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MENDAERA

Background

- Early detection to Prostate cancer is vital and screenings are performed by testing for prostate-specific antigen (PSA) levels with levels higher than 2.5 ng/mL for men in their 40s indicating prostate cancer.
- PSA is collected through transrectal or tranperineal biopsies.
- The process involves retrieving at least 12 core samples from different regions of the prostate and histologic analysis of the tissue

2nd

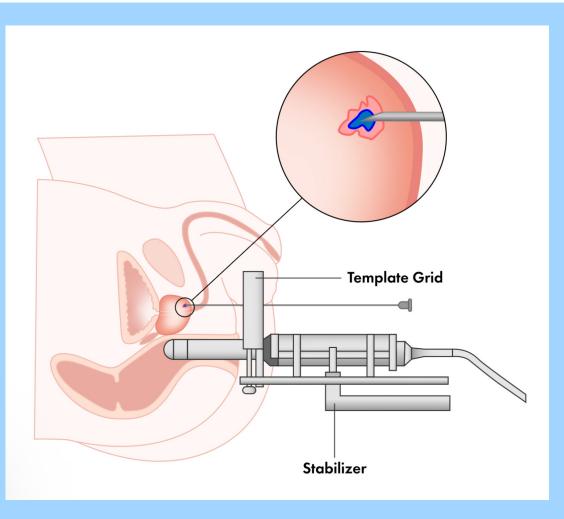
Most commonly diagnosed cancer among men worldwide

5th

Leading cause of cancer death among men worldwide

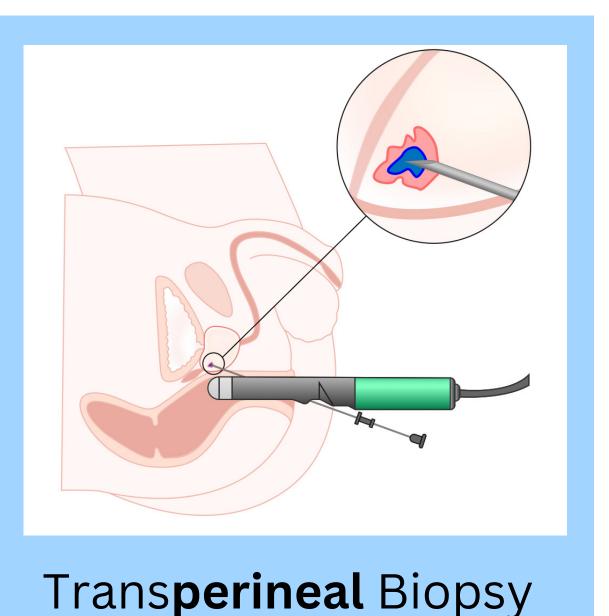


Prostate biopsies performed each year in the US



Trans**rectal** Biopsy

- Procedural time: 15 Min
- requires localised anaesthesia
- higher rate of infection



- Procedural time: **30 Min**
- requires general anaesthesia, increasing patient discomfort
- lower rate of infection

Needs Statement

Urologists need a method with a low task-load index for reducing procedural time to decrease patient discomfort and enable the use of both transperineal and transrectal approaches

User Needs and Design Requirements



Should **maintain** the clinician's accuracy and obtain **high-quality cores**



Biopsy time should be <13 minutes with 1 minute per core retrieval time



Should **not increase** the existing cognitive burden on clinicians



Post-biopsy cores should be **traceable** to their sample region within the patient

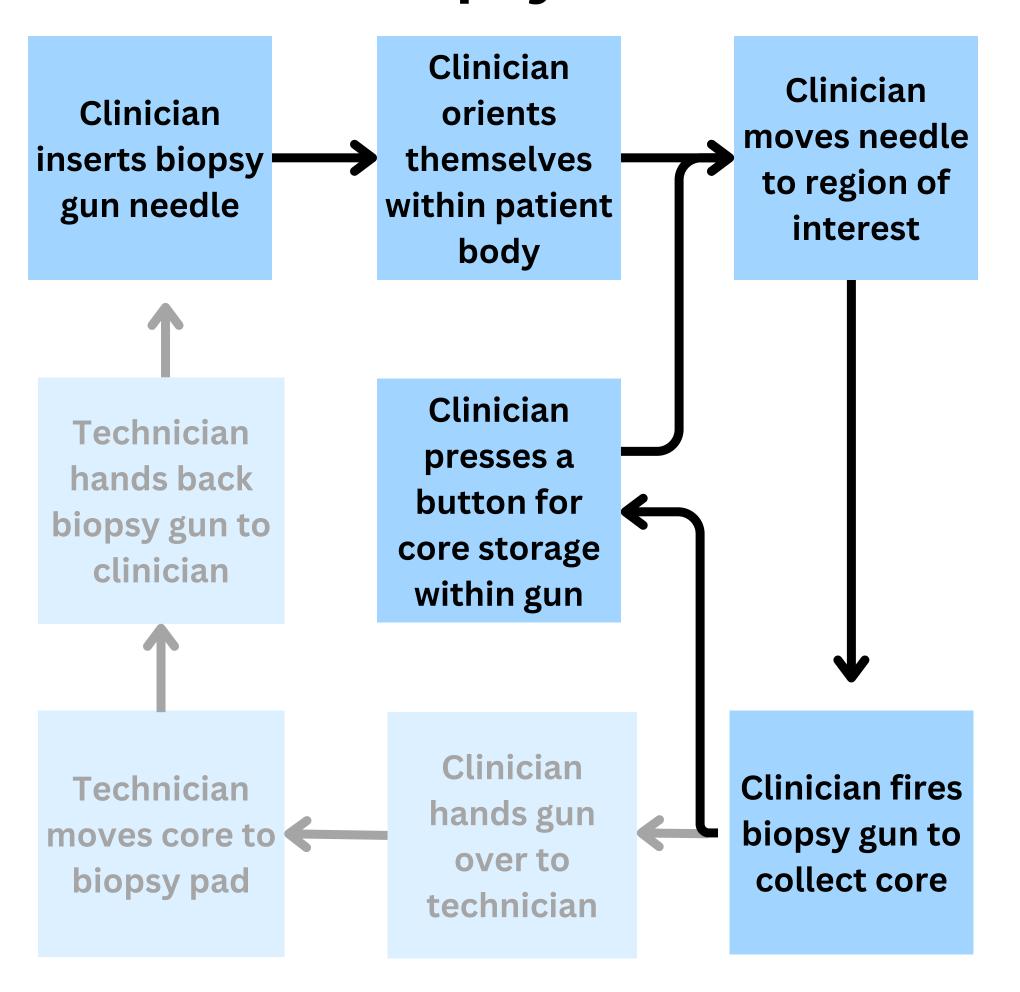


Should not require more than 20 **procedures** for clinicians to become proficient.

Pinnacle enables seamless core collection without unnecessary gun removals, lowering patient pain and ultimately benefiting patient outcomes



Prostate Biopsy Workflow



Current Standard

96 Step Procedure

Pinnacle **Biopsy Gun**

38 Step **Procedure**

Testing Pathway

