A New Self-Report Measure of Self-Management of Type 1 Diabetes for Adolescents

Running Title: New Self-Report Measure of Self-Management

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Abstract

Background: The development of instruments to measure self-management in youth with type 1 diabetes has not kept up with current understanding of the concept.

Objective: The purpose of this paper is to report the development and testing of a new self-report measure to assess self-management of type 1 diabetes in adolescence (SMOD-A).

Method: Following a qualitative study, items were identified and reviewed by experts for content validity. A total of 515 adolescents, 13 to 21 years, participated in a field study by completing the SMOD-A (either once or twice) and also by completing additional measures: diabetes related self-efficacy (SEDS), quality of life (DQOL), self-management (DSMP) and adherence (SCI). Data were also collected on metabolic control (HbA1c).

Results: The content validity of the scale (CVI) was .93. Exploratory alpha factor analyses revealed five subscales -- Collaboration with Parents, Diabetes Care Activities, Diabetes Problem-Solving, Diabetes Communication, and Goals (α = .71 to .85). Test-retest correlations of the SMOD-A ranged from .60 to .88 (two weeks) and .59 to .85 (three months). Correlations of SMOD-A subscales with SEDS-Diabetes; DQOL impact, worry, and satisfaction; DSMP; and SCI were generally significant and in the expected direction. Collaboration with Parents and HbA1c values were significantly and positively related (r =.11); all other SMOD-A subscales were significantly and negatively related to HbA1c (r = -.10 to -.26), demonstrating that better self-management is somewhat associated with better metabolic control, and supporting construct validity of the new measure.

Discussion: The SMOD-A has been found to be a reliable, stable, and valid measure of self-management of type 1 diabetes in adolescence.

Key Words: Self-Management, Type 1 Diabetes, Adolescence, Instrument Development

A New Self-Report Measure of Self-Management of Type 1 Diabetes for Adolescents

The management of type 1 diabetes in youth has changed dramatically in recent years. The American Diabetes Association (2005) now recommends that all youth over the age of seven be managed with flexible regimens. Such regimens include the use of insulin pumps (continuous subcutaneous insulin infusion [CSII]) and basal-bolus injectable insulin (Weinzimer, Kikes, Steffen, & Tamborlane, 2005)). Self-management is important to the overall management of the disease and becomes even more important as individuals and families make the complex (and frequent) management decisions that flexible regimens demand.

There has been conceptual confusion about the definitions of *self-management* and *adherence.* This confusion has seeped into descriptions of how youth self-manage type 1 diabetes and into selection of the measures used in research reports. Researchers often use the two terms inter-changeably in the same paper, or use a measure of self-management and discuss results in terms of adherence.

The following distinctions between the two concepts are intended to contribute to a more nuanced understanding of how youth care for their type 1 diabetes. Adherence is usually described as the degree to which an individual follows medical advice (Greening, Stoppelbein, & Reeves, 2006). In contrast, self-management is a multi-dimensional concept that includes activities that youth and their parents perform to care for the disease, as well as processes of collaboration between youth and their parents and between youth and health care providers as youth move toward the goal of assuming full responsibility for managing their diabetes (Schilling, Grey, & Knafl, 2002). Self-management is an evolving process reflecting a trajectory that begins with dependence on parents and moves toward a more collaborative relationship with

them. There is an overlap between self-management and adherence in that some of what youth do to care for their disease (self-management) is what they were told to do (thus, also adherence).

The development of instruments to measure self-management in youth has not kept pace with the evolving concept of self-management. The most commonly used instrument is the Diabetes Self-management Profile (DSMP), an interview measure developed by Harris et al. (2000) and later revised (Ianotti et al., 2006). The DSMP (Harris et al., 2000) has 5 subscales (exercise, management of hypoglycemia, diet, blood glucose testing and insulin administration, and adjustment). These subscales assess the performance and adjustment of diabetes care activities, but do not evaluate the process (including collaboration with parents and health care providers) and goals of self-management. As such, the DSMP provides a more circumscribed assessment of self-management than does the SMOD-A.

The Self-Management of Type 1 Diabetes in Adolescence (the SMOD-A) was developed to broaden the scope of measurement of self-management and to give researchers the option of a self-report instrument. The purpose of this paper is to report on its development and the results of our reliability and validity assessments.

Research Design and Methods

In developing this instrument we used state of the art methods in a three-step process. The steps included a qualitative study to identify potential item content and create the initial items for the instrument, expert review for item refinement (and elimination of some items), and field testing to assess psychometric characteristics of the new instrument. Results from the first two phases are published and are summarized here (Schilling et al., 2007; Schilling, Knafl, & Grey, 2006).

In the qualitative descriptive study, we conducted semi-structured interviews with 22 youth, from 8 to 19 years, and one parent of each youth (Schilling et al., 2006). From these data 99 potential items for the SMOD-A were written in three different categories. The three categories were previously identified in a concept analysis (Schilling et al., 2002) and included: activities of self-management, processes of self-management, and goals of self-management.

Content Validity

The content validity of these potential SMOD-A items was assessed by three panels of expert judges: 12 clinicians from two university pediatric diabetes clinics, 5 behavioral diabetes researchers, and a group of "experiential experts" (p. 363) composed of 6 adolescents judged to be good self-managers of type 1 diabetes by clinic health care providers, and 5 of their parents (Schilling et al., 2007). The details of our content validity assessment have been reported elsewhere (Schilling et al., 2007). In summary, we used the judgments of multiple groups of experts, obtained via content validity questionnaires focused on the relevance and clarity of items, to decide which items should be kept, eliminated, or re-written. Based on these judgments, thirteen items were eliminated. The content validity index based on the remaining 86 items was a robust .93.

Field Study

The psychometrics and underlying structure of the 86 items remaining after content validity analysis were tested in a field study conducted at two university-based diabetes centers in the northeast. IRB approval was obtained from each institution.

Sample. Eligible adolescents were approached in clinic waiting rooms to assess their interest in participating. Criteria for participation were: (1) age 13- 21 years, (2) English speaking, (3) diagnosed with type 1 diabetes for at least one year, (4) not pregnant, and (5)

having no condition/ chronic illness that could impact how the individual cared for their diabetes (e.g., mental disability or illness, celiac disease). For interested adolescents under age 18, written parental consent and adolescent assent were obtained; for adolescents over age 18, written consent was obtained. Of 595 adolescents approached, 60 declined to participate. Twenty adolescents either were excluded after consenting when it became apparent they did not meet enrollment criteria or they failed to complete the questionnaire packet. Data were gathered from 515 adolescents, aged 13 to 21 years. Participants ranged in age from 13 to 21 years (mean = 15.8 years ± 2.14 years). The sample was predominantly white (80% White, 9.7 % Black, 1.6% Asian, 8.8 % American Indian or Alaskan Native, Other or Multiple), fairly equally divided between genders (53% male), and middle class (mean income $63,859 ± $28,756). About six percent (5.8%) reported Hispanic ethnicity. Income was estimated based on address of residence, using American Factfinder (US Census Bureau, n.d.), a system of using US census tract data to determine median income. Almost half of the participants used CSII (*n* = 250, 48.5%) and 66.4 % were on flexible rather than conventional regimens (*n* = 342). The mean HbA1c, taken from the chart at the time of the clinic visit, was 8.47% ± 1.78%. The mean duration of diabetes was 6.92 years ± 3.92 years.

Procedures. To assess the temporal stability of the SMOD-A, participants at both sites were randomly selected to re-take the SMOD-A at either 2 weeks (± 3 days) or 3 months (± 1 week). After sufficient numbers had been recruited for the assessment of stability (*n*= 187), remaining participants (*n* = 328) completed the SMOD-A only one time. At one of the sites, 16 participants also completed the original DSMP (Harris et al., 2000).

Measures. All participants completed a Demographic Form and three other measures to assess the construct validity of the SMOD-A.

Measures included the following: The SMOD-A, The Self-Efficacy for Diabetes Scale (SEDS) (Grossman, Brink, & Hauser, 1987), The Diabetes Quality of Life for Youth Questionnaire (DQOL-Y) (Ingersoll & Marrero, 1991), and the Self-Care Inventory (SCI) (La Greca, Swales, Klemp, Madigan, 1988; La Greca, Swales, Klemp, Madigan, & Skyler, 1995;).

The SMOD-A, as it was used in the field study, consisted of 86 items divided in two parts. Part I was made up of items related to the activities and processes of self-management. Part II was made up of items related to the potential goals of self-management. Participants were asked to respond to items on a 4-point scale, ranging from "never" to "always" for items in Part I and from "never a goal for me" to "met this goal" for items in Part II.

The SEDS (Grossman et al., 1987) measures self-perceptions or expectations held by youth with diabetes about their confidence regarding successfully managing their diabetes. The SEDS has three subscales addressing different aspects of self-efficacy: diabetes-specific, medical, and general situations. For the purpose of this report, only the diabetes-specific subscale scores (24 items) are reported. To complete the SEDS, the respondent rates her/his degree of confidence for items on a five-point scale ranging from "very sure I can't" to "very sure I can." Lower scores indicate higher self-efficacy. Reliability coefficients on the diabetes-specific subscale are reported to be .90 to .92.

The DQOL-Y (Ingersoll & Marrero, 1991) measures perceptions of the impact of diabetes, general satisfaction with life, and worries over social, school and relationships with peers among youth with type 1 diabetes. Three subscales measure Diabetes Life Satisfaction (17 items), Disease Impact (23 items), and Disease-Related Worries (11 items). Each scale has adequate internal consistency (.77 to .94). Each item has a 5-point response format. Higher

scores on the Satisfaction scale indicate higher quality of life; higher scores on the Impact and Worries scales indicate lower quality of life.

The SCI (La Greca et al., 1988, 1995) is a measure of adherence to performing diabetes self-care activities as recommended by health care providers. The measure is composed of 13 items regarding such things as insulin administration, blood glucose testing, and treatment of hypoglycemia. Respondents rate items on a five-point scale reflecting how frequently they follow recommendations for the performance of a self-care activity. The scale has good internal consistency (Cronbach's alpha = .87; La Greca et al., 1995).

The original DSMP (Harris et al., 2000) is a semi-structured interview measure that assesses self-management of type 1 diabetes by youth over the past 3 months. Harris et al. (2000) reported the Cronbach's alphas for the total scale and five subscales to be >.50. Test-retest reliability over 3 months was reported as .67 for the total scale and ranged from .34 to .47 for the 5 subscales. The DSMP was administered over the telephone.

The SEDS, DQOL-Y, SCI and DSMP are widely used in studies involving adolescents with type 1 diabetes and there is evidence to support their construct validity.

Glycosylated hemoglobin (HbA1c) was used as a measure of metabolic control. The majority of participants (n = 484) had their HbA1cs assessed by the Bayer Diagnostics DCA2000 (normal range = 4.0 to 6.3%) method. Thirty-one participants had their HbA1cs assessed by another method and were excluded from analyses involving HbA1c for this paper.

Analyses. Descriptive statistics were compiled on all study measures and demographic variables. Cronbach's alphas were computed for the measures used in concert with the SMOD-A. Item analyses were conducted on the SMOD-A items, and 13 items with little or no variability were eliminated. We conducted a series of exploratory factor analyses with the remaining 73

items. Since response options were different for items of Part I (61 items) and Part II (12 items), these were analyzed in separate factor analyses. Missing data by item ranged from 0 to 16 (3.1%) subjects. Using the analysis default option, subjects with missing data were not included in factor analyses, leaving 432 for these analyses**.** The preferred solutions (based on interpretability and internal consistency of the factors) were obtained via alpha factor analysis. Cronbach's alphas were computed for subscales resulting from the factor analysis, and subscales were further refined to eliminate items that detracted from reliability. Then scores were computed for each study participant on each of the subscales. The final phases of data analysis included evaluating the stability of SMOD-A scores over 2 weeks and 3 months and evaluating the relationship of SMOD-A scale scores to both demographic variables and participant scores on the other study measures.

Results

Readability

The SMOD-A was evaluated using the Flesch-Kincaid Grade Level score that is calculated in Microsoft Word and found to be at the 5.9 grade level.

Factor analysis and subscale development

Five subscales were identified through exploratory factor analysis – based on a four-factor solution for Part I items and a one-factor solution for Part II items. These accounted for 27.9% and 29.6% percent of inter-item variance, respectively for the two solutions. Varimax rotation of the four-factor solution yielded conceptually interpretable factors which were named Collaboration with Parents, Diabetes Care Activities, Diabetes Problem-Solving, and Diabetes Communication. Eigenvalues of rotated factors ranged from 3.1 to 5.9, and proportion of variance accounted for ranged from 5.3% to 10.1%. The single factor (Eigenvalue = 3.3) of the

one factor solution was named Goals. Items with factor loadings of .20 or greater were included in analyses of subscale reliability, but items detracting from reliability were then dropped. Table 1 displays the sub-scales, with items ordered by item-total correlations, which are also provided.

Reliability

Table 2 displays SMOD-A subscale definitions, reliabilities (internal consistency and temporal stability), and descriptive statistics (mean and standard deviation).

Internal consistency. Cronbach's alphas for the five SMOD-A subscales range from .71 to .85 and were considered acceptable (DeVellis, 2003).

Temporal stability. Correlations assessing temporal stability also were acceptable, ranging from .60 to.88 for the two week interval (n = 74), and from .59 to .85 for the 3-month interval (n =113). All were statistically significant (p = .0001). Although these two analyses involved different subsets of the sample, stability followed similar patterns, with highest stability found for the Collaboration with Parents factor, and lowest stability for the Goals factor in both the 2-week and 3-month periods.

Construct Validity Testing.

Table 3 presents alpha reliabilities for study measures and correlations with SMOD-A subscales. With the exception of short DSMP sub-scales (those with only 3-6 items), reliabilities of study measures were acceptable, ranging between .82 and .92. For the three measures obtained from the full sample (DQOL –Impact, Worry and Satisfaction; SEDS, SCI), most correlations with SMOD-A subscales were statistically significant, and in the expected direction (positive for DQOL-Satisfaction, and SCI; negative for SEDS, DQOL-Impact, and DQOL-Worry). As expected, the correlation between SCI scores and the Diabetes Care Activities subscale (r = .62, p = .0001) was of high magnitude. Other statistically significant correlations

ranged from .14 to .38 in magnitude. Only correlations with the Collaboration with Parents subscale followed a different pattern – opposite direction of relationship with SEDS-Diabetes, and virtually no relationship with DQOL subscales. Results indicate that self-management is positively related to satisfaction with quality of life, adherence as measured by the SCI, and self-efficacy; self-management is negatively related to quality of life- impact and worries (better self-management, less impact and worries).

Only 16 of the 515 study participants completed the DSMP interview, so only correlations of high magnitude achieved statistical significance. Nevertheless, three DSMP subscales and total scores also were strongly, positively, and significantly associated with the SMOD-A Diabetes Care Activities subscale, with correlations ranging from .53 to .80. Finally, there were small but significant relationships between HbA1c and all SMOD-A subscale scores, ranging in magnitude from .10 to .26, with all except Collaboration with Parents in inverse direction, as expected.

Relationship of sub-scales and characteristics of subjects

Comparisons of subscales were conducted across gender, age and regimen categories. Girls scored significantly higher than boys on Diabetes Care Activities ($p<.005$) and Diabetes Communication ($p<.01$). Two subscales show an age gradient, with ages categorized by stage of adolescence (11-14, 15-16, 17-21). Collaboration with Parents decreases with age, from 18.0 for the youngest age category to 9.9 for the oldest age category ($p<.0001$). Conversely, Diabetes Problem-Solving increases by age category from 15.3 for the youngest category to 16.9 for the oldest age category ($p<.0001$). The middle age category had intermediate values on both subscales. For four of five subscales, there were significant differences between adolescents on conventional regimens and those on flexible regimens, with those on conventional regimens

higher on Collaboration with Parents (p<.005), and lower on Diabetes Care Activities (p<.05), Diabetes Problem-Solving (p<.0001), and Diabetes Communication (p<.05).

Discussion

The SMOD-A, a 52-item self-report measure, has excellent content validity (CVI = .93), acceptable subscale reliability (α = .71 to .85), and is stable as assessed at 2 weeks (r = .60 to .88) and at 3 months (r =.59 to .85). Preliminary assessment of construct validity testing was promising as well, with the SMOD-A having relationships in the expected directions with QOL (impact, worry and satisfaction), SED-Diabetes, SCI, DSMP, and HbA1c. It was particularly promising that the SMOD-A had a similar pattern of associations with QOL and HbA1c as the DSMP (5), since the SMOD-A goes further than the DSMP in assessing aspects of the process and goals of self-management and has higher reliability estimates. While further information about construct validity will be obtained about the SMOD-A in subsequent uses, the evidence obtained thus far leads us to the conclusion that it fills a here-to-for unfilled niche in its focus (self-management) and target population (adolescents). On this latter point, the SMOD-A was well accepted by the adolescents and their parents. We believe this reflects its focus on areas of particular importance in the adolescents' progress towards independence. This additional asset of the SMOD-A derives from the origin of the items being adolescents and parents themselves. Moreover, during the content validity assessment phase of instrument development, adolescents and parents provided valuable feedback on the relevance and clarity of items.

The SMOD-A offers an opportunity for clinicians and researchers who want to look at self-management in adolescents. A frequently used measure, the SCI (La Greca, Follansbee, & Skyler, 1990; La Greca et al., 1988, 1995), is a measure of adherence which, as noted earlier, provides a limited view of self-management. While the Diabetes Care Activities subscale of the

SMOD-A was associated with the SCI score (r = .62), it is clear that the SMOD-A subscales and the SCI do not measure the same construct. Our research demonstrates that self-management as measured by the SMOD-A is a broad (multi-dimensional) construct that includes: collaboration between adolescents and their parents; how frequently key diabetes care activities are performed (the subscale most strongly associated with adherence); how frequently the adolescent adjusts his/her diabetes regimen; how frequently the adolescent communicates about his/her diabetes with parents, health care providers and friends; and the degree of endorsement of relevant diabetes-related goals. The SMOD-A may be a useful addition to the battery of measures that are often used to evaluate how adolescents with type 1 diabetes are managing their disease (SEDS, DQOL-Y, HbA1c, etc.).

The SMOD-A, in its entirety, may be too long to be useful to clinicians. However, depending on which aspect of self-management is of interest to clinicians (and this may change from setting to setting and patient to patient), individual subscales of the SMOD-A may be administered and prove useful as talking points.

This study is limited by the relative homogeneity of the sample. The sample was predominately White, middle class, and in reasonably good metabolic control. Although data were collected in two different settings, both are in the same geographic region, the northeast. The reliability and validity of the SMOD-A in more diverse populations need to be explored.

A total score on the SMOD-A was not calculated and is not recommended. Rather, we have identified five unique subscales, each of which captures a meaningful aspect of self-management, and each of which shows acceptable reliability and beginning validity evidence. We suggest that they are best used as separate indicators, which, in combination, may provide a holistic picture of self-management status.

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Table 1

Table 1. SMOD-A Subscales with items and item-subscale correlations

Subscale	Item	Item-total (scale) correlation
Collaboration with Parents		
	My parents help me decide my insulin dose.	.64
	My parents tell me how much insulin to take.	.62
	My parents count carbohydrates with me.	.59
	I ask my parents what to do when my blood sugar is out of range.	.56
	I tell my parents when my blood sugar is out of range.	.52
	My parents and I look together at the record of my blood sugar readings to make adjustments.	.52
	My parents check to see if I've taken my insulin.	.49
	I handle my high blood sugars myself. (R)	.46
	My parents talk to me about what to eat or not to eat.	.45
	My parents check my meter to see if I've tested my blood sugar.	.43
	I ask my parents how many carbohydrates are in some foods.	.41
	I consult my parents when I'm not sure what to do to manage my diabetes.	.40
	I adjust my insulin dose by myself. (R)	.39
Diabetes care activities		
	I check my blood sugar before eating.	.52
	I eat without first checking my blood sugar. (R)	.48
	I check my blood sugar without being reminded.	.47
	I follow my meal plan or count carbohydrates.	.43
	If my blood sugar is high, I check it again in 1 to 2 hours.	.41
	I carry glucose tabs or some quick-acting sugars.	.40
	I test for ketones if my blood sugar is high.	.39
	I keep my own record of blood sugar numbers	.39
	If my blood sugar is too low, I treat and then check later if I still feel low.	.36
	I need to be reminded to take my insulin. (R)	.34
	My parents and I argue about when I should test my blood sugar. (R)	.34
	I skip insulin injections or boluses. (R)	.32
	I carry something with me that says I have diabetes.	.27
	I go out without my diabetes supplies. (R)	.25
	I don't like it when someone reminds me to check my blood sugar. (R)	.19
Diabetes Problem-solving		
	I decide how much insulin to take	.55

	To figure my insulin dose, I consider my blood sugar and what I will eat.	.50
	I adjust my dose of insulin based on my blood sugar numbers.	.49
	When I exercise I change how I eat or how much insulin I take.	.37
	If my blood sugar is high, and it's not mealtime, I give myself insulin.	.37
	I remember what my HbA1c (A1c) number is from my last clinic visit.	.33
	I know what my HbA1c (A1c) number should be.	.32
Diabetes Communication		
	When my diabetes bothers me, I talk to my nurse or doctor about it.	.55
	If something is bothering me about the way things are going with my diabetes, I talk to my parents about it.	.49
	I try to change my diabetes routine if my nurse or doctor asks me to.	.45
	If my parents have a problem with how I manage my diabetes, we talk about it.	.40
	Before clinic visits I think about what I want to say to my nurse or doctor.	.40
	I contact my nurse or doctor when I can't get my blood sugars back into range.	.40
	I stay informed about what's new in diabetes.	.36
	I review my blood sugar records with my nurse or doctor.	.33
	During clinic visits, I spend some time alone with my nurse or doctor.	.27
	I tell my friends that I have diabetes.	.25
Goals		
	One of my goals is to take care of my diabetes more on my own.	.53
	One of my goals is to be in charge of taking care of my diabetes.	.53
	I take care of my diabetes to try to not have problems in the future.	.50
	I take care of my diabetes to feel good.	.50
	I take care of my diabetes so I'm able to do things with my friends.	.44
	One of my goals is to be able to stay away from home overnight.	.41
	I want to understand why sometimes my blood sugar numbers are too high or too low.	.35

(R) – Item responses are reversed before subscale total is calculated.

Table 2

Table 2. SMOD-A subscale definitions, reliability estimates, means and standard deviations

Subscale	Definition	# Items	Reliability estimate			Mean	SD
			alpha	Two week	Three month		
Collaboration with parents	This subscale assesses how frequently parents are involved in diabetes management.	13	.85	.88	.85	13.7	7.0
Diabetes care activities	This subscale assesses how frequently the adolescent performs key activities of diabetes management.	15	.77	.78	.76	30.9	6.1
Diabetes problem-solving	This subscale assesses how frequently the adolescent adjusts his/her regimen and knows HbA1c numbers and goals.	7	.71	.72	.78	16.1	3.6
Diabetes communication	This subscale assesses how frequently the adolescent communicates with parents, health care providers and friends about their diabetes.	10	.73	.69	.70	16.8	5.0
Goals	This subscale assesses the degree to which the adolescent has endorsed seven potential diabetes goals.	7	.75	.60	.59	14.2	3.3

Table 3

Table 3. Alpha reliability for study measures and correlation with SMOD-A subscales.

Measure	*n*	Items	α[1]	Correlations with SMOD-A subscales				
				Collaboration with parents	Diabetes care activities	Diabetes problem-solving	Diabetes communication	Goals
DQOL- Impact	490	23	.85	.04	-.28****	-.14**	-.18****	-.23****
DQOL - Worry	511	11	.88	-.00	-.24****	-.13**	-.08	-.17***
DQOL - Satisfaction	494	17	.92	.04	.25****	.17***	.19****	.15***
SEDS - Diabetes	471	24	.87	.23****	-.30****	-.38****	-.35****	-.35****
SCI	515	7	.83	.29****	.62****	.21****	.34****	.24****
DSMP - Exercise	14	3	.04	.51	.43	.24	.52*	.30
DSMP - Hypoglycemia	16	3	.33	.12	.35	.03	.21	.21
DSMP - Diet	16	6	.50	.59*	.80***	.35	.32	-.01
DSMP - Insulin	16	4	.43	.28	.53*	.26	-.01	.32
DSMP - Glucose Testing	16	9	.82	.20	.56*	-.00	.26	.29
DSMP - Total	16	25	.82	.40	.75***	.14	.30	.28
HbA1c	484	--	--	.11**	-.24****	-.26****	-.10*	-.26****

[1] Standardized alphas; * $p = \leq .05$; ** $p = \leq .01$; *** $p = .001$; **** $p = .0001$