Development of a Nationally Representative Coordinated Registry Network for Prostate Ablation Technologies

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Abbreviations and Acronyms

CRN = coordinated registry network

EPIC-26 = Expanded Prostate Cancer Index Composite-26

FDA = Food and Drug Administration

HIFU = high intensity focused ultrasound

HRQOL = health related quality of life

IIEF-5 = International Index of Erectile Function-5

I-PSS = International Prostate Symptom Score

MRI = magnetic resonance imaging

MSHQ-EjD = Male Sexual Health Questionnaire for Ejaculatory Dysfunction

PGA = partial gland ablation

PI-RADS™ = Prostate Imaging Reporting and Data System

PSA = prostate specific antigen

Purpose: The accumulation of data through a prospective, multicenter coordinated registry network is a practical way to gather real world evidence on the performance of novel prostate ablation technologies. Urological oncologists, targeted biopsy experts, industry representatives and representatives of the FDA (Food and Drug Administration) convened to discuss the role, feasibility and important data elements of a coordinated registry network to assess new and existing prostate ablation technologies.

Materials and Methods: A multiround Delphi consensus approach was performed which included the opinion of 15 expert urologists, representatives of the FDA and leadership from high intensity focused ultrasound device manufacturers. Stakeholders provided input in 3 consecutive rounds with conference calls following each round to obtain consensus on remaining items. Participants agreed that these elements initially developed for high intensity focused

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ultrasound are compatible with other prostate ablation technologies. Coordinated registry network elements were reviewed and supplemented with data elements from the FDA common study metrics.

Results: The working group reached consensus on capturing specific patient demographics, treatment details, oncologic outcomes, functional outcomes and complications. Validated health related quality of life questionnaires were selected to capture patient reported outcomes, including the IIEF-5 (International Index of Erectile Function-5), the I-PSS (International Prostate Symptom Score), the EPIC-26 (Expanded Prostate Cancer Index Composite-26) and the MSHQ-EjD (Male Sexual Health Questionnaire for Ejaculatory Dysfunction). Group consensus was to obtain followup multiparametric magnetic resonance imaging and prostate biopsy approximately 12 months after ablation with additional imaging or biopsy performed as clinically indicated.

Conclusions: A national prostate ablation coordinated registry network brings forth vital practice pattern and outcomes data for this emerging treatment paradigm in the United States. Our multiple stakeholder consensus identifies critical elements to evaluate new and existing energy modalities and devices.

Key Words: prostatic neoplasms, high-intensity focused ultrasound ablation, registries, patient outcome assessment, biomedical technology

After FDA clearance for market distribution of HIFU in 2015 as a Class II medical device for the indication of prostate tissue ablation[1,2] the technology is now offered in the United States. With improvements in imaging and biopsy technologies partial gland ablation offers a novel approach for treating men in whom prostate tissue ablation is clinically indicated while preserving genitourinary function.[3] As physicians and patients navigate the evolving landscape of treatment modalities, the role of post-market evaluation is taking on a greater role in terms of evaluating real world evidence of the safety and effectiveness of various device based therapies.

In 2015 the National Medical Device Registry Task Force recommended strategic CRNs as a practical and efficient way to capture and evaluate the use of medical devices during routine clinical care with a standardized, harmonized and interoperable approach.[4,5] A registry network, acting as a reliable system to capture information on medical devices throughout the device life cycle, is a valuable instrument to monitor the use, safety and results of the device in the United States.

On July 22, 2016 representatives of the FDA, industry, nonprofit organizations, patient advocacy groups, payers and clinical experts in the field of urological oncology met at the FDA White Oak Campus in Silver Spring, Maryland to discuss the application of HIFU in the United States in men with prostate cancer. At the meeting there was strong support for the development of a CRN in the United States which would evaluate the clinical usefulness and safety of this technology as it is being used for prostate ablation. Subsequently it became evident that such a CRN may incorporate existing and future prostate ablation technologies which may be used in the United States.

To create a registry that is comprehensive in nature and less burdensome to providers we used the Delphi method[6,7] to survey national experts to identify and define the items that would be captured in a nationwide CRN.

METHODS

Following the meeting 3 rounds of anonymized surveys were sent to urologists present at the meeting as well as experts unable to attend. The surveys were devised according to the Delphi technique[6,7] and administered through a secure anonymous online questionnaire (https://www.surveymonkey.com) between October 13, 2016 and December 7, 2016. The Delphi method was developed in the 1950s at the RAND Corporation to create a technique that would eliminate the influence of psychological and group dynamic factors on committee decisions.[8] In this approach the opinion of experts is obtained during multiple rounds with the goal of ultimately obtaining a group consensus.[6–8] We elected to use this process of selecting the registry items, given that with many participating institutions agreement by stakeholders would be critical to continued collaboration. In this study we did not review or capture protected health information or involve human subjects.

Consensus was established when 60% or more of the participants agreed on a particular item in question. Subsequent rounds were structured based on aggregate results and comments provided at the prior round. Two of us (RG and AB) designed the 3 rounds of surveys under the supervision of the senior authors (JCH and AS), and included opportunities in the survey to provide feedback. When consensus was not established, it was addressed in the subsequent round using the top answers from the previous round. Experts who completed the online rounds were eligible for participation in the final round.

Conference calls were held following the completion of each round to review topics which had not reached consensus or generated many comments and mutual agreement was obtained. Elements of the registry were ultimately reviewed by representatives of the FDA. Based on the FDA evaluation of common study metrics additional elements were identified and added. In the last