
Germline testing for prostate cancer: community urology perspective

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In an attempt to better understand how community urology practices would begin to incorporate hereditary testing in prostate cancer patients, we developed an eight-question on line survey to identify current testing patterns, utilization of genetic counseling and barriers that practices face. Fifty-two large community urology

practices participated. A total of 32/52 (63%) of the responders were already offering testing to select patients. The big hurdles practices were concerned when initiating testing were fear of medical/legal liability (22%), concerns over reimbursement and out of pocket patient expense (20%) and the complexity, time and difficulty to enter a complete family history/pedigree into the EHR (18%).

Key Words: germline testing, community urology practices

Akin to many industries in the United States and independent of each other during the 1990's, there was consolidation and merging of community urology groups in various markets across the country. As a result of these trends, a notable proliferation of large single specialty urology practices began to surface across the U.S.¹ And with federal regulations and statutes that are still in existence today (<https://www.auanet.org/advocacy/comment-letters-and-resources/in-office-ancillary-services-exception/preserve-the-ioase-exception-to-the-stark-law>), integrated services, including anatomic pathology, laboratory services, ambulatory surgery centers, radiation centers and dispensing pharmacy capabilities, could now be potentially housed under a single practice, resulting in more efficient and cost effective care.² Consequently, many of these entities, some of which may number up to 100 urologists under a single provider number, are diagnosing hundreds of new prostate cancer cases and managing thousands of existing prostate cancer patients, at various stages of the disease, annually. In conjunction with these large

volume of cases, regardless of the disease state, that exist within a single practice, sub-specialization within the groups also began to emerge in an attempt to enhance care and optimize outcomes.

One of the early service lines developed was the incorporation of advanced prostate clinics within the practice, which was a direct result of the rapid approvals of many agents during the early part of this decade for the treatment and management of metastatic castration resistant prostate cancer (mCRPC).³ Because of this paradigm shift away from urologists managing only localized disease and transitioning to caring for the patient across the disease spectrum, it becomes necessary and a mandate for groups that have adopted this philosophy to provide services and testing that will facilitate this culture of providing continuity of care. With the recent discoveries that lethal prostate cancer may have a germline component⁴ and that men with mCRPC who have been heavily treated with multiple agents may develop somatic DNA repair gene mutations,⁵ it is incumbent on the urology practices to have a thorough understanding of who are candidates that require testing and how to incorporate this into a busy clinical setting.

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However, there are many obstacles that community urology practices face when trying to operationalize a new service line that is not readily inherent to their surgical practice. These potential hurdles, specific to hereditary testing, include:

1. Fear of medical/legal liability if mutations are discovered and are not addressed with the patient or family members.
2. Lack of certified genetic counselors in the immediate area.
3. Concerns over reimbursement and potential out of pocket expense to the patient.
4. Lack of education/awareness of somatic vs. germline testing.
5. Complexity, time involved and difficulty in entering family history/pedigree into the electronic health record (EHR).
6. Lack of education/understanding of the various genes that are associated with increased risk or disease progression.

Given the clinical significance that hereditary testing potentially represents for high risk prostate cancer patients, their families and the potential large volume of these patients within a single practice, we need a better understanding of which factors are resulting in under testing of appropriately identified patients. Knowing that there is marked variability in the organizational and daily operational structure of large urology groups, we devised an eight-question survey to help interrogate this issue. The survey was posted on line and hosted by Integra Connect (West Palm Beach, FL, USA). Emails were sent to members of LUGPA (Chicago IL, USA), a not for profit entity that represents the interest of independent urologic practices in the United States, inviting them to take part in the survey. A total of 52/149 (34.9%) responded to the online survey. Key findings from the survey:

1. Representation of respondents had group size of 0-10, 11-25, 26-50, > 50 providers in the practice of 25%, 33%, 29% and 13% respectively.
2. 21/52 (40%) of the respondents had > 500 newly diagnosed cases per practice in 2018.
3. Cumulatively, a total of 154,640 unique prostate cancer patients (defined by at least 1 office visit based on ICD 10 and CPT code) were seen in these 52 practices in 2018.
4. 48/52 (94%) of the respondents were aware of the most recent SUO policy statement on hereditary testing in prostate cancer.
5. 32/52 (63%) of the respondents were already offering hereditary testing to their patients
6. 33/52 (65%) of the respondents had access to genetic counseling within a 20 mile radius of their office location.

7. Fear of medical/legal liability (22%), concerns over reimbursement and out of pocket patient expense (20%) and the complexity, time and difficulty to enter a complete family history/pedigree into the EHR (18%) were the three most commonly cited issues that concerned the respondents when implementing or considering a hereditary testing program.

Conclusion

Based on a sampling of 52 large community urology practices geographically distributed across the United States, 94% of the practices are currently aware of the recent SUO policy statement. 63% of the groups had already incorporated testing for select patients and another 25% in the active process of developing an in house testing program. The primary practice concern for offering and initiating a hereditary testing program is the fear of medical/legal liability if mutations are identified but not addressed with the patient and/or family. Given the large volume of prostate cancer patients diagnosed and managed by these large groups, we hope this will increase utilization in appropriately identified patients.

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Disclosures

Dr. Raoul S. Concepcion is a consultant for Dendreon, Integra Connect, Cella, Invitae, Merck, Pfizer, Astellas, Janssen, Sun Pharma, CUSP and Clovis. He is a speaker for Astellas, Pfizer, Amgen and Sun Pharma. □

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