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As an adjunct to clinical practice, his research has focused on outcomes research and quality improvement initiatives related to head and neck surgery, and oncology as a whole. Within these areas, Dr. Mehta has authored several publications related to HPV oropharyngeal cancer, and head and neck and thyroid racial/socioeconomic disparities. He has extensive experience with database research and study design utilizing large institutional and national datasets (NCDB, SEER, and NSQIP), and has developed an increasing interest in utilizing quality improvement methodology to address disparate oncologic outcomes for historically disadvantaged populations.

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Time for Timeliness: A Proposal for Establishing Time to Treatment Initiation as a Quality Measure

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A diagnosis of cancer, which approximately 40% of those born in the United States will receive in their lifetime, is a major life-defining moment that often results in significant physical, mental, emotional, and financial strain for patients and their families.¹ Understandably, patients expect, and deserve, timely treatment of their cancer. Delays in treatment can have devastating consequences, including a significant impact on cancer burden, recurrence, and mortality. A portion of the delay in time to treatment initiation (TTI) can certainly be attributed to the increasing complexities of modern cancer care, which often involve various pretreatment imaging modalities, genomics, ancillary services, and multidisciplinary/multimodality therapeutic planning; all of which require ever-increasing administrative burden due to the authorization process for each step in our fee-for-service healthcare system. Navigating this complex pretreatment process while simultaneously dealing with a new cancer diagnosis presents a significant challenge for any individual, and there are not always adequate resources to help patients. Additionally, these treatment delays disproportionately occur within marginalized communities due to underlying challenges with social determinants of health, baseline disengagement with the healthcare system, and issues with healthcare literacy that can limit the ability of a patient and their family to advocate for timely and appropriate care. Delayed TTI thus serves as a major source of disparities seen in oncologic outcomes. We propose instituting TTI as an oncology, site-specific quality measure as a means to improve oncologic outcomes, especially for disparate populations.

Delays in TTI of cancer care are associated with worse survival outcomes for several different cancer sites and types. Khorana et al² found in a large cohort study using National Cancer Database records of >3.5 million US patients newly diagnosed with cancer that TTI lengthened by 38% (range, 20%–86%) for stage I–III breast, prostate, lung, colorectal, renal, and pancreas cancer from 2004 through 2013. The overall median TTI was 21 days in 2004 to 2005 and increased to a median of 29 days in 2013 to 2014. For early-stage breast, lung, renal, and pancreas cancers, TTI was also found to be associated with absolute increased risk of mortality from 1.2% to 3.2% per week of delay. The most substantial differences were seen with 6 weeks used as a TTI cutoff point, with a 5-year overall survival rate of 56% versus 43% for ≤6 versus >6 weeks, respectively, in patients with stage I non-small cell lung cancer, and 38% versus 29%, respectively, in those with stage I pancreas cancer ($P < .001$ for both). Hanna et al³ published a large systematic review and meta-analysis including 34 studies, 7 major cancer types, 3 treatment modalities (surgery, systemic treatment, and radiation therapy), and nearly 1.3 million patients in total. The meta-analysis found that across all 3 treatment modalities, a delay of 4 weeks was associated with increased risk of death. For example, surgical delay ranged from a 6% increased risk of death for each 4-week delay in TTI in breast cancer to 8% for head and neck cancer. The greatest deleterious effect was seen in adjuvant systemic treatment for colorectal cancer, for which there was a 13% increased risk of death for each 4-week delay in TTI. Additionally, the negative impact of delay on survival worsens with longer delays. For breast cancer surgery, a delay of 8 weeks and 12 weeks increased the risk of death by 17% and 26%,

respectively. In a population of 1,000 women with breast cancer, assuming a baseline 12% mortality, these findings translate to 10 projected additional patients dying solely due to the 4-week delay, 20 additional deaths due to an 8-week delay, and 31 additional deaths due to a 12-week delay.³ These data underscore the importance of expediting care, especially in early-stage, histologically aggressive malignancies, and highlight that tens of thousands of US patients with cancer are experiencing worsened outcomes due to delays in TTI.

Recently, delays in TTI were brought to light during the COVID-19 pandemic, as cancer care had to be triaged, modified, and often delayed. The lack of well-established, evidence-based guidelines on optimal TTI across cancer types led to reliance on mostly expert opinion for dictating timing of oncology care delivery. In England, for example, Sud et al⁴ reported that the approximate 95,000 oncologic resections annually resulted in 80,406 long-term survivors and 1,717,051 life-years gained. Based on estimates of delayed oncologic resections due to the pandemic, the authors found that surgical delays of 3 and 6 months over 1 year would result in an excess of 4,755 deaths and 10,760 deaths, respectively. Given that the population of the United States is roughly 5 times that of England, these data further highlight the significant number of lives that are adversely impacted by delayed cancer care on a national scale.

In 2001, the Institute of Medicine's (IOM's) *Crossing the Quality Chasm* cited "timely treatment" as one of 5 key areas for improvement in the 21st century. Specifically, the IOM identified "reducing waits and sometimes harmful delays for both those who receive and those who give care."⁵ An important, early example of successful time-based quality metrics was 30-day mortality postcoronary artery bypass graft surgery. Initial data accumulated in New York State was compelling, and prompted national public reporting of this data by from the Centers for Medicare & Medicaid Services in 2015.⁶ More specific to cancer care, the American College of Surgeons created the National Accreditation Program for Breast Centers (NAPBC) in 2008 to improve quality using 29 evidence- and consensus-based standards—many of which are based on appropriate treatment intervals according to cancer stage and treatment modality. For instance, the NAPBC requires programs to report the frequency at which combination chemotherapy is considered or administered within 4 months of diagnosis for women aged <70 years with AJCC T1c, stage II, or stage III hormone receptor–negative breast cancer. Adequate compliance with a number of these NAPBC measures to meet accreditation standards is associated with higher performance on accepted quality measures when compared with non-NAPBC centers, including those measures based on specific intervals of diagnosis to treatment initiation, which has been shown to improve oncologic outcomes.⁷ These examples serve as supporting evidence that the act of longitudinally measuring established quality metrics of time intervals before, during, or after cancer treatment may improve performance and outcomes.

Still, one may argue that using TTI as a quality metric is problematic. Specific concerns would include that the quality metric does not capture the complexity of modern cancer care or that public reporting of such data would lead to unintended consequences that outweigh the utility of such metrics in improving oncologic care delivery. Importantly, using TTI as a quality measure could deter providers from adequately working up patients to ensure they are medically cleared for initiation of the most appropriate treatment modality, whether that be for surgery, chemotherapy, or radiation therapy.³ Additionally, providers or cancer centers may be more reluctant to treat patients considered "high-risk" for treatment delay. These issues will merit further investigation as this metric matures, but thus far these types of concerns have been unrealized in other similar examples of publicly reported quality measures. Further complicating the use of TTI as a quality metric is the concern about accurately risk-adjusted measures that should be tailored to patient-specific



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pathologic and clinical characteristics. Evidence-based TTI metrics must be developed from high-fidelity data with several of these confounding factors taken into account, thereby ensuring that the established TTI cutoffs are optimized for improving oncologic outcomes while still allowing for reasonable time frames to diagnostic workup, therapeutic planning, second opinions, and so forth.

As the healthcare system pivots more toward value-based care, TTI metrics should become a key component of what defines “high-value” oncology care. Ideal TTI could serve as further justification for the development and incorporation of predetermined pathways that help streamline care and avoid administrative-associated delay. Alternative payment models would eliminate the need for preauthorizations at each and every step within the diagnostic and therapeutic workflow, thereby removing a key barrier to timely care delivery. Additionally, widely accepted, evidenced-based TTI will help guide cancer treatment centers on the appropriate allocation and increased use of resources that

optimize TTI (and therefore payment), such as oncology navigators, timely imaging, and improved access to operating rooms, infusion chairs, and radiation gantries. With an ever-increasing emphasis on improving disparate care for disadvantaged populations, value-based oncology payment models that incorporate TTI measures within their reimbursement structure could help finance many of the abovementioned resources for patients who would normally experience delayed care under a traditional fee-for-service model. Overall, we feel that the impact of developing and incorporating more TTI-based, cancer-specific quality metrics could be tremendous for optimizing oncologic outcomes, especially in disparate populations.

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