

Development of the TBQ+D: A Novel Patient-Reported Measure of The Burden of Digital Care

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Background: Patients with diabetes manage complex treatment regimens that include the use of digital medicine tools. Existing instruments do not explicitly capture treatment burden, i.e., workload and its effect on patient's quality of life, from using digital medicine tools.

Objective: To engage patients and clinical experts in adapting the Treatment Burden Questionnaire (TBQ) to capture digital treatment burden. The adapted instrument underwent cognitive testing and refinements to ensure it captures the burden of using digital medicine tools in diabetes self-management.

Methods: This two-phase study was conducted with adults with diabetes at the Division of Endocrinology at Mayo Clinic (Rochester, MN). First, we mapped themes from prior concept elicitation interviews to existing TBQ items to identify content gaps related to digital burden. Based on these gaps, the study team and expert panel generated new items and adapted existing ones to better reflect the workload and burdens from using digital medicine tools. The resulting instrument underwent three rounds of cognitive testing with adult patients living with diabetes, using a think-aloud protocol to assess clarity, relevance, and comprehensiveness. Results of cognitive testing informed iterative refinements across three rounds of interviews, leading to improved clarity, reduced redundancy, and improved relevance of items.

Results: The final TBQ+D retained the original 15-item TBQ structure, added 8 new items, and modified 8 extant ones to capture burden of digital care (e.g., syncing issues, discomfort from sensors, and device malfunctions). Cognitive testing demonstrated strong content relevance and patient comprehension.

Conclusion: The TBQ+D can measure digital treatment burden in patients with diabetes. Limitations include a relatively homogeneous sample drawn from a single center. Next steps include field testing for validation across diverse populations and settings.

Keywords: treatment burden questionnaire, burden of digital care, diabetes mellitus, self-management, patient-reported outcome measures, cognitive interviewing

Background

Chronic conditions, such as diabetes, affect over 100 million adults in the United States,¹ placing a significant workload on patients to access care, follow treatment plans, and engage in daily self-management.^{2–6} For patients living with diabetes, this often includes monitoring blood glucose, making self-management decisions, implementing insulin dosing, and managing food choices and exercise.^{7–10} This cumulative workload, and its impact on a patient's quality of life is known as treatment burden.^{7,11–14} Higher treatment burden is linked with poorer health outcomes, including reduced adherence to care plans and increased hospitalization rates.^{7,15}

In response to these challenges, digital medicine tools and applications that aim at supporting self-management—such as continuous glucose monitors (CGMs), insulin pumps, patient portals, mobile apps, and telemedicine—have been increasingly integrated into diabetes care.^{16–20} These offer potential benefits by automatic or supporting self-management tasks.^{17,19–23} However, they can also introduce new work and source of strain, including technical malfunction, usability issues, and information overload, particularly those less familiar with or with limited access to digital technology.^{24,25} In our prior work patients describe how digital tools sometimes complicated rather than eased the workload of managing chronic illness.²⁶

Despite this growing digital landscape, existing instruments that assess treatment burden such as the Treatment Burden Questionnaire (TBQ) and Patient Experience with Treatment and Self-management (PETS) do not capture the burden associated with digital tools.^{5,13,15,24,27} This gap hinders our ability to understand and address the challenges patients face by using digital medicine tools.²⁶

To fill this gap and capture the burden of using digital medicine tools, the Treatment Burden Questionnaire Plus Digital (TBQ+D) was developed to capture the burden of treatment in patients living with diabetes, including the burden of digital medicine tools.

Methods

The study builds on previously reported concept elicitation interviews of patient work and experience of using digital tools.²⁶ This report includes two phases (Figure 1): (1) mapping concept elicitation themes to the existing TBQ items and generating new or modified items and (2) cognitive testing and refinement to address gaps.

Participants

For both of the phases, adult patients aged 18 years or older with a diagnosis of type 1 or type 2 diabetes and attending the diabetes clinic in the Division of Endocrinology at Mayo Clinic (Rochester, Minnesota) were eligible to participate if they used at least one digital medicine tool for diabetes management (eg glucometer, insulin smartpens, pumps, etc.), were proficient in English, and were able to complete informed consent (ie, had no major functional impairment). Patients whose caregivers were the primary users of digital tools or who had significant cognitive or sensory impairments were excluded.

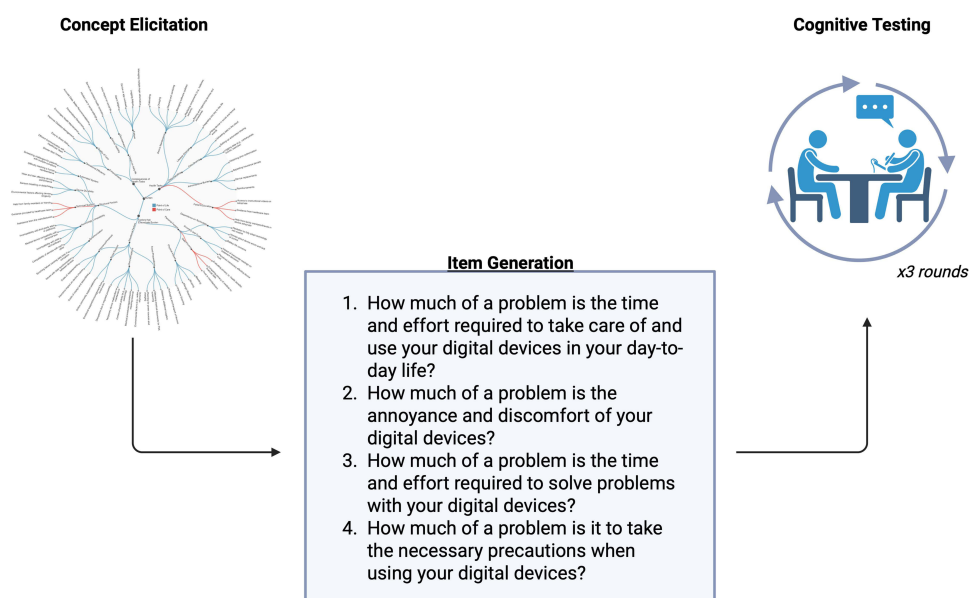


Figure 1 The process used to develop the Treatment Burden Questionnaire + Digital (TBQ+D). Bold indicates the three main phases: Concept Elicitation, Item Generation, and Cognitive Testing.

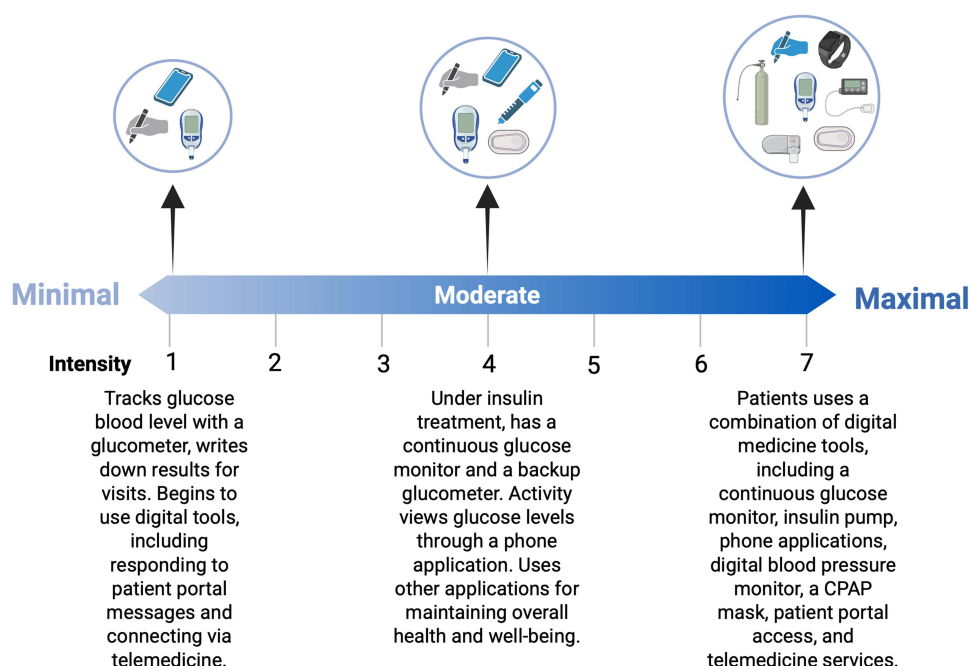


Figure 2 Digital Medicine Tools Intensity Scale.

Eligible patients were identified from the daily appointment calendar and approached in-person by study staff. Recruitment aimed to maximize diversity in diabetes type (type 1 or type 2) and intensity of digital tool use which was measured using the Digital Medicine Tools Intensity Scale—a 7-point scale ranging from “none” to “maximal” (Figure 2).²⁶

Item Generation

To guide item generation, we conducted a structured mapping exercise linking qualitative data from the concept elicitation study²⁶ to items in the original TBQ (Table 1). Using content analysis, two team members reviewed patient responses to each TBQ item and coded themes that reflected how digital tools impacted the same burden domains. When novel burden domains emerged that were not addressed by existing TBQ items, new items were generated guided by the original item stems and adapted to reflect the digital context. A multidisciplinary expert panel reviewed all proposed additions and modifications to ensure conceptual clarity and relevance prior to cognitive testing.

Cognitive Testing

Once the initial draft of the TBQ+D was complete, a new sample of patients was recruited to pre-test the TBQ+D over three rounds of cognitive interviews, each involving up to 10 participants. Participants completed the TBQ+D during in-person private sessions using a think-aloud protocol by the same trained researcher (M.A.Z). As they responded to each item, participants verbalized their thought processes, interpretations, and any confusion they experienced. This approach allowed researchers to assess the clarity, relevance, and wording of the questionnaire items. Participants were asked about difficulties in understanding any items, suggestions for improving item wording or content, and whether any aspects of their digital tool use experience were not captured by the questionnaire.

Data Handling

Survey responses, demographic, and clinical data were managed using REDCap electronic data capture tools hosted at Mayo Clinic (UL1TR002377).

Table 1 Mapping Burden of Digital Tool Themes to TBQ+D Items

Theme	Examples	Corresponding TBQ+D Item	Item Type
Physical Impact	Discomfort due to the size, shape, or fit of devices (eg, insulin pumps or continuous glucose monitoring systems), including pain, bruising, scarring, sleep disruption, or device disconnection.	"The size, shape, or fit of your digital health tools..."	Adapted
Dependence on Technology	Struggles remembering to use or interact with tools; feeling burdened by constant reminders of illness; discomfort with automatic control of care by devices.	"The number of times you interact." "The need for my digital health tools reminds me." "Giving control of your health to digital devices."	Adapted + New
Technical & Maintenance Burden	Challenges with charging, syncing, updating, managing alarms, and general upkeep.	"The effort you make to remember to manage your digital health tools..." "Self-monitoring: frequency..."	Adapted
Precaution & Travel Planning	Need for planning around tool use while traveling; avoiding certain activities; preparing backups (eg, swimming, flying, etc.).	"The necessary precautions when using your digital health tools..."	Adapted
Scheduling & Appointment Burden	Frustrations with scheduling medical visits via portals; difficulty accessing telehealth; preference for human interaction.	"Doctor visits and other appointments using digital health tools..."	Adapted
Communication with Providers	Delayed responses from portals; feeling unheard or having impersonal interactions during telehealth.	"The difficulties you could have in your relationships with healthcare providers while using digital health tools..."	Adapted
Administrative Complexity	Trouble navigating automated systems or replacing devices; confusion with system interfaces.	"The administrative burden related to your digital tools..."	Adapted
Financial Burden	High costs, insurance issues, and maintenance expenses of digital tools.	"The financial burden associated with your digital health tools..."	Adapted
Diet & Nutrition Tracking	Burden of logging meals or dietary info into apps.	"The burden related to dietary changes (eg, using applications to track diet)..."	Adapted
Physical Activity Tracking	Mixed experiences with tracking steps, workouts, etc.; some find it useful; others find it frustrating.	"The burden related to doctors' recommendations to practice or track physical activity using digital tools..."	Adapted
Social Impact	Needing help from others, feeling judged in public, or experiencing discomfort with alarms or injections in social settings.	"How do your digital health tools impact your relationships..." "The burden related to using your digital health tools discreetly in social/public settings."	Adapted + New
Privacy & Security Concerns	Worries about who sees their health data; concerns about sharing information with insurance or through portals.	"Your concerns about the privacy and security of your health information when using digital health tools."	New
Device Malfunction & Troubleshooting	Frustration due to software bugs, syncing errors, sensor detachment, or unclear troubleshooting steps.	"The challenges you face in troubleshooting technical issues with your digital health tools."	New

Data Analysis

As previously published, themes from the concept elicitation phase were derived from patient interviews exploring the work and experience of using digital medicine tools.²⁶ In the current study, two members of the research team reviewed these published themes and mapped them to items from the TBQ to evaluate item coverage and identify content gaps. When burden domains related to digital care—such as syncing errors, device alarms, technical malfunctions, or data management—were not adequately addressed by existing TBQ items, new items were generated using patient language and contextual detail.

For the cognitive testing phase, data from the think-aloud interviews were analyzed for patient interpretations of specific questions and overall survey clarity, applicability, and completeness. Notes and transcripts were reviewed after

each round to identify issues with item interpretation, clarity, or relevance. Revisions were made iteratively following each round, and refinement continued until no new changes were suggested, indicating saturation.

Ethical Consideration

This study was conducted in accordance with the Declaration of Helsinki and was approved by the Mayo Clinic Institutional Review Board (IRB Number 23–007631). Before any study procedures, each participant gave written informed consent.

Results

Item Generation

Themes informing item development were derived from a previously published concept elicitation study.²⁶ In that work, patients described the effort, complexity, and consequences of using digital tools for self-management, identifying sources of burden such as syncing failures, technical malfunctions, device-related discomfort, and frequent alerts.

For example, the TBQ item on “pain or discomfort from device” was expanded to include discomfort specific to sensor insertions, allergic reactions to adhesives, and scarring from continuous glucose monitors. Other examples, such as device malfunctions, syncing errors, and disruptions from frequent alarms, led to the generation of new items.

Informed by these themes, eight new items were developed, and several original TBQ items were refined to incorporate digital-specific examples (eg, discomfort from sensors or issues with online scheduling). [Table 1](#) presents a theme-to-item mapping that illustrates how patient feedback guided the adaptation process.

Cognitive Testing

Between April and May 2024, 24 eligible patients were approached to participate in cognitive testing, with 20 consenting (median age: 57 years, IQR: 36–67; 60% female; 40% with type 2 diabetes) ([Table 2](#)). Four patients declined due to time constraints. Participants represented a range of digital medicine tool use intensities, with 8 (40%) categorized as maximal-intensity users.

The TBQ+D was refined across three rounds of cognitive interviews with up to 10 participants per round. Revisions after each round are summarized in [Figure 3](#). Refinements focused on improving clarity, resolving redundancy, and enhancing item relevance. Revisions were completed when no additional changes were suggested, indicating saturation. [Table 3](#) presents the final version of the TBQ+D.

Discussion

We adapted the TBQ to capture the workload of using digital medicine tools and its negative impact on quality of life. The resulting instrument, TBQ+D, is a brief, self-reported measure of the overall burden of treatment inclusive of accessing and using digital medicine tools. Our findings demonstrate that digital burden is a distinct and meaningful component of treatment workload. By incorporating patient input throughout development, this work not only introduces a new tool to quantify digital burden in future research but also offers a patient-informed model for adapting existing measures to reflect modern care contexts.

Comparison with Prior Research

Existing research has highlighted the potential for digital medicine tools to add to patients’ workload, particularly when these tools are poorly integrated or difficult to use.^{17,28–31} Our previously published work confirmed that digital self-management technologies can introduce unique forms of digital treatment burden, including device malfunctions, alert fatigue, data synchronization issues, and emotional distress.²⁶

Despite growing recognition of this burden, no existing patient-reported instruments systematically capture the digital-specific components of treatment burden for patients with diabetes or one or more chronic conditions.

Table 2 Patient Characteristics

Patient Characteristics	Total (N=20)
Age at enrollment, Median (IQR)	57 (36, 67)
Gender, n	
Female	12
Male	8
Race, n	
White	19
Black or African American	1
Hispanic or Latino ethnicity, n	1
Body Mass Index, Median (IQR)	31 (25, 35)
Diabetes type, n	
Type 1	12
Type 2	8
Treatment, n	
Diet and activity	20
Medications, not insulin	6
Insulin, not intensive	5
Once-daily insulin alone	3
Once-daily insulin plus fast-acting corrections	2
Insulin, intensive	16
Basal-bolus insulin	7
Continuous insulin infusion (pump)	9
HbA _{1c} levels, Median (IQR)	7.4 (6.5, 8.2)
Hypoglycemia documented in past 6 months, n	
No	4
Not severe	15
Severe (requiring third-party assistance)	1
Health insurance, n	
Public (Medicare, Medicaid)	9
Private	11
Intensity of digital use for self-management, n	
Minimal (1)	3
Low (2,3)	2
Moderate (4,5)	7
Maximal (6,7)	8
Maximum academic level, n	
11th grade	1
Some college, no degree	1
Associate degree	3
Bachelor's degree	10
Master's degree	4
Professional school degree	1
Subjective social status*, n	
High	11
Low	9

Notes: *Subjective social status was measured using the MacArthur Scale of Subjective Social Status, a 10-rung ladder scored; respondents placing themselves on the top half of the ladder were classified as "high" status and those on the bottom half as "low" status.⁵

Abbreviations: IQR, interquartile range; HbA_{1c}, hemoglobin A_{1c}.

Measures like the TBQ and PETS offer valuable insights into treatment burden but do not explicitly capture digital burden. This study addresses that gap by adapting the TBQ to include the burden of using digital tools directly informed by patient experiences.

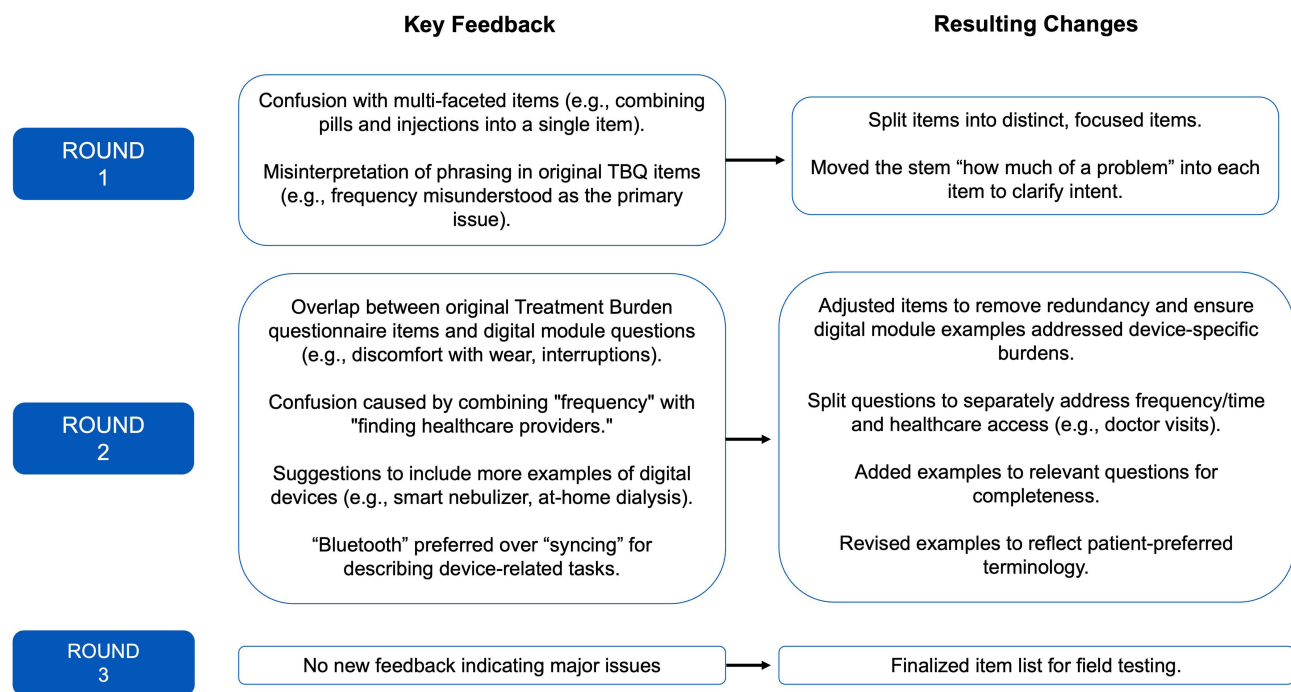


Figure 3 Summary of item revisions for the Treatment Burden Questionnaire + Digital (TBQ+D) across cognitive testing rounds.

Implications for Clinical Practice

The development of the TBQ+D has two important implications for clinical practice. First, it offers a patient-informed instrument specifically designed to capture digital treatment burden among people with diabetes and, possibly, other chronic conditions—an increasingly important issue as chronic disease management becomes more reliant on digital

Table 3 Finalized Items of the TBQ+D

Item No.	Item
1	How much of a problem is the taste, shape, or size of your pills?
2	How much of a problem are the annoyances caused by your injections (For example: bleeding, bruising, or scarring)?
3	How much of a problem is the number of times that you should take your medication daily?
4	How much of a problem are the efforts you make to help you remember to take your medications (For example: managing your treatment when away from home, preparing pillboxes, or setting reminders on your phone)?
5	How much of a problem is it to take the necessary precautions when taking your medication (For example: taking your medication at specific times of the day or meal or being unable to do certain things after taking medications such as driving or lying down)?
6	How much of a problem is it to arrange medical appointments (finding and scheduling doctor visits, telehealth visits, lab tests, and other exams) and to reorganize your schedule around these appointments (For example: coordinating fasting blood draws)?
7	How much of a problem is it to attend doctor's visits and other office visits: given their frequency and time spent participating in these visits?
8	How much of a problem is it to complete lab tests and other exams: given their frequency, time spent and associated nuisances or inconveniences (For example: getting your blood drawn or checking your lab results on the patient portal)?
9	How much of a problem are the difficulties you have in your relationships with healthcare professionals (For example: feeling not listened to enough, not taken seriously, or feeling uneasy or disconnected during telehealth visits)?

(Continued)

Table 3 (Continued).

Item No.	Item
10	How much of a problem is the time and effort required for self-monitoring: given their frequency, time spent and associated nuisances or inconveniences (For example: taking your blood pressure or keeping diary for your diet)?
11	How much of a problem is the administrative burden related to healthcare (For example: managing account details and passwords, and filling out paperwork or online forms for prior authorizations, reimbursements, and device orders or replacements)?
12	The administrative burden related to healthcare (For example: keeping track of account details and passwords, filling out paperwork/online forms or making calls to arrange for hospitalizations, prior authorizations, reimbursements, social services, or device orders/replacements)?
13	How much of a problem is the financial burden associated with your healthcare (For example: paying for treatments or providers not covered by insurance or out-of-pocket expenses like the cost of devices or device replacements)?
14	How much of a problem is it to make changes in eating and other habits (For example: avoiding certain foods or alcohol, having to quit smoking.)?
15	How much of a problem is it to follow doctors' recommendations to practice physical activity (For example: walking, jogging, swimming...)?
16	How much of a problem is how your healthcare affects your relationships with others (For example: Having to rely on family and friends for assistance or needing to educate them about your condition)?
17	How much of a problem is it to manage your health discreetly (For example: checking blood sugar levels or administering injections in public, the visibility of your devices, or concerns about being judged)?
18	How much of a problem is the privacy and security of your health information (For example: the confidentiality of your health information, managing who can have access to it, sharing your data with insurers in ways that could affect your coverage or claims, or feeling less free to live your life the way you want)?
19	The need for healthcare on a regular basis reminds me of my health problems
Digital Module	
1	How much of a problem is the time and effort required to take care of and use your digital devices in your day-to-day life? (For example: logging on for a telehealth visit, remembering to change sensors or charge devices, syncing multiple devices/applications, or doing routine checks/calibrations on devices)
2	How much of a problem is the annoyance and discomfort of your digital devices? (For example: device alarms or notifications interrupting daily activities or difficulty in wearing device with formal attire or beachwear)
3	How much of a problem is the time and effort required to solve problems with your digital devices? (For example: troubleshooting a new or old device, or finding educational resources from the healthcare team or device manufacturer)
4	How much of a problem is it to take the necessary precautions when using your digital devices? (For example: protecting your digital devices from drops, certain temperatures, or radiation (security checkpoint, MRIs, etc.) or carrying backups like a glucometer for continuous glucose monitors, or insulin pens for insulin pumps, etc.)
5	How much of a problem is it to give control of your health to digital devices? (For example: feeling uneasy or worried about the automatic functions of your device)
6	The need for digital devices (including their visibility) on a regular basis reminds me of my health problems

tools. While additional validation is needed, the TBQ+D may help clinicians and researchers identify areas where digital tools contribute to care complexity, particularly for patients with high treatment demands.

Second, once validated, the TBQ+D can assist clinicians in recognizing that increased use of digital tools, even those meant to automate tasks, does not always lead to a reduction in burden. Patients with more complex treatment needs may face a higher digital workload, highlighting the importance of a patient-centered approach to their implementation in practice.

Limitations and Future Research

This study has two key limitations. First, it was conducted at a single academic medical center with a relatively homogenous patient population, which may limit the generalizability of the findings. The sample size, while appropriate

for cognitive interviews, further limits the diversity of perspectives represented. Future work should actively recruit more racially and ethnically diverse participants to strengthen the tool's relevance across populations.

Second, while the adaptation process included rigorous qualitative methods and patient input, this work focused on item development and cognitive testing. The third phase in the process of developing TBQ+D involves its field testing, to test hypotheses that test its validity, ie, its ability to truly capture the workload and negative effect on quality of life it may have induced by the work of accessing and using healthcare and enacting self-care tasks supported by digital tools. This process should continue with a range of other populations with chronic conditions and variable digital care use, thus advancing the evidence of the validity and responsiveness of the TBQ+D.

Conclusion

This study describes the development of the Treatment Burden Questionnaire Plus Digital (TBQ+D), an adaptation of the original TBQ designed to capture burden associated with digital medicine tools. Grounded in patient experiences and refined through cognitive testing, the TBQ+D represents a step toward measuring the burden of digital care in patients with living with diabetes.

By incorporating patient-centered design and directly addressing gaps in existing measures, the TBQ+D can support future research and clinical efforts to ensure digital tools reduce, rather than add to, the workload of living with diabetes. As the use of digital tools in care continues to grow, measuring burden of digital care will be essential to designing tools and workflows that promote patient centered care that is minimally disruptive. Future work should also include cross-cultural adaptation and translation of the TBQ+D to ensure its validity and utility in international settings.

Abbreviations

CGM, Continuous Glucose Monitoring; EHR, Electronic Health Record; IQR, Interquartile Range; REDCap, Research Electronic Data Capture; TBQ, Treatment Burden Questionnaire.

Acknowledgments

This work was funded by a competitive grant awarded by the Center for Digital Health at Mayo Clinic underwritten by the Noaber Foundation. The authors bear full responsibility for the content and any errors or omissions, and the views expressed do not necessarily reflect those of these entities.

For information on, or permission to use, the TBQ+D, please contact the authors (VMM, V-TT).

This paper has been uploaded to medRxiv as a preprint: <https://pubmed.ncbi.nlm.nih.gov/40492074/>.

Disclosure

The authors declare that they have no conflicts of interest related to this study.

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