Optimizing Prostate Cancer Care:
Integrating Risks, Benefits, and Patient Experiences in the New Era of Molecular Imaging

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A molecular imaging revolution is underway in prostate cancer. To overcome longstanding limitations in prostate cancer staging, several positron-emission tomography (PET) scans have recently been approved and rapidly integrated into clinical care based on evidence of improved diagnostic accuracy. However, the consequences of widespread PET imaging are unknown. This is because the approvals of these tests are based on improved diagnostic accuracy, a surrogate endpoint, rather than direct evidence of patient benefit. By finding small sites of cancer earlier, PET imaging could introduce a cascade of effects—both positive and negative—that could vary from patient to patient. PET imaging could lead to improved survival and fewer symptoms from metastatic cancer in a subset, but could also increase treatment toxicity, psychological burdens, and costs in others. Currently, no information is available to help guide patients or stakeholders when considering these tradeoffs. To reduce these uncertainties, our goal is to develop a decision model that considers the effects of PET imaging across multiple dimensions. To inform this model, we will generate real-world evidence from a diversity of sources. In aim one, we will conduct complementary analyses of large, nationally representative databases to evaluate the effectiveness of PET imaging, focusing on the associations between imaging initiation of systemic therapy, progression to hormone-refractory disease, and costs. In aim two, we will measure the longitudinal impact of PET imaging on patient-reported outcome measures relating to psychological effects (anxiety and uncertainty) and health-related quality of life. To gain a deeper perspective about patient experiences with testing we will also conduct longitudinal qualitative interviews among a smaller subset of patients and integrate the findings from quantitative and qualitative sources. In the third study aim we will incorporate inputs from Aims 1 and 2 to construct individual-based state-transition microsimulation models examining common scenarios for PET imaging use. The outputs from these models will include estimates of effectiveness, as well as patient characteristics that may be associated with greater or lesser degrees of benefit or harm. The results of this study will equip patients, providers, and other prostate cancer stakeholders with practical, new information about the potential short and long-term effects of PET imaging. If successful, this approach for evaluating effectiveness will be applicable to other similar molecular imaging modalities that will soon enter clinical care on the basis of surrogate endpoints of improved diagnostic accuracy, but without evidence of long-term clinical efficacy.