

## BACKGROUND

Health economics and outcomes research (HEOR) relies on administrative claims and other secondary data sources to examine the economic burden of disease and the value of healthcare interventions. However, many conditions lack referenceable diagnostic or procedural codes. Examples include:

- Generalized myasthenia gravis (MG), indistinguishable from ocular MG.
- Underactive bladder (UAB), represented only by nonspecific urinary symptom codes.
- Desmoplastic small round cell tumor, bundled under generic malignancies.
- Periprosthetic joint infection (PJI) surgical treatment represented by a wide variety of diagnostic and procedure code combinations with variable specificity depending upon place of service.

These limitations hinder HEOR initiatives, introduce misclassification, and threaten interpretability and validity of results.

## OBJECTIVE

To propose and illustrate a 7-step structured process to improve identification of clinical conditions and interventions in administrative data that minimize misclassification and increase clinical face validity.

## METHODOLOGY

**Approach:** Development and implementation of a structured, expert-informed, iterative process for developing operational criteria for diseases and interventions that have no existing standard or generally-accepted definitions.

**Data Sources Required:** Linked administrative insurance claims and clinician narratives documented in electronic health record progress notes. The backbone to the following process is the healthcare practitioner clinical narrative, which establishes a source of truth from which to assess the accuracy and relevance of HEOR-based administrative definitions.

### Proposed 7-Step Process

- 1) Convene clinical experts to define the target condition or intervention and to reach consensus on the real-world clinical patterns associated with the target condition (presenting symptoms, diagnostics, sequence and timing of encounters, involved specialties, places of service, and a priori expectations of healthcare utilization).
- 2) Select the optimal “fit for purpose” data sources, that include linked administrative healthcare data with clinical notes to establish the association between patterns of diagnostic/procedure/treatment coding and clinician documentation of the clinical target.

- 5) Perform data discovery on structured datasets to identify relevant codes and concepts.
- 6) Translate the clinician-defined real-world clinical patterns into preliminary working computable definitions and review with clinical experts.
- 7) Apply the operational definitions to the administrative data and construct a comprehensive evaluation of identified populations or interventions, including a natural history profile of encounter, treatment, and management events – evaluating both recent historical and subsequent patterns.
- 8) Review empirical results with clinical experts, compare with priori anticipated results, and assess the clinical face validity of the operationally defined entities within the context of insights derived from the analysis, focusing on concordance or discordance with clinical expectation.
- 9) Revise definitions based upon feedback to reduce misclassification, and repeat Steps 5 and 6, if necessary.

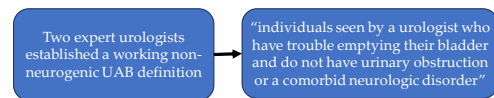
## ILLUSTRATION

### Case Example: Identifying Underactive Bladder (UAB)

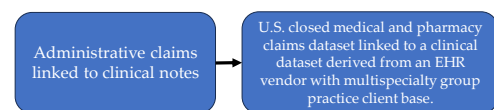
Background: UAB is defined by dysfunction of the detrusor muscle, which can be of neurogenic or myogenic origin<sup>1,2</sup>. There is no ICD-10-CM for UAB. ICD-10 diagnosis codes related to individuals with UAB include urinary symptoms (i.e., weak flow, incontinence, urinary retention, recurrent urinary tract infections), or non-specific urinary conditions (i.e., difficulties with micturition, neuromuscular dysfunction of the bladder), none of which uniquely identify individuals with UAB. Though there are numerous novel treatments for UAB in development, use of urodynamic testing (the gold-standard for identifying UAB) is inconsistent and underutilized.

Challenge: Assess the national clinical and economic burden of a disorder with no operational definition.

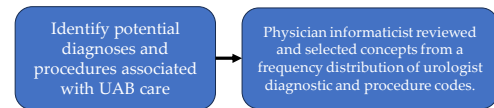
### Step 1. Clinical expert panel



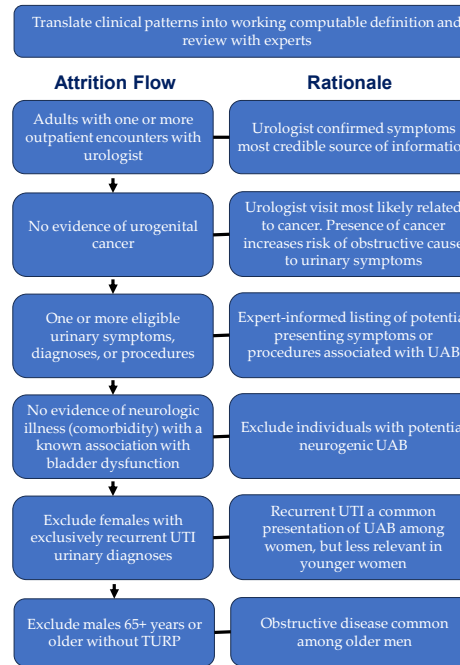
### Step 2. Fit for purpose data selection



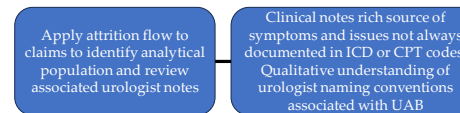
### Step 3. Data discovery



### Step 4. Data discovery



### Step 5. Apply definitions and perform empiric analysis

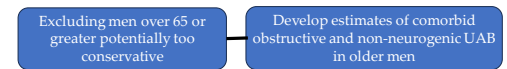


### Step 6. Review empirical results with clinical experts

By Notes	Assignment of UAB by Codes		
	UAB (potential cases)	Other urinary condition	Obstruction
UAB	24%	10%	15%
UAB excluded	47%	50%	85%
Undetermined	19%	40%	0

- In this illustration, clinical notes review confirmed UAB definition in 24% of potential cases, excluded 47% of potential cases, and were non-contributory in 19%.

### Step 7. Revise definitions to reduce misclassification



## SUMMARY AND WHAT TO EXPECT

- The UAB example highlights key features of performing HEOR in the absence of code-based populations: engage clinical experts to establish working definitions and review empiric results; analyze specialty physician clinical patterns including documented diagnoses, diagnostic testing, and procedures; review clinical notes to clarify strengths and weakness of claims-based definitions; use clinical concepts to include and exclude patients from your population definitions.
- Almost always, three distinct groups emerge: 1) positive cases - those easily defined and identified; 2) negative cases - individuals easily excluded from the target condition; and 3) undetermined cases - individuals who lack evidence for inclusion or exclusion from the target condition.
- Even when ICD-10 diagnosis and CPT procedure codes exist, incorporating validation steps reduces misclassification. Options include validating against clinically confirmed diagnoses and verifying face validity with experts.
- This structured 7-step definition workflow is designed to achieve clinical face validity of an operational definition in an unclear coding environment. This process increases the utility and validity of administrative healthcare data, is directly applicable to conditions with ambiguous or nonspecific coding and can be used to strengthen HEOR study design and reporting.

## CITATIONS

1. LaFrance, Emily M.; Liberman, Joshua N.; Darer, Jonathan; Kotkar, Anagha; Seidl, Stacey E.; Singla, Ajay; Woods, Michael S. Epidemiology and Treatments for Nonobstructive, Non-Neurogenic Underactive Bladder: A Systematic Literature Review. *JU Open Plus* 3(9):e00098, September 2025. | DOI: 10.1097/JU9.0000000000000343.
2. Razi B, Zhuo K, Cole-Clark D, Chung A. The underappreciated underactive bladder. *Transl Androl Urol*. 2025 Mar 30;14(3):841-847. doi: 10.21037/tau-2025-61. Epub 2025 Mar 26. PMID: 40226053; PMCID: PMC11986530.

## DOWNLOAD POSTER

To receive a copy of this poster, scan the QR code via a barcode reader application.



By requesting this content, you agree to receive a one-time communication using automated technology. Message and data rates apply. Links are valid for 30 days after the congress presentation.