

Chancellor M<sup>1</sup>, Burks J<sup>2</sup>, Signori M<sup>3</sup>, Globe D<sup>3</sup>, Hudgens S<sup>4</sup>, Perrin-Ross A<sup>5</sup>, Gonzales G<sup>6</sup>, MacDiarmid S<sup>7</sup>, Nitti V<sup>8</sup>, Mehnert U<sup>9</sup>, Bates D<sup>10</sup>, Panicker J<sup>6</sup>

1. University of Pittsburgh School of Medicine, 2. Burks & Associates, 3. Allergan, 4. Mapi Values, 5. Loyola University Medical Center, 6. Department of Uro-Neurology, University College London, 7. Alliance Urology Specialists, 8. New York University Langone Medical Center, 9. Balgrist University Hospital, Zurich, 10. University of Newcastle

## DEVELOPMENT AND VALIDATION OF URINARY INCONTINENCE IN MULTIPLE SCLEROSIS SCREENING TOOL

### Hypothesis / aims of study

Urinary incontinence from neurogenic detrusor overactivity is a common problem in patients with multiple sclerosis (MS). Currently there is no screening tool specifically developed for bladder overactivity in the MS population. The aim of the study was to develop and psychometrically validate a patient-completed screening tool to identify MS patients who could benefit from neurogenic detrusor overactivity specific treatment.

### Study design, materials, and methods

The initial draft of the screening tool was developed using three sources of information: a review of existing instruments; expert clinician input (from urologists, neurologists, physiatrists, and MS nurse specialists in Europe and North America); and semi-structured patient interviews (n=20). The draft tool included 23 items assessing symptoms, impacts, and coping strategies. The draft tool was then refined following cognitive interviews of 15 patients to determine understandability, relevance, word choice, item preference, and importance of items. Psychometric validation of the draft Actionable MS Incontinence Screening Tool developed from these qualitative studies is currently underway in an observational study of 150 MS patients, with and without urinary incontinence or urgency.

### Results

The initial version of the screening tool consisted of 23 items. The concept of incontinence was represented by three sets of two questions (frequency and severity) in order to test which were preferred by patients. A similar strategy was employed by testing four items for nocturia. During the cognitive interviews, the patients identified their preferred wording for the incontinence and nocturia items, as well as noting several other wording options and preferences. Patient feedback about response option similarities resulted in the reduction of response options from five to four for all items. The items about incontinence severity (amount) and travel impacts were deleted because of varied interpretations by patients and minimal clinical usefulness in the screening tool as identified by the key opinion leaders. The cognitive interviews supported the content validity of the draft screening tool.

Following the cognitive interviews to support the content validity, the draft Actionable MS Incontinence Screening Tool is currently undergoing psychometric validation. The tool consists of seventeen items covering symptoms, coping strategies, and impacts of urinary incontinence in MS patients which provide useful screening information to clinicians in determining whether patients are appropriate for referral for urologic evaluation. The psychometric validation study will be used to develop the scoring algorithm and cut off scores for clinical practice utilization.

### Interpretation of results

MS patients involved in the development process were able to communicate symptoms, coping strategies, and impacts of urinary incontinence. The urinary symptoms most commonly reported by MS patients interviewed were urgency to urinate, nocturia, leakage, frequency of urination, and incontinence. The impacts of urinary incontinence included emotional impacts (embarrassed, frustrated, worried, annoyed, depressed, angry); social impacts; impacts on relationships with partners, spouse and/or friends; and sexual intercourse. Additional impacts included changes in wearing clothing, effects on walking, and impact on sleep. The balance of patient-centric concepts and clinical insight into importance for screening highlights the benefits and outcomes of the qualitative work directly with patients and refined with clinician input. This maintains a balance between patient focus and clinical relevance for this screening tool.

### Concluding message

The Actionable MS Incontinence Screening Tool, when finalized, will have a psychometrically validated scoring algorithm and clinical cut off score for feasible use in clinical practice. The development of this screening tool was patient-centric, and this focus will continue through the psychometric validation study including further item reduction and scoring.

<b>Specify source of funding or grant</b>	<b>Allergan</b>
<b>Is this a clinical trial?</b>	<b>No</b>
<b>What were the subjects in the study?</b>	<b>HUMAN</b>
<b>Was this study approved by an ethics committee?</b>	<b>Yes</b>
<b>Specify Name of Ethics Committee</b>	<b>Copernicus Group IRB</b>
<b>Was the Declaration of Helsinki followed?</b>	<b>Yes</b>

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*Was informed consent obtained from the patients?*

Yes

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