PROMIS Trial: Counter Point

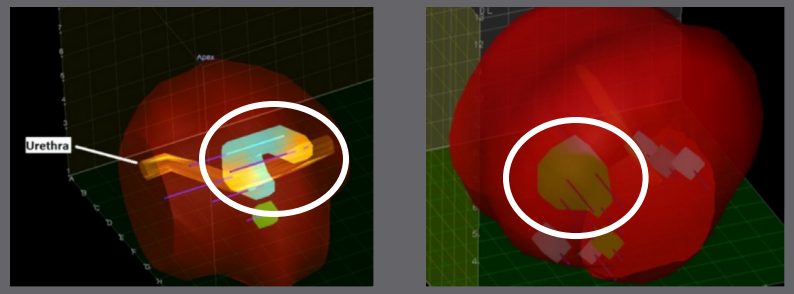
1. UK cohort is "symptomatic" - May harbor large lesions (≥ 0.5cc) easily visible on mpMRI whereas US cohort is largely "asymptomatic" and may harbor smaller clinically significant (CS) lesions (≤ 0.5cc)
2. Success/Failure based on a single PIRADS Lesion per Patient – Disease is multifocal and there can be more than one clinically significant (CS) lesion based on histopathology data
3. Absence of Lesion-Level Analysis – No information whether mpMRI diagnosed all of the CS significant lesions based on histopathology as opposed one CS lesion per patient
4. Anterior versus Posterior Lesions – TRUS biopsies miss anterior lesions. Need a comparison (sensitivity) of mpMRI and TRUS biopsy for posterior lesions. mpMRI is less effective for anterior lesions
5. Lack "concordance" and "discordance" information of PIRADS lesions and Histopathology – No information how this was done unless PIRADS lesions and corresponding cancer lesions are large ("symptomatic") and quite obvious. PIRADS score given to a lesion or to a sector?

UCH Study: mpMRI miss CS tumors

- 47 patients had mapping biopsy after MRI
  - 34 had clinically significant cancer
- MRI missed **6/34 (18%)** patients with CS cancer (table)
- MRI missed **10/25 (40%)** tumors with Gleason Score ≥ 7 and **27/60 (45%)** CS cancer (table)
- Some patients may harbor more than one CS lesion (figure)

- Some potentially important cancers are MRI-invisible
- Cost-effectiveness is yet to be resolved
- High "interobserver variability" between radiologists

Gleason Score 7 and 8 tumors > 0.5 cc



Indication to Biopsy by PIRADSv2 ≥ 3		
Statistics	Patient Level	Lesion Level
	N = 47 (CS=34)	N =122 (CS=60)
Sensitivity	**82%**	**55%**
Specificity	54%	74%
PPV	82%	67%
NPV	**54% (87%*)**	**63%**