Development and Utility of an At Home Urine (EPI) Test Kit During COVID-19 Pandemic to Support Prostate Cancer Diagnosis Shared-decision Making and Telehealth

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INTRODUCTION

The ExoDx Prostate, EPI test, is a urine exosome gene expression assay that does not require a pre-collection digital rectal exam (DRE) to make informed prostate biopsy decisions. The EPI test algorithm does not include any clinical/standard-of-care features and is a standalone test that provides a risk stratification/assessment score to discriminate between no cancer/low-grade PC (Gleason Grade Group 1 [GG1], EPI≤15.6) and HGPC (≥GG2, EPI>15.6).[2,3] The EPI test was included in the National Comprehensive Cancer Network guidelines for PC Early Detection in 2019. Previously, we partnered with a major healthcare insurer to execute a unique, prospective, randomized, blinded, two-armed clinical utility study to determine the impact of the EPI test on the biopsy decision-making process between patients and urologists.[4] The utility study found that doctors that had access to the EPI result found 30% more HGPC compared to the blinded arm receiving standard of care.

COVID-19 led to widespread cancellation of office visits and reduction of diagnostic biopsy procedures in men with elevated PSAs. This resulted in the need for an At Home Collection Kit to assess risk of aggressive prostate cancer (PCa) and aid prioritization for biopsy procedures.

The ExoDx Prostate (EPI) At Home Collection Kit for PCa risk assessment is now a viable tool that supports urologic telehealth and the shared decision-making in prostate cancer.

Here, we reviewed EPI effectiveness using a home sample collection kit to provide easier access for patients and helpful processes for clinicians.

METHODS

A development program for the ExoDx At Home Collection Kit was initiated in April 2020 during the COVID-19 pandemic. Phase 1 study (100 patients, 6 sites) was completed in June 2020. Based on feedback from physicians, patients, and office mangers in Phase 1, the test was made available in Phase 2 to all urologists in the US. Satisfaction and real-world utility of the Kits were measured via physician and patient feedback.

RESULTS

- Extensive feedback from the pilot program (100 test kits) was obtained from the ordering urologists, their office managers, and the patients and the Exosomes Diagnostics Client Services team responsible for shipping the test kits.
- Feedback led to process and ordering improvements
- Significant growth in home sample collection which has not abated as practices have returned to increasingly normal operation.
- As of January 31st, 2022, 30+% of all the ExoDx Prostate Tests are At Home Collection Kits and patient and physician satisfaction exceeds 97%.
- No significant differences in EPI score distribution rates have been detected between clinical and home collection approaches.
- No significant differences in rejection rates have been detected between clinical and home collection approaches.

EPI Score	Mean	Median	Minimum	Maximum	Median Absolute Deviation
Home Collection	28.378	23	0	99	11
Clinic Collection	29.705	24.67	0.49	97.90	11.70

Table 1. EPI score distribution compared from home to clinic sample collection.

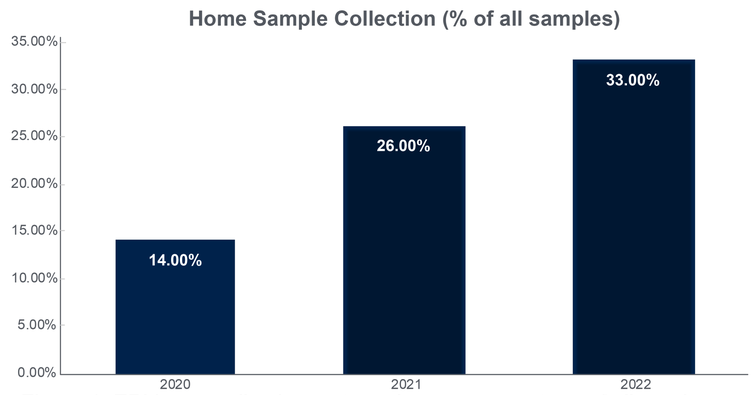

Figure 1. EPI home collection test results as a percentage of all results.

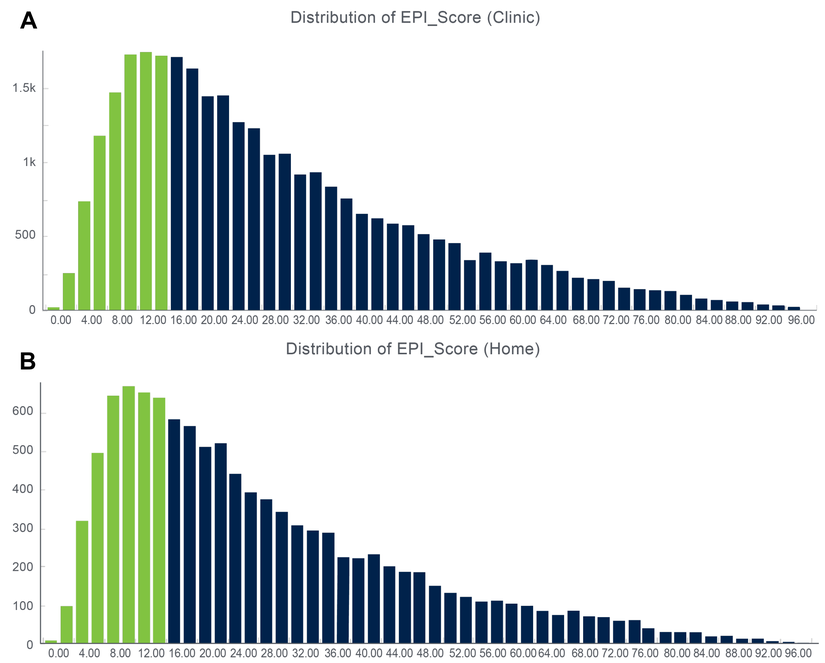

Figure 2. (A) EPI score distribution for urine sample collection in the clinic is identical to (B) EPI score distribution for home sample collection.

CONCLUSIONS

The ExoDx Prostate (EPI) At Home Collection Kit was successfully developed and employed to help men (>50 years old) with elevated PSAs (2 – 10 ng/ml) with pandemic-related fears of office/hospital visits considering initial or repeat prostate biopsy or wanting to avoid long distance travel from rural areas.

The ExoDx At Home Kits provides an easy non-invasive, non-DRE urine test for genomic risk assessment of aggressive cancer. At Home testing is poised to be increasingly utilized (cancer biomarkers, benign urology diseases) and become an integral part of urology telehealth.

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AUA Northeastern Section Meeting, October 27-29, 2022 , Charlotte, NC

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