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A Patient-Centric Tool to Facilitate Goal Attainment Scaling in Neurogenic Bladder and Bowel Dysfunction: Path to Individualization

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ABSTRACT

Objectives: People with neurogenic bladder and/or bowel dysfunction experience diverse challenges that can be difficult to evaluate with standardized outcome measures. Goal attainment scaling (GAS) is an individualized, patient-centric outcome measure that enables patients/caregivers to identify and track their own treatment goals. Because creating goals de novo can be cumbersome, we aimed to develop a neurogenic bladder/bowel dysfunction goal menu to facilitate goal attainment scaling uptake and use.

Methods: We conducted a workshop with 6 expert clinicians to develop an initial menu. Individual interviews with 12 people living with neurogenic bladder and/or bowel dysfunction and 2 clinician panels with 5 additional experts aided us in refining the menu. A thematic framework analysis identified emergent themes for analysis and reporting.

Results: Interview participants were adults (median = 36 years, range 25-58), most with spinal cord injury (75%; 9/12). Of 24 goals identified initially, 2 (8%) were not endorsed and were removed, and 3 goals were added. Most participants listed "Impact on Life" goals (eg, Exercise, Emotional Well-Being) among their 5 most important goals (58%; 35/60). Three main themes emerged: challenges posed by incontinence, limitations on everyday life, and need for personalized care.

Conclusions: We developed a clinical outcome assessment tool following a multistep process of representative stakeholder engagement. This patient-centric tool consists of 25 goals specific to people living with neurogenic bladder and/or bowel dysfunction. Asking people what matters most to them can identify important constructs that clinicians might have overlooked.

Keywords: goal attainment scaling, neurogenic lower urinary tract dysfunction.

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Introduction

People with nervous system disorders often experience neurogenic bladder (also known as neurogenic lower urinary tract dysfunction¹) and/or bowel dysfunction, with symptoms that can vary markedly from person to person.^{2,3} For example, some people with neurogenic bladder experience bladder storage issues, whereas others have difficulty emptying their bladder.³ Similarly, people with neurogenic bowel can experience fecal incontinence, constipation, or both.² These conditions can result in additional pathologies such as progressive renal deterioration,⁴ anorectal disorders,⁵ and frequent readmission to hospitals.⁶ Symptoms associated with neurogenic bladder and/or bowel dysfunction can be physically, socially, and psychologically challenging in ways that are also highly individualized.⁷ This heterogeneity makes it difficult to quantify change in an individual's symptoms using standardized outcome measures.

Personalized outcome measures are designed to capture the heterogeneity of an individual's experience with various treatments and devices in different disease states.⁸⁻¹⁰ Goal attainment scaling (GAS) is an established, individualized patient-reported outcome measure that enables patients/caregivers to identify and track their own treatment goals.¹¹ A crucial step in GAS is to set quantifiable, meaningful, condition-specific goals and to assess goal attainment over time.¹² However, developing goals de novo, without a goal menu, can be cumbersome even with clinical guidance.⁹ Healthcare practitioners often require training programs targeted at setting effective and measurable goals.¹³

Capturing the patient's voice is a critical step in the development of any clinically meaningful outcome measure including GAS.⁹ Actively involving patients in healthcare decisions (eg, goal setting in GAS) has potential to improve clinical outcomes.¹⁴ Although patient-centered outcome measures and quality of life measures are used in this population, few have been designed

specifically for people with neurogenic bladder and/or bowel dysfunction.^{15,16} In this study, our overall objective was to develop a clinically meaningful menu of goal areas applicable to anyone with neurogenic bladder and bowel dysfunction to facilitate the use of GAS in this population. Here, we primarily interviewed people with spinal cord injury or spina bifida. This approach also provided insights into the lived experiences of people with neurogenic bladder and/or bowel dysfunction and the challenges they face living with these conditions.

Methods

Sample

Qualitative studies typically allow smaller samples to offer a great deal of in-depth information from people knowledgeable in each area, in virtue of their lived experience. Standard recommendations on concept elicitation suggest that, although there is no formula as in quantitative research, 7 to 10 interviews typically suffice.¹⁷ Here, we recruited 12 people living with neurogenic bladder and/or bowel dysfunction from both the United States and the UK between November 2018 and February 2019. People with neurogenic bladder or bowel dysfunction were contacted through a recruiting company to participate in this study. Participants primarily reported T5-T12 spinal cord injuries or mild-moderate spina bifida. We also recruited an expert, multidisciplinary review panel of 11 clinician researchers. Clinicians were registered nurses (N = 10) and a physician each with 14-33 years of experience with neurogenic bladder/bowel dysfunction who specialized in spinal cord injury, rehabilitation, or stroke. Interviews, workshops, and panels were audio-recorded and transcribed verbatim. The sample included only English-speaking people with neurogenic bladder and/or bowel dysfunction and clinicians with expertise in this condition who were comfortable using the online video conferencing tool.

Menu Development

A flowchart depicting the menu development process is outlined in [Figure 1](#). Initial concepts for the goal menu were derived from a workshop with 6 expert clinicians. Initially, clinicians were introduced to GAS and the goal-setting process. Three researchers then facilitated an open-ended discussion to identify and record important constructs that affect their patients. The recorded list of common and important areas was reviewed until clinicians

reached consensus that the list was exhaustive. Next, we elicited specific descriptions and manifestations for each goal area. These more detailed explanations were called “descriptors.” For example, a descriptor for the Intermittent Catheterization goal was “I need help doing my intermittent catheterization.” Clinicians were prompted to propose descriptors in the language that their patients would use. Researchers then aggregated and refined these concepts and descriptors to operationalize our preliminary neurogenic bladder/bowel goal menu.

Next, 12 participants (people living with neurogenic bladder and/or bowel dysfunction) were recruited to participate in individual semistructured interviews. Participants provided informed consent before interviews, and verbal consent to be recorded at the start of each interview. Interviews were conducted using an online video conferencing tool to facilitate slide sharing and audio recording. Each interview took approximately 1.5-2 hours and consisted of 4 sections ([Table 1](#)). Participants were encouraged to suggest changes to the goals or descriptors they rated “not clear” or “not relevant.” They were given an opportunity to identify additional goal areas or descriptors.

We recruited 5 additional expert clinicians, including 1 physician, to provide feedback on the preliminary goal menu in 2 panels, conducted concurrently with participant interviews. Clinician panels lasted approximately 2 hours and were also conducted using an online video conferencing tool. Each clinician panel began with a project overview and introduction to GAS. Next, we facilitated an open-ended discussion on the goal menu including the new concepts identified by people living with neurogenic bladder and/or bowel dysfunction. Specific goal areas requiring further input were reviewed in detail. For example, if participants were not concerned with any given goal, we discussed its importance relative to our goal menu, informing the decision to remove or keep the goal. The clinicians also provided insights into these concepts by adding supplementary descriptors appropriate for use in the menu.

Data Analysis

Feedback on menu items was systematically coded by 3 researchers as “clear/keep,” “unclear/modify,” “remove/disliked,” or “add/missing.” The clarity and relevance of menu items was assessed by reviewing the proportion of participants who rated each item “clear/keep.” Menu items were removed if they were rated “remove/disliked” by more than 50% of participants. Descriptors were reworded if 1 or more participants rated them as

Figure 1. Goal menu development overview. Flowchart that illustrates the multistep process undertaken to develop our new neurogenic bladder/bowel goal menu.

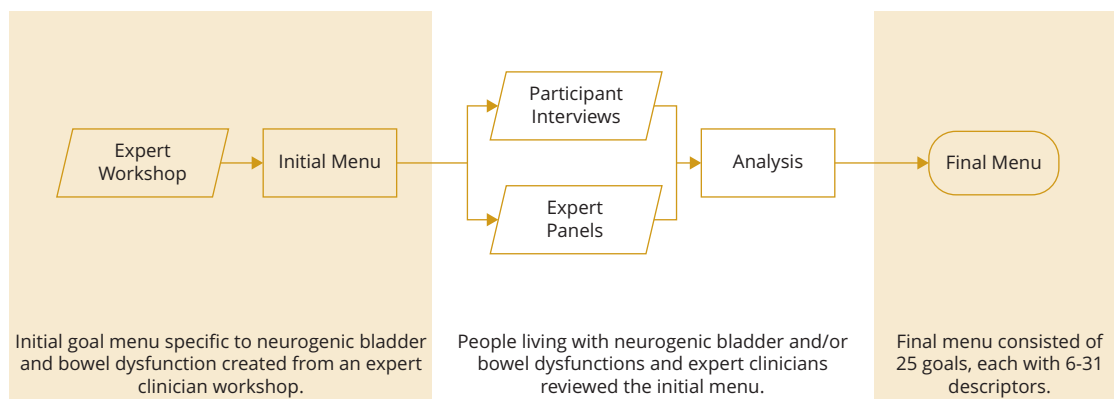


Table 1. Individual interview structure.

Section	Description	Approximate time (minutes)
1 – structured	Formal review of the consent form followed by verbal consent from participants and collection of demographic data	15
2 – open-ended	Discussion of the challenges faced in the day-to-day life of individuals living with neurogenic bladder and/or bowel dysfunction	30-45
3 – structured	In-depth review of a subset of neurogenic bladder/bowel goal areas including each of their descriptors. Participants assessed goals and descriptors individually for clarity, comprehensiveness, and relevance to the lives of people living with neurogenic bladder and/or bowel dysfunction.	30-45
4 – open-ended	Discussion of the most important challenges faced, specific to the individual participant.	15

unclear. Concepts not otherwise specified in the menu were added if at least 1 participant reported a new concept and 1 clinician panel agreed the concept was relevant.

Two researchers performed a thematic framework analysis¹⁸ of interview transcripts. Qualitative data analysis began with data familiarization, where both researchers independently reviewed transcripts while listening to audio recordings. Researchers then independently coded quotes by menu topic (eg, “accidents” and “leaking” were both coded as incontinence). New concepts uncovered during the open-ended sections of the interviews were used to inform the development of new descriptors. Additionally, researchers proposed thematic codes for quotes not specific to the menu. The 2 researchers modified thematic codes to resolve uncertainties and differences. Quotes were charted into 2 data matrices: 1 by menu topic and 1 by thematic code. Emergent themes were identified by reviewing the data matrices with both inductive and deductive approaches. To ensure the trustworthiness of our findings, researchers coded the open-concept portion of each interview independently and blinded to each other’s codes. The structured menu review portion was systematically coded into 4 predetermined codes. All codes and findings were discussed regularly until a consensus was reached for each.

Demographic information was summarized by medians and ranges, means and standard deviations, or with frequency and proportions.

Ethics

Ethical approval was granted by the Nova Scotia Health Authority Research Ethics Board. The approval number is ROMEO FILE #:1020385. All participants provided informed consent.

Results

Sample

The interview participants (n = 12) were adults living with neurogenic bladder and/or bowel dysfunction (Table 2). Their average age was 36 years old (range 25-58 years); more than half were women, and most were from the United States. A majority (67%) had both neurogenic bladder and bowel dysfunction, but

only 17% had a caregiver. The most common cause of their neurogenic bladder and bowel dysfunction was spinal cord injury.

Menu Development

The clinician workshop resulted in a draft menu consisting of 24 goal areas and 297 descriptors. Participants reviewed a median of 10 goal areas (range 5-12). Each goal and its descriptors were reviewed a median of 5 times (range 3-6). Participants endorsed 92% (22/24) of the goals in the draft menu. The 2 goals not endorsed were Flatulence and Urethral Strictures. Participants were not concerned with flatulence:

“I think it’s just a normal thing. I don’t know if people are really concerned.”

“No, I’m not really worried... I’m not worried about embarrassing anybody.”

And few understood the term urethral strictures:

“What is that in layman’s terms?”

Table 2. Characteristics of participants with neurogenic bladder and/or bowel dysfunction.

Characteristic	Participants (N = 12)
Age, median years (range)	36 (25-58)
Gender, % women (N)	58% (7)
Country, % USA (N)	58% (7)
% UK (N)	42% (5)
Education, % ≥15 years (N)	75% (9)
% <15 years (N)	25% (3)
Proportion with both neurogenic bladder and bowel dysfunction (% , N)	67% (8)
Proportion who had a caregiver (% , N)	17% (2)
Cause of neurogenic bladder and/or bowel dysfunction (% , N)	
Spinal cord injury	75% (9)
Spina bifida	17% (2)
Unspecified	8% (1)

Table 3. Examples of menu changes based on participant feedback.

Goal area	Descriptor	Participant comments	Researcher comments
Time Management	I order supplies too often	"No... I think it's the insurance that mandates how many they're supposed to have and so it just sends them."	Remove. Participants indicate that they do not typically order supplies.
Travel	I do not know what to bring with me when I travel	"I think that's silly. Excuse me for saying that. If it's in terms of supplies, medication, that's silly."	Remove. Participants agreed that individuals living with neurogenic bladder and/or bowel dysfunction understand their needs.
Fluids and Nutrition	I feel like I have no choice in what I eat/drink	"No, I definitely have a choice, so I don't agree with that." "No. I think you have a choice. There is. There's so much."	Remove. Although participants acknowledged limitations, most did not endorse this descriptor.
Being Social	Socializing is not worth the effort	"...that's a bit extreme. I wouldn't say not worth it but sometimes it can be challenging."	Modify. Replace "not worth it" with "challenging." New wording: "Socializing can be a challenge."
Independence	I do not understand why it is important to be independent	"You need to be independent. You can't expect to rely on everybody else all the time. You have to have some sort of independence."	Modify. All participants agreed independence was important. New wording: "I am unsure how to be more independent."
Adherence/ Compliance	-	Regarding the goal title: "I mean, I'm familiar with both terms I suppose." "...I think of OSHA standards or something, I don't know."	Modify. Participants had trouble identifying the context of the goal from the title. New goal title: "Following My Plan"
Bowel Management	-	"I would like to be able to eat and drink whatever I want... I don't want to get diarrhea."	Add. Participants often described diarrhea. New descriptor: "I get diarrhea"

"I'm not familiar with what urethral strictures are."

Of the 297 descriptors, participants endorsed 227 (76%). Those not recommended were modified ($n = 23$; 8%) or removed ($n = 47$; 16%). Descriptors marked "relevant" in removed goals were moved to other goal areas. For example, "I have gas" from the Flatulence goal was moved to the Bowel Management and Diarrhea goals. A further 35 descriptors were added to include concepts not otherwise specified. Examples of menu changes made in response to participant feedback are shown in [Table 3](#).

Three new goal areas were added to the menu. These were Accessibility, Diarrhea, and Urinary Management. Participants called for a broad goal termed Accessibility that encompassed finding and using appropriate bathrooms.

"The only other thing that really affects everybody would just be the accessibility in general."

"It's more the accessibility side, just being able to get anywhere I need to go when I need to be able to go pee."

Clinicians agreed that accessibility would be a useful goal.

"It's all about accessibility, and it's accessibility 'where.' Could be accessibility in the workplace, in the school. It could be traveling. It's all about accessibility to bathrooms."

"Even accessibility at home is an issue."

"Home or visiting friends. Everywhere is an issue."

Participants often described diarrhea and worry about fecal incontinence.

"I worry about diarrhea. I would probably add that one."

"Include not only the constipated part of it but the other part of it, where it's like you're going, you can't stop."

Clinicians first suggested to divide incontinence into fecal and urinary incontinence.

"I think if you had fecal incontinence, that would cover diarrhea really, wouldn't it?"

"It would... It's overflow really."

The clinicians then later agreed that the term "diarrhea" was more patient friendly.

"Patients do not use the word fecal incontinence. It's a very small number who do."

Participants also suggested a general goal for urinary management. Many described their embarrassment and the time spent performing urinary management.

"With the bladder control... It's embarrassing at times but I think over time everybody just tends to understand and deal with it."

"I want to do it by myself but I want it to take less time."

Clinicians agreed that there should be a broad goal for urinary management, like bowel management, and that it should be separate from intermittent catheterization.

"Intermittent catheterization is just one area so it would be better to have that broader."

"Sometimes people might be on an indwelling long-term catheter. They might just have [external catheter] drainage. There are other, different ways that they empty their bladder."

Table 4. Neurogenic bladder/bowel goal menu.

Domain	Goal area
Impact on Life	Accessibility
	Being Social
	Emotional Well-Being
	Exercise
	Financial Concerns
	Fluids and Nutrition
	Relationships
	Time Management
	Travel
	Work and School
Treatment and Management	Bowel Management
	Urinary Management
	Following My Plan
	Independence
	Intermittent Catheterization
	Medication Use
	Treatment Challenges
Treatment Devices	
Symptoms and Complications	Bladder Stones
	Constipation
	Diarrhea
	Incontinence
	Pressure Ulcers
	Urinary Retention
	Urinary Tract Infections

From the participant and clinician feedback, the neurogenic bladder/bowel goal menu was revised to include 25 goals, each with 7 to 27 descriptors (334 total). Descriptors can be seen as specific problems related to the broader goal area. For example, a descriptor for the Intermittent Catheterization goal area was “I have trouble inserting my catheter.” The list of goal areas can be found in [Table 4](#).

Thematic Framework Analysis

We next conducted a thematic framework analysis to identify key themes based on our interviews with participants. Three main themes emerged from these interviews: challenges posed by incontinence, limitations on daily living, and a desire for individualized care management. The primary theme of incontinence was identified as a clinically relevant medical issue and a common one.

“Anytime I see that question [incontinence] on a form I check yes.”

Additionally, participants stressed its impact on their daily life.

“I plan my life around when I'm going to have to catheterize myself.”

“I've just become reliant on using [adult diapers] on a regular basis, all the time.”

“I've been told to drink lots of water, and I'm like... well, it's all right for you to say that, but it's not you having to have incontinence part take over you.”

“At night, sometimes I'll leak and that just starts the day horrible.”

“Working full time, I don't want to have accidents during the day.”

Participants reported avoiding public activities due to fear of incontinence and lack of sanitary, accessible bathrooms.

“I am afraid of leaking in public.”

“Just accidents in public has kind of been the main thing... It's also difficult to stay clean.”

“I get really paranoid even if I have a slight leakage.”

“I stopped going anywhere.”

“The whole, not finding an accessible bathroom or a clean bathroom.”

Regarding the various limitations that arise due to their neurogenic bladder and/or bowel dysfunction, participants chiefly expressed frustration and a loss of sense of self.

“Just going to a company happy hour, I have to make sure I ask that ‘is it upstairs?’ ‘Do they have an elevator?’ ...And if it is, I will just decline and say I'm not going to be able to go because I don't want to cause any hassle.”

“If you haven't had hot wings, you're not going to try them because you don't know how your body's going to react because you haven't had spicy food in a long time.”

“There's consequences for pretty much all of my choices.”

“Honestly, I don't feel like 100% woman.”

“I get frustrated... I cry sometimes.”

“I can't really have a social life.”

“You really do have to kind of put your schedule around it and you have those days where you're tired and you just don't want to do it, or you don't feel well already, and you have to do it.”

Participants expressed a strong desire for clinicians to recognize their individual challenges.

“You might be a urologist, but dealing with me is totally different than dealing with the other 10,000 patients you have.”

“Everybody is different. They have different wants, needs, and perspectives. There needs to be a human aspect [to care].”

Participants also endorsed the use of the goal menu.

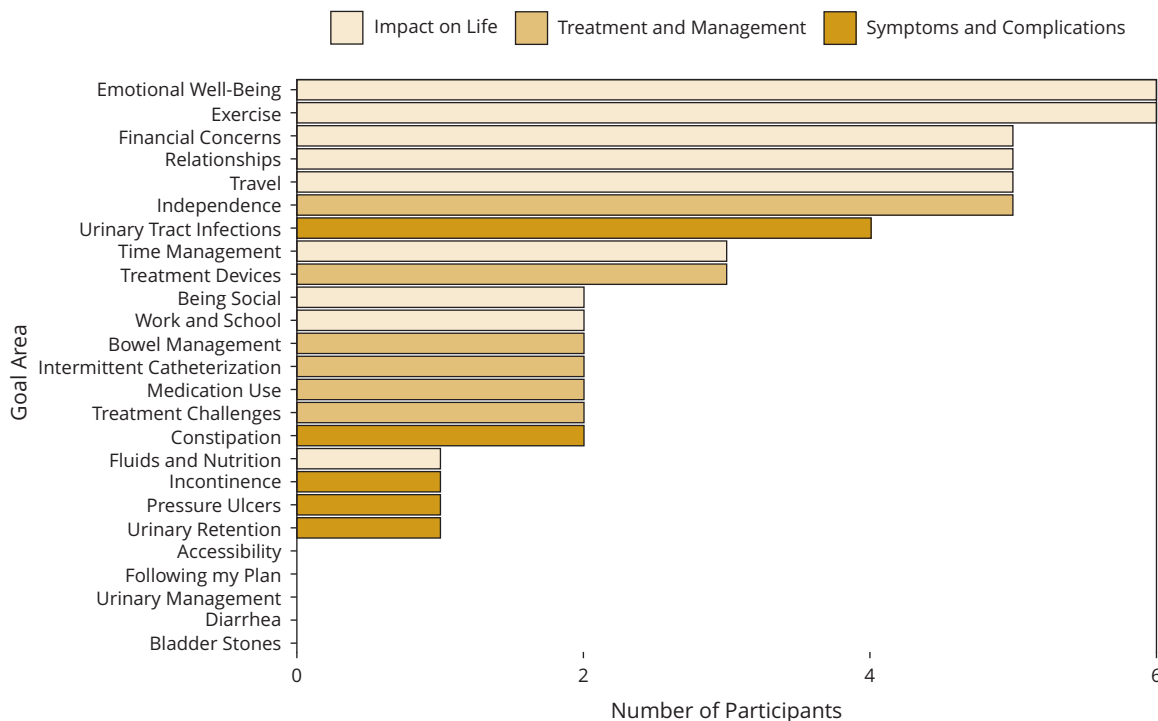
“I never really actually had something like this where I could break down all different sections and just make goals.”

“When you first showed me the goals I was like ‘oh, this is cool’ and then seeing specifically, it's making me think of how, like where it might be going, and I like it a lot.”

“Starting or creating these kinds of goals or even little personal; starting off small and then gradually building... that's something... It's definitely something that I'd want to do.”

Following menu review, participants were asked to identify their 5 most important goals and were not required to choose menu items. Goals from the Impact on Life domain were most commonly identified (35/60, 58%) by participants. This was followed by Treatment and Management goals (16/60, 27%) and then Symptoms and Complications goals (9/60, 15%). Half of participants (6/12) listed Emotional Well-Being and/or Exercise in their top 5 goals. All participant-reported goals were captured by the menu. Accessibility, Following My Plan, Bladder/Urinary Management, Diarrhea, and Bladder Stones appear on the menu but

Figure 2. Participants' most important goals by domain. The number of participants was plotted as a function of the specific goals they identified as most important in this study. The goals were subdivided into domains: "Impact on Life," "Treatment and Management," and "Symptoms and Complications." The goals related to impact on life were most commonly viewed as important by the participants.



were not identified as a top 5 most important challenge by participants. Figure 2 illustrates the number of participants who identified Impact on Life, Treatment and Management, and Symptoms and Complications goals as the most important.

Discussion

The aims of this study were to describe the lived experiences and challenges faced by people affected by neurogenic bladder and/or bowel dysfunction and develop a clinically meaningful menu of goal areas to enable the use of GAS in this population. Measuring outcomes that reflect personalized issues around neurogenic bladder/bowel dysfunction is still in its early days.^{15,16} We used a multistep process, with input from both clinician and patient stakeholders, to develop a menu of 25 goals specifically tailored to the needs of people with neurogenic bladder and/or bowel dysfunction. Although some menu items are directly related to the condition (eg, difficulty with catheterization), others are indirectly related (eg, embarrassment, low self-esteem). Interestingly, many indirectly related Impact on Life goals, including exercise and emotional well-being, were identified most often as important and for those individuals bore a clear personal relationship with bowel and bladder dysfunction. Curiously, despite their importance, these outcomes commonly are not captured in standardized outcome measures, perhaps reflecting the difficulty in quantifying across the wide range of relevant inter-individual diversity, and a notion of subjectivity that rejects people ranking their own goals. Here we have adopted an approach^{9,19}—asking people which symptoms matter most to them—that provides information about patients' perspectives that is both necessarily subjective and allows the incorporation of new

goals that may not be obvious to clinicians.²⁰ Even so, it provides a standardized and quantifiable method for rating change²¹ by using GAS. We do draw the distinction however between 2 levels of inference. The first is in understanding the extent to which, on whatever grounds, patients felt that their goals had been met. The second is to understand those goals. The approach we are suggesting both quantifies the first inference—the extent to which patients met their goals—and organizes information to allow the second question—just which goals did they meet—to be answered more readily. With GAS, patients develop a 5-point scale of possible outcomes for each goal at baseline and rate the level of attainment against those scales in subsequent visits. This new patient-centric tool, built with patients and for patients, will more readily enable the use of GAS in individuals with neurogenic bladder and/or bowel dysfunction. It will allow affected individuals to choose from a list of goals that reflect their lived experience or create their own goals, providing a novel, individualized outcome measure. This approach, using patient input for instrument development, is strongly recommended by the US Food and Drug Administration for patient-centric outcome measures.²²

Previous work suggests that there are few patient-reported outcome measures developed for people with neurogenic bladder and/or bowel dysfunction.^{15,16} In the present study, both the people with neurogenic bladder and/or bowel dysfunction and the clinicians who care for them recognized a need to involve personalized measures in their care. Previous studies that have used qualitative analysis of GAS show strong support for this approach in other conditions. For example, both clinicians and people living with hemophilia endorsed the use of GAS as a clinically meaningful outcome measure.²⁰ Likewise, participants in this study endorsed the use of our menu, noting the level of

individualization that it provides. For these reasons, the goals and descriptors identified here will be used to develop a GAS tool to reflect symptoms that are important to people living with neurogenic bladder and bowel issues.

A critical step for any new outcome measure is to assess its feasibility. The next phase will be to complete a feasibility study, designed to evaluate how this new goal menu can be used to gather data and conduct investigations in routine care. This process of eliciting a range of opinions from people living with neurogenic bladder and bowel dysfunction and clinicians experienced in the area to develop a GAS tool and evaluate its measurement properties (responsiveness, content validity, and construct validity) parallels an approach with GAS used in other disease conditions.^{9,23} Similarly, studies that elicit feedback as part of the goal attainment process can give rise to comprehensive accounts of the challenges posed in particular conditions.¹³

Although there are few studies with individualized outcomes measures in people with neurogenic bladder and/or bowel dysfunction,^{15,16} there has been some development in this area. A recent study used a mixed-methods application of the response shift model to examine quality-of-life factors such as bowel and bladder dysfunction in people with spinal cord injuries.²⁴ Their qualitative analyses identified 4 behavioral themes: (1) behavior-driven individuals who take an active role in their condition; (2) awareness-driven individuals who focus on self-worth; (3) a social comparison group who compare themselves to others; and (4) a resignation and despair group who have given up.²⁴ In the longer term, it could be interesting to determine whether structured goal setting with GAS could be used to motivate these different types of people, especially those in group 4. In practice, the menu developed in this study could also be used to help patients identify the treatment challenges they would like to focus on and discuss those challenges in the clinic.

Limitations and Future Work

Several aspects of our study design may influence generalizability or confirmability of our findings. The objective of this study was to develop a menu applicable to all people with neurogenic bladder or bowel dysfunction; however, this sample was composed primarily of people with spinal cord injury or spina bifida. It is possible that other important symptoms may emerge with a larger sample that includes other causes of neurogenic bladder/bowel dysfunction. On the other hand, our menu allows for both further individualization of each item and the ability to record, track, and enter completely new goals or descriptors. Not everyone sees goal setting as benign; whereas many people value the opportunity, others are suspicious of what they might view (for personal, cultural, or religious reasons) as an unwarranted intrusion on the future.

Fortunately, for others whose concern might be that a goal important to them has not been represented, the GAS method not just allows but encourages individualization, so that with time the menu can be altered to reflect additional input from users. Most commonly, modifications are made to further personalize goals—for example, to make them particular to the individual's settings or circumstances. These patient-specific modifications are not likely to result in changes to the goal menu; therefore, allowing personalization becomes a sufficient remedy. An accessibility goal, for example, may be an issue not because there are no restaurants with wheelchair accessibility, but rather because there are too few, or none catering to an individual's tastes. These issues can be described with specific descriptors.

Finally, although this study can point us to the internal validity of the approach, if we are to understand its external validity (ie, its generalizability), then we need to test the results in a larger

clinical study and evaluate the extent to which the present results are confirmed. Clinical studies also afford the opportunity to see how baseline scores might predict relevant and nonarbitrary outcomes (eg, did the people with the greatest satisfaction at baseline have the highest adherence over the observation period?). Precisely, validation in that context as an aspect of criterion validity offers the severest test of an instrument's measurement properties.²⁵

Conclusions

Our findings suggest that, as in many other disease areas in which heterogeneity of needs and desires are common, an individualized approach based on patients' preferences and expressed as goals allows for a diverse range of outcomes to be measured. This can be achieved efficiently by having people who live with the disorder discuss what is important to them, as well as the potential generalizability of the resulting menu. Here we have reported steps taken to develop and refine such a goal menu. The next steps will require evaluation of its feasibility and measurement properties in a clinical study setting.

Article and Author Information

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Conflict of Interest Disclosures: Dr Goldstine and Mr Inglesse are employed by Hollister Incorporated. Mss Knox and England, Mr Stanley, and Drs Howlett and Rockwood are employed by DGI Clinical Inc. Mr Beekman and Drs Cobussen-Boekhorst, Conti, Gray, Rodriguez, and Vaughn reported being expert advisors to Hollister Incorporated for concept elicitation and the review of goal menu items outside the submitted work. Dr Cobussen-Boekhorst reported that her hospital received fees from Cogentix Medical and from Workgroup government outside the submitted work. Dr Rockwood reported stock ownership in DGI Clinical Inc during the conduct of the study; receiving grants from the Alzheimer's Society of Canada outside the submitted work; serving as associate

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REFERENCES

- Schops TF, Schneider MP, Steffen F, Ineichen BV, et al. Neurogenic lower urinary tract dysfunction (NLUTD) in patients with spinal cord injury: long-term urodynamic findings. *BJU International*. 2015;115(Suppl 6):33–38.
- Coggrave M. Neurogenic continence, part 3: bowel management strategies. *Br J Nurs*. 2008;17(15):962–968.
- Pellatt GC, Geddis T. Neurogenic continence, part 2: neurogenic bladder management. *Br J Nurs*. 2008;17(14):904, 906, 908–913.
- Harris CJ, Lemack GE. Neurourologic dysfunction: evaluation, surveillance, and therapy. *Curr Opin Urol*. 2016;26(4):290–294.
- Qi Z, Middleton JW, Malcolm A. Bowel dysfunction in spinal cord injury. *Curr Gastroenterol Rep*. 2018;20(10):47.
- Gabbe BJ, Nunn A. Profile and costs of secondary conditions resulting in emergency department presentations and readmission to hospital following traumatic spinal cord injury. *Injury*. 2016;47(8):1847–1855.
- Cotterill N, Madersbacher H, Wyndaele JJ, et al. Neurogenic bowel dysfunction: clinical management recommendations of the Neurologic Incontinence Committee of the Fifth International Consultation on Incontinence 2013. *Neurolog Urodyn*. 2018;37(1):46–53.
- Rockwood K. An individualized approach to tracking and treating Alzheimer's disease. *Clin Pharmacol Ther*. 2010;88(4):446–449.
- Roberts JC, Lattimore S, Recht M, et al. Goal attainment scaling for haemophilia (GAS-Hem): testing the feasibility of a new patient-centric outcome measure in people with haemophilia. *Haemophilia*. 2018;24(4):e199–e206.
- Turner-Stokes L, Ashford S, Esquenazi A, et al. A comprehensive person-centered approach to adult spastic paresis: a consensus-based framework. *Eur J Phys Rehabil Med*. 2018;54(4):605–617.
- Kiresuk TJ, Sherman RE. Goal attainment scaling: a general method for evaluating comprehensive community mental health programs. *Community Ment Health J*. 1968;4(6):443–453.
- Turner-Stokes L. Goal attainment scaling (GAS) in rehabilitation: a practical guide. *Clin Rehabil*. 2009;23(4):362–370.
- Turner-Stokes L, Fheodoroff K, Jacinto J, Maisonobe P, Zakine B. Upper limb international spasticity study: rationale and protocol for a large, international, multicentre prospective cohort study investigating management and goal attainment following treatment with botulinum toxin A in real-life clinical practice. *BMJ Open*. 2013;3(3):e002230.
- Vahdat S, Hamzehgardeshi L, Hessam S, Hamzehgardeshi Z. Patient involvement in health care decision making: a review. *Iran Red Crescent Med J*. 2014;16(1):e12454.
- Clark R, Welk B. Patient reported outcome measures in neurogenic bladder. *Transl Androl Urol*. 2016;5(1):22–30.
- Patel DP, Elliott SP, Stoffel JT, Brant WO, Hotaling JM, Myers JB. Patient reported outcomes measures in neurogenic bladder and bowel: a systematic review of the current literature. *Neurolog Urodyn*. 2016;35(1):8–14.
- Patrick DL, Burke LB, Gwaltney CJ, et al. Content validity—establishing and reporting the evidence in newly developed patient-reported outcomes (PRO) instruments for medical product evaluation: ISPOR PRO Good Research Practices Task Force report: part 2—assessing respondent understanding. *Value Health*. 2011;14(8):978–988.
- Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol*. 2013;13:1–8.
- Rockwood K, Mitnitski A, Black SE, et al. Cognitive change in donepezil treated patients with vascular or mixed dementia. *Can J Neurol Sci*. 2013;40(4):564–571.
- Lattimore S, Chapman C, Fay S, Schwartz E, Goldstine J. Patient and clinician experience of using goal attainment scaling for hemophilia (GAS-Hem), an innovative patient-centered outcome measure. 69th Bleeding Disorders Conference. <https://www.hemophilia.org/Researchers-Healthcare-Providers/Health-Care-Provider-Education/Research-Poster-Abstracts>. Accessed December 20, 2019.
- Yip AM, Gorman MC, Stadnyk K, et al. A standardized menu for goal attainment scaling in the care of frail elders. *Gerontologist*. 1998;38(6):735–742.
- US Food and Drug Administration. Guidance for industry, patient-reported outcome measures: use in medical product development to support labeling claims. <https://www.fda.gov/media/77832/download>. Accessed February 11, 2020.
- Recht M, Konkle BA, Jackson S, Neufeld EJ, Rockwood K, Pipe S. Recognizing the need for personalization of haemophilia patient-reported outcomes in the prophylaxis era. *Haemophilia*. 2016;22(6):825–832.
- Rohn EJ, Tate DG, Forchheimer M, DiPonio L. Contextualizing the lived experience of quality of life for persons with spinal cord injury: a mixed-methods application of the response shift model. *J Spinal Cord Med*. 2019;42(4):469–477.
- Streiner DL, Norman G, Cairney J. *Health Measurement Scales: A Practical Guide to Their Development and Use*. 5th edition. Oxford: Oxford University Press; 2014.