Conceptualization and Design
of an Individualized Measure of BPH (Benign Prostatic Hyperplasia) Impact

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ABSTRACT

Patient reports of the impact of Benign Prostatic Hyperplasia (BPH) symptoms on their lives are important for treatment decisions making and and evaluating outcomes of new treatments. The relevance and importance of the impact of PBH on different aspects of patient's lives are diffuse and patterns of occurrence among the targeted patient group are unpredictable. Eliciting this information from patients using standardized response options tends to statistically 'normalize them, leaving no room for individuality. Hence we developed a measure of BPH-specific patient impact that would benefit from both the statistical strength of a standardized measure as well as form the adaptability and high content relevance of an individualized measure.

Qualitative interviews and literature review provided an initial list of 71 different topic areas that were grouped in to 9 separate domains. The item generation process yielded an initial long-list of three types of questions: Functional impact items (n=13); BPH symptoms items (n=21); and Psychological impact items (n=13). An initial measure was drafted which incorporated these items into a standardized format with a five point Likert-type response scale. The content was duplicated in a prompter list followed by an individualized section for the top five individualized patient choices.

The two versions of the measure were pilot tested on 49 patients. Final designation of items to the standardized versus individualized versions was determined through a combination of qualitative and quantitative methods. This resulted in the development of the BPH Patient Impact Measure© with 15 standardized items (highest frequency of reporting by the pilot group). Those items representing a lower report-frequency (yet still presented important and relevant data to a portion of the patient group) were assembled into a prompter list for the individualized portion of the measure.

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OBJECTIVE

- To identify the optimal method for reflecting a wide range of QOL impacts on the lives of patients with urinary symptoms of BPH
- To develop a BPH-specific QOL measure

METHODS

Step 1:
- Literature Review
- Qualitative Interviews
- Qualitative Analysis and Initial Item Generation

Results:

- Qualitative data indicated a wide variety of types of QOL impact
- No area of impact had a clearly significantly predominance
- All areas expressed were extremely important to those who expressed the areas, but not necessarily of the same importance to others

Conclusions:

While some items appeared to have relevance to most of the subjects, impact on some areas were relevant only for some individuals.

Step 2:
- Initial Item Generation (from Qualitative data)
- Sort "long list" items by basic content and question-type

Results:

(34) FUNCTION-RELATED ITEMS	(21) SYMPTOM-RELATED ITEMS	(13) PSYCHOLOGICAL RELATED ITEMS
- intimate (3)	- intimate (1)	- intimate (added)
- personal (5)	- personal (4)	- personal (10)
- functional work (2)	- social (4)	- function-home (1)
- functional home (8)	- sleep (2)	- social (2)
- travel (5)	- physical (10)	- sleep (added)
- social (8)		
- sleep (4)		

Step 3:
- Refine content
- Draft Standardized Items
- Draft Individualized Items

Step 4:
- Pilot Test on Patients (debriefing interviews with 8 patients with BPH)
- Review perceived meaning of items
- Review clarity of instructions
- Review acceptability of format

Ranked Responses Frequency from Standardized Pilot Items

	Count	Pct of Responses
▲ I have difficulty sleeping through the night	23	11.6
I have erectile difficulties 🚫	18	9.1
I have difficulties with ejaculation 🚫	18	9.1
Interfere with my sexual functioning/performance	16	8.1
▲ Prevent me from drinking beverages in the evening	14	7.1
I am limited by having to plan activities toilet	10	5.1
I am limited in the kind of beverages I	8	4
I require more time to travel for frequent stops	8	4
Interfere with my social life	7	3.5
How much does tiredness interfere with your life	7	3.5
Limit the activities I can participate in	6	3
Interfere with my participation in outdoor acts	6	3
I have to plan travel routes carefully access toilet	6	3
I spend longer than usual in the bathroom	6	3
Interfere with my ability to perform usual activities	6	3
Limit my ability to attend social events	5	2.5
Due to lack of sleep my mind is not as s	5	2.5
Get in the way of my participation in family acts	4	2
I have difficulty falling asleep	4	2
My ability to concentrate is affected	4	2
My ability to relax is affected	4	2
Limit the leisure activities I can participate in	4	2
How much does physical discomfort interfere with life	4	2
My family relationships are affected	3	1.5
I am unable to leave my home for more than 2 hours	2	1

Ranked Responses Frequency from Standardized Pilot Items

	Count	Pct of Responses
Ability to sleep through the night	37	15.7
▲ Drinking fluids in the evening	26	11.1
Travel without having to make frequent s	25	10.6
Ability to fall asleep	17	7.2
▲ Sexual activity 🚫	16	6.8
Sexual functioning or performance 🚫	14	6
Spending normal amounts of time in the t	12	5.1
Being away from home for long periods of	11	4.7
Participating in outdoor activities or s	8	3.4
▲ Exercise (run, bike, weights)	8	3.4
Participating in leisure activities	7	3
Drinking what I want to drink	7	3
Social life	7	3
Attending social events	7	3
Performance of usual activities or job	6	2.6
Having a sharp mind	6	2.6
Spending normal amounts of time on hygie	6	2.6
Participating in activities with my fami	6	2.6
Intimate relationships	6	2.6
Family relationships	1	0.4
OTHER#1: Going to church	1	0.4
OTHER#2: Fear of urination on self	1	0.4

▲ Items that were incorporated into the standardized section (due to high frequency response)

🚫 Items that were dropped because they represented symptoms more than interfering impacts
(all remaining items were moved to individualized "activity prompter" list)

What Patients Had to Say About the Two Sections

Standardized Section
- All patients found items clear and easy to understand
- All patients found the content of these items to be relevant to their situation
- All patients found instructions and format very clear and easy to follow.
- Most comments from patients were regarding spacing of the items and the need to highlight the recall period.

Individualized Section
- All patients were able to find items in this section that were of high relevance to them
- All patients found the prompter list to be helpful and most patients noted instructions that they could write in their own areas of impact
- All patients found instructions to be clear
- Not all patients were able to find a full five areas of limitation or impact, but all could find at least three areas.

CONCLUSIONS

While the symptoms of BPH have an impact on patients lives, the extent of the disruption to activities varies. A combination of standardized and individualized items would provide the best information regarding the impact of BPH symptoms on patients. The BPH Patient Impact measure© is an attempt to develop an instrument that would provide comprehensive information on the impact of urinary symptoms in patients with BPH. The results of preliminary testing indicate that the new questionnaire is acceptable to patients.

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