

# Content Validity of the Current Health Satisfaction Questionnaire (CHES-Q) Among People Living With Type 2 Diabetes Mellitus and Comorbid Chronic Kidney Disease

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## INTRODUCTION

- Health satisfaction, defined as the level of contentment an individual feels regarding various aspects of physical or emotional health, may predict adherence to type 2 diabetes mellitus (T2DM) self-care behaviours<sup>1</sup>
- Self-care behaviours, such as maintaining a healthy diet and exercising regularly, are essential for optimal T2DM management and the prevention of microvascular and macrovascular complications<sup>2</sup>
- The Current Health Satisfaction Questionnaire (CHES-Q) is a 14-item instrument developed to assess health satisfaction and knowledge among people living with T2DM<sup>1</sup> (Figure 1); higher scores indicate greater levels of satisfaction
  - The CHES-Q has been demonstrated to be easy to understand and to capture health-related concepts that are meaningful and relevant to people with T2DM<sup>1</sup>
  - In a Phase 3 trial that evaluated canagliflozin (CANA), a sodium glucose co-transporter 2 (SGLT2) inhibitor, versus sitagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, in patients with T2DM on background metformin plus sulphonylurea, the CHES-Q was implemented to assess the impact of weight loss on physical and emotional health satisfaction<sup>3</sup>
    - Weight loss of an amount demonstrated in clinical trials of CANA (~2%-5% body weight reduction)<sup>4</sup> was associated with improvements in satisfaction with physical and emotional health, as measured by the CHES-Q<sup>3</sup>
  - In clinical studies, CANA has demonstrated improvement in glycaemic control and reductions in body weight and blood pressure in patients with T2DM and chronic kidney disease (CKD)<sup>5,6</sup>
- Renal impairment is a common comorbidity of T2DM<sup>7</sup>; however, there is no existing patient-reported outcome (PRO) instrument specifically designed for individuals across varying levels of renal impairment. Therefore, we explored the content validity of the CHES-Q in a sample of people with T2DM and CKD as a foundation for establishing the "fit for purpose" of the CHES-Q in this expanded population

## OBJECTIVE

- To better understand the experiences of people with T2DM and comorbid CKD and their interpretation of the CHES-Q items

## METHODS

- In-depth interviews were conducted with 20 adults with T2DM and CKD to explore the content, clarity, and relevance of the CHES-Q
- Interviews were conducted in January and February 2015 at 3 qualitative research facilities in the United States (Raleigh, North Carolina [n = 8]; Dallas, Texas [n = 6]; and St. Louis, Missouri [n = 6])
- Interview participants were recruited by the qualitative research firms and/or referred by clinicians
- Inclusion criteria
  - Males or females aged ≥30 years
  - Physician-confirmed diagnosis of T2DM
  - Physician-verified (preferred) or self-report of a clinician-confirmed diagnosis of CKD of any stage (Stages 1-5)
  - Documented estimated glomerular filtration rate (eGFR) within the past 6 months
    - Due to difficulties in obtaining a detailed physician-completed verification form, the inclusion criteria were relaxed after recruitment was underway; thus, eGFR measurements were not available for all participants
  - Willing and able to participate in a 1-hour, in-person interview
  - Able to read, speak, and understand English
- Each interview began with a brief discussion about the participant's experiences and the impact of T2DM and CKD, including questions about disease duration and symptoms at the time of diagnosis of each condition, complications of T2DM, and any impact of T2DM and CKD since diagnosis and during the past year
- Participants were asked to "think out loud" about their process for answering each item and to identify words, terms, or concepts that were unclear
- The discussion was followed by cognitive debriefing of the CHES-Q, during which participants were asked to provide feedback on the instructions, item wording, response options, and recall period of the instrument
- Although participants were not specifically asked to answer each item of the CHES-Q during the debriefing exercise, scores were calculated for those who did provide item responses
- Follow-up questions or probes were used to obtain additional feedback on the measure and to assess whether participants felt there were any important concepts missing

## RESULTS

### Participants

- Characteristics of the interview participants are summarised in **Table 1**
- The majority of participants (n = 14; 70%) had microvascular complications of T2DM in addition to CKD, including eye problems (retinopathy, glaucoma, or impaired vision), neuropathy, and erectile dysfunction
- Participants had a variety of comorbidities, including hypertension (n = 8), hyperlipidaemia (n = 3), and cardiovascular disease (n = 4); 7 participants (35%) did not report any comorbid conditions other than T2DM and CKD
- The majority of participants (n = 16; 80%) reported having no symptoms that they specifically attributed to CKD before or after being diagnosed

### General Impression of the CHES-Q

- All participants found the instructions and most items clear and easy to understand
- During the first set of 8 interviews, 4 participants had difficulty reading the CHES-Q because of its small font size; after the font size was increased following the first set of interviews, no readability issues were reported in subsequent interviews
- Participants noted that most items were important to understanding the health of an individual with T2DM; items that did not specifically refer to T2DM or blood sugar were correctly interpreted by participants as relating to their health in general
- The concepts identified as being most important in understanding the current health of an individual with diabetes are shown in **Figure 2**; few participants singled out any concept as unimportant or less important than the others
- Few concepts were reported as missing from the CHES-Q, and these are shown in **Figure 3**

### CHES-Q Responses

- Not surprisingly, given the small sample of participants, mean scores by stage of CKD did not vary and there was no pattern or trend in CHES-Q responses
- As seen with other PRO instruments using the reference period of "current," cognitive debriefing results for individual CHES-Q items showed great variability across participants and across items in the interpretation of the term "current," which is used in each CHES-Q item
  - For some items, "current" meant today or at this moment (eg, current weight, mood, blood pressure, blood sugar)
  - For other items, "current" meant satisfaction with that aspect for as long as it had been approximately the same (eg, current ability to sleep through the night meant several years for 1 participant)
  - Despite this variability, all participants found the items clear and easy to answer
- Half of the participants (n = 10) thought that the item response choices were clear, distinct, and appropriate. Several participants expressed a preference for fewer response options
- Although all the response choices were used by at least 1 participant, responses were generally clustered at the high end of the scale (ranging from "somewhat agree" to "strongly agree") for approximately half of the items (mainly items 6-11), which is indicative of a potential ceiling effect
  - However, given the small sample size, these results were not sufficient to warrant modification of the items

**Figure 1. CHES-Q<sup>1</sup> English version.\* Please circle one number for each question to indicate how much you agree or disagree with each of the following statements about your current health and knowledge of diabetes.**

	Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Agree	Strongly agree
1. I am satisfied with my <u>current</u> body weight.	1	2	3	4	5	6	7
2. I am satisfied with my <u>current</u> level of energy.	1	2	3	4	5	6	7
3. I am satisfied with my <u>current</u> appetite (my overall desire to eat).	1	2	3	4	5	6	7
4. I am satisfied with my <u>current</u> ability to sleep through the night.	1	2	3	4	5	6	7
5. I am satisfied with my <u>current</u> ability to do physical activities such as walk or climb stairs.	1	2	3	4	5	6	7
6. I am satisfied with my <u>current</u> ability to have social interactions with family and friends.	1	2	3	4	5	6	7
7. I am satisfied with my <u>current</u> attitude toward diabetes.	1	2	3	4	5	6	7
8. I am satisfied with my <u>current</u> mood.	1	2	3	4	5	6	7
9. I know my <u>current</u> blood sugar levels.	1	2	3	4	5	6	7
10. I am satisfied with my <u>current</u> blood sugar levels.	1	2	3	4	5	6	7
11. I know my <u>current</u> blood pressure.	1	2	3	4	5	6	7
12. I am satisfied with my <u>current</u> blood pressure.	1	2	3	4	5	6	7
13. Overall, I am satisfied with my <u>current</u> health.	1	2	3	4	5	6	7
14. My current level of knowledge about diabetes is...		1	2	3	4	5	
		Not at all knowledgeable	Somewhat knowledgeable	Knowledgeable	Very knowledgeable	Extremely knowledgeable	

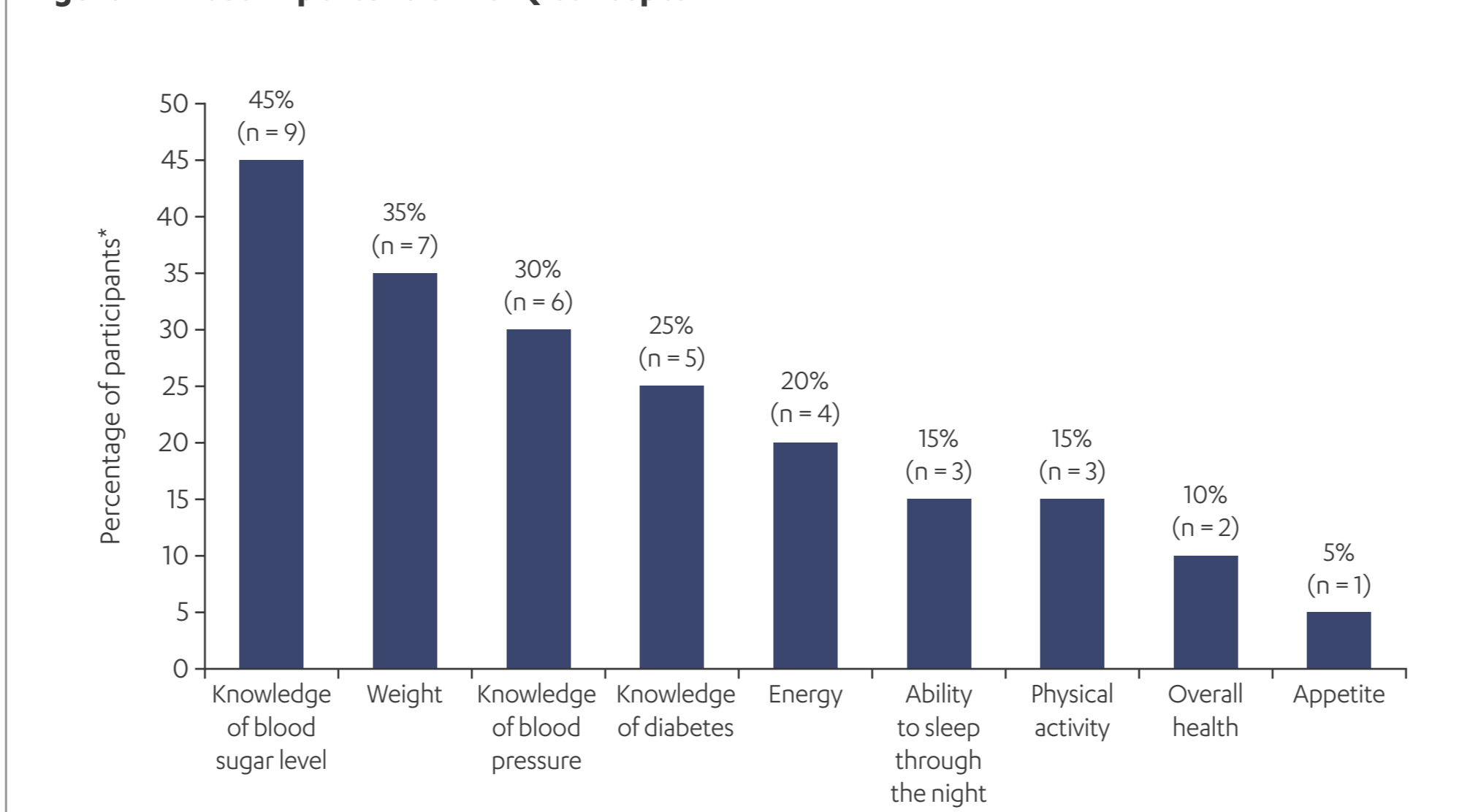
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**Table 1. Characteristics of the Interview Participants by CKD Stage (N = 20)\***

Characteristic	CKD Stage 1 (n = 2)	CKD Stage 3 <sup>†</sup> (n = 3)	CKD Stage 4 (n = 3)	CKD Stage 5 (n = 11)	Other* (n = 1)	Total (N = 20)
Age, mean (range), y	69.0 (64-74)	51.7 (43-56)	63.7 (54-69)	57.8 (45-71)	60.0 (-)	59.0 (42-74)
Sex, n (%)						
Male	1 (5)	1 (5)	3 (15)	4 (20)	1 (5)	10 (50)
Female	1 (5)	2 (10)	0	7 (35)	-	10 (50)
Race, n (%)						
White	2 (10)	1 (5)	2 (10)	4 (20)	-	9 (45)
African American	0	1 (5)	0	7 (35)	-	8 (40)
Other	0	1 (5)	1 (5)	0	1 (5)	3 (15)
Ethnicity, n (%)						
Hispanic	0	1 (5)	1 (5)	0	1 (5)	3 (15)
Not Hispanic	2 (10)	2 (10)	2 (10)	11 (55)	-	17 (85)
Education, n (%)						
High school/GED	0	1 (5)	0	3 (15)	-	5 (25)
Some college	2 (10)	1 (5)	2 (10)	4 (20)	-	8 (40)
College degree	0	0	1 (5)	3 (15)	1 (5)	5 (25)
Professional/advanced	0	1 (5)	0	1 (5)	-	2 (10)
Time since T2DM diagnosis, n (%)						
5-10 y	0	1 (5)	0	1 (5)	-	2 (10)
11-15 y	0	1 (5)	2 (10)	2 (10)	-	5 (25)
>15 y	2 (10)	1 (5)	1 (5)	8 (40)	1 (5)	13 (65)
Kidney transplant, n (%)						
Yes	0	1 (5)	0	0	1 (5)	2 (10)
No	2 (10)	2 (10)	3 (15)	11 (55)	-	18 (90)
On dialysis, n (%)						
Yes	0	0	0	9 (45)	-	9 (45)
No	2 (10)	3 (15)	3 (15)	2 (10)	1 (5)	11 (55)
Treatment for T2DM, n (%) <sup>‡</sup>						
Insulin	0	3 (15)	1 (5)	8 (40)	1 (5)	13 (65)
Liraglutide	1 (5)	0	0	0	-	1 (5)
Albiglutide	0	0	1 (5)	0	-	1 (5)
Glipizide	0	1 (5)	0	1 (5)	-	2 (10)
Sitagliptin	0	0	1 (5)	0	-	1 (5)
Pioglitazone	0	1 (5)	0	0	-	1 (5)
Metformin	1 (5)	0	1 (5)	0	-	2 (10)
Diet and exercise	0	0	0	2 (10)	-	2 (10)
CHES-Q scores <sup>§</sup>						
Physical health satisfaction, n	2	2	3	10	1	18
Mean score (SD)	25.0 (11.8)	16.7 (23.6)	66.7 (16.7)	30.0 (24.6)	0 (-)	32.4 (26.5)
Emotional health satisfaction, n	2	3	3	11	1	20
Mean score (SD)	66.7 (47.1)	33.3 (28.9)	100.0 (0.0)	81.8 (27.3)	33.0 (-)	73.3 (33.1)
Blood sugar satisfaction, n <sup>¶</sup>	2	3	3	9	1	18
Mean score (SD)	2.5 (0.7)	3.0 (1.7)	6.7 (0.6)	5.4 (1.6)	5.0 (-)	4.9 (1.9)
Blood pressure satisfaction, n <sup>¶</sup>	1	2	3	8	0	14
Mean score (SD)	6.0 (-)	6.0 (1.4)	5.7 (0.6)	5.4 (2.1)	-	5.6 (1.6)
Knowledge of diabetes, n	2	3	3	11	1	20
Mean score (SD)	4.0 (0)	3.7 (1.2)	4.0 (1.0)	3.6 (0.8)	2.0 (-)	3.6 (0.9)

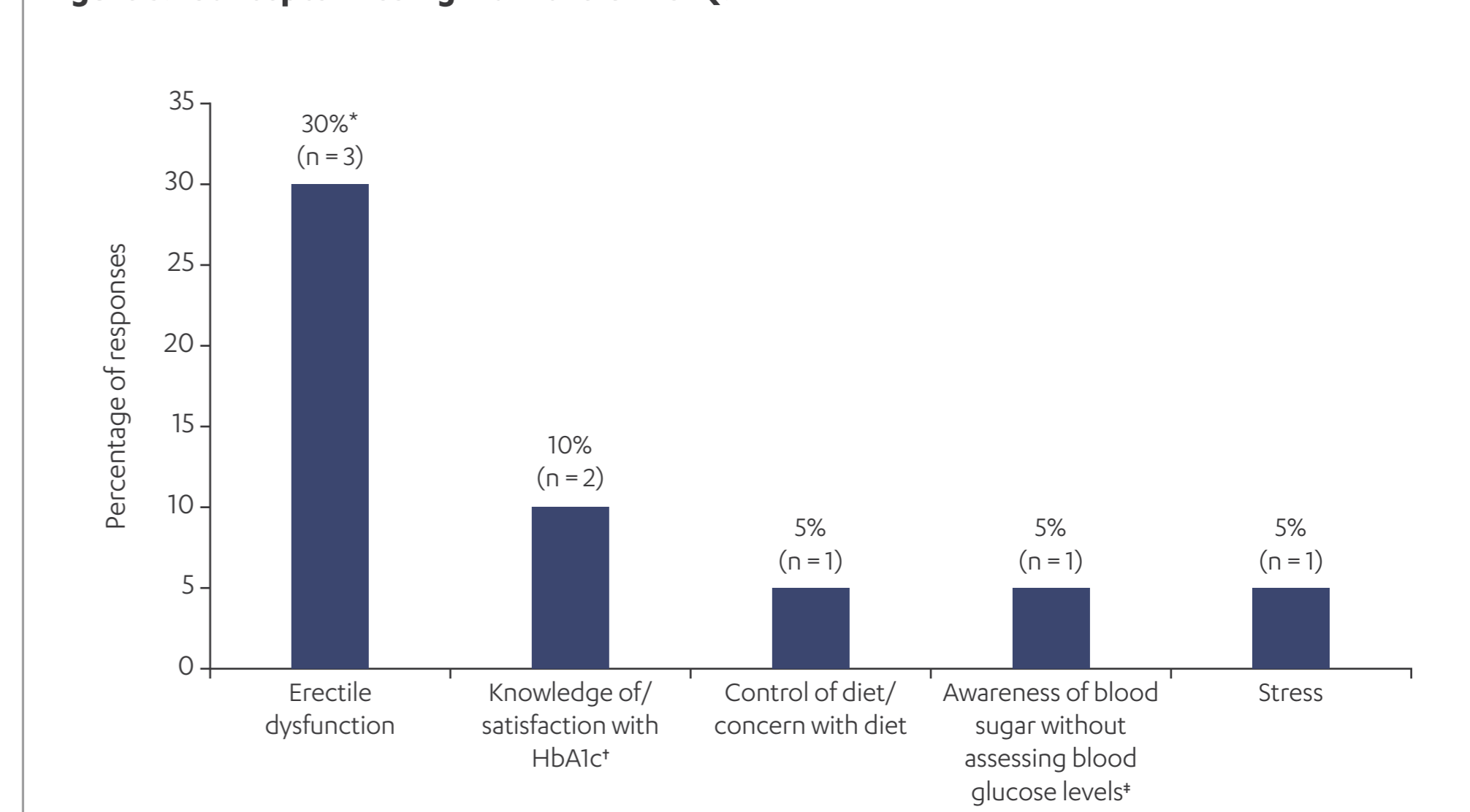
GED, general education development; SD, standard deviation.  
<sup>\*</sup>Percentages are based on a denominator of the entire sample (N = 20).  
<sup>†</sup>No participants with CKD Stage 2 were recruited. Three people with CKD Stage 3 were recruited: 1 had Stage 3a and 1 had Stage 3b; the remaining participant did not have a physician verification form, so Stage 3a or 3b could not be determined.  
<sup>‡</sup>One participant who had received a kidney transplant no longer had CKD or a CKD stage (confirmed by the participant's physician).  
<sup>§</sup>Some participants reported taking >1 medication to control their T2DM.  
<sup>¶</sup>Participants were not specifically asked to answer each item of the CHES-Q during the debriefing exercise. Scores were calculated for those who did provide item responses.  
<sup>||</sup>Scores were calculated only when knowledge was confirmed with a response of "agree" or "strongly agree" to the prior related item.

**Figure 2. Most important CHES-Q concepts.**



\*Percentage of participants who selected each item when asked, "Which of these items do you feel are most important in understanding the current health of someone with diabetes?"; multiple responses were recorded.

**Figure 3. Concepts missing from the CHES-Q.**



\*Male participants only (n = 10).  
<sup>\*</sup>Rather than or in addition to blood glucose level.  
<sup>\*</sup>Based on symptoms and "being in tune with your body."

## DISCUSSION

- Results from this study suggest that the use of the CHES-Q to assess health satisfaction and knowledge among people with T2DM and comorbid CKD may be appropriate**
- Participants with T2DM and CKD generally found the CHES-Q items to be relevant and easy to understand**
- Participants noted that most CHES-Q items were important to understanding the health satisfaction of an individual with T2DM; items considered particularly important were knowledge of blood sugar level, satisfaction with weight, knowledge of blood pressure, and knowledge of diabetes**
- Given the small sample size in the current study and challenges of recruiting patients with early stage CKD, future studies are needed to determine whether the CHES-Q can distinguish between CKD stages**
- Examination of sensitivity to changes over time will require additional studies**

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