“Addressing Gaps, Challenges, and Opportunities Related to Data and Metadata Standards for NIDDK Research Priorities”

Measurement of lower urinary tract function

Claire C. Yang, MD

University of Washington, Seattle, WA

James Hokanson, PhD

Medical College of Wisconsin, Milwaukee, WI

Why measure lower urinary tract (LUT) function?

- To develop or select treatments to reverse or improve dysfunction
- Extent of urinary tract disorders: most who live past middle age will have experienced temporary or long-standing LUT dysfunction +/- symptoms
- LUT dysfunction extremely distressing
  - Involuntary loss of urine = loss of control, loss of humanity

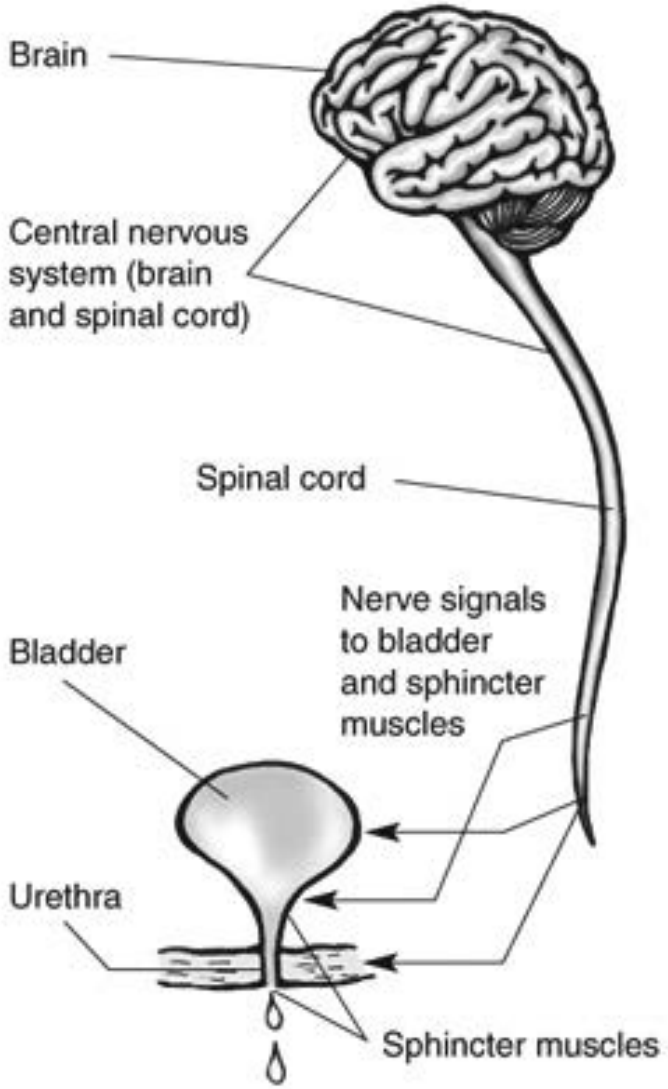
lower urinary tract dysfunction = NIDDK research mission area

Lower urinary tract function and its measurement

LUT function is:

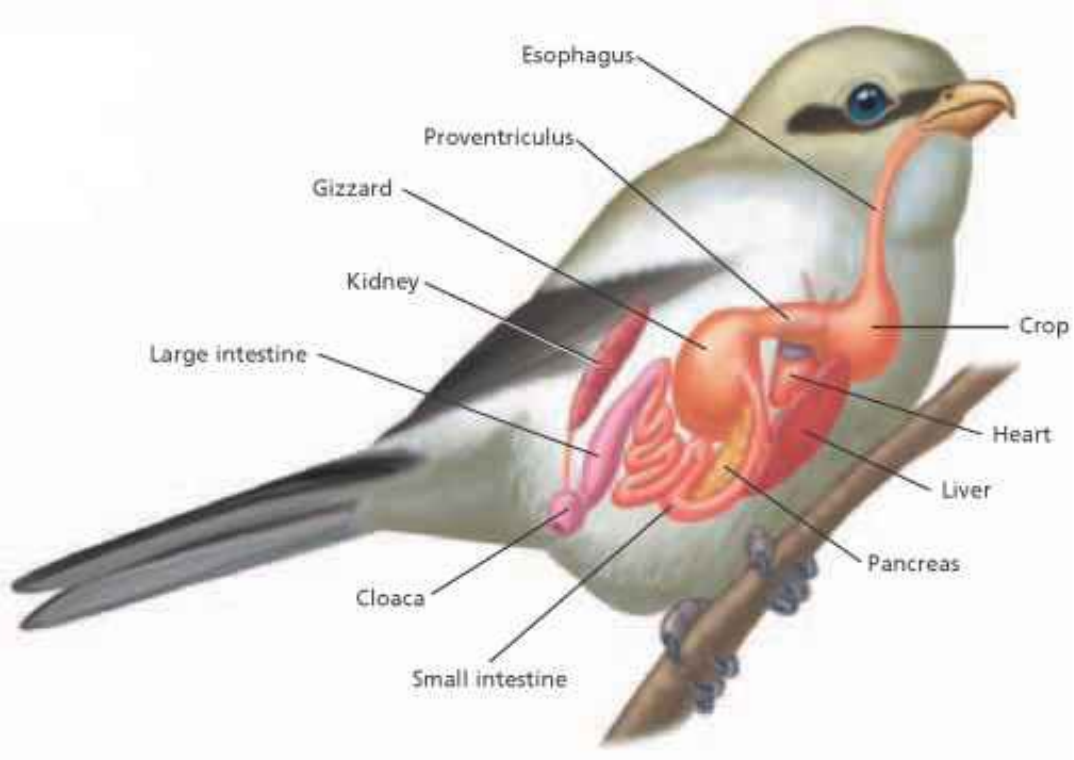
- Multidimensional - no single biological marker
- Dynamic - different functions at different times
- Complex - requires coordination of autonomic and somatic nervous systems with end-organs
- Modulated - by factors outside of the urinary tract

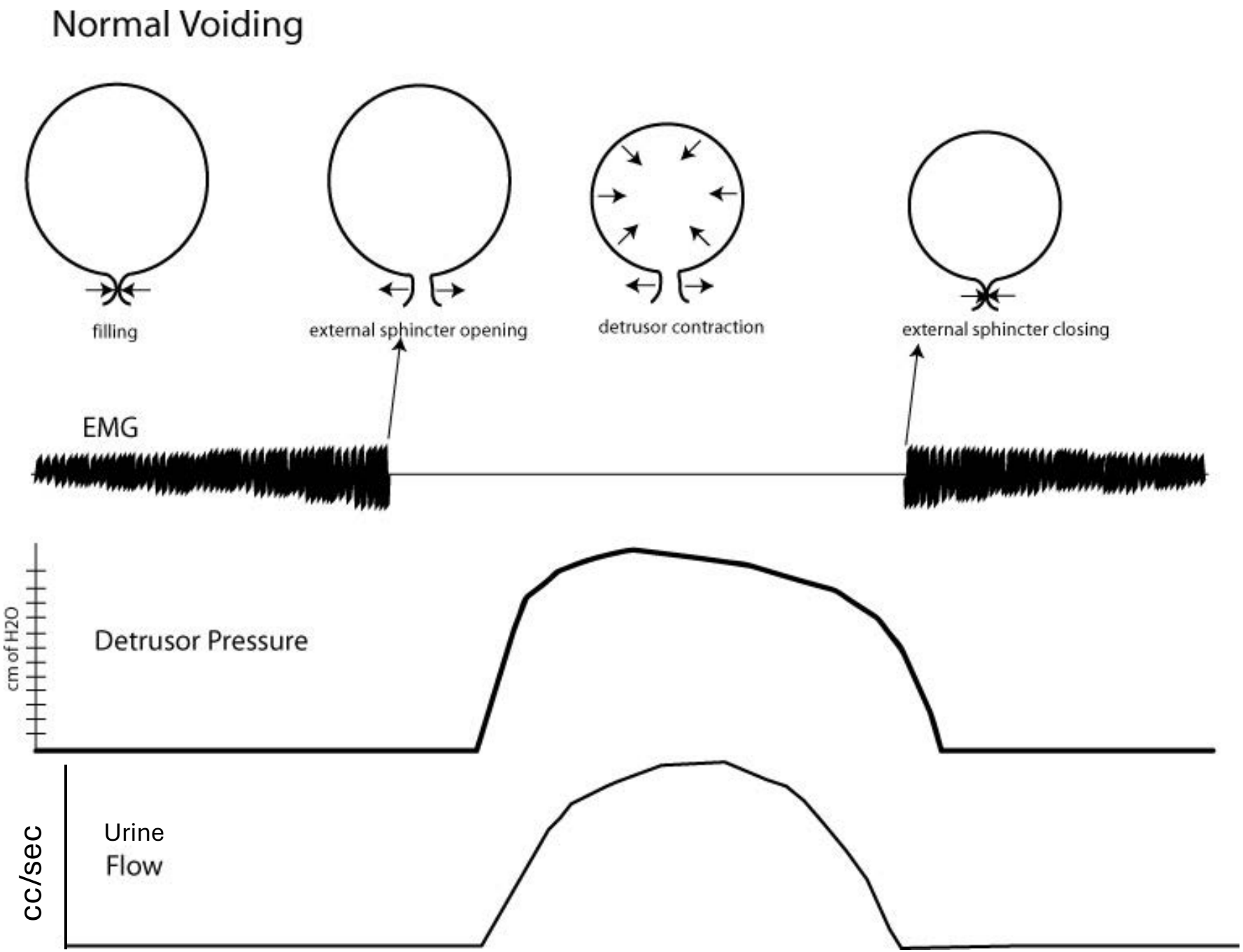
Functions of the LUT



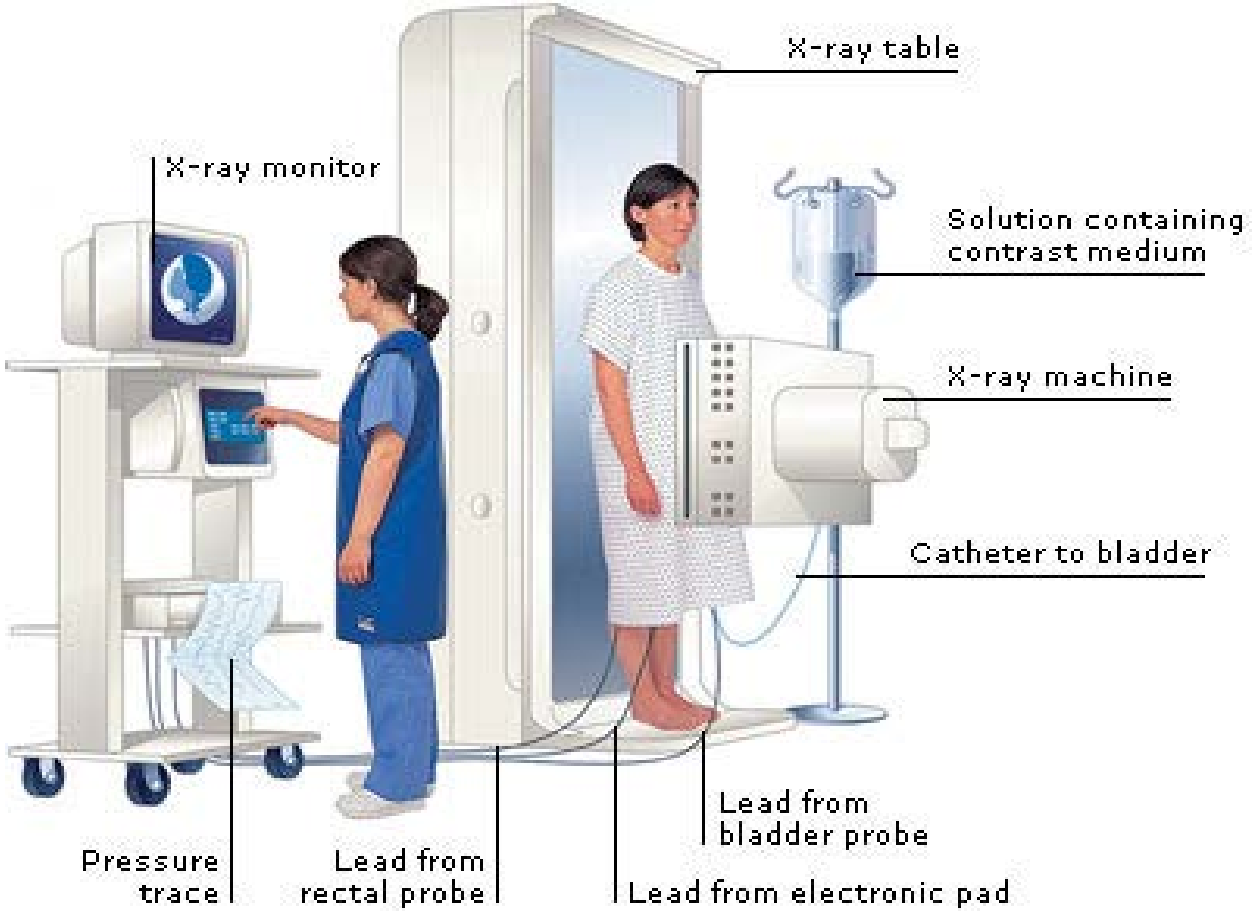
- Store urine until socially appropriate
  - reservoir, filling phase, ‘diastole’
  - store urine at low pressures = compliance
- Evacuate urine efficiently
  - emptying phase, ‘systole’
  - low pressure contraction for evacuation

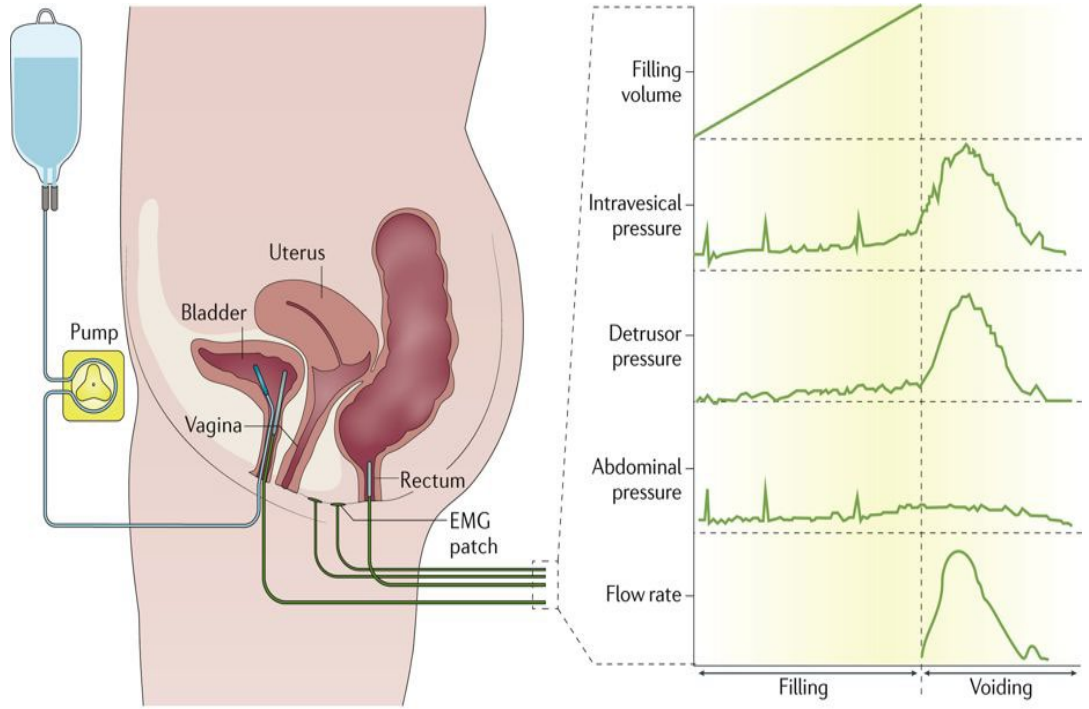
No reservoir




Normal Voiding
filling
external sphincter opening
detrusor contraction
external sphincter closing
EMG
cm of H2O
Detrusor Pressure
cc/sec
Urine
Flow

In the urodynamics suite





Components of a urodynamics study

- Bladder storage
  - cystometrogram (CMG)
    - Compliance (volume/pressure)
    - Detrusor overactivity (involuntary contraction)
    - Leak point pressures
    - Sensation
  - urethral function: EMG, pressure
- Voiding
  - cystometrogram
  - uroflow
  - post void residual measurement
- Fluoroscopy (dynamic imaging)

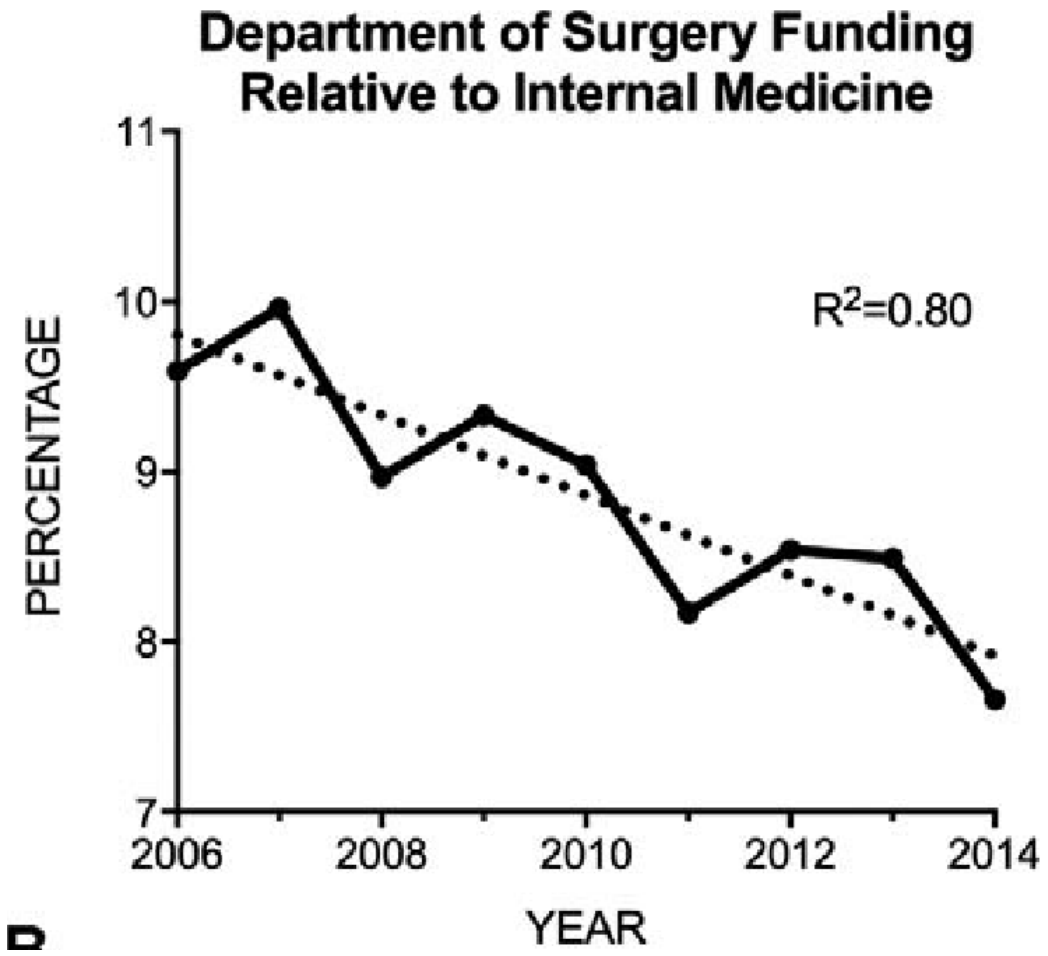
Standards

Data Collection

Data Sharing

Gaps, Challenges,
& Opportunities

Challenges in Urology Research



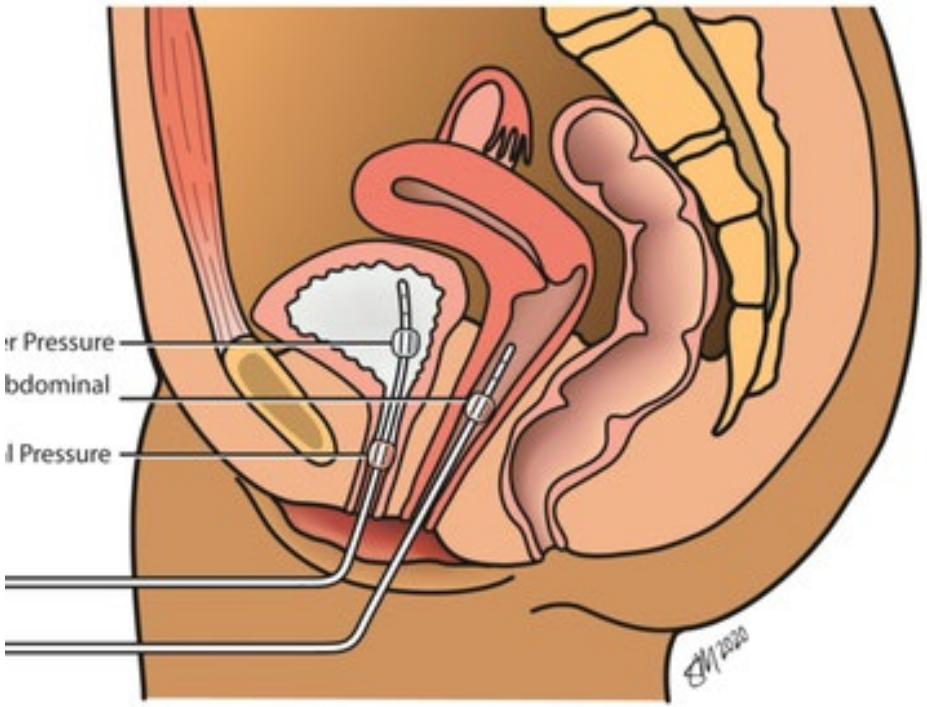
Keswani et al. (Goldstein) 2017 Annals of Surgery

- Urology residencies eliminating research year, fewer than 10 remain nationally
- Urologists/urogynecologists (surgeons) being paid to do surgery, not research
- Human physiology research (in urology) largely being done by Europeans
- **Impact:** Fewer, busier, clinical collaborators, harder to do clinical/translational urology research

Urodynamics: a “sensitive” subject

Balance diagnostics with:

- physical invasiveness
- emotional burden



https://urogynecology.nm.org/urodynamic-testing.html

Data Collection Standards

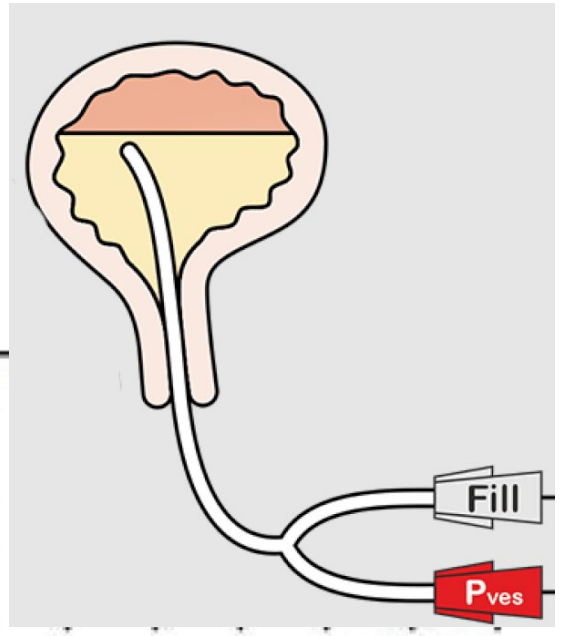
International Continence Society (ICS) defines standards.

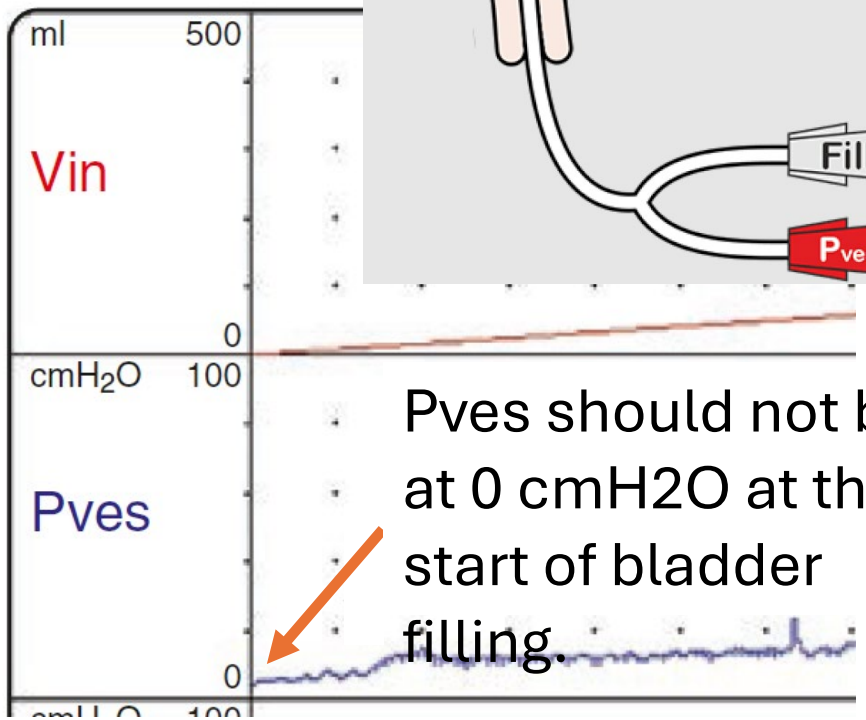
- **ICS Good Urodynamic Practices and Terms 2016**
  *(Rosier et al. 2016, Neurology and Urodynamics (**NAU**))*
- **Good Urodynamic Practices: Uroflowmetry, Filling Cystometry, and Pressure-Flow Studies** *(Schäfer et al. 2002, NAU)*
- **ICS Guidelines on Urodynamic Equipment Performance**
  (Gammie et al. 2014 NAU)

- Standards are not strictly followed (Schaefer et al. 2010)
- Training, or lack there-of, is partially an issue
- Poor linking between standards and impact (more on this in a bit)

Example Standards

good standard



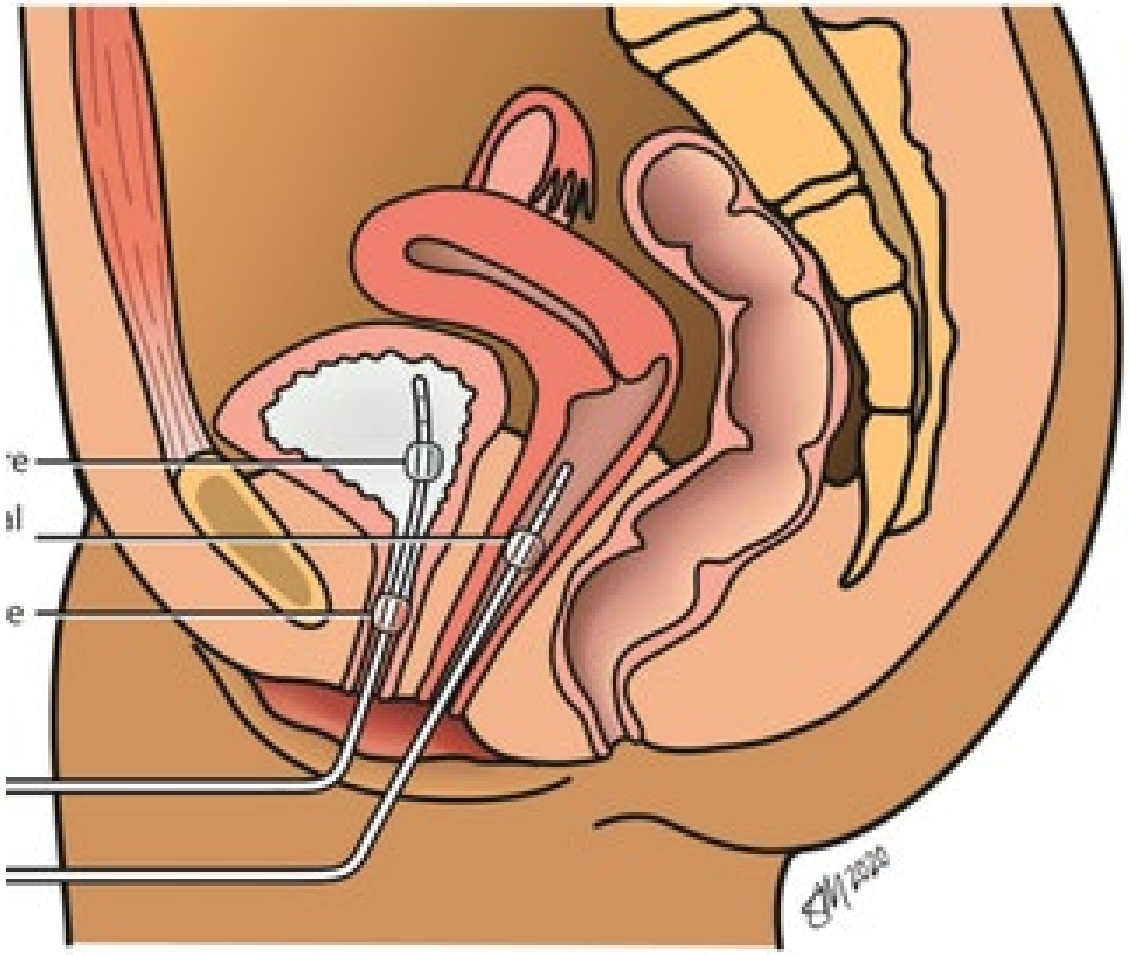


Pves should not be at 0 cmH2O at the start of bladder filling.

Interpretation of Urodynamic Studies
Oh, 2018 ch8

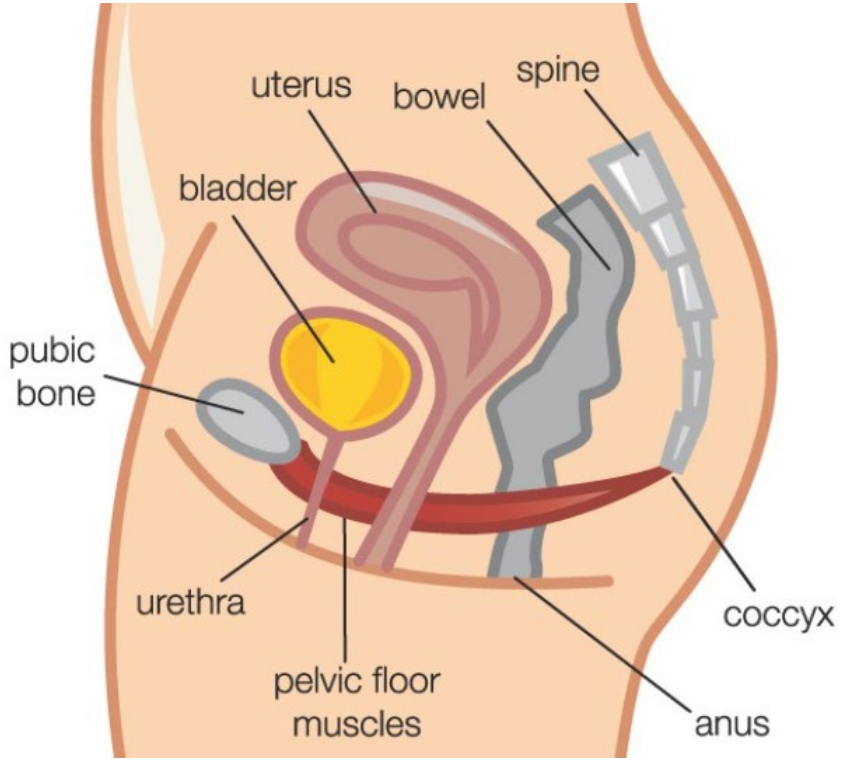
helpful?

Use rectal catheters for abdominal pressure proxy, not vaginal catheters.



Standards for Standard Urodynamic Tests Uroflowmetry, Cystometry, Pressure/Flow

But are these the best tests?



Impairment		Incontinence
"Support Loss"	→	Stress
"Detrusor Overactivity"	→	Urge

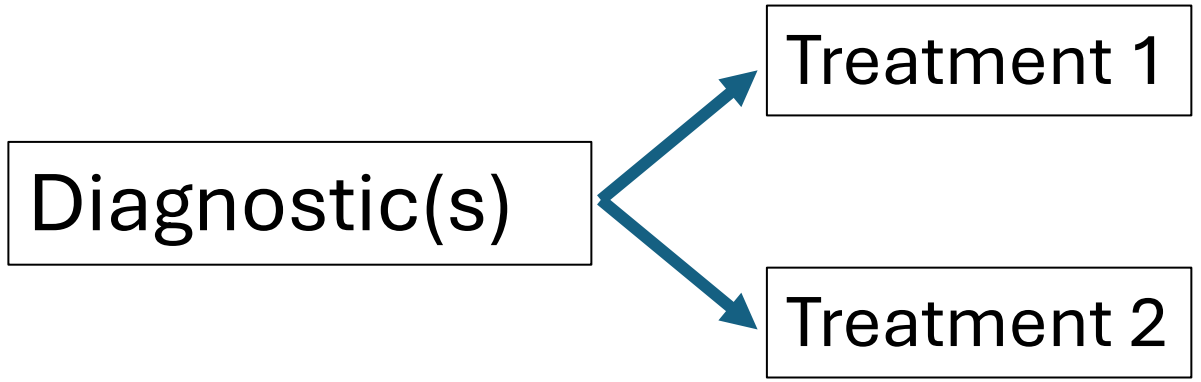
Other "neglected" areas: (besides the urethra)

- Brain
- Vasculature
- Reflexes
- Genetics

Hokanson & DeLancey 2022 NAU

Urodynamics and Treatment

Current Approach



We have very little good evidence suggesting diagnostic decisions are warranted (area of hot/huge debate). Largely treating symptoms.

An Alternative Approach

Can we predict Y from X? $Y = f(X)$

Urodynamics vs. Outcomes

Can we use diagnostics to predict outcomes?

Needs:

- more data, shared data
- better tests (and multiple ones together)
- well measured outcomes
- Role of standards?? I would instead advocate for quality control in an organized study.

Data Sharing Standards

Badges. We ain’t got no badges.

Standards. We ain’t got no [data sharing] standards.

The Treasure of Sierra Madre (1948)

Data Sharing Standards

Neurourology and Urodynamics 16:1–18 (1997)

Standardization of Terminology of Lower Urinary Tract Function: Pressure-Flow Studies of Voiding, Urethral Resistance, and Urethral Obstruction

Appendix: ICS Standard for Digital Exchange of Pressure-Flow Study Data*

LIST OF CONTENTS

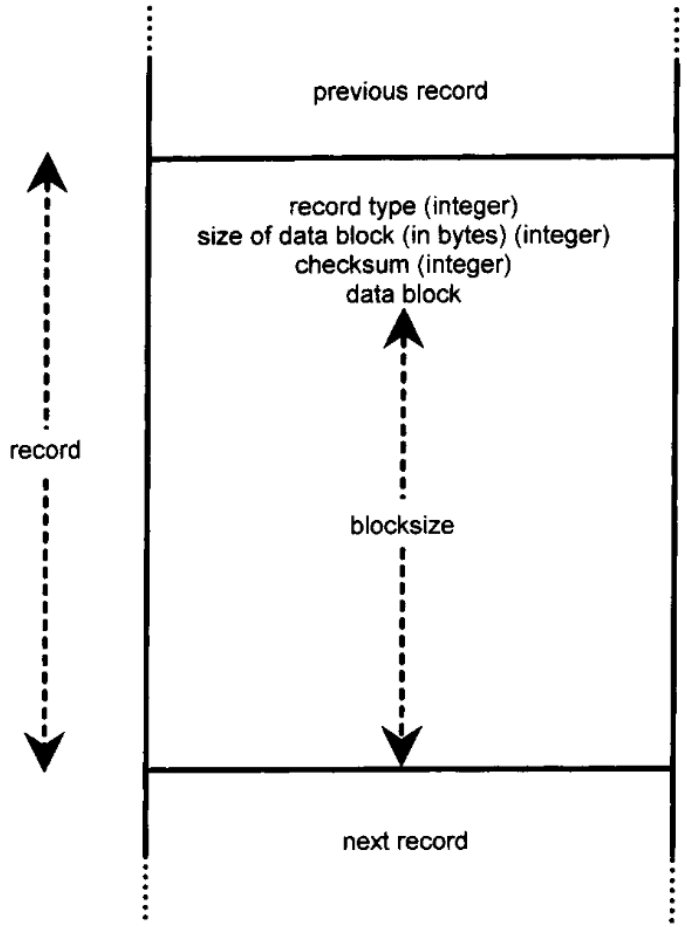
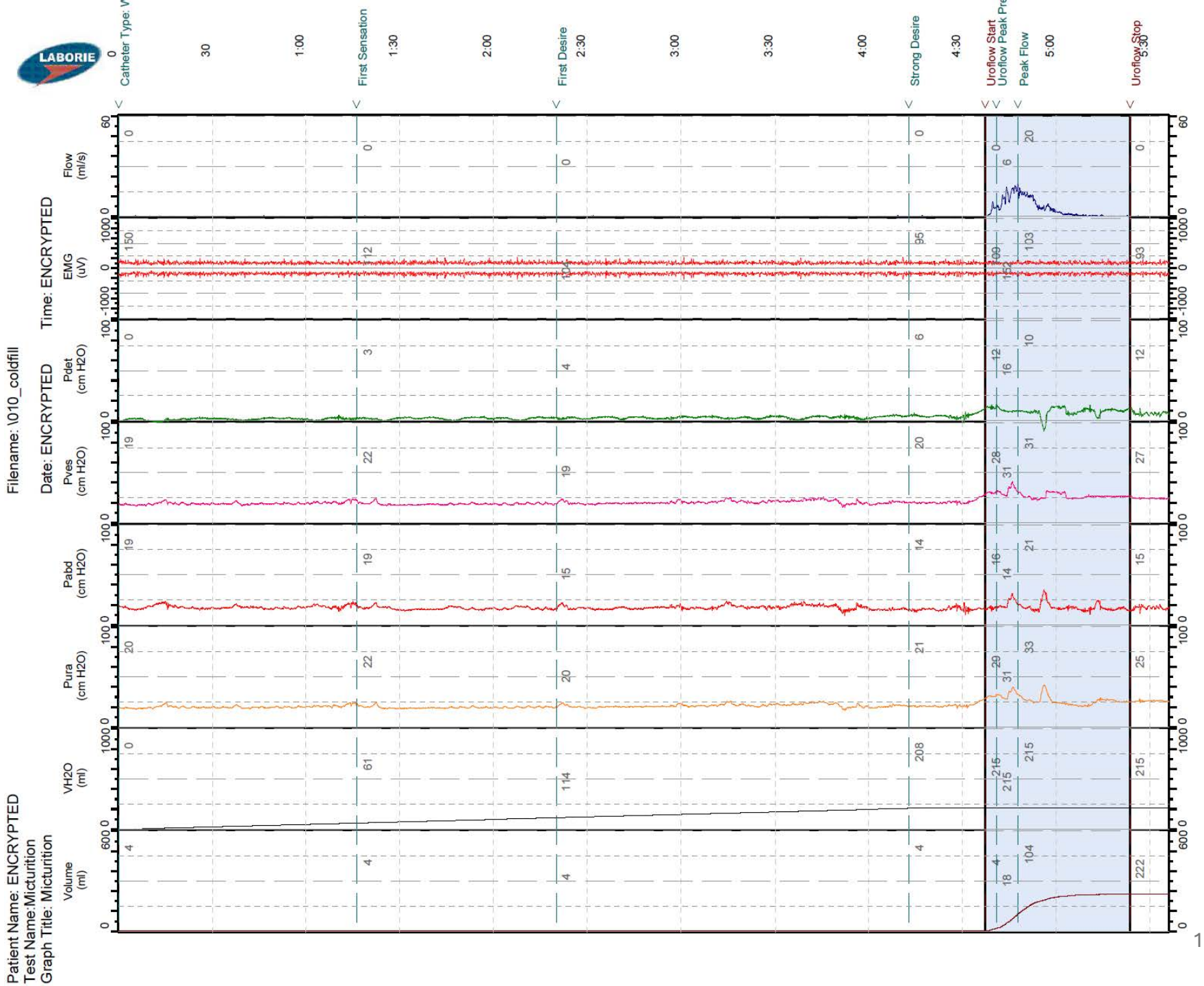


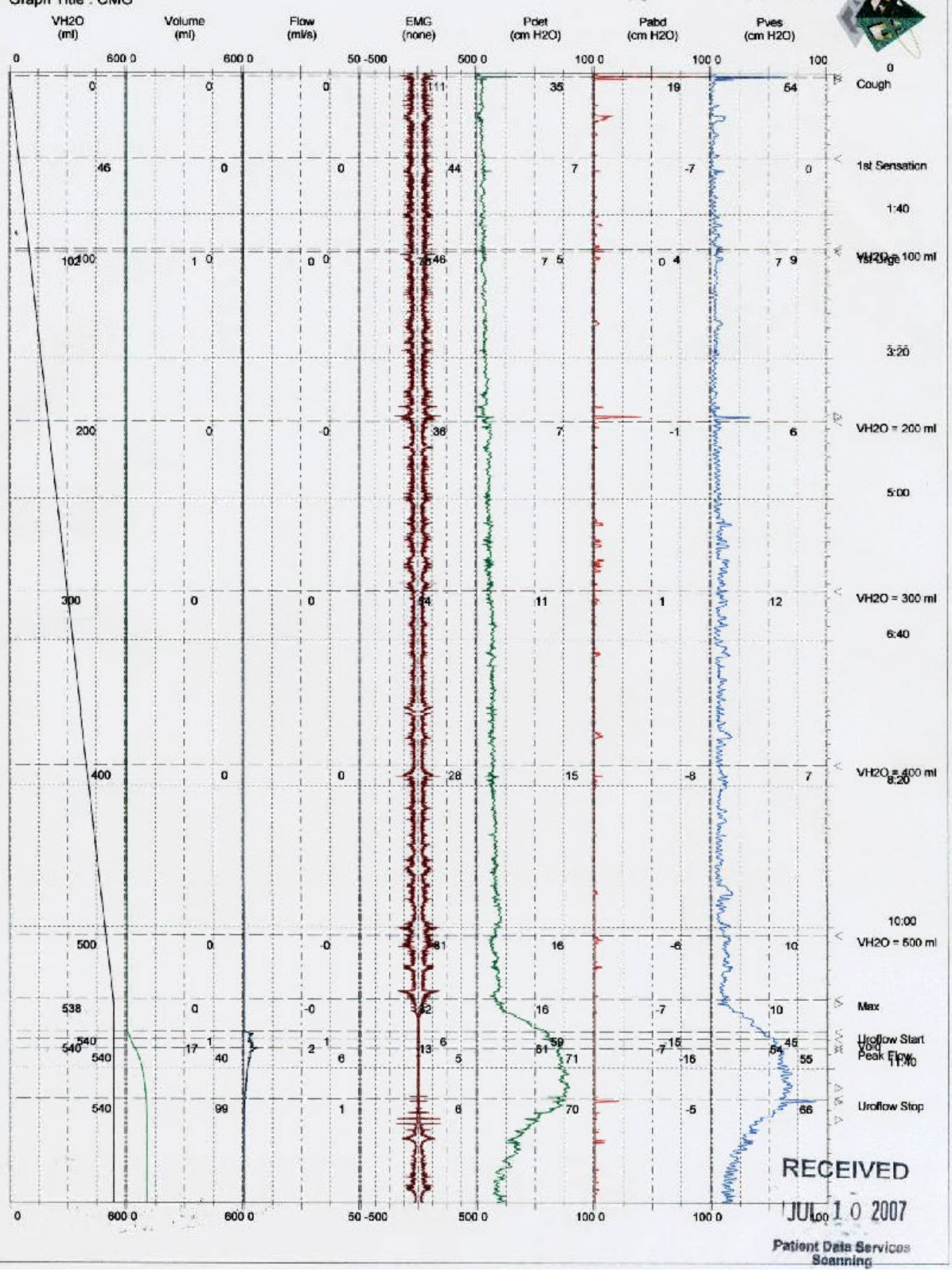
Fig. 4. Schematic structure of file and records.

Data sharing = PDF sharing



Patient Name: [redacted]
Test Name:CMG
Graph Title : CMG

Date: 06/12/2007 Time: 9:41:10 Filename: 0000064B



Laborie Medical Technologies Urodynamic Analyzer

Patient Name:	ENCRYPTED	Gender:	Female
Doctor:	ENCRYPTED	Date of Birth:	1/1/1970
Clinic:		Age:	
MR#:	ENCRYPTED	Comments 2:	
Test Name:	Micturition	Filename:	\010_coldfill
Comments:		Version:	12 Rel 1
Date:	ENCRYPTED	Time:	ENCRYPTED

History

Event Summary (* = moved event)

Annotation	Time	Flow	EMG	Pdet	Pves	Pabd	Pura	VH2O	IH2O	Volume
Catheter Type: Water Based Disp	0.1	0	150	0	19	19	20	0	0	4
First Sensation	1:16.1	0	112	3	22	19	22	61	50	4
First Desire	2:20.0	0	104	4	19	15	20	114	50	4
Strong Desire	4:12.8	0	95	6	20	14	21	208	50	4
Uroflow Start	4:37.2	0	109	12	28	16	29	215	0	4
Uroflow Peak Pressure	4:40.8	6	152	16	31	14	31	215	0	18
Peak Flow	4:47.7	20	103	10	31	21	33	215	0	104
Uroflow Stop	5:23.6	0	93	12	27	15	25	215	0	222

Compliance Summary

No events recorded

Structured data entry (SDES) for EHR

(template of clinical data associated with test)

Van Batavia et al. (Zderic)
2018 J. of Ped. Rehab. Med.

REASON FOR STUDY

HISTORY:

- Diagnosis
- Surgeries
- Voiding
  - Cath history
  - Anticholinergic
- UTI
- Bowel management
- Shunts
- Orthopedic hx
- Radiologic hx

Todays Visit	
Study type	VUDS
Reason for Evaluation today	better af...
History	
Vuds History	Follow Up
Neurogenic Bladder History	
Diagnosis	Spina Bi...
Spina Bifida Type	Myelom...
Spina Bifida Level	L4
Spina Bifida Closure History	Postnatal
Hospital where treated for Spina Bifida	CHOP
Surgical History	
Bladder Surgical History	Urethral ...
Bowel surgical history	None
Other surgical history	none
Voiding histoy	
Voids	Leak
Anticholinergic therapy	Ditropan
UTI history	
History of UTI's	No
Any UTI's since last visit	No
Antibiotic prophylaxis	Yes
Comment	none
Bowel history	
Bowel Medications	Enema
Enema medications	Retrogra...
Retrograde enema medications	Cone en...
Compliance with therapy	Yes
Fecal continence	Yes
Neurologic history	
Neurologic history	Yes
Date of shunt placement	may 2007
Orthopaedic History	
Ambulatory	No
Assistive Devices	yes
Comment	wheelchair
Radiologic History	
Bladder	Thick w...
Kidney	Normal
Starting Uroflow	
Starting Uroflow	No
Starting Residual	100

Patient's Weight in kg	40
Expected Bladder Capacity - mls	280
Calculated Rate of Fill - mls/min	11.2
Actual Rate of Fill - mls/min	5
Number of cycles	1
Volume at 25% EBC Achieved?	Yes
Volume at 25% EBC - mls	70
Storage Pressure at 25% - cm/h20	5
Volume at 50% EBC Achieved?	Yes
Volume at 50% EBC - mls	140
Storage Pressure at 50% of EBC cm/H2O	10
Volume at 75% EBC achieved?	No
Volume at 75% EBC - mls	210
Storage pressure at EBC - cm/H2O	
Actual capacity reached - mls	170
Pressure reached at actual capacity - cm/H2O	25
Compliance	Abnormal
Timing of rise in pressure	Gradual
First Sensation	None
Is there a leak?	Yes
Volume at first leak - mls	170
Leak type	Passive
Pressure at leak - cm/H2O	25
True Contraction?	No
Pressure at peak contraction - cm/H2O	
Sustained contraction leading to empty bladder?	No
Uninhibited Bladder Contractions	No
Detruser External Sphincter Dyssenergia	No
Post-Fill Uroflow	No
Bladder Emptying during study	
Void Volume - mls	0
Cath Volume - mls	260
PVR	260
Post obstructive Diuresis - mls	-90
Reflux on Current VUDS Imaging	No
VUDS Bladder Shape	Trabecul...
VUDS Bladder Neck	Open at...
Volume at SAFE Bladder Capacity - mls	100
Pressure at SAFE Bladder Capacity - cm/H2O	
Care Modification	Yes
Care Modifications	Surgery

TECHNICAL :
Pressure/volume data
Leaks
Uninhibited contractions
DESD

SUBJECTIVE ASSESSMENTS:
Compliance
True contraction

Bladder drainage

Imaging

Management

Structured data entry for EHR

- Unclear that this has gained any traction
- Structured data entry into EHR may be useful – field generally lacking in knowledge how to do this
- Note, this is an abstraction of the raw data, not the raw data

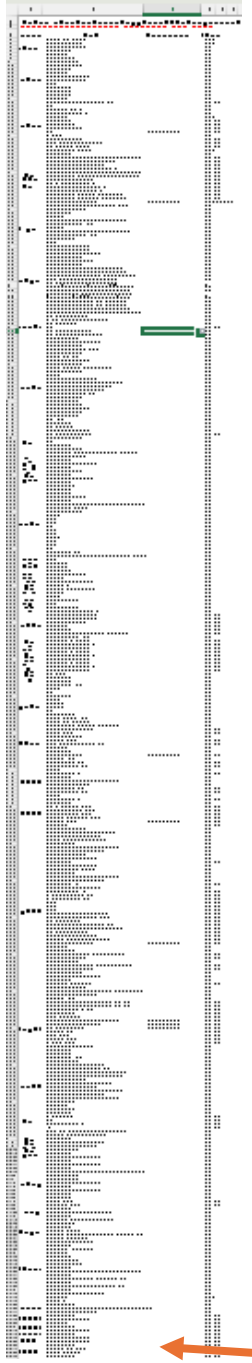
Patient's Weight in kg	40
Expected Bladder Capacity - mls	280
Calculated Rate of Fill - mls/min	11.2
Actual Rate of Fill - mls/min	5
Number of cycles	1
Volume at 25% EBC Achieved?	Yes
Volume at 25% EBC - mls	70
Storage Pressure at 25% - cm/h20	5
Volume at 50% EBC Achieved?	Yes
Volume at 50% EBC - mls	140
Storage Pressure at 50% of EBC cm/H2O	10
Volume at 75% EBC achieved?	No
Volume at 75% EBC - mls	210
Storage pressure at EBC - cm/H2O	
Actual capacity reached - mls	170
Pressure reached at actual capacity - cm/H2O	25
Compliance	Abnormal
Timing of rise in pressure	Gradual
First Sensation	None
Is there a leak?	Yes
Volume at first leak - mls	170
Leak type	Passive
Pressure at leak - cm/H2O	25
True Contraction?	No
Pressure at peak contraction - cm/H2O	
Sustained contraction leading to empty bladder?	No
Uninhibited Bladder Contractions	No
Detruser External Sphincter Dyssenergia	No
Post-Fill Uroflow	No

TECHNICAL
Pressure/vo
data
Leaks
Uninhibited
contraction
DESD

SUBJECTIVE
ASSESSMENT
Compliance
True contrac

Van Batavia et al. (Zderic) 2018 J. of Ped. Rehab. Med.

A database structure for urodynamic records Gammie et al. (Hashim) 2025 Continence

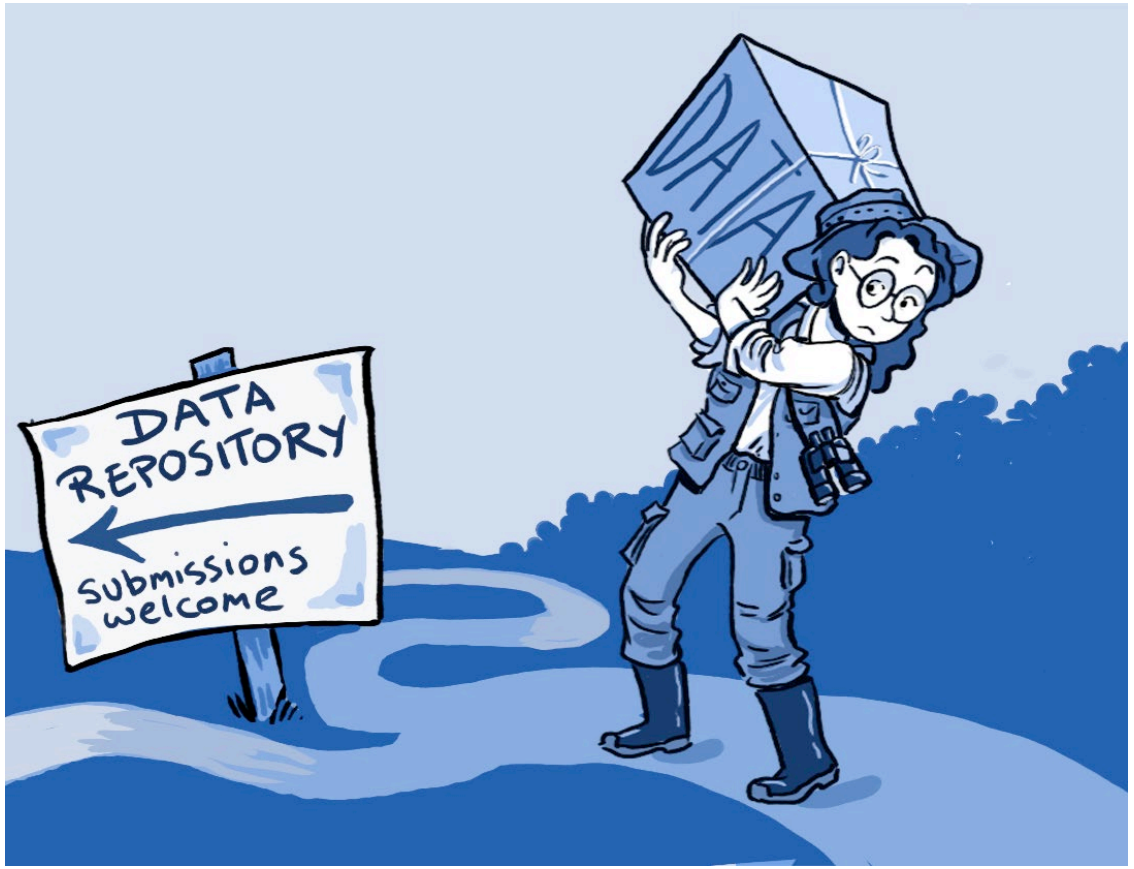


360 rows in Excel file

	A	B	C	D	E	F
1	**Urodynamic Database Structure - Copyright asserted by Bristol Urological Institute**					
2	**Use for commercial and non-commercial purposes requires acknowledgement of and permission from**					
3	**Section**	**Field**	**Value options**	**Field Type**		
4		Date form completed		Date		
				Date		
				Text		
				Text		
				Text		
				Text		
						Text
						xt
98		Post-Defaecation Symptoms	Normal (no straining)			Text
99		Please specify other	Strains			Text
100		Bowel Diagnosis	Suppositories			Text
101		Please specify other	Enemas			Text
102		Neurological features	Manual evacuation			Text
103		Please specify other	N/A			Text
104		Sexual function	Laxatives			Text
105		Comments	Unknown			Text

Again, would be very surprised if this gets taken up by others.

Issues around data sharing



- Lack of centralized repositories for raw data
- Unclear what data needs to accompany urodynamics data
- How to do we collect this data efficiently?

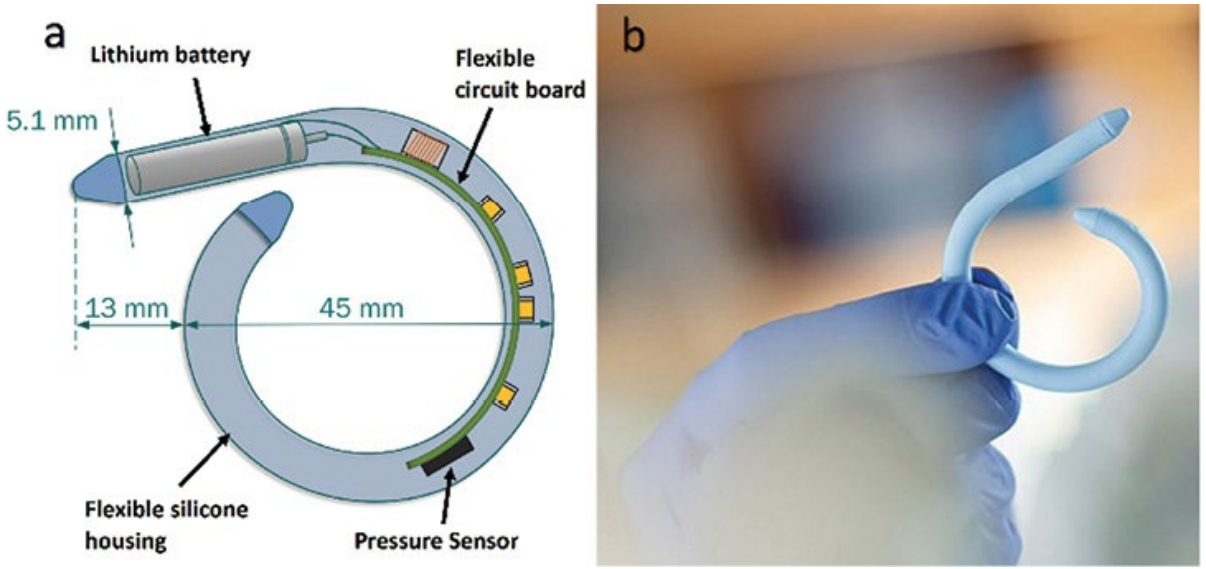
Roche et al. 2014 PLOS Biology

Amount of data captured is increasing. Centralized data repository would help with algorithm development.

old: – 10 minutes of data collection

new: ——————————————————————— 10 days (1440x)

Pressure sensor that goes inside the bladder.



https://auanews.net/issues/articles/2023/july-extra-2023/ju-insight-first-in-human-testing-of-uromonitor-catheter-free-wireless-ambulatory-bladder-pressure-monitor

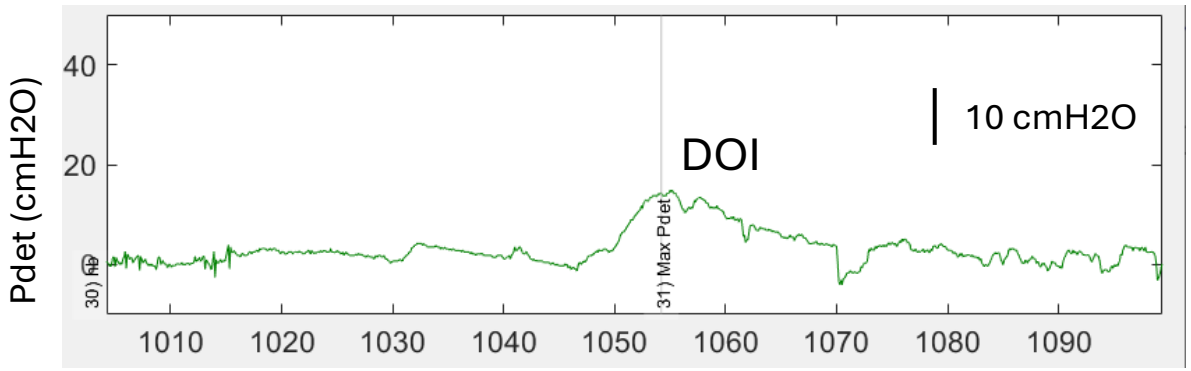
Need for moving beyond visualization. An example.

Large variability in what constitutes detrusor overactivity (DO).

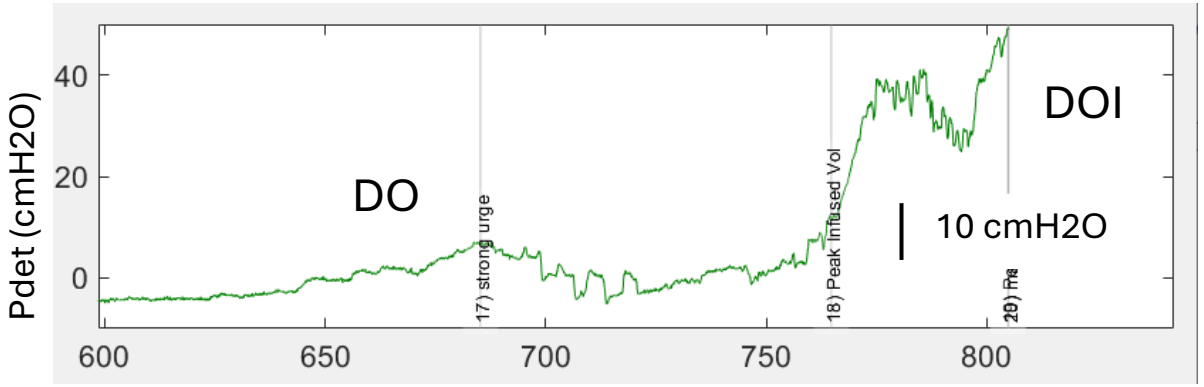
Open to interpretation

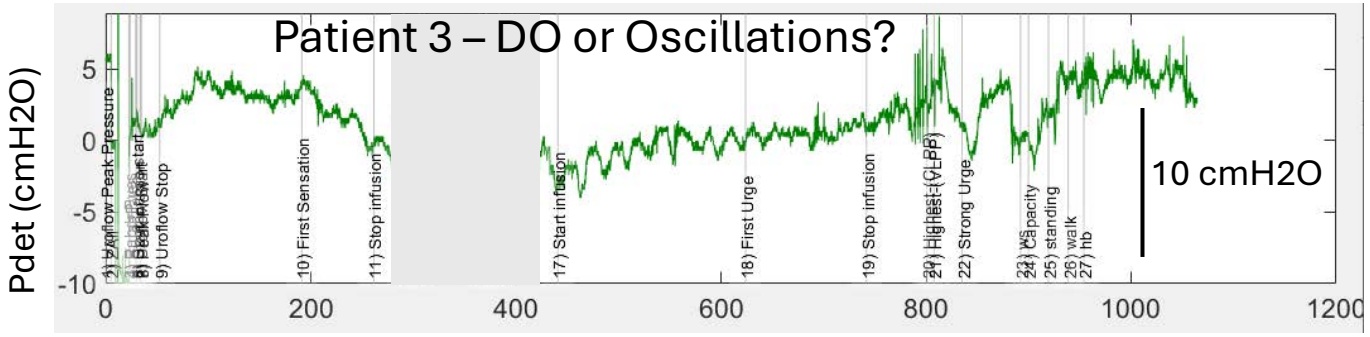
When interpretation is variable, understanding impact becomes challenging.

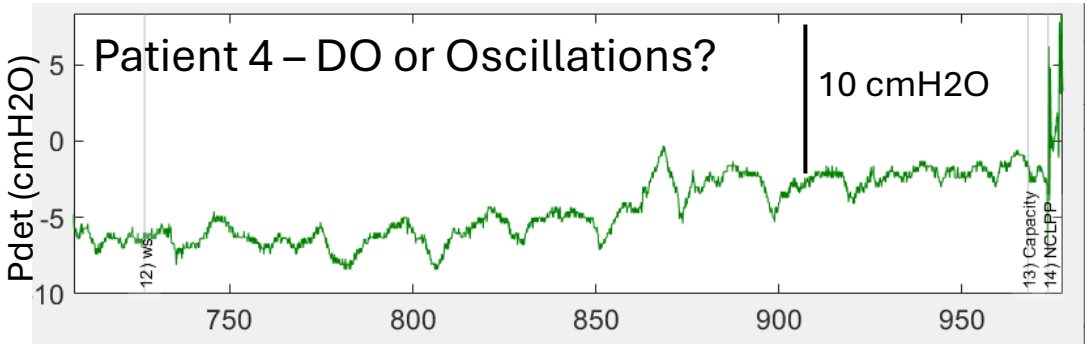
Patient 1 – Smaller DO



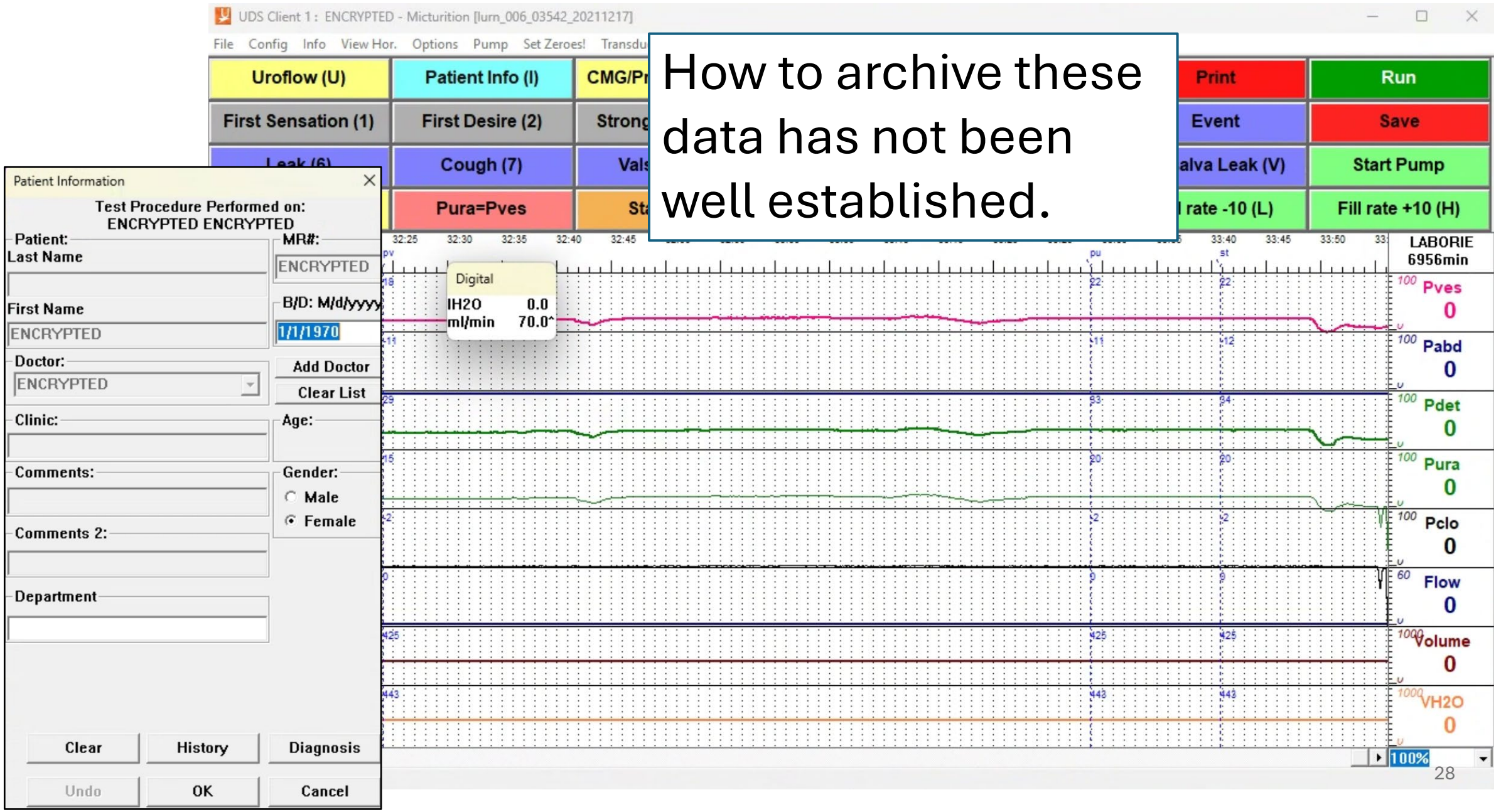
Patient 2 – Larger DO







Most US sites use same urodynamics manufacturer => single data format (benefit)



Beyond urodynamics, what else is needed?
AKA: A common “minimal” data set

Common Minimal Data Set

- Which outcomes?
- Which questionnaires/PROs?
- Other clinical measures?
- **Committees/initiatives needed**

Stress urinary incontinence (as an example):

- Initial guidelines on data collection (Leach et al. 1997 J. Urology)
- 90 articles reviewed, no articles followed all recommendations (Rovner et al. 2008 Urology)
- Recent (2024) effort to define standard minimum data set (Rovner et al. 2024 NAU)
- Presented recently to clinicians. Their response: seems like a lot of work that we don’t have time for

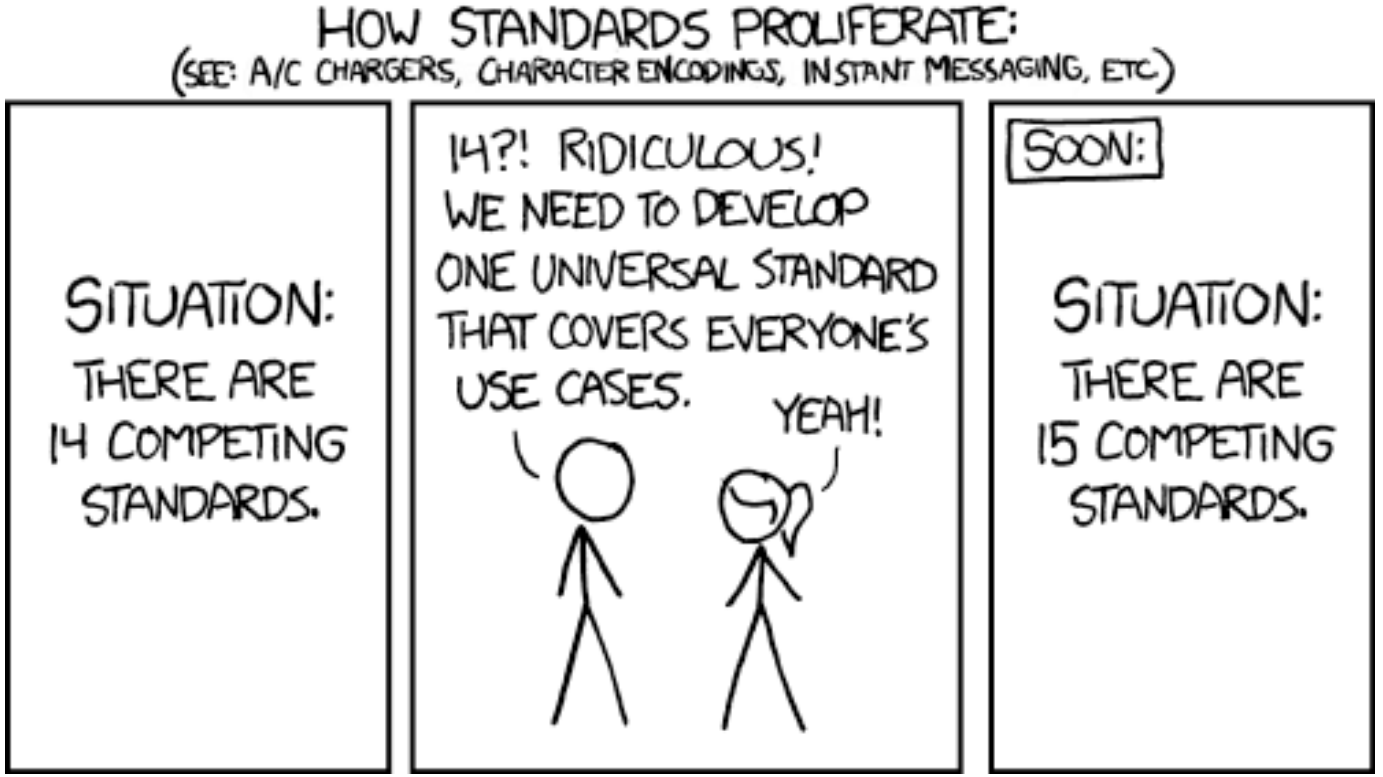
Acknowledgements

U01DK100011 (UW, PI: Yang)
U01DK097780 (Duke, PIs: Amundsen and Jelovsek, co-I: Hokanson)

Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction

(SUFU research network) (SURN)

cyang@uw.edu
jhokanson@mcw.edu



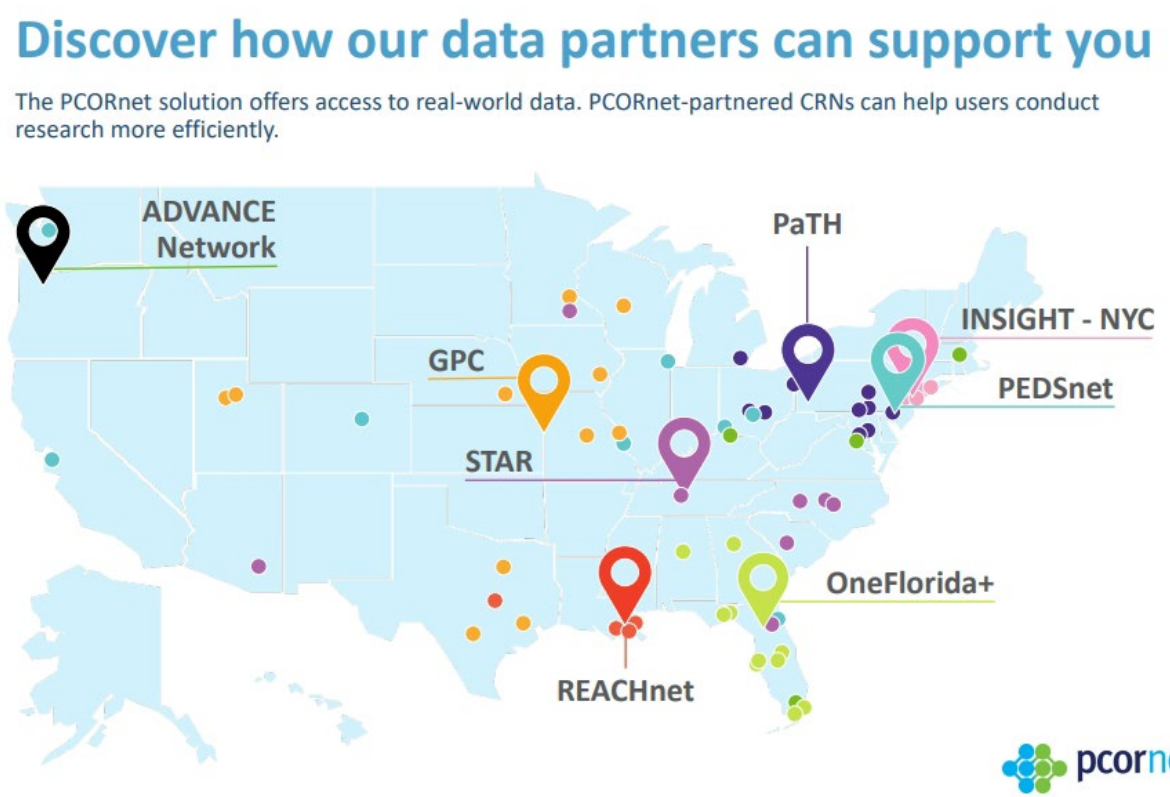
https://xkcd.com/927/

Best approach for cost effective data collection?

Not everything can be a huge $$ initiative.

Issues:

- Efficient consenting
- Easy data entry (vs. manual data entry)
- Easy onboarding of sites and easy data sharing/management



American Urological Association | AQUA AUA Quality Registry

REDCap Research Electronic Data Capture

MyCap electronic data entry

All of Us RESEARCH PROGRAM

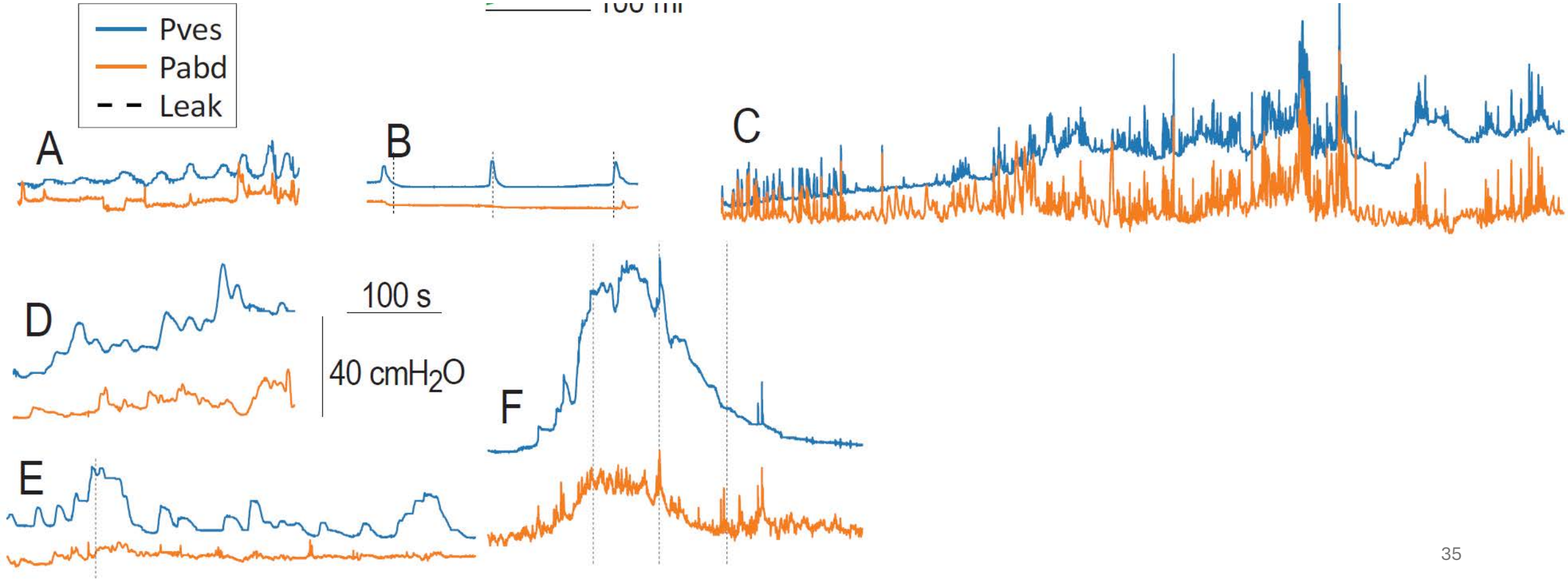
Direct benefits of program?

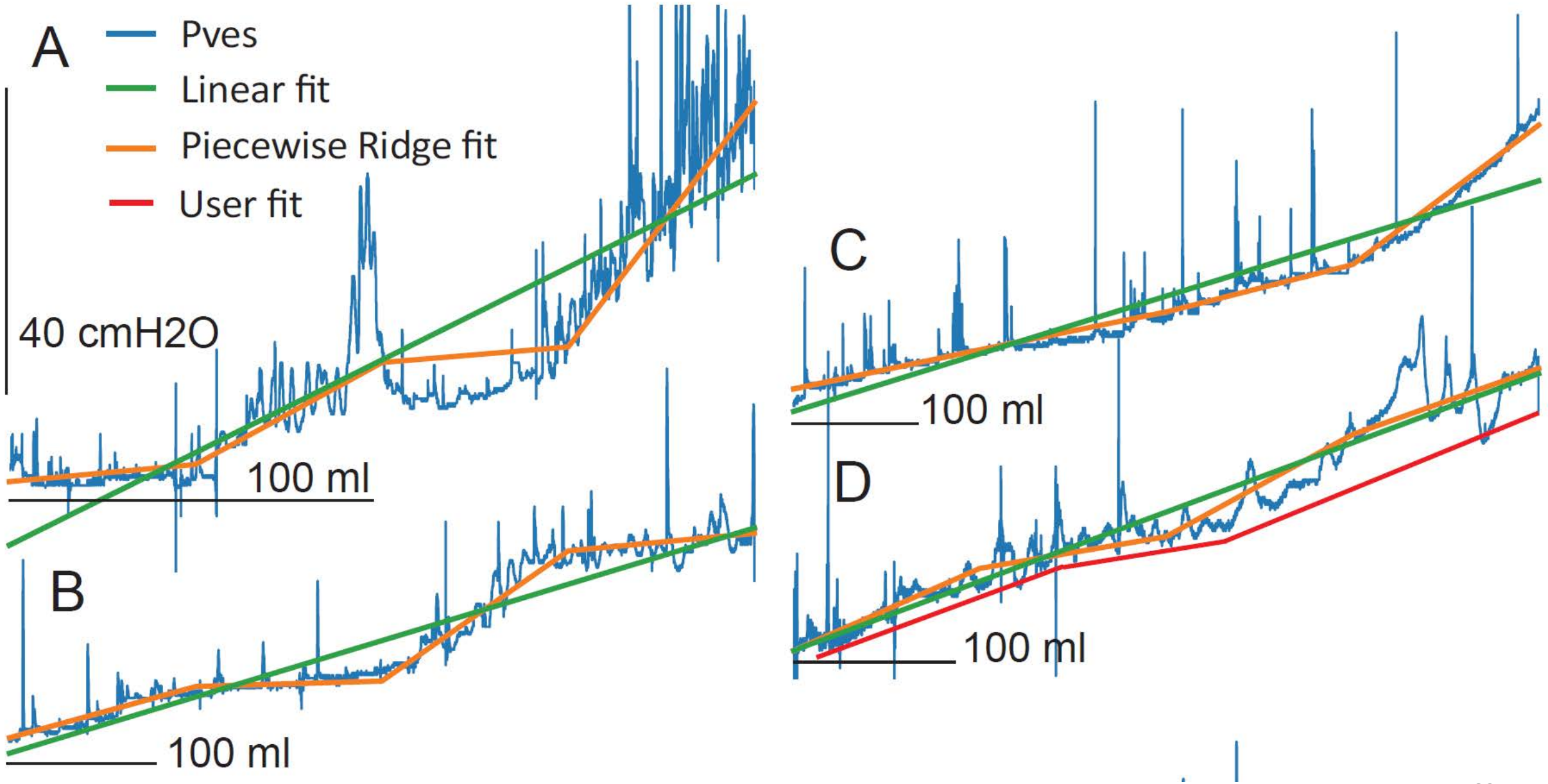
Benefits related to learning from program implementation?

Summary of Opportunities/Challenges

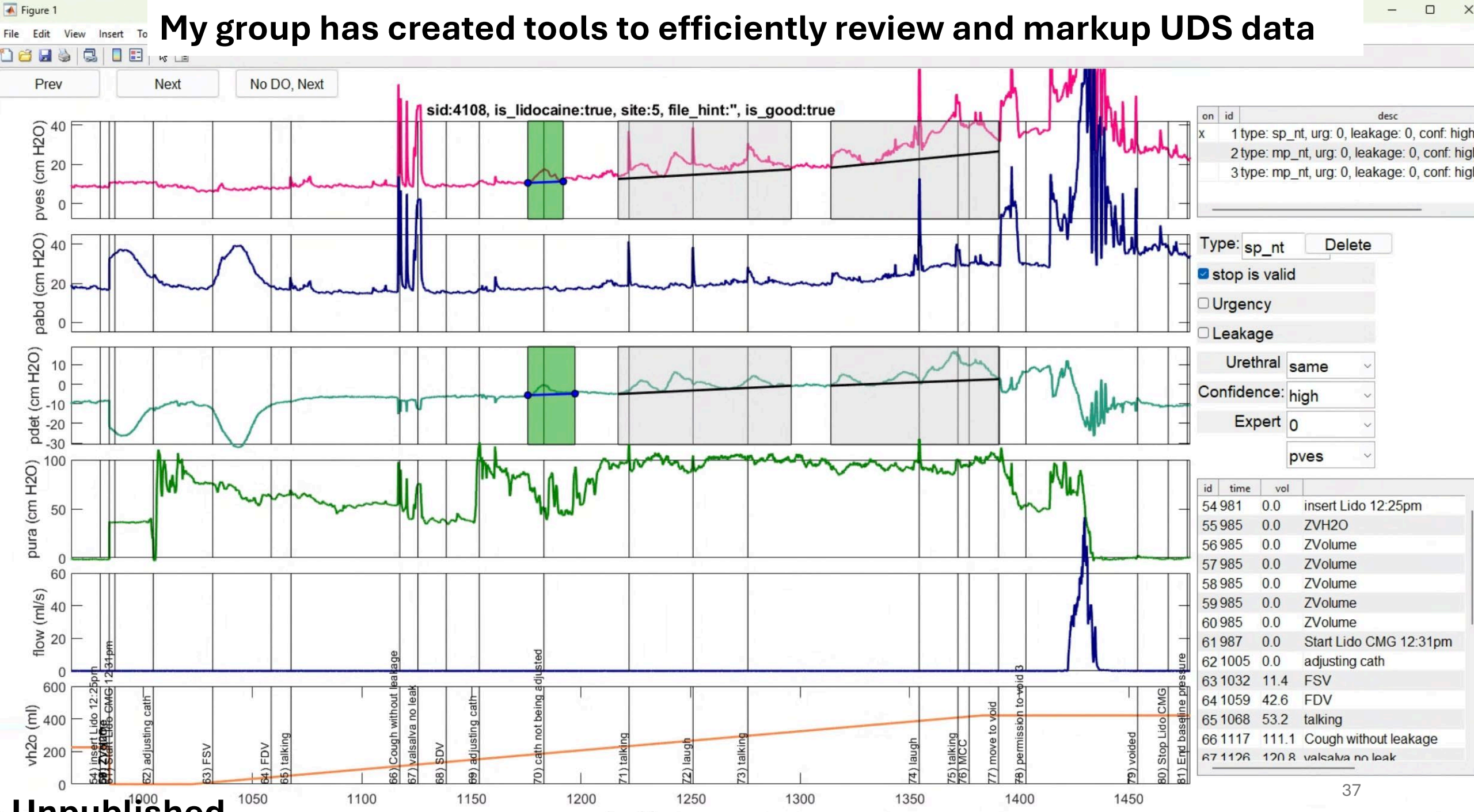
1) We should **expand beyond the "standard" tests** to better characterize urological dysfunction (examples areas: urethra and brain)
2) We should capture diagnostics with outcomes to develop **prediction models** and improve our understanding of how urodynamics informs treatment response.
3) There is a need **for shared urodynamics data repository** both for hypothesis generation and/or testing, as well as algorithm development.
4) We lack established **minimal data sets** for many conditions. Perhaps best to do in conjunction with a study rather than simply mandating things.
5) We would benefit from efforts to determine how to capture **big data at low cost**.

Traces from pediatric urology clinic (Duke)
A-C: not labeled as having DO
D-F: labeled as having DO




A
Pves
Linear fit
Piecewise Ridge fit
User fit
40 cmH2O
100 ml
B
100 ml
C
100 ml
D
100 ml

My group has created tools to efficiently review and markup UDS data



Many issues contribute to variability of urodynamics

Parameters, impact of?:

- Bladder filling rate
- Size and type (water, air-charged) of catheter
- Position of body during filling
- Repeat bladder fills?
- Temperate of infusate
- Stopping during filling

Non-Parameters, impact of?:

- Time of day
- Temperature in the room
- Friendliness of staff
- Variations in symptoms (bad day vs. good day)