Review

Recommendations for evaluation of neurogenic bladder and bowel dysfunction after spinal cord injury and/or disease

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Objective: To provide an overview of clinical assessments and diagnostic tools, self-report measures (SRMs) and data sets used in neurogenic bladder and bowel (NBB) dysfunction and recommendations for their use with persons with spinal cord injury /disease (SCI/D).

Methods: Experts in SCI/D conducted literature reviews, compiled a list of NBB related assessments and measures, reviewed their psychometric properties, discussed their use in SCI/D and issued recommendations for the National Institutes of Health (NIH), National Institute of Neurological Disorders and Stroke (NINDS) Common Data Elements (CDEs) guidelines.

Results: Clinical assessments included 15 objective tests and diagnostic tools for neurogenic bladder and 12 for neurogenic bowel. Following a two-phase evaluation, eight SRMs were selected for final review with the Qualiveen and Short-Form (SF) Qualiveen and the Neurogenic Bowel Dysfunction Score (NBDS) being recommended as supplemental, highly-recommended due to their strong psychometrics and extensive use in SCI/D. Two datasets and other SRM measures were recommended as supplemental.

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Conclusion: There is no one single measure that can be used to assess NBB dysfunction across all clinical research studies. Clinical and diagnostic tools are here recommended based on specific medical needs of the person with SCI/D. Following the CDE for SCI studies guidelines, we recommend both the SF-Qualiveen for bladder and the NBDS for bowel as relatively short measures with strong psychometrics. Other measures are also recommended. A combination of assessment tools (objective and subjective) to be used jointly across the spectrum of care seems critical to best capture changes related to NBB and develop better treatments.

Keywords: Spinal cord injury, Spinal cord disease, Neurogenic bladder, Neurogenic bowel, Clinical assessments, Self- report measures, Data sets

Background

Advancing neurogenic bladder and bowel (NBB) best practices has been relatively slow. A factor contributing to this slowness is the lack of standards and measures to evaluate management methods, symptom severity and related complications. The recommendations in this manuscript address this issue and evolved from a series of collaborative, community-based meetings with spinal cord injury/disease (SCI/D) stakeholders.

In March of 2017, clinicians, researchers, patient advocates, government agencies and potential funding partners attended a workshop hosted by the Craig H. Neilsen Foundation to identify opportunities to improve NBB function following SCI/D. Priorities identified during the workshop were recently published.[1] Of these priorities, the need to describe the seemingly beneficial effect of rehabilitation interventions on NBB was identified as a step requiring additional expertise and involvement from the SCI community. It was also noted that the studies in SCI/D that did include measures of NBB, did so using a wide array of very diverse tools which reduced the ability to compare advances across studies. A working group was established to identify clinical measures and datasets frequently used to evaluate NBB in SCI/D, examine their psychometric properties and, through an evaluative process, provide recommendations for their specific use. This group's charge was to form a consensus around a minimum set of self-reported measures (SRMs) and datasets to be used in interventional studies for NBB. A list of all participants is found in Appendix 1.

Introduction

One of the most important issues in spinal cord injury/disease (SCI/D) care is the treatment of neurogenic bladder and bowel (NBB).[2–5] Neurogenic bladder and bowel dysfunction affects the vast majority of persons with spinal cord injury (SCI).[6,7] Diseases of the genitourinary system are the leading cause of re-hospitalizations after SCI/D and the fifth most common cause of mortality.[8,9] Similarly, bowel dysfunction is the second most common complication reported by persons with SCI and the fourth most common reason for re-hospitalization.[10] Further, NBB dysfunction has a devastating effect on quality of life (QOL) for a significant proportion (40–60%) of individuals, interfering with activities of daily living, creating a barrier to social interaction and social integration.[6,7,10–14] NBB can be costly, is unrelenting over time, and often requires significant caregiver support.[6]

Progress in developing effective treatments for NBB dysfunction has been relatively slow, particularly in bowel. A major deterrent to conducting such studies is the lack of valid and reliable ways of evaluating NBB-related symptoms and complications, both from a clinical and patient perspective. Further, studies that investigate NBB function as primary target or as a secondary outcome associated with other endpoints, such as ambulation, balance and gait are heterogeneous in endpoints and thereby difficult to compare. Thus, the need for greater standardization among measures being used for people with SCI/D undergoing such treatments as well as the ability of such measures to capture changes over time is key.[6]

Assessment modalities for neurogenic bladder and bowel

Broadly speaking, NBB dysfunction after SCI/D may be evaluated through distinct approaches depending on purpose and use: SRMs, medical history, clinical observations, and diagnostic assessments. Objective performance-based measures or database elements include medical history, examination of organs and sphincter, measures of residual urine volume, fecal loading, bladder contractility and intestinal motility, use of imaging tools (e.g. ultrasound, MRI), specimen cultures and microscopy that could be used in both SCI/D clinical studies and clinical care. While some of these clinical assessments are highly-specific with proven reliability and validity to effectively characterize presence, absence or level of NBB related symptoms across the continuum of recovery, not all have published evidence of psychometric strength. Clinicians may also request the patient record information in a diary in order to gain a measure of overall progress.

Despite the self-report nature of this measure, diaries are categorized as a clinical observation due to the subsequent clinical review and assessment derived from them.

These objective assessments can be complemented by more subjective and individualized patient self-reports. SRMs are self-report measures that patients complete in relation to a condition they are experiencing, thus reflecting the person's perspective and experience of symptoms, complications and/or quality of life.[15] These SRM approaches are used to measure a construct (i.e. symptoms, satisfaction) before and after an intervention to determine changes across time.[5,16,17] SRMs include what is known in the literature as patient reported *outcome* measures (or PROMs) which more specifically refers to outcomes of an intervention or treatment.

A number of systematic reviews have been conducted recently to assess SRMs in NBB.[5,16,18,19] A common finding from these reviews, is the need for increased standardization and validation measures of NBB to be used with people with SCI/D.[20,21] Addressing this need, Clark and Welk provide an overview of current SRMs for neurogenic bladder.[15]

Similarly, data capture by a clinician or researcher must be consistent across individuals and institutions to increase confidence in its use for condition characteristics or change over time. International SCI Data Sets were developed for use in clinical management and research in order to establish a common language across institutions and disciplines. Data sets are considered a separate category of evaluation[22,23] as they were not purposely developed to be measures of functional improvement or QOL. They were developed to standardize the collection of the most relevant information on SCI/D care and its consequences, therefore, the criteria of reliability and validity also apply to the Data sets.[24] The International SCI Lower Urinary Tract Function Basic Data Sets and the International SCI Bowel Function Basic Data Sets,[25,26] are discussed in this article in relation to the need to have standardized NBB assessments for clinical practice and research. Data sets include both objective and subjective items requiring individual ratings.[26]

A repository of clinical assessments including SRMs and data sets recommended for use in research about SCI/D is provided by the Common Data Elements or CDEs[24] initiative developed by the National Institute of Neurological Disorders and Stroke (NINDS) at the National Institutes of Health (NIH). The NIH encourages the use of the CDEs in clinical research, patient registries and other human subject research in order to improve data quality and opportunities for comparisons and combination of data from multiple studies and with electronic health records. In this article, we use the CDEs criteria when making recommendations about measures and data sets reviewed here. The purpose of this article is to provide the reader with a list of objective and subjective assessments and related recommendations on the use of these for SCI/D NBB clinical studies.

Methodology

The clinical assessments and diagnostic tools included here were reviewed by an international group of experts and leaders in the field of NBB after SCI/D. They were discussed in terms of potential use and applicability for diagnosing and treating NBB complications of individuals with SCI/D. Commentary on clinical utility of each listed assessment was gathered and shared among group members so that consensus could be reached. Discussions were held on line, via conference calls and at face-to-face meetings until a decision was reached. This process was arbitrated by the article's primary authors. SRMs and datasets were reviewed following two evaluative phases. Phase I produced a selection of measures with preliminary recommendations and Phase II refined these with additional review criteria and literature searches. Each phase consisted of a review of the psychometric properties of the identified measures followed by the use of NINDS CDEs categories in formulating recommendations. These recommendations provide guidance to researchers with respect to the use of selected measures. Definitions of these CDE categories are in Table 1.[27,28]

During the first phase, SRMs and datasets for NBB were identified through literature reviews utilizing electronic databases (i.e. PubMed, Scopus, Google Scholar) and reference lists of key articles. This search focused mainly on NBB assessments for SCI/D but also included a few other neurological conditions (i.e. Multiple Sclerosis, Parkinson's disease). Key words were neurogenic bladder, neurogenic bowel, incontinence, spinal cord injury, spinal cord injury disease or disorder. Titles and abstracts were searched to determine which of the identified measures or datasets contained items on neurogenic bladder or bowel and which were most applicable to SCI/D. Measures that include pertinent items but that were not exclusively focused on bladder or bowel (i.e. the Functional Independence Measure[29] and Spinal Cord Independence Measure[30]) were excluded. See a list of all SRMs and data sets reviewed and discussed in Appendix 2.

Table 1 Criteria for recommendations adapted from CDE categories of recommendations for self-reported measures and international SCI basic datasets.

Recommendation level	CDE definitions	Criteria and ratings of evidence
General core	A data element or assessment that is required for clinical neurological studies.	Assessments reviewed were not relevant for all neurological studies.
Core	A data element or assessment that collects essential information applicable to any SCI/D clinical studies	None of the assessments reviewed met this definition.
Supplemental highly recommended	A data element or assessment which is considered essential based on certain conditions or study types in SCI/D clinical research studies. In most cases, these have demonstrated strong psychometric properties and have been used in more than one SCI/D study	NBB meets the criteria of certain conditions or study types in SCI/D. Measures have extensive psychometrics reported (i.e. reliability, responsiveness) and used in several studies with SCI/D studies. Reports includes concurrent, construct validity often with large samples and/or various supportive studies. Ratings of evidence are at **** or above.
Supplemental	A data element, measure or instrument which is commonly collected in research studies, has some evidence supporting its psychometric properties (at least one validity study) and shows promise for being very relevant for SCI/D studies. Use depends on study design, protocol or type of research.	Documents include internal validity but are based on the development stage for the measure. Also documents at least concurrent validity and/or responsiveness studies. Additional validation studies are desirable. Reliability is reported as moderate to strong. Has been developed and used with SCI/D cohorts. Meets a rating of evidence of ***.
Exploratory	An assessment that shows promise but is highly novel. Has limited or no evidence supporting its psychometric properties in SCI/D but it may fill current gaps in CDEs or substitute for an existing CDE once validation is complete. They are reasonable to use with the understanding that limited study has been done in SCI/D.	Meets the criteria of some types of validity (i.e. face, content, internal consistency). Reliability is reported. Requires further validation and/or development, but may fill current gaps in knowledge. Has been limitedly used SCI and/or in other populations (i.e. MS, IBS). Has potential to evolve into a supplemental recommended tool. Meets a rating of evidence of **.

Experts were asked to conduct a preliminary review of the indices (e.g. measures and data sets) identified based on the following criteria: (1) published reports of reliability and validity; (2) ability to capture change or responsiveness to change across time or in relation to severity of symptoms; (3) ceiling and floor effects; (4) use with SCI/D populations and availability of norms to compare scores; and (5) clinical utility and clinical significance such that scores enable clinical decisions or provide necessary information. Preliminary recommendations for SRMs and data sets inclusion were made using the CDEs classification[27] and ratings of evidence.[28]

Phase I findings were discussed at a meeting held during the 2018 American Spinal Injury Association (ASIA) annual conference with the objective of obtaining consensus from a larger group of experts and attendees on the selected measures and data sets, and related recommendations. As a result, the group felt it was important to consider these selected indices in conjunction with current clinical and diagnostic assessments for NBB in order to obtain a more thorough and complete assessment of NBB dysfunction and its impact on QOL. A second recommendation was that an additional review of SRMs and datasets should be conducted using a confirmatory and more rigorous methodology.[28]

Following these recommendations, in Phase II two independent reviewers were assigned to each measure or dataset. The first reviewer completed his/her review using the "Schema for Rating Measures of Physical and Biological Constructs"[28,31] while the second reviewer confirmed this review and added new information as relevant. Additional literature searches were conducted on each of the selected SRMs and data sets to update information, verify the constructs, parameters, extent of use and utilization in SCI/D studies. This method has been used successfully in other reviews and entails four steps: (1) evaluate face validity in relation to concept, (2) evaluate internal and external validity as reported, (3) determine the index's ability to capture change across time, and (4) determine acceptability for use.

To the extent possible, the datasets were submitted to similar criteria. The reviewers also rated the overall quality of the assessment tool using an adapted version (four instead of five stars) of Johnston and Graves summary rating system:[28]

* = questionable or insufficient validity;
** = minimal validity;
*** = reliability and validity shown;
**** = extensively validated and widely used.

Recommendations made took this system into consideration as well as the information contained in Table 1 depicting CDE categories.

Finally, two experts in measurement and psychometrics conducted independent and final inspections of all selected SRM and data sets recommendations to ensure consistency and accuracy. Thus, each assessment tool had four independent reviews with two focusing on the measure itself and two looking at consistency and data accuracy. The final reviews, with refinements, were submitted to all group members for additional comments in order to reach consensus and provide CDE recommendations.

Results

Clinical assessments for neurogenic bladder and bowel in practice and research

Neurogenic bladder clinical assessments in SCI/D

Fifteen clinical assessment modalities for the evaluation of neurogenic urinary tract symptoms and complications were identified. Targeted conditions included urinary incontinence, recurrent urinary tract infections (UTIs), vesicoureteral reflux, stones, and high detrusor pressure leading to renal deterioration.[16,25] Several of these conditions are also included as part of the International SCI Lower Urinary Tract Function Basic Data Set.[25] A list of these urinary tract assessments and recommendations for use are provided in Table 2.

Neurogenic bowel clinical assessments in SCI/D

Similarly, 12 clinical assessment tools used to assess bowel function in persons with SCI/D were identified. Targeted bowel conditions included fecal incontinence, diarrhea, constipation, infection, and/or obstructions. A listing of these bowel assessments and recommendations for use appears in Table 3.

Self-reported measures (SRMs) and data sets

The initial review of the literature for NBB measures and data sets resulted in a list of 21 measures and three data sets for neurogenic bladder, and 18 measures and two datasets for bowel (basic and extended). Two data sets for urinary tract (urodynamic and imaging) and the urinary tract infection data sets were excluded from these reviews. Although related to NBB assessments, these were found to be beyond the scope of this work which focused primarily on SRMs and the two basic data sets. At the conclusion of this first phase of reviews, five bladder and three bowel SRMs were recommended for consideration as Supplemental measures based on the definition of CDE categories. Bladder dysfunction SRMs included: (1) SCI-QOL Bladder Complications;[102] (2) SCI-QOL Bladder Management Difficulties;[102] (3) Neurogenic Bladder Symptom Score (NBSS);[103] (4) Quality of Life in Spinal Cord Injury Patients with Urinary Difficulties or Qualiveen 30;[104] and (5) Kings Health Questionnaire.[105] For bowel: (1) SCI-QOL Bowel Management Difficulties;[102] (2) Neurogenic Bowel Dysfunction Score (NBDS)[53] and (3) Bristol Stool Form Scale (BSFS).[106] The International Bowel Function Basic data set[26,107] was also recommended as Supplemental. Other indices were recommended as Exploratory based on currently available data.

Phase II reviews were conducted on all eight measures recommended as Supplemental in Phase 1. Two data sets were also reviewed and recommended as Supplemental: The International SCI Bowel Function Basic Data Set and the International SCI Lower Urinary Tract Function Basic Data Set. The latter, which was recommended as Exploratory in Phase I, was added to the reviews during Phase II due to its critical importance for SCI/D care and research and since it is already included in the NINDS/NIH SCI CDEs. In addition, two new SRMs were added to the reviews in Phase II: the Bowel and Bladder Treatment Inventory (BBTI)[108,109] and the Urinary Symptom Questionnaire for Neurogenic Bladder – Intermittent Catheterization (USQNB-IC).[110,111] The BBTI was inadvertently omitted from the reviews in Phase I and the authors became aware of recent publications on the USQNB-IC after Phase I reviews were concluded. The characteristics of these eight selected SRMs recommended as Supplemental or Supplemental Highly Recommended are displayed in Table 4.

Psychometric properties and evidence from SCI/D studies were identified, reviewed and evaluated for these SRMs as described in the methods for Phase II. A summary of these results is provided in Table 5.

In summary, two SRMs, the NBDS[53] and the Qualiveen-30,[104] were included under the Supplemental Highly recommended category due to their wide use in SCI/D and strong psychometric properties with several validation studies completed. The NBDS is a symptom based measure of neurogenic bowel that provides an overall score related to impact on QOL. Similarly, the Qualiveen 30 is a measure of urinary function that relates symptomology to QOL impact. The SF Qualiveen is also available on an eight item version short form.[114] Both versions are copyright-protected therefore, permission for use is required. These measures provide a good overview of issues related to symptoms, complications and impact on life domains, and in many cases can serve as gold standards when examining the validity of other similar SRMs.

Five SRMs were recommended as Supplemental: the SCI-QOL Bladder Management Difficulties,[102] SCI-

Table 2 Clinical urinary tract assessments and recommendations for use in SCI/D.

Tests	Description	Additional Comments and Recommendation for Use in SCI/D	References
Bladder Emptying / Voiding Diary	A patient-generated, time-stamped log of liquid intake and urine output. Records frequency, volume per event, urge sensations and leakage (incontinence). Typically includes record of collecting appliances (e.g. pads) used to manage episodes and potentially related physical activity.	Use to evaluate bladder management routine, characterize daily habits/lifestyle choices and document bladder symptoms. Recommendations: • Also include bladder emptying method(s), number of voluntary voids & catheterizations, high water content food, and if sensation or awareness of need to empty bladder is present. • Request completion of 3–7 days prior to appointment if possible. • International Spinal Cord Injury Lower Urinary Tract Function Basic Data Set (version 2.0) can be used.	25,32
Physical Examination of Bladder Dysfunction	Conducted by a clinician and includes abdominal, pelvic, musculoskeletal and skin assessment. May include cognitive and neural exams as voiding includes voluntary and involuntary control.	Use to identify bladder dysfunction related conditions (e.g. incontinence associated dermatitis, kidney enlargement, palpable bladder, etc.) Recommendations: • Include sensory examination of proprioception, touch, pinprick, and reflex for pudendal nerve function. • Determine extent of hand function for consideration of management approach (self-catheterization, toilet transfer, etc.) • Genital exam – evaluate for skin breakdown (i.e. traumatic hypospadias from indwelling catheter, pressure injuries), lesions or masses on penis or scrotum or vulva.	
Urinalysis (reagent strip "dipstick" or automated testing of urine)	Screening tool for bacteriuria, renal and systemic pathology, and microscopic hematuria which can be performed via reagent strip or by automated methods. Includes assessment of appearance, concentration and content of urine. Routinely includes Glucose, Protein, Blood or hemoglobin, Nitrite, Leukocyte Esterase, Specific Gravity, urine pH.	Use to diagnose Urinary Tract Infection (UTI), kidney disease and diabetes. Recommendations: • Nitrite dipstick is 19–48% effective for predicting UTI whereas, positive leukocyte esterase AND positive nitrite is 32–68% effective. • Blood or hemoglobin, nitrite, and leukocyte esterase are relevant markers of potential UTI. • Culture all suspected negative results for confirmation.	33–36
Urine Microscopy	Manual or automated microscopic examination of the urine. Can confirm presence of erythrocytes (microscopic hematuria) or white blood cells (pyuria)	Use as a screening tool for renal pathology (casts, proteinuria, etc.) Recommendations: • The presence of bacteriuria in a symptomatic patient has sensitivity for UTI between 40–70% and specificity between 85–95%.	33–35
Urine Culture	Test to detect bacteria in the urine that can cause symptomatic UTI.	Use to diagnose UTI in a symptomatic patient. May also be ordered in other conditions (i.e. prior to bladder testing) Recommendations: • Atypical bacteria may require special plating and longer culture time. • Bacterium sensitivity result can be used to guide antibiotic prescription.	35,37

Glomerular Filtration Rate (GFR)	Test of renal function that can be calculated from endogenous (carbamid, cystatin-C, creatinine) markers in blood plasma and patient demographics or exogenous (inulin, iothalamate) markers injected into the patient's bloodstream.	• Use to evaluate kidney function (effectiveness). Note: Typical calculations of GFR from endogenous markers (blood work) must be considered carefully. Recommendations: • Exogenous inulin is considered the gold standard for estimating GFR in SCI/D, but cumbersome to perform. • Endogenous creatinine varies based on muscle mass and therefore is NOT a reliable marker in patients with SCI/D. • Creatine clearance based on 24-hr urine collection IS a reliable marker in patients with SCI/D. • Endogenous cystatin-C increases in hyperthyroid and steroid use and is decreased in women and elderly and hence. Some evidence indicates that assays are more accurate in SCI/D, yet need for additional evidence, cost low availability raise concern. • GFR equations that take into account both creatinine and cystatin-C are recommended ($eGFR_{cr\text{-}cys}$) in SCI/D	38,39
Renal and Bladder Ultrasound (US)	A noninvasive diagnostic exam that produces images of the size, shape, and location of the *kidneys and urinary bladder*. Provides measurement of bladder volume, catheter position, and obstructions (if present).	Use for routine assessment of renal size and investigation of potential masses, obstructions (e.g. blood clot, urinary outlet) cortical thinning, hydronephrosis and urolithiasis. Recommendations: • Assessment of post void residual or bladder volume, diverticuli, and wall thickening in SCI/D patients with neurogenic bladder. • Investigation of blood clot urinary retention. • For evaluation of urolithiasis (bladder or kidney stones): Ultrasound is less sensitive than a computed tomography (CT) scan, but better than kidneys, ureters, and bladder (KUB) radiograph at diagnosing urolithiasis and uses no ionizing radiation, however, a non-contrast CT scan remains the preferred method for this assessment. • Good for guidance and confirmation of interventional applications such as placement of suprapubic catheters in SCI/D.	40–43
Abdominal X-ray	An imaging test to look at structures in the abdomen.	Use to screen for urinary tract calculi and provide information on stool burden. Recommendations: • The sensitivity and specificity of abdominal x-ray for ureteral or renal stone is 44–77% and 80–87%, respectively. A non-contrast CT scan remains the most sensitive test.	25,44,45
Abdominal CT-Scan	An imaging test that uses computer tomography (CT) to create cross sectional images of the abdomen. • Non-Contrast CT: cross sectional imaging without contrast enhancement. • CT Urogram: non-contrast phase, a contrast enhanced nephrographic phase outlining the renal parenchyma, and a contrast enhanced pyelographic phase outlining the ureteral lumen.	Use for patients with symptoms of renal colic; not indicated for routine urinary tract surveillance. Recommendations: • Non-contrast CT is the gold standard to diagnose nephrolithiasis as it is more sensitive and specific for than renal ultrasound and abdominal X-ray. • CT Urogram with 3-D reconstruction may also be considered when detailed anatomic imaging of urinary tract is necessary. Given the much higher dose of radiation compared to a non-contrast CT scan, this modality should be used sparingly and reserved for the urologist to order as necessary.	25,45

Continued

Table 2 ***Continued***

Tests	Description	Additional Comments and Recommendation for Use in SCI/D	References
Renal Scintigraphy	An imaging test that uses a radiotracer to detect different types of tissue to indicate kidney function. Renal Scintigraphy evaluates for renal obstruction as well as renal function or renal cortical scarring, based on the radiotracer utilized.	Use to evaluate renal function, obstruction, and cortical scarring. Not routinely needed for screening though allows differentiation between relative function of both kidneys. Recommendations: • Limited use in patients with poor renal function but is recommended in patients with anomalies on US or CT that are concerning for obstruction or scarring. • Technetium 99m-diethylenetriamine pentaacetic acid (^{99m} Tc-DTPA) is filtered by glomerulus and therefore indicated when ureteral obstruction is suspected. • Technetium 99m-dimercaptosuccinic acid (^{99m} Tc-DMSA) – localizes to the renal cortex and utilized to evaluate for cortical scarring. This does not evaluate for renal obstruction. • Technetium 99m-mercaptoacetyl triglycine (^{99m} Tc-MAG3) – can evaluate renal function, obstruction and renal plasma flow. Diuretic enhanced scans can provide differential function.	25,42,43
Intravenous Pyelography also called and Excretory Urogram	An imaging test that uses sequential X-rays to examine the urinary tract. Composed of a plain abdominal film of the calculi in the kidneys, ureters or bladder followed by contrast injection and obtainment of a nephrogenic phase of the film for renal abnormalities. Finally, films are taken every 5 min to evaluate for excretion of contrast into the ureter and outline the collecting system to evaluate filling defects.	Rarely used in modern healthcare due to the advent of CT and magnetic resonance imaging (MRI) to evaluate the genitourinary anatomy. Recommendations: • Limited applications, used in trauma settings with patients who are unstable for CT to demonstrate renal function.	25,43
Uroflowmetry	Test that measures the volume, speed of flow, and duration of time to expel urine from the body. Poor urine flow can result from either bladder underactivity or outlet obstruction. While the curve generated from the Uroflow can provide clues to the cause of obstruction, uroflowmetry cannot distinguish between the two causes of a poor urine flow.	Use to evaluate poor urine flow. Recommendations: • Only applicable to persons with SCI/D who are voiding. • SCI/D patient bladder capacity must be above 150 mL in order to obtain a valid result.	46,47
Post Void Residual (PVR)	Test that measures the residual urine in the bladder following a voluntary void. Residual urine can be measured by ultrasound or catheterization.	Use to determine whether patients are experiencing urinary retention or incomplete bladder emptying. Recommendations: • Perform PVR during the initial assessment of patients with SCI/D.	46,47
Urodynamic Investigation	A battery of assessments that examine how the bladder and urethra are functioning in terms of storing and releasing urine. Comprised of the following components: • Uroflowmetry and PVR • Filling Cystometrography (CMG) – evaluates the detrusor pressure with changes in bladder volume. • Electromyography (EMG) of the striated sphincter muscles of perineum – evaluates for detrusor-sphincter-dyssynergia (DSD) • Pressure-flow studies – relationship between the pressure generated in the detrusor during voiding and the flow rate. • Fluoroscopy (video-urodynamics) – simultaneous fluoroscopic images during the urodynamic study.	Use during the initial evaluation of patients with SCI/D and as needed during follow-up. Recommendations: • Pressure flow studies are helpful to determine whether poor urinary flow is due to obstruction versus underactivity in SCI/D patients who void. • Fluoroscopy is useful to evaluate for vesicoureteral reflux, especially in SCI/D patients with neurogenic bladder.	25,46–48

Cystourethroscopy	Procedure to examine the linings of the urethra through a cystoscope.	Use to evaluate indications for hematuria, follow-up for malignancy, and unexplained lower urinary tract symptoms. Also helpful in bladder stone or foreign body removal, urethral stricture dilation, and complex catheter placement. Recommendations: • Not recommended in patients with SCI/D without other symptoms or signs such as difficulty performing CIC or hematuria. [49]

QOL Bowel Management,[102] the BSFS,[106] the KHQ[105] and the NBSS.[103] All provide sufficient psychometric information about reliability and validity with some degree of variation in using with SCI/D populations. Evidence of responsiveness was provided by most of these measures with some differences in methodologies used and timing of published results.

The KHQ has been designed to use with women with incontinence problems. Two SCI trials show relevant changes in scores. See Table 5. The BSFS is an observational SRM and as such requires the presence and ability of someone (e.g. person with SCI/D or caregiver) to observe results. Responsiveness is noted by two SCI clinical trials. The NBSS[103,125] has strong correlations with the SF-Qualiveen and moderate correlations with the SCI-QOL Bladder Management Difficulties SF. The NBSS is available for free use but requires permission from the developer.

The SCI-QOL item banks and SFs for bladder and bowel have strong content validity. These were developed especially for SCI/D through a very thorough and comprehensive process, using cognitive interviews with stakeholders. Developed in 2015, the SCI-QOL can benefit from additional external validation studies. This SRM is being used by a number of new studies in SCI/D. PDF copies of the SCI-QOL item banks and SFs are freely available. Computer Assisted Testing or CAT versions are available through multiple platforms (i.e. free in REDCap for institutions that support this platform or as an iPAD app for a minimal fee). The SCI-QOL is also included in the NIH toolbox[149] but may require a fee for use.

Two SRMs were recommended as Exploratory: the USQNB-IC,[110,111] and the BBTI.[108,109] These are new promising measures with great potential for use in SCI/D. The USQNB focus on the evaluation of UTI symptoms and their impact on life. Since this is a frequent complication for those with SCI/D, this measure has significant potential to advance the quality of healthcare in relation to UTI. The USQNB version reviewed here is specifically designed to be used with people who use intermittent catheterization. Different versions of the USQNB are also available. The version reviewed has shown good internal consistency with limited construct validity[110] The BBTI includes items from the basic and extended bowel function and lower urinary tract international SCI data sets, adapted as SRMs items, and addressing issues of management, complications and satisfaction. These items can be directly administered to patients during interviews. As such, it is less dependent on

Table 3 Clinical assessments for neurogenic bowel and recommendations for use with SCI/D.

Test	Description	Additional Comments and Recommendations for Use in SCI/D	References
Bowel Diary	A patient-generated time-stamped log of bowel action. Records stool type (Bristol Stool Scale), amount, incontinence episodes, urgency, straining and all current medications (not just those targeting bowel function). Complications such as nausea or hemorrhoids can be captured in comments.	Use to evaluate bowel management routine, characterize daily habits/lifestyle choices and document gastrointestinal symptoms. Recommendations: • Include documentation of time taken for bowel care episode from start to finish. • Uncover patient perception of ideal/reasonable timing and frequency of bowel evacuation for comparison to current experience. • Also include assistance such as physical interventions (i.e. digital stimulation, disimpaction, enemas, etc.), position (in bed or over toilet), caregiver support, and use of suppositories or oral medications in terms of type, amount and timing related to bowel movement. • International Spinal Cord Bowel Function Basic Data Set (version 2.1) and the Neurogenic Bowel Dysfunction Score (NBDS) can be used.	26,50–54
Physical Examination of Bowel Dysfunction	Conducted by a clinician and includes abdominal examination, rectal ampulla exam (for hard stools or tumors), tests of sacral reflexes (anocutaneous and/or bulbocavernosus), anal sphincter tone, sensation and voluntary contraction.	Use to identify bowel dysfunction related conditions. Recommendations: • Important to determine the level of injury and verify upper vs. lower motor neuron deficits. • Verify SCI/D pelvic floor muscle function during defecation for role in defecation disorder. • Auscultation of the abdomen followed by palpation and percussion should be included. • In patients with an ostomy, include examination of stoma and check for direct or indirect hernia.	50,55
Stool Sampling for Analysis	A series of tests to help diagnose certain conditions affecting the digestive tract. Stool sample often collected by the patient at home.	Use when screening for cancer, infection, or suspicion of parasites. Recommendations: • Tests for toxins or leukocytes may be included if concern about infection. • Consider evaluation of guaiac or fecal occult blood (starting at age 50 or sooner if problems arise).	50,55–57
Abdominal X-ray	Standard testing to evaluate extent and location of fecal loading.	Use to determine of megacolon, degree of constipation, and site of impaction as well as the need for a more aggressive bowel management strategy. Recommendations: • Helpful to determine if oral versus rectal route of treatment is needed based upon site of impaction.	58–60
Computed Tomography (CT) Scan	Standard radiologic imaging helpful in delineating gastric, small intestinal, colonic or pelvic structural or anatomical abnormalities.	Use to exclude lesions that may cause GI symptoms and constipation.	61
Endoscopy (Rectosigmoidoscopy, Anoscopy, and Colonoscopy)	Standard test if cancer or structural abnormalities are suspected.	Use to diagnose or rule out colon abnormalities and carcinoma.	62–65

Continued

Table 3 ***Continued***

Test	Description	Additional Comments and Recommendations for Use in SCI/D	References
Gastric Emptying Study	Test to determine the time is takes for food to move through a person's stomach.	Useful in evaluating for gastroparesis in persons with SCI/D experiencing significant upper abdominal symptoms such as abdominal pain/discomfort, bloating, and distention and treating accordingly.	66–75
Total and Segmental Colonic Transit Time (CTTs)	Test that uses radio-opaque markers to investigate small and large bowel motility through objective time course measurement.	Use in determining worsening colonic function and if there is a need for surgical intervention. Recommendations: • Although easy to perform, CTT should only be used to support clinical evaluation as large variations in transit time normally exist which reduces its diagnostic value.	76–81
Wireless Motility Capsule for Bowel Transit	Test that involves ingesting a capsule that simultaneously measures the gastrointestinal and colonic pH, temperature and intraluminal pressure to provide information on gastric emptying, small intestine transit and total colorectal transit.	Use to gain comprehensive information on gastrointestinal motility and how motility of each gut segment is correlated to the other (gastric vs small intestinal vs colon). Recommendations: • Consider use only in SCI/D patients with intact swallowing capability. • Not universally available.	82
Anorectal Manometry ± Balloon Expulsion Test (BET)	Test that uses a balloon in the rectum and a pressure sensor at the sphincter to measures contractility in the anus and rectum.	Use to determine internal anal pressure and the presence or absence of the rectosphincteric reflex. Recommendations: • Can be very helpful in delineating defecation disorders related to pelvic floor dysfunction in incomplete SCI/D. • Can provide information of anorectal physiology including quantitative measures of rectal volume sensations and anorectal pressure during rest and squeeze that is useful for persons with incomplete SCI.	83–98
Pudendal Nerve Latency Testing and Pelvic Floor Electromyography	Electrophysiological examination used to directly investigate the integrity of the somatic innervation of the pelvic floor muscles and urinary and anal sphincters.	Use to evaluate defecation disorder and pelvic floor dysfunction. Recommendations: • Helpful in evaluation of peripheral nerve injuries in incomplete SCI/D and peripheral neuropathy (especially pudendal neuropathy). • Important for consideration of the level of injury and to determine upper vs. lower motor neuron deficits.	55,97–101
Defecography	Medical radiological imaging test in which the mechanics of a patient's defecation are visualized in real time using a fluoroscope.	Use when anatomic causes of outlet obstruction like rectal prolapse, rectocoele or enterocoele are suspected. Recommendations: • Helpful for assessment of progressive worsening or change in bowel patterns in incomplete SCI.	97,98,101

clinicians' time and effort to document this information. For the BBTI, more published validity data is also warranted. As more evidence of validity in SCI/D accumulates over time, these SRMs will likely move into the Supplemental category of CDE recommendations.

The two basic datasets (bowel function and lower urinary tract) were recommended as Supplemental

Table 4 Characteristics of bowel and bladder measures recommended as supplemental highly recommended and supplemental.

Name of Measure	Construct Measured	Parameters	Extent of use	Validation in SCI	Suggested Use
BOWEL MEASURES					
Bristol Stool Form Scale (BSFS),[106] also known as Bristol Stool Scale or Bristol Stool Chart	Form of stool consistency (hard to liquid). Developed as proxy for colonic motility/ whole-gut transit time. Visual representations of 7 possible types of stool based on its form (consistency, shape)	Single 7-point ordinal scale	Extensive use in various diagnostic groups and general population (>1000 PubMed hits) including IBS, patients with constipation and diarrhea.	One validation study of plain abdominal radiography using the BSFS as reference measure.[62] Eight empirical studies.	Quick and easy to use observational scale. Serves as a guide to constipation and diarrhea. Shows utility in clinical practice and research.
Neurogenic Bowel Dysfunction Score (NBD or NBDS)[53]	Degree of NBD symptomatology. Items measure symptoms or current bowel management routines. Items are symptom-based, but weighted according to impact on QOL.	Single 10-item ordinal scale. Multiple response formats. Weighted total score (range 0–47). Interpretation: 0–6 no; 7–9 little; 10–13 some; ≥14 major impact on QOL.	Extensive use in neurological conditions, mainly in SCI and MS (> 100 hits). Reliability and validity confirmed in multiple studies.	Developed for use in SCI. Three validation studies.[54,112,113]	To assess bowel characteristics, methods of management, and symptoms of complications such as incontinence, constipation and impact on QOL.
SCI-QOL Bowel Management Difficulties[102]	Difficulties with bowel management among persons with SCI including feelings of distress in daily life associated with bowel problems.	Item bank of 26 items. With Computer Assisted Technology (CAT), minimum 4 items, minimum 8-items or complete variable-length. Short-Form with 9 items. Response options in a 5-point scale.	Has been used in SCI with diverse sample (>700). Used in ongoing studies.	Developed for use in SCI. One validation study so far published in 2015.[102]	Easy to administer using CAT or short forms. Items focus on issues related to bowel accidents and psychosocial consequences of incontinence.
BLADDER MEASURES	Construct Measured	Parameters	Extend of Use	Validation in SCI	Suggested Use
Qualiveen 30[104] and SF Qualiveen[114]	Impact of urinary limitations on psychosocial wellbeing and QOL. Condition-specific QOL measure for individuals with SCI who have urinary disorders.	30 items. Multiple response formats. Total score and 4 subscale scores: Limitations, Constraints, Fears, and Feelings.[104] 8-item short version with the 2 most responsive items per domain.[114]	Developed for use in SCI with frequent use in SCI and MS samples (>50 hits). 6 validation studies in MS[115–120]	14 validation studies.[104,114–118,121–127] and 4 using the Qualiveen as reference measure[124–126,128]	To evaluate impact of urinary dysfunction, management and symptoms on one's feelings, fears and concerns.
King's Health Questionnaire[105]	Condition-specific quality of life questionnaire for assessment of women with urinary incontinence, and assess the quality of life of women with specific urodynamic diagnoses.	21 items in 9 domains: general health perceptions, incontinence impact, role limitations, physical limitations, social limitations, personal relationships, emotions, Sleep/ Energy, and severity measures[105] and an 11-item symptom severity score.	Extensive use in various diagnostic groups and general population (>300 PubMed hits). At least 4 studies in SCI.[11,129–131] Reliability confirmed in >20 validation studies.	2 validation studies in SCI, of which 1 in a mixed sample (Turkish and Spanish versions)[124,132]	Designed for use in women with urinary incontinence.

Continued

Table 4 ***Continued***

Name of Measure	Construct Measured	Parameters	Extent of use	Validation in SCI	Suggested Use
SCI-QOL Bladder Complications[102]	Measures the impact of bladder complications (only UTIs) on health-related quality of life.	5 items fixed-length form.	Developed and used in SCI with diverse sample (>700).	1 internal validation study with SCI[102]	Designed to assess the impact of UTIs on daily life activities.
SCI-QOL Bladder Management Difficulties[102]	Measures the impact of issues with neurogenic bladder management on health-related quality of life	Item bank of 15 items. CAT administration (minimum 4 items or minimum 8 items). 8 item short-form. All items 5-point response scale.	Developed and used in SCI with diverse sample (>700). Also use in other SCI studies.[20,133]	2 validation studies, 1 of which used the SCI-QOL as reference measure for the NBBS.[20,133,134]	Measures bladder incontinence, leakage, accidents and management and impact on self.
Neurogenic Bladder Symptom Score (NBSS)[103]	Measures urinary symptoms and bladder-related consequences in patients with acquired or congenital neurogenic bladder dysfunction (SCI, MS, spina bifida).	Total 24 items. 22 in three domains: storage,[8] voiding[7] and urinary complications;[7] 1 on type of bladder management; 1 on satisfaction with bladder management. 4–5 points rating scale.	8 PubMed hits, most are authored by the developers of this scale.	4 validation studies (2 in mixed samples).[103,125,135,136] 2 empirical studies.[133,137]	Measures bladder management, urine leakage, behavioral consequences of leakage, complications, medication use, and impact on satisfaction with life.

given their importance to the field in capturing uniform information across sites. Data comparisons can be thus enhanced by these items inclusion in electronic medical record platforms being supported by various clinical institutions around the world treating persons with SCI/D. Being developed by groups of experts and having passed a rigorous approval process, these data sets have obvious content validity. Moreover, information on inter-rater reliability is available, but further validation studies are encouraged for both.[150] Their characteristics and psychometrics are described in Table 6, below. Both include information on methods of management, complications, impact on function and satisfaction with methods of management. Data is collected by clinicians interviewing and/or examining patients and abstracting it from medical records. The International SCI Bowel Function Basic Data Set 2.0[54] offers a score for bowel dysfunction by including items from the NBDS. Currently, the International SCI Lower Urinary Tract Function Basic Data Set[25] does not offer a scoring system.

Conclusions and discussion

This article provides readers with recommendations for clinical and diagnostic tools and measures including SRMs and datasets currently available for use. Studies focusing on NBB as a primary end point or secondary outcome in SCI/D may wish to consult the tables provided here for guidance on the selection and utility of the assessments reviewed. We describe measurement properties, suggested use based on study type or element of clinical interest, and provide recommendations for CDE inclusion.

Two measures were rated as Supplemental-Highly recommended. Of all measures reviewed, none were cited as Core, as these are not required for all NINDS funded SCI research studies and trials. Core data includes only very basic data, such as the date and etiology of SCI, the International Standards for the Neurological Classification of Spinal Cord Injury – ISNCSCI[154,155] and the Columbia Suicide Severity Rating Scale.[156,157]

On the other hand, Supplemental-Highly recommended CDEs are considered essential for studies addressing specific SCI/D study domains or conditions, such as motor function or pain, yet no specific domain for neurogenic bowel and/or bladder function has been defined. Of the eight domains that include Supplemental-Highly recommended CDEs, only one contains questions related to sphincter function and toileting. These questions are included in the Spinal Cord Independence Measure (SCIM)[30,158] in the Outcomes and Endpoints; Functional Outcomes domains of CDEs for SCI/D.

Furthermore, studies that fall in any of the other 17 domains are currently not specifically recommended to collect data on NBB. This is important because recent

Table 5 Summary of psychometric evidence and recommendations for selected measures of bowel and bladder dysfunction.

Name of Measure	Reliability	Validity	Concurrent validity	Responsiveness	Clinical Utility	Rating of Evidence	CDE Recommendations
BOWEL MEASURES							
Bristol Stool Form Scale (BSFS)[106]	Not reported	Face validity as ordinal rating of stool form	No association with Whole Gut Transit Time (WGTT),[62] significant association with NBD score[138]	Two SCI trials showed significant change of BSFS scores[139,140]	Easy to apply observational measure of outcome of bowel management	***	Supplemental
Neurogenic Bowel Dysfunction Score[53]	Test-retest and inter-rater reliability of the selected items good[53,112]	High internal consistency[53,112,113]	Correlation 0.91 between NBD and physician's global assessment[53] Correlation 0.92 between NBDS and impact of NBD on QoL[112]	Correlation 0.82 between change NBDS and global rating of change.[112] Four SCI trials showed significant change of NBDS scores[141–144]	Easy to administer and score when evaluating symptoms and management issues.	****	Supplemental Highly Recommended
SCI-QOL Bowel Management Difficulties [102]	Moderate test-retest reliability (ICC = 0.74)[19,102]	High internal consistency (0.95), good fit to IRT model[19,102]	Not yet reported	Not yet reported	Reference scores available. Easy to use when focusing on incontinence and management.	***	Supplemental
BLADDER MEASURES	Reliability	Validity	Concurrent Validity	Responsiveness	Clinical Utility	Ratings of Evidence	CDE Recommendation
Qualiveen 30[104] SF Qualiveen[114]	Test-retest reliability high for total score and subscales	High internal consistency	Significant correlations with reference measure.[104,114] Weak correlations with urinary symptoms.[123] SF scores different between patients and controls.[121]	Short form (8 items) and long version (30 items) with similar levels of responsiveness (SRM 0.75–1.62)[114] SCI trials showed significant change in Qualiveen scores.[123,145,146]	Can detect bladder adjustment problems in SCI and MS samples. Reference scores available.	****	Supplemental Highly Recommended
King's Health Questionnaire[105]	High test-retest reliability (ICC: 0.69–0.94)[124]	Internal consistency (alpha 0.68–0.93)[124] Validity is widely established in other populations.	Moderate to strong correlations between corresponding scales of the Qualiveen.[124] Moderate to weak correlations with SF-36 scales.[11,124]	Two SCI trials showed change of KHQ scores.[129,130] 1 study showed no differences in scores,[131] yet sensitivity to change has been demonstrated.[147]	Easy to administer. Scoring and interpretation is not always straightforward.[148]	***	Supplemental
SCI-QOL Bladder Complications[102]	Moderate test-retest (ICC = 0.69)[102] Documented reliability.[16]	Good Internal consistency (0.72) [16,102] Good fit and no DIF in IRT-analysis	Not yet reported	Not yet reported	Reference scores available.[102]	***	Supplemental

Continued

Table 5 *Continued*

Name of Measure	Reliability	Validity	Concurrent validity	Responsiveness	Clinical Utility	Rating of Evidence	CDE Recommendations
SCI-QOL Bladder Management Difficulties[102]	Good test-retest reliability (ICC = 0.76)[16,102]	High internal consistency (0.91) Good fit and no DIF in IRT-analysis.[16,102]	Moderate correlation (0.50) with NBSS. Showed significant differences according to type of catheterization.[133] Another study reports significant associations with bladder surgery[134]	Not yet reported.	CAT- and SF-versions and reference scores available Assessment through CAT-center possible. Has been used with surgical and management interventions.	***	Supplemental
NBSS[125]	Good test-retest for total score (ICC = 0.91)[125] and scale scores (ICC = 0.85–0.86).[125]	Good internal consistency total score (0.85). Variable for scale scores (0.46–0.93).[135]	Moderate correlation (0.50) with SCI-QOL BMD. Strong correlations with other bladder scores (AUASS, ICIQ-UI and SF-Qualiveen). Significant differences among known groups.[125,136]	The smallest real difference for group level comparisons ranged from 0.9 for the satisfaction question to 7.7 for the NBSS total score.[136] Significant changes were seen after application of botulinum toxin[134] and mirabegron.[137]	24 questions may be a burden to complete. Patients can complete the NBSS in approximately 6 min.[125]	***	Supplemental

SCI studies designed to address complications such as pain, locomotion and respiration have reported anecdotal evidence of NBB improvements.[1] Thus, having NBB data collected routinely with standard measures could greatly impact future results from clinical studies by offering new insights into treatments.

As we have discussed earlier, NBB is prevalent following SCI/D, is a highly-important medical concern, and has a tremendous impact on the QOL of people living with SCI/D. Therefore, the authors put forth a collective recommendation that the SCI CDEs be updated to include a new domain for NBB as essential to clinical studies in this area. The two measures (Qualiveen 30 / SF-Qualiveen for bladder and NBDS for bowel) that have achieved the level of evidence necessary to be included in the SCI CDE Supplemental-Highly recommended category could then be added under this new domain, as SRMs to be used in SCI/D studies. In fact, the Qualiveen 30 is already listed under the QOL/PRO outcome in the NINDS SCI-CDE website. The short version (SF-Qualiveen) offers similarly strong psychometric properties as the parent instrument and may be preferred since it consists of only eight items.

Although only two measures of NBB are identified that currently meet the criteria for the CDE Supplemental-Highly recommended category at this time, other NBB measures reviewed here are likely to achieve sufficient evidence of validity in the near future and may be preferred for use depending on study purpose and design. Some of these SRMs were designed specifically for SCI/D NBB and therefore, may provide a more complete and relevant characterization of the condition being studied in this population. As more studies continue to be published, it is anticipated that other measures will reach this level of recommendation, giving clinicians and researchers more options to choose from. One of such measure is the Monitoring Efficacy of NBD Treatment On Response (MENTOR) tool,[159] just recently validated in the SCI population, which provides a mechanism to monitor treatment effectiveness of NBD and determine progression through the clinical pathway. Future comparative psychometric studies using large, diverse samples are needed to reveal the relative pros and cons of each measure.

Researchers who perform NBB studies are advised to consider the use of data set items as appropriate. Data set items can be used to describe key bladder/bowel characteristics of the study samples as well as to describe clinically relevant outcomes of bladder/bowel management and functioning. Future studies are recommended to make these data sets easier to use with patients, less

Table 6 Characteristics of the international SCI bowel function and lower urinary tract function basic data sets.

Name of measure	Construct measured	Parameters	Extend of use in SCI	Validation in SCI	Suggested use and CDE recommendation
International Spinal Cord Injury Bowel Function Basic Data Set (version 2.0).[26,107]	The Bowel Function Data Set assess the impact of issues with bowel management (neurogenic bowel), related complications and lifestyle changes on health related quality of life (HRQOL).[107] Version 2.0 includes all items of the Neurogenic Bowel Dysfunction Score (which in itself is a validated 10-item score).[26] A version 2.1 is now available but its development was completed after this review was conducted.	Total 16 items; date of data collection, gastrointestinal and anal sphincter dysfunction unrelated to SCI, surgical procedures on the gastrointestinal tract, defecation method and bowel care procedures, average time required for defecation, frequency of defecation, uneasiness, headache or perspiration during defecation, digital stimulation or evacuation of the anorectum, frequency of fecal incontinence, flatus incontinence, need to wear a pad or plug, oral laxatives and prokinetics, anti-diarrheal agents, perianal problems, abdominal pain and discomfort	Developed for use in SCI. 2 reliability and validation studies.[26,150]	Content validity appears ensured as it was developed by an expert committee and passed an extensive approval process.[26,107] Inter-rater agreement version 1.0 (including extended data set[3] items). Agreement was very good in 5 items, good in 11 items, moderate in 20 items, fair in 11 items and poor in 5 items.[150] Inter-rater agreement study version 1.0. Mean % agreement was 88.6 (range 50–100). Mean Kappa was 0.82 (0.67–0.95) (6 items). Mean ICC was 0.78 (0.50 - 0.97) (3 items).[151]	Can be used by clinicians and researchers to collect clinical relevant data about patients' bowel function after SCI. It includes the validated NBD score. Appropriate for children who have reached the age 3 or older, where bowel continence is typical.[152] CDE Recommendation: Supplemental.[27]
International Lower Urinary Tract Function Basic Data Set or LUTF BDS (version 2.0)[25,153]	The LUTF BDS was developed as a standardized format for which a minimal set of information about lower urinary tract function could be collected and reported across individuals with SCI.[153] A second version was published in 2018 that included new terminology and revised response categories SCI.[25]	Contains 9 parameters: urinary tract impairment unrelated to SCI, awareness of need to empty bladder, method of emptying bladder, average number of voluntary bladder emptying per day, involuntary urine leakage in last 3 months, collecting appliances for urinary incontinence, drugs for urinary tract in last year, surgical procedures on urinary tract, change in urinary symptoms in last year.	Developed for use in SCI. 1 reliability and validation study reported[151].	Content validity appears ensured as it was developed by an expert committee and passed an extensive approval process[25,153]. Inter-rater agreement study. Agreement 85.0% (60–100). Mean Kappa was 0.68 (0.47–0.93)[151]	Designed as a standardized data collection and reporting measure, not necessarily as an outcome measure to detect change in bladder function. Appropriate for pediatric patients, if a child was continent before the injury (i.e. aged 3 or older).[152] CDE Recommendation: Supplemental[27]

time consuming and, with respect to the bladder dataset, formatted so scores can be obtained in assessing NBB dysfunction.

SRMs such as the ones reviewed here can clearly complement diagnostic procedures and objective tests required to treat and diagnose NBB related problems, and are the primary method of evaluating the impact of NBB dysfunction on QOL. The suggestion made by the Federal Drug Administration (FDA) that regulation and labeling should include patient perspectives only solidify the importance of SRMs/PROMS. They provide an important quantification of symptoms which can't be measures objectively.[15]

Finally, to make a sensible choice about which measurement tool to use (SRMs or datasets), one needs a good understanding of what is being measured

or assessed and relate this to one's research or clinical practice. In doing so, a balance between the construct being measured and then psychometric strength of the measures needs to be considered. It is also important to consider how easy it is for individuals to answer the questions and time required to do so. Cost and accessibility of SRMs are also important considerations. Another issue to consider when conducting international multi-center trials is cultural validation across these SRMs and data sets. While some indices may have been used in international samples using a translated version, cross cultural validation studies are encouraged to ensure comparability of the constructs being measured.

This article also provides a synopsis of clinical diagnostics and assessments as recommended by clinicians treating SCI/D patients. Increasing consistency of these assessments and diagnostic tools will aid in continuity of care by setting clinical standards for use in NBB after SCI/D. Studies evaluating the combined use of clinical assessments, SRMs and data sets can inform the validity of this information in guiding best practices and outcomes of NBB interventions. The use of SRMs and data sets should be an accepted part of evidence-based practice to the extent that their use is included in clinical guidelines and core standard of practice. The recommendations put forth in this manuscript are only the beginning. It is our hope that additional validation studies of measures recommended as Supplemental or Exploratory be undertaken to further advance NBB characterization and treatment.

A few limitations should be noted in relation to the work presented here. The need to remain focused on our charge of reaching consensus around a minimum set of assessment items or tools to be used NBB related studies for SCI/D, precluded the inclusion of several other resources that deserve further investigation. For example, this work did not include reviews of SRMs, data sets or other clinical assessment tools for SCI/D pediatric patients. Furthermore, this work did not include a review of the International Standards to document remaining Autonomic Function after Spinal Cord Injury (ISAFSCI),[160] which is used to complement clinical assessments done with the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI), The ISAFSCI contains some information on NBB after SCI among other components of autonomic function. Not included also in the reviews performed here was the International SCI Urinary Tract Infections Data Set.[37] The inclusion of these additional elements in future studies is critical as they complement the work conducted here. An invitation is thus made to the scientific community, stakeholders, administrators and funding agencies to consider recommendations discussed in this article when designing future studies aimed to seeking solutions for NBB dysfunction following SCI/D.

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Appendices

Appendix 1: List of Participants

1. Kim D. Anderson PhD
2. Fin Biering-Sorensen MD PhD
3. Anthony Burns MD
4. Thomas Bryce MD
5. Anne *P.* Cameron MD
6. Susan Charlifue PhD
7. Mathew David MD
8. Kym Eisner
9. Martin Forchheimer MPP
10. Jeffery Johns MD
11. Gregory Holmes PhD
12. Charles Hubscher PhD
13. Lyn B. Jakeman PhD
14. Michael J. Kennelly MD
15. Steven Kirshblum MD
16. Naomi Kleitman PhD
17. Andrei Krassioukov MD PhD
18. Evgeniy Kreydin MD
19. Klaus Krogh MD
20. Giulia Lane MD
21. Maryjane Mulcahey PhD
22. Jeremy Meyers MD
23. Vanessa K. Noonan PhD
24. Marcel W. Post PhD
25. Gianna M. Rodriguez MD
26. David Rosenblum MD
27. Bruno G. Santacruz PharmD
28. Ann M. Spungen EdD
29. John Stoffel MD
30. Denise G. Tate PhD
31. David Tulsky PhD
32. Cheryl L Vines MS
33. Tracey Wheeler PhD

Appendix 2: Self-Reported Measures (SRMs) and SCI Data Sets for Neurogenic Bowel and Bladder

These measures were identified during our initial literature (Phase 1) searches and considered for review based on their potential use in SCI/D. Not all were included in the final reviews.

BOWEL

1. International Bowel Function Basic SCI Data Set[1,2]
2. International Bowel Function Extended SCI Data Set[3]
3. Modified Lynch GI Survey for Patients with Spinal Cord injury[4]
4. Neurogenic Bowel Dysfunction score – NBD Score[5]
5. SCI-QOL Bowel Management – Item Bank[6–10]
6. Ten Question Bowel Survey (adapted from Lynch)[4]
7. Bristol Stool Form Scale[11–12]
8. Gastrointestinal Symptom Rating Scale[13]
9. Patient Assessment of Constipation – Quality of Life (PAC-QOL)[14]
10. Patient Assessment of Constipation-Symptom Questionnaire (PAC-SYM)[15]
11. Fecal Incontinence Quality of Life Scale[16]
12. Fecal Incontinence Severity Index[17]
13. 13.Coggrave Bowel Care Survey[18]
14. PROMIS Scale for GI[33]
15. PROMIS GI Constipation[33]
16. PROMIS GI Bowel Incontinence[33]
17. PROMIS GI Diarrhea[33]
18. PROMIS GI Gas and Bloating[33]

BLADDER

1. International Lower Urinary Tract Function Basic SCI Data Set[19]
2. International Urodynamic Basic SCI Data Set[20]
3. International Urinary Tract Imaging Basic SCI Data Set[19]
4. Neurogenic Bladder Symptom Score (NBSS)[21]

5. Qualiveen – Quality of Life in Spinal Cord Injury Patients with Urinary Difficulties[22]
6. SCI-QOL Bladder Complications – Scale[6–10]
7. SCI-QOL Bladder Management Difficulties – Item Bank[6–10]
8. Incontinence Symptom Index[23]
9. Incontinence Symptom Severity Index[24]
10. Urogenital Distress Inventory (UDI-6)[25]
11. American Urological Association (AUA) Symptom Index[26]
12. Incontinence Quality of Life (I-QOL)[27]
13. Overactive Bladder Symptom and Health related Quality of Life Questionnaire (OAB-q)[28]
14. Patient Global Impression of Severity Improvement Questionnaire (PGI-I, PGI-S)[34]
15. Bristol Female Lower Urinary Tract Symptoms (B-FLUTS)[35]
16. International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF)[36]
17. Pelvic Floor Distress Inventory Short Form (PFDI-20)[37]
18. Michigan Incontinence Symptom Index (M-ISI)[38]
19. Lower Urinary Tract Symptom Tool (LUTS tool)[39]
20. Kings Health Questionnaire[40]
21. USQNB[41]

BOWEL and BLADDER

1. Incontinence Impact Questionnaire (IIQ-7)[29]
2. Bowel and Bladder Treatment Inventory (BBTI)[30–32]

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