Optimizing Diabetes Self-management Using the Novel Skills, Confidence, and Preparedness Index (SCPI)

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OBJECTIVE

The Skills, Confidence, and Preparedness Index (SCPI) is an electronic tool designed to assess three dimensions (knowledge, confidence, and preparedness) in a clinically relevant measure, with immediate feedback to guide the individualization of patient education. This study sought to assess the validity and reliability of the final SCPI generation, its relevance to glycemia, and its responsiveness to patient education.

RESEARCH DESIGN AND METHODS

In Part 1, patients with type 1 and type 2 diabetes were recruited from specialist clinics over a 6-month period and completed the 23-item SCPI using a tablet. In Part 2, participants also underwent a diabetes self-management education (DSME) program. Baseline SCPI score was used to guide the DSME, and SCPI and glycemia were assessed at completion.

RESULTS

In total, 423 patients met inclusion criteria and 405 had evaluable data. SCPI scores were found to have a high degree of validity, internal consistency, and test-retest reliability, with no floor or ceiling effects. Scoring was negatively correlated with HbA_{1c} (type 1 diabetes: $r = -0.26$, $P = 0.001$; type 2 diabetes: $r = -0.20$, $P = 0.004$). In 51 participants who underwent a DSME intervention (6.4 ± 0.6 visits over a mean 3.4 ± 0.8 months), mean HbA_{1c} improvement was 1.2 ± 0.2% (13.1 ± 2.2 mmol/mol, $P < 0.0001$). Total SCPI score and each subscore improved in parallel.

CONCLUSIONS

The SCPI tool is a quick and easy-to-use measurement of three domains: skills, confidence, and preparedness. The instant scoring and feedback and its relationship to glycemic control should improve the efficiency and quality of individualizing care in the diabetes clinic.

The past decade has seen significant growth in the breadth of oral antihyperglycemic agents (AHAs), insulin and other injectable therapies, and of new technologies available to people with type 1 and type 2 diabetes. The move toward patient-centered therapy has also led to more robust diabetes self-management education (DSME) programs. Despite these advances, achievement of optimal glycemic control remains low and may have actually deteriorated (1,2). Optimal diabetes care uniquely entails the rate-limiting step of an individual's own ability to provide his/her self-care.

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Although DSME programs have impacted patients' self-care (3) and their health outcomes (4,5), a systematic review for the American Association of Diabetes Educators (AADE) (4) found that 45 of 118 (38.1%) DSME programs reviewed were not able to improve HbA_{1c}. For each individual learner, carefully selecting the delivery method, provider, and duration were part of the recommendations.

Persistent poor glycemic control occurs in 15.5% of American populations with diabetes ($HbA_{1c} > 9.0$) (2) and in 25% of primary care practices in Canada ($HbA_{1c} > 8.5$) (6), consistent with several international registries (7). In chronically uncontrolled patients, the Diabetes Registry Outcomes Project for A1C Reduction (DROP A1C) study (8) found that identifying individual barriers allowed successful customization of care paths and that no single barrier (psychological, socioeconomic, comorbidity, accessibility, or cultural) could predict response. Similarly, neither particular mode of education delivery (4) nor any specific learning paradigm (9,10) has shown definitive benefit over any other. If any DSME intervention can be potentially effective, and if any barrier can be potentially overcome, then the key to success is in providing the modern health care provider (HCP) with a tool to quickly assess the customizations needed for success for each patient.

Assessment tools were initially developed to assess current patient practices, effectively supplementing a traditional medical history with a validated index (Summary of Diabetes Self-care Activities [11], Diabetes Self-management Assessment Report Tool [12], Personal Diabetes Questionnaire [13], and Diabetes Self-Management Questionnaire [14]). More recent tools that have targeted individual barriers (self-efficacy: Diabetes Empowerment Scale [15] and Diabetes Self-efficacy Scale [16]; confidence: Confidence in Diabetes Self-care Scale [17]; preparedness to change: Patient Activation Measurement [18]) have had limited success in assessments of their validity, reliability, and/or responsiveness (19,20). Most were validated against each other and have not shown correlation with health outcomes, unless they happen to be measuring a current behavior (Diabetes Self-Management Questionnaire [14], at a specialist in-patient education program, and Diabetes Self-management Assessment Report Tool [12]). More recently, two general scales reflecting self-esteem (21) and sense of coherence (22) were each shown to be correlated with HbA_{1c} in a small group of individuals with type 1 diabetes (10).

Based on the experience of the DROP A1C study, Canadian experts in diabetes care developed the Skills, Confidence, and Preparedness Index (SCPI), using the assessment standards of the International Society of Quality of Life Research (ISOQOL) (23). Their goals were to create a tool that would be web based and accessible, would give immediate feedback to the HCP, and would be clinically meaningful in that it reflected actual health outcomes, such as glycemia. The tool was designed to allow an HCP to individualize the education/support by assessing the three critical dimensions of self-management: knowledge of skills, confidence in ability to change a behavior, and preparedness to begin implementing the behavior change. The resulting SCPI was an easy-to-use, web-based, 25-item questionnaire, based on the AADE7 Self-Care Behaviors (24). The SCPI was validated in two cohorts of people with type 1 diabetes and type 2 diabetes who had poorly controlled HbA_{1c} (25) and in a broader specialist clinic population (26). In both populations, the SCPI showed high internal consistency, reliability, and generalizability, with scoring unaffected by sociodemographic variables, including age, sex, ethnicity, and education level. It also showed convergent validity in comparison with existing scales (Michigan Knowledge Test [3] and the Diabetes Empowerment Scale [15]) and a close relationship with glycemia.

After a 3-month series of six focus groups with experienced HCPs and 10 patient interviews reflecting a range of diabetes type, educational attainment, and therapy complexity, the original SCPI questions and response scale were edited to further optimize clarity. In this study, the final SCPI tool (Supplementary Table 1) was assessed in a large population of individuals with type 1 diabetes and type 2 diabetes for consistency, validity, reliability, and clinical responsiveness to a DSME program intervention.

RESEARCH DESIGN AND METHODS

The study was conducted in compliance with the ethics principles of the Declaration of Helsinki and in compliance with all International Council on Harmonization Good Clinical Practice Guidelines. An independent ethics committee approved the protocol, and written informed consent was obtained from all study participants.

The initial formation of the multidisciplinary expert panel in November 2013, its mission, and the qualitative phase of the formation and evaluation of questionnaire items has been previously described (25). Contributors included physicians (primary care and specialists in endocrinology and psychiatry), physician assistants, registered nurses, registered dietitians, and pharmacists. A sequential exploratory mixed-methods design was used to develop the questions, based on the AADE7 Self-Care Behaviors (24) and informed by the Diabetes Canada Clinical Practice Guidelines (27), Social Cognitive Theory (28), and the Transtheoretical Model of Health Behavior Change (29). A prototype of the tool had already shown internal validity, readability at an eighth or ninth grade level (30), convergent validity to existing scales (Diabetes Empowerment Scale [15] and Michigan Knowledge Test [31]), and criterion validity to HbA_{1c} (25,26). After a series of patient interviews and HCP reviews, several changes were implemented to enhance clarity and ease of use of this final version of the SCPI: *1*) the number of questions was reduced from 25 to 23; *2*) the 1–10 horizontal visual analog scale was changed to a 7-point Likert scale to reduce clustering of responses; *3*) individual questions were organized within their respective subscale; *4*) an eighth response option, "already doing", was added to the Preparedness subscale (scored as a 7); and *5*) a "not taking diabetes medications and/or insulins" option was added to four applicable questions.

In Part 1 of this study, participants with either type 1 or type 2 diabetes were recruited from the waiting rooms of seven LMC Diabetes & Endocrinology clinics in Ontario, Canada between October 2017 and April 2018. Any adult individual with type 1 or type 2 diabetes who could read English was eligible to participate. LMC clinics are

large, multidisciplinary, community-based, specialist-led clinics providing comprehensive adult diabetes care as part of the Canadian public health system. Participants completed the final form of the 23-item online questionnaire using a tablet (www.scpindex.com) with minimal assistance, and their time to completion was recorded. Each question contained a 7-point Likert scale, with radio buttons creating scoring between 1 and 7. The total score was reported as a simple mean out of 7, and each of the three subscales (Skills, Confidence, and Preparedness) was similarly reported as their respective average out of 7. After 1 week, participants were invited to again complete the questionnaire to assess test-retest reliability.

Demographic data such as age, sex, ethnicity, and education and diabetes data such as duration of diabetes, current therapies, clinic duration, and most recent HbA_{1c} laboratory results (within 3 months of their enrollment) were extracted from their records.

In Part 2 of this study, a smaller cohort of participants underwent a DSME program routinely provided to clinic patients who have shown a persistent degree of suboptimal glycemic control, defined as HbA_{1c} >8.0% (64 mmol/mol). Participants completed the SCPI at a baseline visit, and the individual baseline SCPI scores were used to guide the care paths that were then customized for that participant. The DSME program provided five to seven visits with a certified diabetes educator, in clinic and remotely, occurring every 2 weeks over 3 months, with a total program duration of up to 6 months. Participants completed the SCPI again at their final visits.

The coprimary outcomes of the study were to *1*) evaluate the internal consistency, reliability, and validity of the SCPI questions and *2*) evaluate the responsiveness of the tool to the change in HbA_{1c} after an intervention.

Sample size estimation for Part 1 assumed a population SD of 1.8 and a margin of error of 0.25 of the total score and, based on prior standards (32), led to a sample size requirement of 200 patients per cohort. For Part 2 of this study, 55 patients were required, assuming a correlation between change in SCPI total score and change in HbA_{1c} of $r = 0.37$, power of 0.80, and a two-sided α of 0.05. Data were analyzed separately for participants with type 1 and type 2 diabetes, and the subset of participants with type 2 diabetes using insulin were analyzed as a third cohort.

Internal consistency was determined using Cronbach α for each of the subscale scores as well as the total score. Construct validity of the scale was assessed by the correlations between the total scores and age, sex, diabetes duration, ethnicity, income, education level, insulin use, and baseline HbA_{1c}.

In assessments of validity, Spearman nonparametric correlation (R_s) was used for continuous variables, and Student *t* test and ANOVA were used for categorical variables. For test-retest reliability, R_s was applied. To compare the means of HbA_{1c} between two or three groups, Student *t* tests and ANOVA were performed. A value of $P < 0.05$ was considered statistically significant. All analyses were completed using R version 3.4 (https://www.r-project.org/about.html).

RESULTS

Baseline characteristics of the study participants are reported in Table 1. In Part 1, 423 individuals were enrolled. Eighteen of them had not completed the questionnaire correctly (scoring a 7 repeatedly) and were excluded, producing cohorts of 200 participants with type 1 diabetes and 205 with type 2 diabetes. Mean HbA_{1c} was (mean ± SD) 7.9 ± 1.3% (63 ± 14.2 mmol/mol) among participants with type 1 diabetes and 7.6 ± 1.3% (60 ± 14.2 mmol/mol) among participants with type 2 diabetes. Participants with type 1 diabetes were younger (41.9 ± 14.7 vs. 57.3 ± 11.5 years) and had a longer duration of diabetes (19.9 ± 13.0 vs. 10.5 ± 7.7 years) compared with those with type 2 diabetes. Participants were mostly Caucasian (type 1 diabetes 80% and type 2 diabetes 49.3%) and were otherwise representative of the ethnicities typical of an Ontario resident population. Among individuals with type 1 diabetes, 51% were using an insulin pump. People with type 2 diabetes were using a mean of 2.1 ± 1.2 noninsulin AHAs; of those using insulin, 54.1% were using basal insulin (± AHAs) and a further 41.2% were using a basal-bolus regimen. Among participants, 49.1% had attended or completed a postsecondary education program.

Reliability and Validity

As in prior validations, Cronbach α showed strong interclass correlation (ICC) for the 23-item scale (ICC 0.93) and for the individual subscales (ICC 0.84–0.88) (Table 2). Age, sex, ethnicity,

Table 1—Baseline participant characteristics in Part 1

	Type 1 diabetes	Type 2 diabetes using insulin	Type 2 diabetes
Number of patients, *n* (%)	200 (49.4%)	85 (41.5%)	205 (50.6%)
HbA_{1c} (%)	7.9 ± 1.3	7.8 ± 1.5	7.6 ± 1.3
HbA_{1c} (mmol/mol)	62.4 ± 14.4	61.5 ± 16.8	59.2 ± 14.6
Age (years)	41.9 ± 14.7	50.0 ± 15.0	49.7 ± 15.2
Male, *n* (%)	112 (56%)	53 (62.4%)	117 (57.1%)
Duration of diabetes (years)	19.9 ± 13.0	14.8 ± 11.8	10.5 ± 7.7
Ethnicity, *n* (%)			
African	1 (0.5%)	0 (0%)	7 (3.4%)
Caribbean	5 (3.5%)	2 (2.2%)	7 (3.4%)
Caucasian	160 (80%)	56 (62.2%)	101 (49.3%)
East Asian	9 (4.5%)	10 (11.1%)	22 (10.7%)
South Asian	13 (6.5%)	11 (12.2%)	37 (18.0%)
Other*/unspecified	12 (6%)	11 (12.2%)	31 (16.1%)
Education, *n* (%)			
University	71 (35.5%)	34 (40.0%)	69 (33.7%)
College	25 (12.5%)	13 (15.3%)	34 (16.6%)
Secondary	43 (21.5%)	14 (16.5%)	32 (15.6%)
Declined/unspecified	61 (30.5%)	24 (28.2%)	70 (34.1%)
Number of noninsulin AHA	0.1 ± 0.4	1.3 ± 1.3	2.1 ± 1.2
Using insulin, *n* (%)			
Basal only	1 (0.5%)	46 (54.1%)	46 (22.4%)
Basal and bolus	96 (48%)	35 (41.2%)	35 (17.1%)

Data are presented as mean ± SD unless otherwise indicated. *"Other" includes Arab, Oceania, Hispanic/Latino, and First Nations.

Table 2—Reliability and validity for total and subscale SCPI scores

	Statistic	Measure
Internal consistency		
Skills	0.88 (0.86–0.91); 9 items	Cronbach α (95% CI)
Confidence	0.87 (0.85–0.90); 7 items	Cronbach α (95% CI)
Preparedness	0.84 (0.81–0.87); 7 items	Cronbach α (95% CI)
Total	0.93 (0.92–0.94); 23 items	Cronbach α (95% CI)
Construct validity		
Age	$r = -0.03$, $P = 0.51$	R_s
Sex	$P = 0.12$	Student t test, P value
Ethnicity	F[5, 357] = 0.92; $P = 0.47$	ANOVA, F Test, df; P value
Education	F[4, 269] = 0.27; $P = 0.89$	ANOVA, F Test, df; P value
Income	F[4, 212] = 0.97; $P = 0.42$	ANOVA, F Test, df; P value

income, and education level were not associated with SCPI scores. Duration of diabetes was correlated with the SCPI score ($r = 0.12$, $P = 0.01$). Neither total score nor the subscale scores showed floor effects (>15% of patients with a score of 1) or ceiling effects (>15% of patients with a score of 7). Completion time was 4.9 ± 4.3 min and test-retest reliability was high at $r = 0.79$ ($n = 28$, $P < 0.001$).

Participants with type 1 diabetes had higher total SCPI scores than those with type 2 diabetes (6.0 ± 0.6 vs. 5.7 ± 0.8, $P < 0.0001$) and in most subscales. In both type 1 diabetes and type 2 diabetes cohorts, participants with HbA_{1c} <7.0% had significantly higher scores in total and subscales than those with HbA_{1c} >7.0% (Table 3). Insulin users also had significantly higher total and skills scores than noninsulin users (5.9 ± 0.7 vs. 5.7 ± 0.8, $P = 0.03$, and 6.0 ± 0.7 vs. 5.6 ± 1.0, $P = 0.001$, respectively).

The total SCPI score was negatively correlated with HbA_{1c}, and the correlation was significant for each cohort. The total score correlations with HbA_{1c} ranged from $r = -0.26$ ($P = 0.001$) and -0.30 ($P = 0.005$) among insulin users (type 1 diabetes and type 2 diabetes using insulin cohorts, respectively) to $r = -0.20$ ($P = 0.004$) in the entire type 2 diabetes cohort. Among the subscales, the total score was also negatively correlated with HbA_{1c}, reaching significance for Skills ($r = -0.18$, $P < 0.001$) and Confidence ($r = -0.22$, $P < 0.001$) but not for Preparedness ($r = -0.10$, $P = 0.06$).

HbA_{1c} tertiles were determined in each of the type 1 and type 2 diabetes cohorts. The emergent tertile cutoffs were precisely 7.0% (53 mmol/mol) and 8.0% (64 mmol/mol), aligning with clinically meaningful HbA_{1c} thresholds. With each diminishing HbA_{1c} tertile, the expected pattern of increasing mean SCPI score was seen (Supplementary Table 2).

Responsiveness

In Part 2, 60 patients were enrolled and 9 became lost to follow-up after the first or second visit, producing a cohort of 51 participants who underwent the DSME program (baseline characteristics in Supplementary Table 3), made up of 17 (33%) with type 1 diabetes and 34 (67%) with type 2 diabetes. These participants were older than the general cohort (53.9 ± 12.7 years), but with a similar duration of diabetes (15.3 ± 10.7 years), and, as expected based on their eligibility criteria, showed a higher mean HbA_{1c} of 9.3 ± 1.0% (78 ± 10.9 mmol/mol). Participants experienced a mean of 6.4 ± 0.6 education visits (4.3 ± 1.8 in clinic and 2.1 ± 1.8 remote) over a mean 3.4 ± 0.8 months, and 21 (41%) had a change in their diabetes therapy regimen. Their resulting HbA_{1c} was 8.2 ± 0.9% (66 ± 9.8 mmol/mol), representing a mean improvement of 1.2 ± 0.2% (13.1 ± 2.2 mmol/mol, $P < 0.0001$) (Fig. 1).

Each SCPI subscale score similarly improved from the first to the last visit, with the total score increasing significantly from 5.3 ± 1.0 to 5.9 ± 0.8, Skills subscore increasing from 5.1 ± 1.2 to 5.9 ± 0.8, Confidence from 5.1 ± 1.2 to 5.8 ± 1.0 (all $P < 0.001$), and Preparedness from 5.9 ± 1.0 to 6.2 ± 0.9 ($P = 0.01$) (Fig. 1). Among participants with a significant HbA_{1c} improvement (>0.5%) without a treatment change ($n = 22$), the HbA_{1c} improvement was negatively correlated with the SCPI score improvements but did not reach statistical significance (total SCPI score $r = -0.31$, $P = 0.17$).

CONCLUSIONS

The SCPI is a simple tool, based on the AADE7 Self-Care Behaviors, that meets ISOQOL standards for patient-reported outcomes research (23) and is easy for a patient to complete on a tablet (in ~5 min) and with minimal instruction. In large cohorts of individuals living with type 1 and type 2 diabetes, the SCPI showed a high degree of validity (both construct and convergent [26]), internal consistency, and test-retest reliability and with no influence from age, sex, ethnicity, income, or level of education. Questionnaire generalizability across varying levels of individual health literacy is a common concern (19), and SCPI scoring was not related to level of education, income, or ethnicity. Validity was also confirmed in the expected consistency with different type and duration of diabetes and in relation to levels of glycemia. Both linear correlations and tertile analyses showed the expected pattern of higher scores associated

Table 3—Mean SCPI scores by cohort

	Type 1 diabetes			Type 2 diabetes		
Scale	HbA_{1c} ≤7.0% ($n = 60$)	HbA_{1c} >7.0% ($n = 136$)	All ($n = 200$)	HbA_{1c} ≤7.0% ($n = 88$)	HbA_{1c} >7.0% ($n = 117$)	All ($n = 205$)
Skills	6.2 ± 0.6	6.0 ± 0.7*	6.1 ± 0.7	5.8 ± 0.9	5.6 ± 0.9	5.7 ± 0.9†
Confidence	5.9 ± 0.7	5.6 ± 0.8*	5.7 ± 0.8	5.7 ± 0.8	5.3 ± 1.0*	5.5 ± 0.9†
Preparedness	6.2 ± 0.8	6.1 ± 0.7	6.1 ± 0.8	6.1 ± 0.9	5.9 ± 0.8*	6.0 ± 0.9
Total score	6.1 ± 0.6	5.9 ± 0.6*	6.0 ± 0.6	5.9 ± 0.7	5.6 ± 0.8*	5.7 ± 0.8†

Data are presented as mean ± SD. *$P < 0.05$, comparison of scores between HbA_{1c} ≤7.0% (53 mmol/mol) and HbA_{1c} >7.0% (53 mmol/mol) within participants with type 1 and type 2 diabetes. †$P < 0.05$, comparison of scores between participants with type 1 and type 2 diabetes.

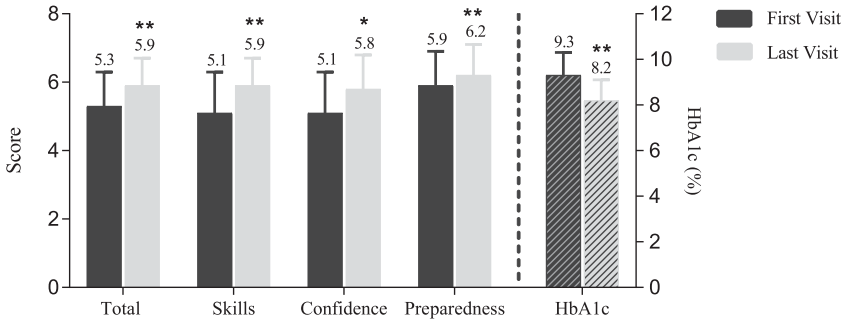

Figure 1—SCPI scores and HbA_{1c} before and after a DSME intervention. Data are presented as mean ± SD. Dark gray bar, first visit; light gray bar, last visit. *$P < 0.05$, compared with values in the first visit; **$P < 0.001$, compared with values in the first visit.

with better glycemic outcomes. The relationship to HbA_{1c} was consistent across the total SCPI score, Skills subscale, and Confidence subscale. The Preparedness subscale followed the same association trend but may represent future potential change, rather than the current HbA_{1c}.

Validity was further established in the responsiveness shown in a smaller cohort undergoing a typical 3-month DSME intervention, made up of a series of live coaching sessions to set individualized objectives and problem-based learning pathways. The use of the SCPI at baseline may have allowed for optimization of the DSME curriculum for each individual and possibly contributed to the HbA_{1c} improvement of 1.2 ± 0.2% (13.1 ± 2.2 mmol/mol) in this relatively brief period of time. The total and subscale scores each increased significantly after the intervention. In participants who showed a clinically meaningful HbA_{1c} improvement (>0.5% [5.5 mmol/mol]) that could be attributed to the DSME, the HbA_{1c} improvement was correlated with the SCPI score improvement but did not reach statistical significance.

Few of the tools that have been studied over the past two decades are in routine use in current DSME programs. Most were developed during a post-DCCT period but before the normalization of our current standards of glycemic control attainment and of individual precision for people living with diabetes (11,12,15,17,31). Innovations in diabetes therapies have also unintentionally commandeered large parts of the curriculum time, including basic skills in new injectable therapies and in self-assessment, such as "carbohydrate counting" and support apps. Many tools have been developed to specifically measure the impact of a particular educational intervention and were not a priori designed to measure effect on disease outcomes (33). Many are too lengthy to use in clinical practice (12,13) and too slow to generate reports, and most were only validated in paper format.

The limitations of this study include the setting in the specialist clinic, and the results may not generalize to patients within primary care. Although participants were recruited sequentially in the course of routine care, they may not necessarily represent the entire population under specialist care. The Preparedness subscale did not significantly correlate with baseline glycemia and may better reflect the potential for future behavioral change. Using the tool on an electronic tablet may pose some difficulty for some patients where tablet literacy may be a limitation or some clinics where a tablet or computer may not be accessible. We had targeted an eighth to ninth grade reading level in order to express nuances between questions, but we recognize that the sixth grade level is a generally recommended target for educational materials. Finally, of the seven behaviors identified in the AADE7, "healthy coping" was assessed only through questions probing stress management and may not be fully represented.

The SCPI was developed in a contemporary diabetes care context, based on extensive experience with refractory patient cohorts, and specifically designed to provide insight into specific behaviors in an easy-to-read and easy-to-administer approach. The SCPI is also the first "all in one" scale to evaluate three key dimensions simultaneously, variously described as behavior or knowledge, self-efficacy or confidence, and coherence or activation or preparedness. The real-time scoring and the immediate feedback into the AADE7 behavior gaps encourage the individualization of a planned DSME and should provide significant value as a routine component of the diabetes clinic visit.

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