated, and it was significantly related to A1C.

The revised DBRS may be less useful as a clinical tool, as the structure does not provide an opportunity for the clinician to discuss responses during administration of the instrument. However, there are several advantages to the use of the DBRS as a research instrument. The time for administration of the revised DBRS is ~7 min, a

substantially reduced subject burden compared with the DSMP, and because the DBRS is self-administered, there is no need for extensive interviewer training. Also, included in the DBRS but absent from the DSMP are questions about the interaction between the patient and the diabetes health care team (16). The reliability and validity of the revised DBRS make it a very reasonable substitute for the DSMP.

### Limitations

There are several disadvantages to the current study. The sample includes patients from three different sites and patients that were randomly assigned to participate in an intervention. Methods for assessing A1C and for administering the adherence instruments (in person versus by telephone) varied across sites. Although this may increase the generalizability of these findings, there might be some concern that differences across sites and across intervention and control groups biased the results. The significant effect of method of administration for youth-reported DSMP deserves further investigation. However, variations across sites are more likely to mask significant relationships than to enhance them, and when site, method of administration, and group assignment were statistically controlled there was little effect on the results. Finally, some of the criticisms of the DSMP and the DBRS were addressed with standardized interviewer training and modifications to the items. It is possible that comparisons between the original DSMP and the original DBRS would have provided different results.

### Implications

Both the revised DSMP and the revised DBRS are suitable measures of conventional and flexible self-management of type 1 diabetes. The evidence from this study indicates that the revised DSMP provides an effective standardized system for interviewing patients about adherence. The revised DBRS provides a measure of diabetes regimen adherence that can be self-administered with youth as young as age 11 years with good internal consistency and criterion validity. Investigators and clinicians should consider their goals and resources in deciding which instrument best suits their needs.

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