# Defining Novel and Practical Metrics to Assess the Deliverables of Multiparametric Magnetic Resonance Imaging/Ultrasound Fusion Prostate Biopsy

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**Purpose:** Multiparametric magnetic resonance/ultrasound targeted prostate biopsy is touted as a tool to improve prostate cancer care and yet its true clinical usefulness over transrectal ultrasound guided prostate biopsy has not been systematically analyzed. We introduce 2 metrics to better quantify and report the deliverables of targeted biopsy.

**Materials and Methods:** We reviewed our prospective database of patients who underwent simultaneous multiparametric magnetic resonance/ultrasound targeted prostate biopsy and transrectal ultrasound guided prostate biopsy. Actionable intelligence metric was defined as the proportion of patients in whom targeted biopsy provided actionable information over transrectal ultrasound guided prostate biopsy. Reduction metric was defined as the proportion of men in whom transrectal ultrasound guided prostate biopsy could have been omitted. We compared metrics in our cohort with those in prior reports.

**Results:** A total of 371 men were included in study. The actionable intelligence and reduction metrics were 22.2% and 83.6% in biopsy naïve cases, 26.7% and 84.2% in prior negative transrectal ultrasound guided prostate biopsy cases, and 24% and 77.5%, respectively, in active surveillance cases. No significant differences were observed among the groups in the actionable intelligence metric and the reduction metric ($p = 0.89$ and 0.27, respectively). The actionable intelligence metric was 25.0% for PI-RADS™ (Prostate Imaging Reporting and Data System) 3, 27.5% for PI-RADS 4 and 21.7% for PI-RADS 5 lesions ($p = 0.73$). Transrectal ultrasound guided prostate biopsy could have been avoided in more patients with PI-RADS 3 compared to PI-RADS 4/5 lesions (reduction metric 92.0% vs 76.7%, $p < 0.01$). Our results compare favorably to those of other reported series.

**Conclusions:** The actionable intelligence metric and the reduction metric are novel, clinically relevant quantification metrics to standardize the reporting of multiparametric magnetic resonance/ultrasound targeted prostate biopsy

**Abbreviations and Acronyms**

AIM = actionable intelligence metric
AS = active surveillance
BN = biopsy naïve
GG = Gleason Grade Group
mpMRI = multiparametric MRI
MRI = magnetic resonance imaging
NPV = negative predictive value
PI-RADS™ = Prostate Imaging Reporting and Data System
PNB = prior negative (benign) prostate biopsy
ReM = reduction metric
TB = multiparametric magnetic resonance imaging/ultrasound fusion targeted prostate biopsy
TRUS-B = transrectal ultrasound guided prostate biopsy

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deliverables. Targeted biopsy provides actionable information in about 25% of men. Reduction metric assessment highlights that transrectal ultrasound guided prostate biopsy may only be omitted after carefully considering the risk of missing clinically significant cancers.

**Key Words:** prostatic neoplasms, magnetic resonance imaging, ultrasonography, early diagnosis, biopsy

In 2017 prostate cancer was expected to account for 161,360 cancer cases in the United States.[1] Although TRUS-B is the standard for initial diagnosis,[2] test characteristics of TRUS-B are imperfect since over diagnosis of indolent cancers and under diagnosis of biologically aggressive disease remain common.[3,4]

mpMRI/TB has emerged as a technique to improve prostate cancer care. TB is associated with reduced diagnosis of low grade cancers and greater detection of high grade cancers relative to TRUS-B.[5] Moreover, TB demonstrates high (90%) index lesion and favorable (70%) overall grade concordance compared to whole mount prostatectomy pathology findings.[6]

To date the evaluation of TB has focused on traditional measures of test performance (eg sensitivity, specificity and predictive values).[7,8] Yet these parameters do not fully communicate TB usefulness and clinical value (ie the deliverables of TB). For instance TB harbors the promise of identifying clinically significant disease that would be missed on TRUS-B and the potential to forgo TRUS-B by limiting biopsy to targeted lesions only. Quantification and standardized communication of these deliverables is lacking. To this end we examined our institutional database and available published reports to propose 2 novel metrics that better quantify the clinical usefulness of TB.

## MATERIALS AND METHODS

### Patient Cohort

After receiving institutional review board approval data on patients who underwent TB were indexed in a prospectively collected institutional database. TB was offered to men with targetable lesions on mpMRI, including those who were BN, those with prior negative (ie benign) TRUS-B (PNB) and those on AS. Men on AS at our institution undergo mpMRI biopsy within 1 year of being placed on AS and before the confirmatory biopsy. Patients with targetable lesions on mpMRI are advised to undergo TB. At our institution TB commenced in 2014. Data were censored at the end of 2016.

### Magnetic Resonance Imaging

mpMRI was performed on a 1.5 Tesla scanner with an endorectal coil. Abnormal regions were classified according to the PI-RADS version 2 grading system[9] by 4 radiologists with more than 20 years of experience with interpreting prostate mpMRI. PI-RADS version 2 was retrospectively applied to MRI interpretation in 68 patients who were imaged prior to 2015.

### Biopsy Protocol

After providing informed consent the patients received antibiotic prophylaxis. A transrectal periprostatic block was performed. The UroNav (InVivo®) fusion biopsy system was used to perform TB. One to 4 samples were taken from each marked lesion. TB was followed by 12-core TRUS-B to obtain bilaterally, medially and laterally directed peripheral zone biopsies from the prostate apex, middle and base. All biopsy specimens were reviewed using standard procedure by pathologists at our institution and reported based on START (Standards of Reporting for MRI-targeted Biopsy Studies) recommendations.[10]

### Defining Multiparametric Magnetic Resonance Imaging/Ultrasound Fusion Targeted Prostate Biopsy Deliverables

The definition of clinically significant prostate cancer was GG 2 or greater.[11] We compared TB and TRUS-B results in the same patient. Any clinically significant intrapatient discrepancy between TB and TRUS-B was tabulated. For example, GG 2 prostate cancer found on TB and GG 1 prostate cancer found on TRUS-B in the same patient represented a clinically significant grade difference. However, when concurrent TRUS-B demonstrated no cancer, GG 1 prostate cancer on TB was not deemed a significant grade difference since this result may be viewed as clinically undesirable.[3]

AIM was created to indicate the percent of men in whom TB provides data likely to change treatment over TRUS-B. AIM is the number of patients with a clinically significant increase in GG identified from TB compared to TRUS-B divided by the total number of patients with clinically significant cancer who undergo biopsy with the result converted to a percent (fig. 1).

ReM was created to estimate the proportion of men in whom TRUS-B might be omitted. To determine ReM the number of patients with a clinically significant increase in GG found on TRUS-B compared to TB is divided by the total number of patients undergoing biopsy and converted to a percent. This value is then subtracted from 100%, leaving patients in whom deferring TRUS-B may be considered (fig. 1).

Men were stratified by clinical scenario (BN, PNB or AS) and by mpMRI abnormality (PI-RADS 3, 4 or 5). In patients with more than 1 prostate lesion on MRI the highest PI-RADS score was used. Literature reports with adequate data to calculate AIM and ReM were identified for comparator analyses.[12–16]

### Statistical Analysis

The calculated AIM and ReM percents were compared using binomial tests of proportions. The chi-square test