UCARE Collaborative Applied Research

SIU BPH Global Registry

1. PRINCIPAL INVESTIGATOR

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2. OBJECTIVES

The purpose of this study is to record demographic data and clinical outcomes after medical therapy or different surgical interventions for benign prostatic hyperplasia.
The ongoing global registry will provide important baseline data, functional outcomes and complications following medical and/or surgical intervention for men with symptomatic BPH.

3. BACKGROUND

There has been a significant expansion in the number of approved medical and surgical interventions with symptomatic BPH. There is a significant research interest in monitoring clinical outcomes including improvements in urinary function, impact on sexual function, postoperative morbidity as well as retreatment. A registry such as what is proposed provides real time data accounting for relevant baseline demographic characteristics in this population of men. The SIU is an academic organization that is uniquely positioned to initiate such a registry because of its global outreach including countries where data are lacking

4. SELECTION CRITERIA

We will identify medical records of all men who have a primary diagnosis of BPH with LUTS that are prescribed BPH medications or a surgical intervention.

5. RESOURCES FOR EXISTING MATERIALS DATA

- This is a prospective longitudinal ongoing registry
- Data extraction will include baseline data, peri-operative data and followup data
- Please see the attached data sheet (Appendix 1)
- Validated patient reported outcome tools will be digitized and used (IPSS, SHIM, MSHG-EjD)
- There is no end point for follow-up

6. BIOSPECIMENS

- N/A

7. STUDY TIMELINE AND DATA ANALYSIS

Charts will be retrospectively reviewed and all recorded data will be coded. No key to codes or any other mechanism for identifying the data will be retained at the end of the study.

8. INFORMED CONSENT

We will be retrospectively reviewing and collecting data that already exists in patient's medical records. We will not be contacting participants or including any sensitive data included in HIPAA section (i.e. HIV/AIDS status, mental health, and alcohol/drug abuse records). Full waiver of informed consent is being requested in the IRB submission form.

9. HIPAA

The study will access limited PHI (MRN without identifier for the clinical site), which will undergo HIPAA approved methods for maintaining data security.
Full waiver of HIPAA authorization is being requested in the IRB submission form.

10. DATA COLLECTION AND STORAGE

Developer: Hefficient Analytics

- The Registry provides secure access to registered users using a web browser.
- Users are registered for use and set up with username and password authentication. User registrations are site-specific, which means that users can access data that is specific to their own site only.
- All users with Registry Administration privileges are setup with two-factor authentication.
- Any biographical data is stored using HIPAA approved mechanisms of encryption.
- Biographical data is stored in a separate database from the registry database. That database holds site and patient biographical information only. The registry database holds an internal site code and the encrypted MRN of the patient.
- The Registry application and databases are hosted in AWS on servers running Ubuntu Linux LTS version OS.
- The Registry application sits behind an AWS WAF and a Reverse Proxy using NGINX.
- Registry database servers are protected by firewall and made accessible to only the Registry application servers on a specific port. All other routes and ports are blocked by firewall.
- All databases are held on encrypted disks.