



Development of a Preliminary Conceptual Model for Overactive Bladder

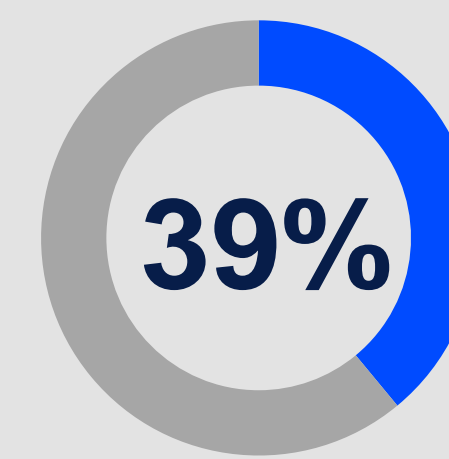
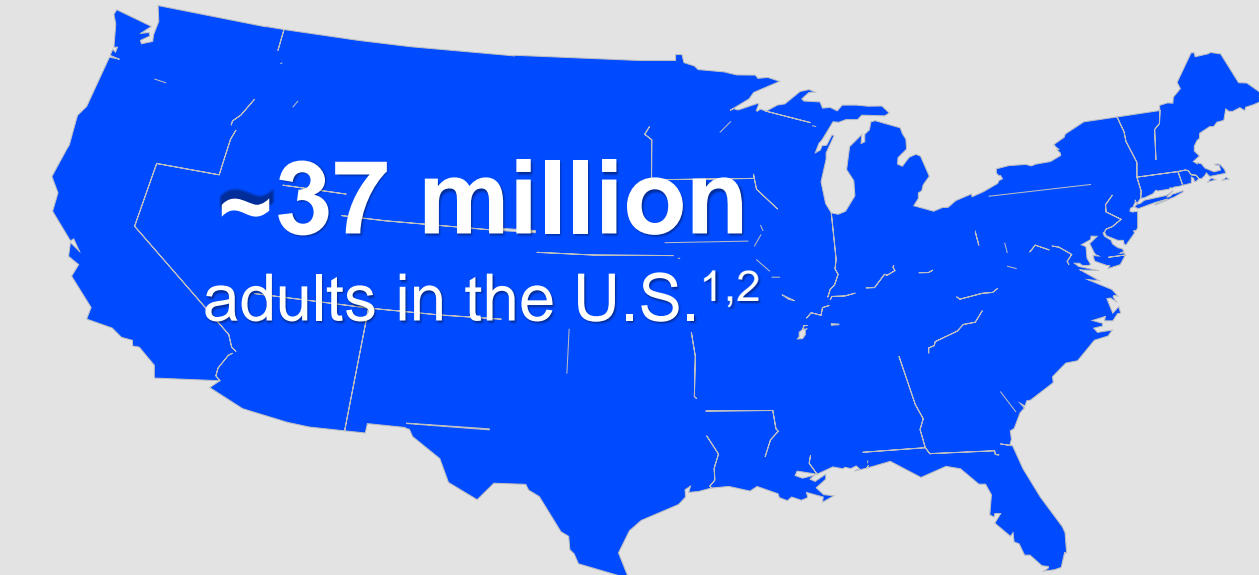
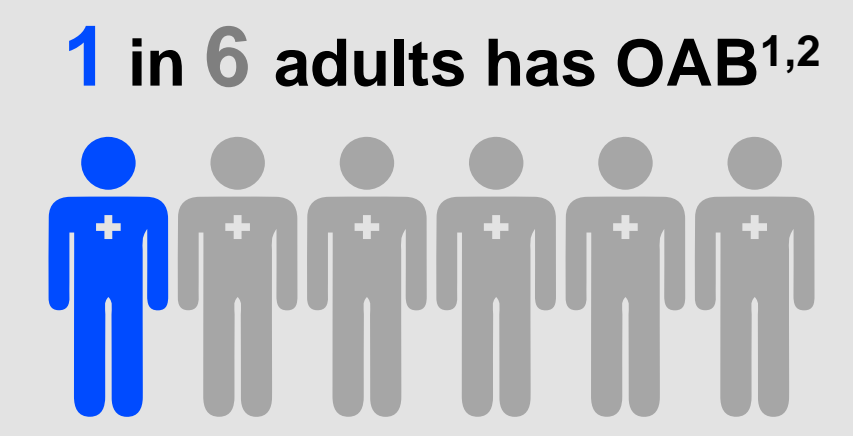
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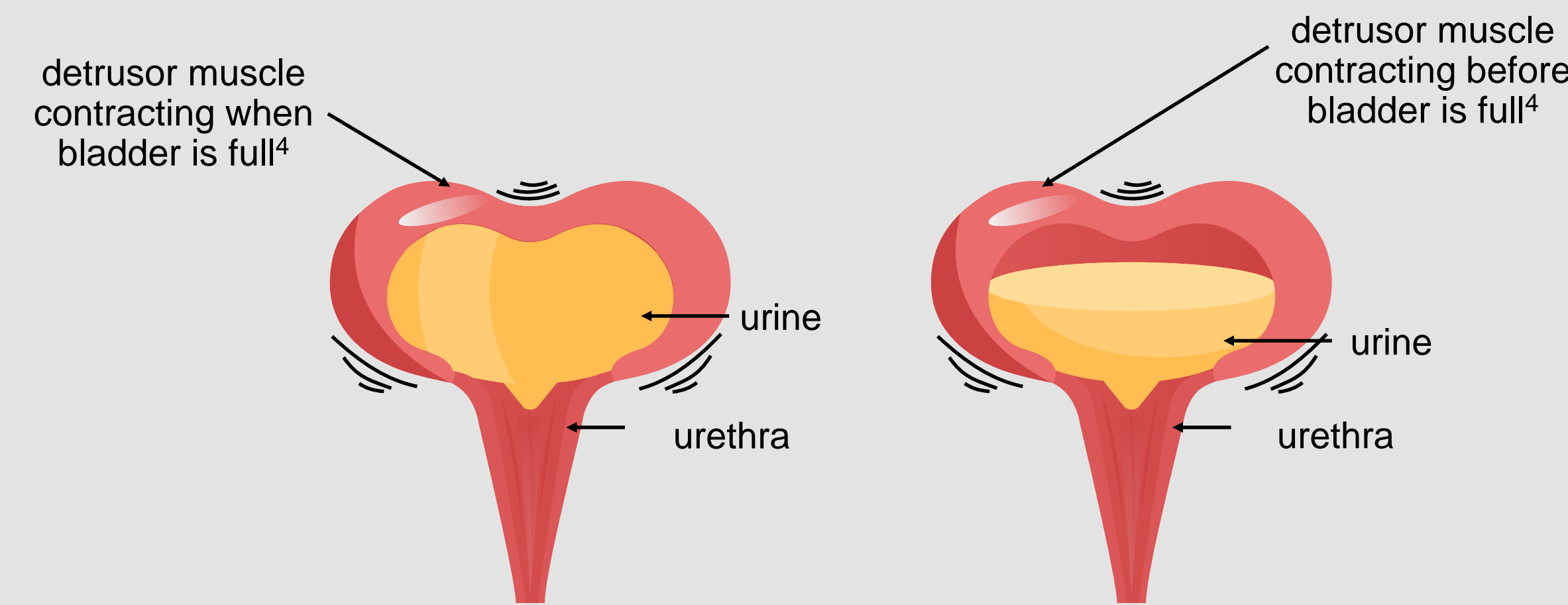
Background

Overactive bladder (OAB) is extremely common, and significantly interferes with patients' quality of life³.



39% of adults reported that OAB interfered with daily activities³

Overactive bladder is defined as a sudden, uncontrollable urge to urinate, often leading to frequent bathroom visits and in some cases, involuntary loss of urine



There is a need for a conceptual model to gain an understanding of the signs, symptoms and impacts of OAB to inform a patient-centered Clinical Outcome Assessment (COA) strategy. This model will help us understand the patient experience of OAB by mapping out key symptoms and functional impairments, which will inform evidence-based approaches to future study designs with the goal of improving access to effective therapies.

Objective

To identify key patient experiences associated with OAB through a targeted literature search and develop a preliminary conceptual disease model.

Methodology

- A targeted literature review was conducted to identify key concepts (signs, symptoms, and impacts) from the perspective of patients who have been diagnosed with OAB
- Database:** PubMed, PsycINFO, PubLab
- Search limits:** 15 years 2009–2024; Humans; No comments, letters, or editorials
- Languages:** English-language publications only
- Concepts of interest were identified, and data on concept frequency in literature, prevalence in the studied population, patient-reported importance, and bothersome ratings were recorded for selected articles

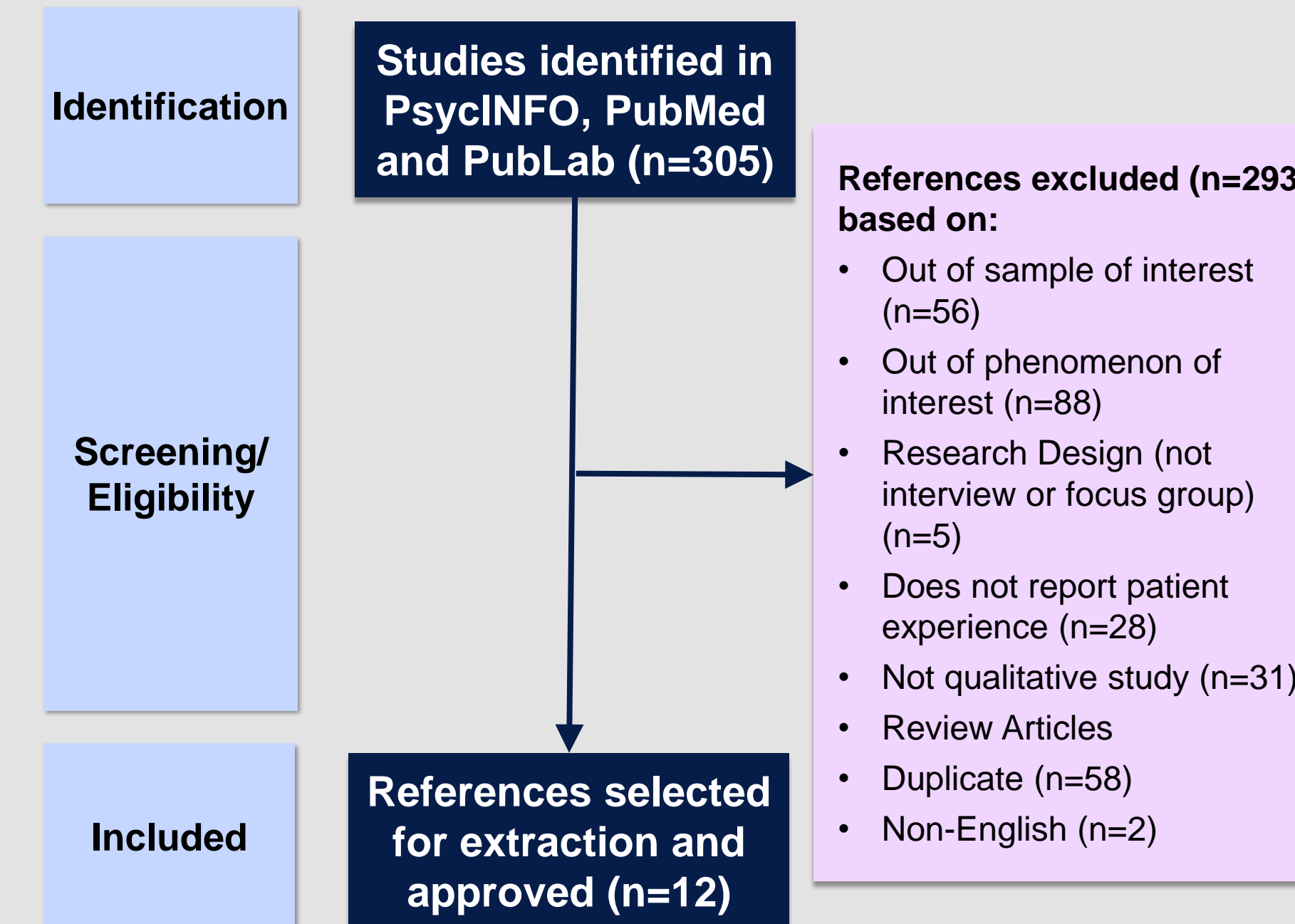
Inclusion and exclusion criteria^{*5}

S-Sample	Patients with Overactive Bladder
PI -Phenomenon of interest	Reporting of any point of view regarding the signs and symptoms and the impact of the disease on the patients' life from the patients' perspective
D-Design	Semi-structured in-depth interview or focus group
E- Evaluation	Patient's experiences
R- Research type	Qualitative studies or mixed-method studies with a qualitative element. Relevant survey studies including open-ended questions will also be selected

* Defined by the SPIDER tool which facilitates rigour in research by defining key elements of non-quantitative research questions.

Results

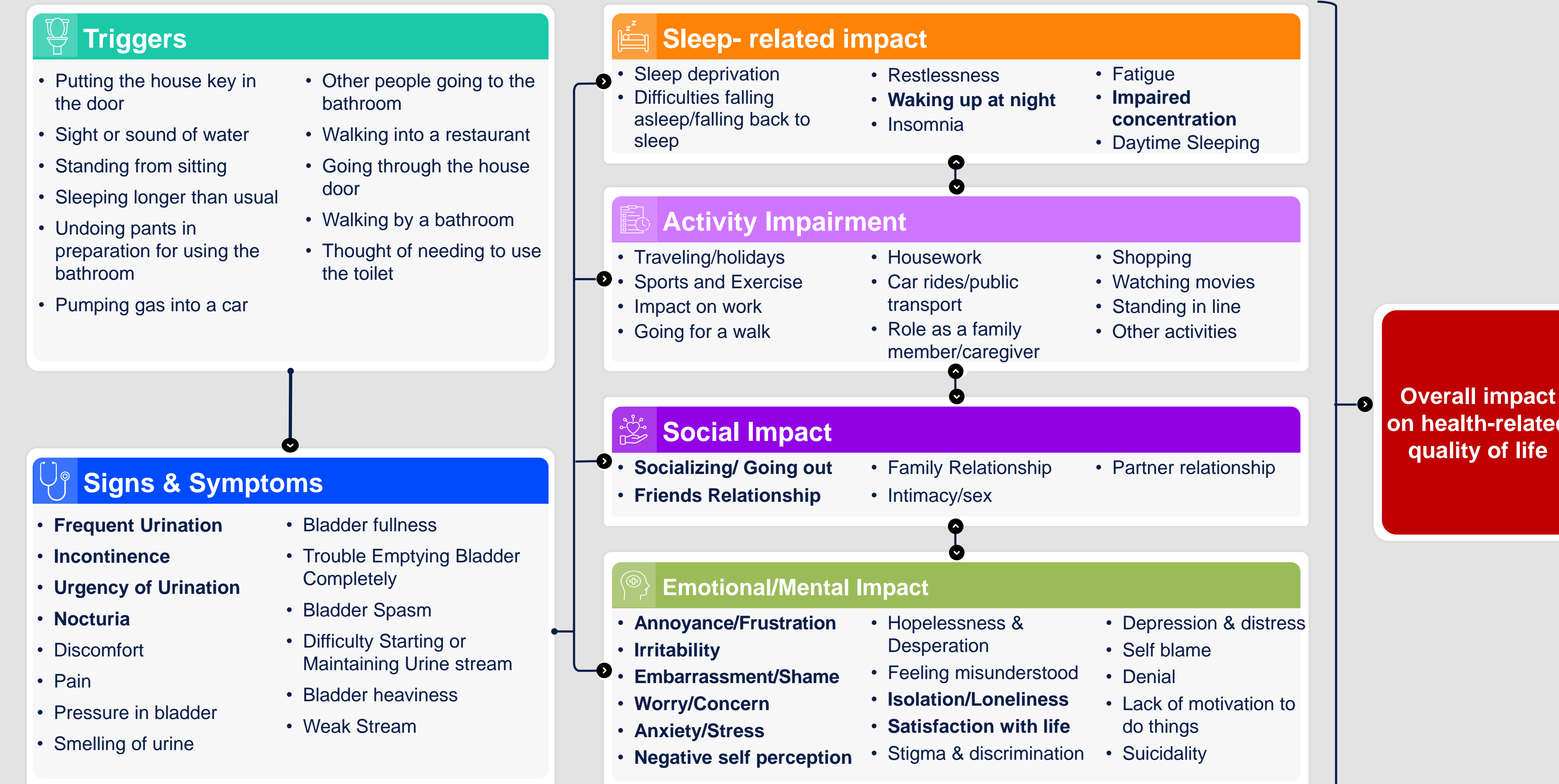
Article screening and extraction



Study Characteristic

Author, Year	Regions	Study Design	Sample size
Hawken et al., 2016	United Kingdom	Semi-structured telephone interviews	30
Anger et al., 2011	United States	Focus group	33
Coyne et al., 2012	United States	Open-ended question interview	19
Gonzalez et al., 2021	Global	Social media data mining	1867
Iyer et al., 2021	United States	Semi-structured interviews	51
Filippetto et al., 2014	United States	In depth qualitative interview via phone	40
Kelleher et al., 2018	United States	In-person interview	30
Palmer et al., 2019	United States	Focus group	24
Siu et al., 2014	Hong Kong	In-depth, semi-structured interviews	30
Rantell et al., 2017	United Kingdom	Open-ended goals questionnaire	331
Siu et al., 2016	Hong King	Semi-structured interview	30
Smith et al., 2011	United States	Focus group	33

Preliminary Conceptual Disease Model for OAB



***Bolded symptoms/impacts appear in > 50% of publication or >50% in frequency in studied population** and are key concepts of interest that will be used to inform a patient-focused clinical outcome assessment (COA) strategy for the phase 2 trial and future clinical trials

Patient's Quote exemplifying the impact of OAB

Activity Impairment- Impact on Work

"I couldn't go to work and constantly be running to the loo. [...] I gave my job up."

-Female, 39 years from Hawken et al., 2016

Signs & Symptoms, Social Impact-Intimacy/sex

"The urgency and leaking are horrible. I cannot date so I'm single...I'm missing out...not to mention the sex"

-Gonzalez, 2021

Emotional/Mental impact-Anxiety & stress

"I'm always anxious all the time. I've got to make sure I've got my pads and there's a toilet somewhere, where I'm going."

-Female, 75 years from Hawken et al., 2016

Sleep impact-Sleep deprivation

"I haven't slept through the night in years. I think that is a profound impact on my life."

-Anger et al., 2011

Emotion/mental impact-shame/ embarrassment & Social Impact – friends' relationship

"Now I rarely hang out with my friends because I feel insecure when going out."

- Siu et al., 2014

Emotional/ mental impact-hopelessness

"I have lost my hope to get cured. I am tired of the treatment, and maybe I will give up one day."

- Siu et al., 2016

Discussion

Patients with OAB report a range of trigger factors leading to symptoms such as frequent urination, incontinence, urgency, and nocturia. These symptoms cause significant impacts:

- Sleep Impairment:** Nocturia leads to nighttime awakenings, restlessness, and difficulty falling back asleep, resulting in sleep deprivation and daytime dysfunction.
- Activity Impairment:** OAB can hinder daily activities, with tasks as simple as walking.
- Social Impact:** It affects social interactions, strains relationships with friends, family and partners, and impairs intimacy.
- Emotional and Mental Impact:** Patients often experience annoyance, frustration, irritability, embarrassment, anxiety, and stress. Worry due to odor and leakage can lead to isolation and loneliness, with the condition also associated with stigma and hopelessness. This emotional burden can contribute to mood declines, distress, depression, and in severe cases, suicidality.

Strengths: The review employed a thorough search strategy across multiple databases, leading to the identification of numerous relevant studies that offered comprehensive insights into patient-reported signs, symptoms, and impacts of OAB.

Limitations: The scope was limited to the past 15 years and did not involve direct patient interviews, leaving room for potential gaps in patient-reported experiences. The model's generalizability could be enhanced through patient confirmation. Additionally, the review was restricted to English-language publications, possibly overlooking experiences from underrepresented populations or regions.

Conclusion

The interplay of these factors leads to a notable decrease in overall quality of life for patients with OAB, highlighting the comprehensive nature of the disease's impact. This conceptual disease model aids in understanding the patient experience with OAB and can be leveraged to inform the selection of measurement concepts for patient-centered clinical trials.

References

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Acknowledgement and Disclosure

Thank you to all the mentors that have supported me through out this project! This study was sponsored by AbbVie Inc. Financial arrangements of the authors with companies whose products may be related to the present report are listed, as declared by the authors. Colleen Castro, Elaheh Shirnesan, and Darshini Shah are full-time employees of AbbVie Inc. Anh Duong was an intern through the AMCP Foundation and AbbVie Inc. and functioned as an external author after the internship was completed.