Exhibit 362

JOHNS HOPKINS
MEDICINE

Brady Urological Institute
600 North Wolfe Street | Marburg 401C
Baltimore, Maryland 21287-2101
Office: 410-614-0009
Fax: 410-614-3695
Email: mkates@jhmi.edu

Max Kates, M.D.
R. Christian B. Evensen Professor of Urology and Oncology
Director, Division of Urologic Oncology
Associate Professor of Urology and Oncology

April 8, 2025
United States Department of Justice
1100 L St. NW
Washington, DC 20005

Re: *Dyer v. United States, Case No: 7:23-cv-00357*
Request for Urologic Oncology Expert Review

I, Max Kates, M.D., was retained by the United States Department of Justice to write an expert report and provide my expert opinions in this case. I am providing my expert opinions as a medical doctor and expert in Urologic Oncology to evaluate Terry Dyer's allegations about the cause of her bladder cancer and to respond to the expert report and opinions of Mrs. Dyer's expert, Dr. Thomas Longo. Mrs. Dyer alleges, and Dr. Thomas Longo opines, that Mrs. Dyer's bladder cancer was as likely caused by exposure to water at the Camp Lejeune military base located in North Carolina as other risk factors. However, based on my training, experience, and expertise, it is my opinion, to a reasonable degree of medical certainty, that Mrs. Dyer's bladder cancer was most likely caused by a combination of risk factors and unlikely caused by exposure to water at Camp Lejeune. Specifically, Mrs. Dyer's bladder cancer was most likely caused by a

combination of the idiopathic nature of bladder cancer with possible contributing risk factors of a short-term smoking history, an elevated BMI, and environmental exposure in Southeast North Carolina.

I. Summary of My Qualifications

I am a board-certified urologist, and a fellowship trained urologic oncologist, and one of the few clinicians in the United States whose clinical practice is more than 90% focused on diagnosing and treating bladder cancer. Currently, I am Associate Professor of Urology and Oncology, Director of the Bladder Cancer Program, and Director of the Urologic Oncology Division for the Brady Urology Institute at Johns Hopkins. The Brady Urologic Institute is the country's first urologic training program and one of the premier programs in the United States.

I received my BA from Wesleyan University in 2006 and my MD from Mount Sinai School of Medicine in 2012. During my medical training, I spent a year at Columbia University College of Physicians and Surgeons as a Doris Duke Clinical Research Fellow, where I focused on bladder cancer clinical trials and research. I then completed a six-year residency in Urology at the Brady Urologic Institute.

Following residency, I remained at the Brady Urologic Institute for a two-year Society of Urologic Oncology (SUO) fellowship, where I completed subspecialty training in Urologic Cancer Surgery and Care. In 2018, I received the prestigious American Cancer Society Clinician Scientist Development Grant, and I was one of the few urologists and bladder cancer experts to receive five years of funding in cancer research. In 2018, I was named an Assistant Professor of Urology and Oncology. In 2020, I was named Director of the Bladder Cancer Program, and in 2022, I was promoted to Associate Professor of Urology and Oncology. In 2023, I became Director of the Division of Urologic Oncology, where I oversee a busy group of clinicians that

diagnose and treat the spectrum of genitourinary malignancies and oversee a group of researchers that aim to make important discoveries to improve the lives of patients suffering from those same cancers.

As a Urologist who specializes in bladder cancer and as Director of the Bladder Cancer Program at Johns Hopkins Hospital, I lead one of the busiest clinical bladder cancer groups in the United States. I personally see 6-8 new bladder cancer patients each week and manage the care of more than 1,000 bladder cancer survivors. In these visits, I use a differential etiology approach to evaluate risk factors for the patient developing bladder cancer, in order to assess whether mitigation of those risk factors can improve the patient's prognosis or prevent bladder cancer development in their family. Surgically, I perform 50-90 cystoscopies (procedure for examining the bladder), 25-30 transurethral resections of bladder tumors (a minimally invasive surgical procedure referred to as TURBTs used to diagnose and treat bladder cancer), and 4-10 radical cystectomies (bladder removal surgery) each month. I actively manage bladder cancer at all stages, sometimes alone, and often times on a multidisciplinary team. Thus, I am qualified to speak to any aspect of bladder cancer diagnosis, etiology and clinical care.

In conjunction with my clinical duties, I maintain ongoing and active academic and clinical research in the field of bladder cancer. My research interests involve novel treatments for cancers of the urinary tract. I currently have a provisional patent for a novel intravesical chemotherapy developed with nano-engineer collaborators. Additionally, I have made scientific discoveries related to the mechanism of action of intravesical BCG, the most common treatment for bladder cancer. I am the principal investigator on multiple clinical trials, and I am currently leading EA8212 BRIDGE, which is a randomized trial open in over 150 centers in the United States comparing BCG to GemDoce chemotherapy for early-stage bladder cancer.

I have authored more than 140 journal articles in the field of bladder cancer. I have coauthored the chapter entitled "Tumors of the Bladder" in Campbell-Walsh-Wein Urology, which is the most widely used and the only comprehensive urology textbook in my field. In that chapter, I review the epidemiology risk factors for the development of bladder cancer. Additionally, I was a panelist on an American Urologic Association global webinar on bladder cancer, and I am currently giving the main lecture on muscle invasive bladder cancer for the American Urologic Association board review course. I thus am qualified to speak to ongoing scholarship and scientific literature in bladder cancer with a particular emphasis on bladder cancer risk, diagnosis, and staging. I have testified as an expert witness at trial or deposition in the past four years in one medical malpractice case: *Otis F. Noboa v. Scott D. Boruchov*, M.D. *et al*., Civ. No. 1:20-cv-6871 (S.D.N.Y).

My CV with my qualifications and a list of all my publications is attached. I am being compensated $600/hour for my time working on this case. A list of the materials that I considered in forming my opinions will be provided at a later date.

II. Summary of Bladder Cancer Risk Factors, Diagnosis, and Management[1]

A. General Epidemiology(1)

Bladder cancer is one of the most common cancers diagnosed each year in the United States, with an estimated 83,190 new cases and 16,680 deaths in 2024.(2) The lifetime risk of developing any cancer is 40% for men and 42% for women. In the United States, 1 in 27 men will develop bladder cancer over their lifetime, whereas 1 in 89 women will develop bladder cancer.(3) Additionally, because bladder cancer has fewer deaths relative to incident cases

[1] Section adapted from the chapter that I coauthored entitled "Tumors of the Bladder" in Campbell-Walsh-Wein Urology 12th Edition.

compared to several other common malignancies (for example, lung and colon cancers), it is one of the most prevalent cancers in the United States as well.(2) For example, it was estimated that in 2024, 83,190 patients would be diagnosed with bladder cancer, and 16,840 patients would die of their disease, providing a ratio of 0.20 deaths to diagnoses.(2) By comparison, it was estimated that 234,580 patients would be diagnosed with lung cancer in 2024, and 125,070 patients would die of their lung cancer (ratio 0.53). It was estimated that 152,810 patients would be diagnosed with colorectal cancer in 2024 with 53,010 deaths (ratio 0.35).(2)

Bladder cancer is typically a disease of aging, with age adjusted incidence rates increasing with each decade of life. The average age of diagnosis in the US is 73, with 90% of patients diagnosed after the age of 55. Men have a 3 times higher increased risk of developing bladder cancer compared to women. Several hypotheses have been proposed for increased bladder cancer rates among men. Smoking is more common in men in comparison to women, with age standardized prevalence of smoking declining in men from 41.2% in 1980 to 31.1% in 2012 in comparison from 10.6% to 6.2% among women.(1,4) However, even when controlling for smoking, gender related incidence disparities persist.(5,6) It has been hypothesized that cellular metabolism of carcinogens may be different. In other words, there may be differences between genders in the body's ability and rate of breaking down and absorbing certain carcinogens. Glutathione-S-transferase M1 (GSTM1) and 5′-diphosphoglucuronosyltransferase (UGT) are enzymes that aid the body in breaking down environmental toxins, certain drugs, and other carcinogens. Aromatic amines are a class of organic compounds comprising an aromatic ring and a nitrogen group and have been implicated as carcinogens—particularly in tobacco smoke. Enzymes such as GSTM1 and UGT that regulate how these amines are metabolized and absorbed have thus been themselves implicated in cancer development, and their increased

expression in men thus is hypothesized to increase the metabolism and absorption of carcinogens leading to a higher incidence of bladder cancer in men.(7,8)

Although women have lower bladder cancer incidence, they are more likely to present with an advanced stage of disease, in part because hematuria (blood in urine) in women is often misattributed to urinary tract infections which delays the bladder cancer workup and diagnosis.(9),(10) Bladder cancer is most common among Caucasian Americans, with an incidence rate 1.5 times that of Black Americans and twice that of Hispanic Americans. However, similar to gender differences, Black patients are more likely to present with muscle invasive disease compared to White patients, and it remains unclear whether this increased risk is due to factors involving access to care or tumor biology. (9)

One of Plaintiff's experts, Dr. Longo, classified bladder cancer as "a disease of toxic exposure." (*See* Dr. Longo – Criswell Report; p. 2). I disagree with this assessment and view it as an oversimplification of the disease. Some bladder cancer is attributable to carcinogens such as in smoking. However, as will be discussed subsequently, there is a hereditary component to bladder cancer, as evidenced by the frequency of germline mutations identified in recent studies. (11,12) Bladder cancer risk is multifactorial, with multiple pathways and mechanisms for development in each individual. While some of these pathways are known, some are still unknown, which is why idiopathy continues to play a role in assessing the differential etiology for a particular patient.

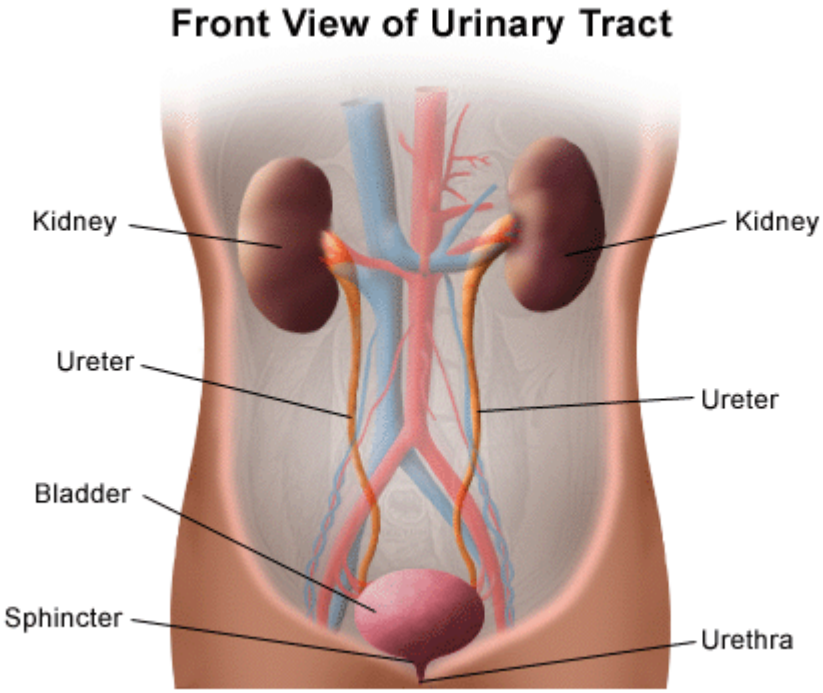
B. Bladder Cancer Subtypes and Upper Tract Urothelial Carcinoma

Urothelial cancer is the most common histology involved in bladder cancer, accounting for over 90% of cases. Urothelial carcinoma can further be subdivided by the 2004 WHO classification of low grade and high grade urothelial carcinoma.(13) The grade of the cancer

contributes to its pathologic stage as will be discussed in Section D. While urothelial carcinoma is most common, variant histologies, including micropapillary, sarcomatoid, plasmacytoid, squamous differentiated, and glandular differentiated are often mixed with urothelial carcinoma and are treated similarly to it. Neuroendocrine bladder cancer, including small cell bladder cancer and large cell bladder cancer, are histologic variants which are treated differently, often with a chemotherapy as the first approach. Additionally, pure squamous cell carcinoma (i.e., not mixed with urothelial carcinoma) and pure adenocarcinoma of the bladder are also treated differently from conventional urothelial carcinoma, as these histologic subtypes are often treated primarily with surgery as they are resistant to other therapies.

Upper Tract Urothelial Carcinoma (UTUC) is a related but biologically distinct entity from bladder cancer. Because of its rarity and distinctiveness, the FDA views UTUC as a disease that can be designated for orphan drug approvals.[2] UTUC involves cancer of the renal pelvis and ureter and only account for about 5-8% of all urothelial carcinomas.(14) UTUC has a few commonalities when compared to bladder cancer and some clear differences particular with regard to risk factors associated with each. There have been several studies comparing the molecular profile of upper tract urothelial carcinoma and bladder cancer, and these have demonstrated that there are distinct molecular differences between the two cancers, supporting the evidence that these are two separate diseases.(15) [3]

[2]U.S. Food & Drug Administration Orphan Drug Designations and Approvals (https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=445114).
[3] Illustration modified from Johns Hopkins Medicine (https://www.hopkinsmedicine.org/health/wellness-and-prevention/anatomy-of-the-urinary-system).



For example, FGFR3 mutations are widespread in the majority of UTUC cases, while they are present on a more limited scale among bladder cancers. With just 7,000 patients diagnosed with UTUC annually, there are limited clinical trials and evidence to support various management strategies, and because of this, the management of UTUC is often similar to bladder cancer where there is more robust data. For example, neoadjuvant chemotherapy is widely recommended at my institution for high grade UTUC based on a randomized trial evaluating it for bladder cancer, and more limited retrospective data supporting its use in UTUC.

C. Bladder Cancer Risk Factors

There have been many risk factors proposed in the literature that may increase the risk of developing bladder cancer. The risk factors identified below have the most evidence in peer reviewed studies demonstrating risk.

i. Smoking

Tobacco use comprises the largest known risk factor for bladder cancer development, and accounts for 30-40% of all bladder cancer. Dr. Sfakianos, an expert for the plaintiffs, has stated that "approximately 50% of the patients who develop bladder cancer is due to their exposure to cigarettes." (See Dr. Sfakianos – Cagiano Report; p. 15). Similarly, expert for the plaintiff Dr. Longo states that smoking may account for 50% of all bladder cancer cases. (See Dr. Longo – Criswell Report; p. 17). Further, Dr. Culp cites the 2014 Vlaanderen study which states that cigarette smoking accounts for "approximately 66% of new cases in men."[4] (See Dr. Culp December 9, 2024 Report p. 12). To be conservative in my approach regarding attributable risk, it is my opinion that the percentage of bladder cancer attributable to smoking cigarettes is slightly lower—on the order of 30-40%. Worldwide there are more than 1 billion current smokers, and smokers have a 2 to 3 times increased risk of bladder cancer.(16) Cigarette, pipe, and cigar smoking have all been linked to bladder cancer development.(17) Aromatic amines are the primary carcinogens contained in tobacco smoke that lead to bladder cancer development.(18) In general, the relative risk (RR) of developing bladder cancer increases with the intensity of cigarette smoking, with some studies showing up to a five times higher risk of bladder cancer with more than 15 cigarettes (3/4 pack) per day compared to a 2 times higher risk with less than 10 cigarettes (1/2 pack) per day.(19) Similarly, relative risk increases with the duration of smoking, from 1.2-1.9 times increased risk for those smoking less than 10 years to a 9.4 times increased risk for those smoking more than 40 years.(19) Additionally, the age of onset for smoking is highly associated with bladder cancer risk, with one study demonstrating a 4

[4] Vlaanderen, Jelle *et al. (2014)* study "Tetrachloroethylene exposure and bladder cancer risk: a meta-analysis of dry-cleaning-worker studies." Environmental health perspectives vol. 122,7 (2014): 661-6.

times increased risk among those who begin smoking between ages 18-20 compared to a 2 times increased risk among those who begin after 31 years. Time since quitting also mitigates risk, with relative risk decreasing from 3-5 times among current or recent smokers to 1-2 times among those who quit more than 15 years prior.(19) Nevertheless, even individuals with a long latency period who smoked relatively few cigarettes are still at increased risk compared to the general population.(19) Unlike lung cancer, where one study estimates more than 80% of cases are diagnosed within 20 years of quitting cigarette smoking, bladder cancer has a longer lag time, with only 50% diagnosed in that first 20 year period.(20,21) In that study approximately 15% were diagnosed 20-29 years after quitting, 15% diagnosed 30-39 years after quitting, 13% diagnosed 40-49 years after quitting, and 7% diagnosed more than 50 years after quitting.(20)

I agree with United States expert, Dr. Peter Shields, that "tobacco smoking is among the best examples of a human carcinogen" and that "tobacco smoke contains more than 100 carcinogens and mutagens." (*See* Dr. Shields – General Causation Report, p. 76-81). I would also agree with Dr. Longo's assessment that "conventional wisdom would suggest that secondhand exposure to cigarette smoke may contribute to bladder cancer carcinogenesis." (*See* Dr. Longo – Criswell Report, p. 17).

ii. <u>Occupational Exposures</u>

Occupational exposures have been linked to 5-10% of all bladder cancers. Occupations that are considered high risk for developing bladder cancer include but are not limited to: analine dye, rubber, and tobacco workers, hairdressers, painters, leather workers, nurses, waiters, petroleum workers and seamen.(22) Workplace exposure to silica and asbestos in particular have also been linked to a 20% increased risk of bladder cancer.(23) More data exists linking occupational exposures to bladder cancer among petroleum workers, with one meta-analysis of

eight studies demonstrating a 40% increased risk.(24–26) The typical latency period from workplace exposures to bladder cancer diagnosis is thought to be variable.(27) One study evaluated factory workers from a dyestuff plant in Japan and found that the mean latency period was 29.5 years from initial work exposure to bladder cancer diagnosis and 20 years from the final exposure to tumor development. (28)

The chemicals at issue with respect to Camp Lejeune water are not ones that treating urologists typically consider as having a causal association with bladder cancer. In considering whether any relationship exists between bladder cancer and the exposure to the chemicals at issue with respect to Camp Lejeune water, I am relying on the opinions of the United States' toxicology and epidemiology experts, Dr. Julie Goodman and Dr. Peter Shields. Dr. Goodman and Dr. Shields have concluded to a reasonable degree of scientific certainty that the currently available scientific evidence does not support a causal association between TCE, PCE, benzene, or vinyl chloride and bladder cancer.

iii. Radiation

Radiation to the pelvis is commonly performed to treat several malignancies, including prostate, cervical, vaginal, and rectal cancer. These patients are at a 2-4 fold increased risk of developing bladder cancer.(29) While tumors can develop within 5 years, the risk increases rapidly with longer latency. For example, among prostate cancer patients who received radiation therapy, the risk of secondary bladder cancer compared with the general population was 15% increased risk among all radiated patients to 55% among those diagnosed with bladder cancer more than 5 years after radiation and 75% among those diagnosed more than 10 years after radiation.(30)

iv. Family History

First degree relatives of bladder cancer patients have a 2 times higher risk of developing bladder cancer. Sometimes this risk is part of a broader cancer syndrome such as Lynch syndrome.(31) Lynch syndrome is a hereditary, autosomal dominant disorder that increases one's risk of many cancers. Patients with Lynch syndrome have a 22 times increased risk of developing UTUC. While Lynch syndrome is primarily associated with UTUC, patients with bladder cancer do have a modest increased risk with a cumulative incidence of 2-5% over their lifetime. However, germline testing, which assesses hereditary risk, suggests that 13-24% of patients with urothelial carcinoma will harbor pathogenic germline variants, most commonly *MSH2* and *BRCA1/2*.(11) These germline mutations are passed down generations and are responsible for the development of bladder cancer within families.

v. Body Mass Index (BMI)

Increased body mass index (BMI) has been shown to be an independent risk factor for bladder cancer development. There is also a dose response relationship where it appears that the relative risk of developing bladder cancer increases as BMI increases.(32,33) While lifestyle-associated factors including high BMI, low physical activity, and related metabolic disorders are associated with bladder cancer, these relationships are most evident in never smokers because smoking dominates bladder cancer risk, obscuring the contributions of these other factors.(34)

I would agree with Dr. Shield's assessment that "[b]eing overweight and obese, and with metabolic syndrome, have been reported to increase the risk of bladder cancer, which may be more pronounced for never smokers. IARC considers there to be sufficient human evidence for obesity as a cause of bladder cancer. This includes in conjunction with diabetes for persons with metabolic syndrome (obesity, diabetes, hypertension and high cholesterol)."

(Dr. Shields - General Causation Report; p. 209). Data regarding UTUC and BMI is even more limited, as is with all risk factors typically associated with bladder cancer.

vi. Chronic Inflammation and Chronic Infections

Certain medical conditions in which the bladder is in a chronically inflamed state increases one's risk of developing bladder cancer. Diseased states in which the bladder is exposed to repeated trauma, infection, or inflammation increase the risk of particular types of bladder cancer, most notably squamous cell carcinoma and adenocarcinoma of the bladder. This would include chronic infections such as Schistosomiasis or recurrent urinary tract infections (UTIs).(35,36) It also includes conditions that cause a neurogenic bladder, requiring frequent catheterizations.(37,38) Patients with congenital anomalies such as bladder exstrophy and spina bifida that lead to bladder dysfunction and often require catheterizations are also at increased risk for bladder cancer development. Having a chronic catheter, whether due to a neurogenic cause such as a spinal cord injury or from a non-neurogenic cause such as benign prostate hyperplasis, primary bladder hypermotility, or urethral stricture disease has, on their own, been linked to a 4-8 fold increased risk of bladder cancer development.(39,40) The latency period from chronic catheter use to bladder cancer diagnosis is thought to be 20-30 years depending on the type of bladder drainage.

vii. Idiopathy

Despite all that is known about bladder cancer risk factors, its estimated that approximately 40% of bladder cancer cases cannot be attributed to a known risk factor.(41) These cases are termed idiopathic, as the underlying cause is either spontaneous or not yet known. Dr. Longo states in his report that it is his opinion that "bladder cancer is rarely idiopathic in the sense that it is likely to have a known cause." (Longo - Criswell Report, p. 14).

He previously cites to the American Cancer Society website, which states that, in fact, "researchers don't know exactly what causes most bladder cancers. But they have found some risk factors and are starting to understand how some of them might cause cells in the bladder to become cancer."[5] I would agree with this statement. Despite all that is known in the literature regarding risk factors, when I perform a differential etiology on my patients, I am often left with a lifetime non-smoker, without a family or occupational significant for bladder cancer development, and without any other contributing risk factors. This is a common occurrence in my bladder cancer focused practice and is termed idiopathy. It should also be noted that idiopathy is not a diagnosis sole of exclusion. When building a differential etiology, there are sometimes several weak potential risk factors, such as a very light smoking history or a single cousin with a bladder cancer history. In these cases, idiopathy may still be the most likely etiology even when there are other potential contributing risk factors.

D. Diagnosis and Management

i. **Initial Presentation and Workup**

Bladder cancer is typically discovered when a patient notices blood in their urine (termed gross hematuria) or when their doctor discovers microscopic blood in the urine (microscopic hematuria). Occasionally, a bladder mass is uncovered on imaging studies (i.e. a CT or ultrasound) performed for another reason. Typically, a patient with hematuria is referred to a urologist where a cystoscopy is performed. During a cystoscopy, a small flexible scope is placed through the urethra into the bladder where a tumor (benign or malignant) may be identified. The patient then undergoes a Transurethral Resection of a Bladder Tumor (TURBT), which is a

[5] American Cancer Society website (https://www.cancer.org/content/dam/CRC/PDF/Public/8558.00.pdf).

surgery performed under anesthesia where the bladder mass is resected endoscopically. This is both therapeutic in that it removes the mass, and diagnostic in that if the mass is found to be malignant, the TURBT will stage the cancer. Bladder cancer stages are typically divided into 3 major subcategories: non-muscle invasive bladder cancer, comprising approximately 70% of all new bladder cancer cases, muscle invasive bladder cancer, comprising 25% of new cases, and metastatic cancer, comprising 5% of new cases.(1)

ii. Non-Muscle Invasive Bladder Cancer

Patients whose bladder cancer does not invade the muscularis propria (muscle layer) of the bladder are considered to have non-muscle invasive bladder cancer (NMIBC), which is Stage 1 bladder cancer. NMIBC can be further subdivided into low, intermediate, or high risk NMIBC. Low risk NMIBC is defined by a patient with a low grade, noninvasive tumor less than 3cm in size. Intermediate risk is defined by recurrent low grade noninvasive tumors, multiple low-grade tumors in the bladder, or a smaller than 3cm high grade noninvasive tumor. High risk NMIBC is defined by carcinoma in situ (CIS), high grade cancer invading the lamina propria (HGT1), or a larger than 3cm high grade noninvasive tumor.(42) Depending on the NMIBC risk category, these patients are treated with observation or bladder immunotherapy or chemotherapy washes (termed intravesical instillations). The most common intravesical therapy is Bacillus Calmette-Guerin (BCG), which is the recommended treatment for high risk NMIBC. The typical course of treatment involves aqueous drug delivered through a urinary catheter, where it dwells within the bladder for 1-2 hours. BCG is given weekly for 6 weeks in the induction phase, and then if there is no evidence of recurrences, maintenance phase instillations would be given weekly for 3 weeks at 3, 6, 12, 18, 24, 30 and 36 months.

iii. Muscle Invasive Bladder Cancer

Patients whose bladder cancer invades their muscle wall but does not involve their lymph nodes or distant organs have Stage 2 muscle invasive bladder cancer (MIBC). These patients typically undergo chemotherapy with radiation or chemotherapy with radical cystectomy (bladder removal) and urinary diversion. The latter more common option involves 2-3 months of chemotherapy followed by a radical cystectomy, in which the bladder, urethra, and certain gender-specific organs (and prostate in a man and uterus, fallopian tubes, ovaries, and anterior vaginal wall in a woman) are removed along with pelvic lymph nodes, and the urinary system is then reconstructed. After surgery patients may receive immunotherapy (nivolumab) for a year if they continue to have muscle invasive cancer on their pathology report, or if cancer is found in their lymph nodes. Patients typically choose one of three urinary diversions: 1) a ileal conduit, which is an incontinent diversion in which the urinary system is reconnected to a piece of intestine that functions as a tube, bringing urine to the skin where it drains through a stoma into an external appliance; 2) an ileal neobladder: in which a much larger piece of intestine is formed into a sphere within the body and attached on one end to the ureters and the other end to the urethra, functioning as an internal option in which patients learn to urinate by creating intraabdominal pressure to void; or 3) a continent cutaneous diversion, in which part of a patient's large and small intestine are used to formulate a reservoir internally, and patients eliminate urine by catheterizing themselves through a channel made of intestines connecting their umbilicus (belly button) to the reservoir. While clinical outcomes related to radical cystectomy have improved over the last several decades, the surgery continues to be associated with a an approximately 20% rate of hospital readmission and an approximately 40% rate of complications of varying severities. Some patients are candidates for bladder preservation based

on the location, stage and histology of the bladder cancer. One such bladder preservation treatment modality is termed trimodality therapy (TMT). With TMT, the cancer is treated with 4-6 weeks of daily radiation with concurrent weekly chemotherapy. Approximately 5-10% of patients with MIBC in the United States are treated with this modality, which is always coupled with routine imaging (i.e. CT scan or MRI) as well as cystoscopies to assess for local and systemic cancer recurrences.

iv. Locally Advanced and Metastatic Bladder Cancer

Patients with Stage 3-4 bladder cancer have locally advanced or metastatic disease and these patients receive systemic therapy (either chemotherapy, immunotherapy, targeted therapies, or combination therapy) with a more limited role for surgery or radiation. In recent years there have been dramatic changes in therapies approved for advanced bladder cancer. While historically chemotherapy was the only treatment option for locally advanced or metastatic bladder cancer, more recent immunotherapies in the form of immune checkpoint inhibitors (i.e. pembrolizumab) have been approved, and in 2024 combination therapies (i.e. Enfortumab Vedotin/pembrolizumab or cisplatin/gemcitabine/nivolumab) have now largely replaced traditional chemotherapy as a new standard of care for these patients.

v. Prognosis

Stage is a crucial indicator of prognosis, with estimated 5-year cancer specific survival (CSS) for patients with High-Risk Non-muscle invasive bladder cancer (Stage 1) being 90%, while patients with locally advanced bladder cancer (Stage 2) have a 5 year CSS of 48% and patients with metastatic disease (Stage 3-4) have a 5 year CSS of 8%.(43)

III. Summary of Pertinent Facts in Terry Dyer's Case

A. Diagnosis

Terry Dyer, at the age of fifty-two, was diagnosed with non-muscle invasive bladder cancer on May 20, 2009, based on a surgical pathology report obtained from a transurethral resection of a bladder tumor (TURBT).

B. Camp Lejeune Exposure History

Mrs. Dyer is a 68-year-old female born on [redacted], 1956, who claims to have resided at Camp Lejeune military base as a child from January 1958 to January 1973, with her father, John L. Fristoe, a civilian educational specialist and, later, school principal. Mrs. Dyer claims to have frequented the Hadnot Point and Tarawa Terrace areas of the Camp Lejeune.

I am relying on the opinions of the United States' risk assessment experts, Dr. Judy LaKind and Dr. Lisa Bailey. In her report, Dr. LaKind describes the daily exposure doses for oral and dermal exposures and daily exposure concentrations for inhalation exposures calculated for Mrs. Dyer for the volatile organic compounds at issue with respect to Camp Lejeune water. Using Dr. LaKind's exposure estimates, Dr. Bailey performed a risk assessment to assess Mrs. Dyer's cancer risk with respect to her estimated chemical exposures. Based on conservative regulatory risk calculations, it is Dr. Bailey's opinion to a reasonable degree of scientific certainty that there is insufficient evidence to conclude that Mrs. Dyer's exposures to TCE, PCE, benzene, vinyl chloride, and 1,2 tDCE from tap water during her residence at Camp Lejeune are causally associated with his bladder cancer.

C. Social and Family History

Mrs. Dyer is reported to a have a minimal, remote smoking history. Mrs. Dyer testified to a social smoking history, and her husband corroborated this history. Medical reports have

reported her smoking history as "previous smoker, very light," "two cigarettes a day for two years," "former smoker [of cigarettes] - .25 packs/days for 1 year [starting 4/24/1974]," and ¼ pack of cigarettes per day from April 1972 to January 1974 between ages 18 and 22. In addition to cigarette smoking, Mrs. Dyer smoked marijuana in her youth and reported daily use as recently as 2024. Mrs. Dyer also appears to have been exposed to secondhand cigarette smoke at times between 1974 to 2018 through her husband of Mrs. Dyer, John Dyer, who reported smoking cigarettes around Mrs. Dyer. Mr. Dyer reported smoking less than one pack per day when he smoked.

In his report, Dr. Longo confirmed Mrs. Dyer's smoking history but discounted it as too remote to be relevant. Dr. Longo discussed the definition of "nonsmoker" as "[a]n adult who has never smoked, or who has smoked less than 100 cigarettes in his or her lifetime" and concludes that Mrs. Dyer fits into this category. Despite the remote smoking history Mrs. Dyer's smoking history per her medical records, as referred to by Dr. Longo, confirms two cigarettes a day for two years. Dr. Longo concludes that Mrs. Dyer's testimony is consistent with the definition of "nonsmoker", but reliance on her medical records would place her into the CDC definition of a smoker. I would view Mrs. Dyer as a former smoker with a short duration and low intensity smoking history.

In addition, Mrs. Dyer worked in the 1980s as a licensed nail technician and manicurist for an unspecified period of time in a spa. In the 1980s and early 1990s, Mrs. Dyer left the spa and began taking clients at her house sometime. With respect to her at-home clients, it is reported that Mrs. Dyer had her clients remove their nail polish themselves.

Mrs. Dyer's maternal Grandmother, Reca Floyd Boyette, died of breast cancer. While some urinary bladder health issues are noted within Mrs. Dyer's family history, there is no reported familial history of bladder cancer.

D. Bladder Cancer Medical History

On May 12, 2009, Mrs. Dyer presented to Dr. John Lovett with gross hematuria. She subsequently had a cystoscopy demonstrating a 5mm anterior bladder mass. On May 20, 2009, she underwent a transurethral resection of a bladder tumor (TURBT—referenced subsequently as "TURBT 1"), which revealed a low grade noninvasive (LgTa) bladder cancer. In the recovery room she was administered intravesical mitomycin C (MMC) chemotherapy. She was thus managed without further therapies and two months later, on July 17, 2009, a surveillance cystoscopy revealed 2 bladder tumors. Three days later, on July 20, 2009, she underwent another TURBT (subsequently referenced as "TURBT 2") and an immediate instillation again of mitomycin C. Pathology from TURBT 2 was consistent with a high-grade urothelial bladder cancer, invading into the lamina propria, with surrounding carcinoma in situ. The stage at that time would thus be High Grade T1 with CIS (HGT1 w/CIS). Eleven days later, on August 1, 2009, the patient underwent a restaging TURBT (subsequently referred to as "TURBT 3"), and the pathology revealed benign tissue and no evidence of residual cancer. She was referred to Dr. Raj Pruthi at University of North Carolina Medical Center who recommended an induction course of intravesical BCG for Mrs. Dyer's high risk non-muscle invasive bladder cancer (NMIBC). She began these treatments on August 24, 2009, 23 days following her restaging TURBT.

From August 24, 2009, to October 19, 2009, she underwent six intravesical installations of the BCG, and during these instillations she experienced both gross hematuria and severe

cystitis manifested as urinary frequency and urgency. Despite these symptoms, she underwent a post-BCG TURBT (referred to as "TURBT 4") on November 11, 2009, 23 days after completing the BCG. Pathology from this TURBT 4 revealed granulomatous inflammation with no evidence of cancer. On December 17, 2009, she started maintenance BCG, and this was complicated by severe BCG cystitis, manifesting as fever, back pain, and continued gross hematuria. Despite many of these symptoms she undergoes a full BCG maintenance cycle on December 17, 2009, December 23, 2009, and December 31, 2009, and according to Dr Lovett she actually received INH therapy with BCG. It should be noted that INH would be a treatment for BCG cystitis, which would be given while withholding BCG. It would not be standard practice to continue BCG therapy while simultaneously treating for BCG cystitis with INH.

On February 7, 2010, a surveillance cystoscopy is performed in which a raised erythematous (i.e. red and inflamed) area is identified. Despite the fact that urine cytology was negative for cancer, she underwent a TURBT (subsequently referred to as "TURBT 5") to resect this raised area. During that TURBT 5 on March 6, 2010, 6 grams of tissue – which constitutes a large amount – was resected and pathology demonstrated "granulomatous inflammation", consistent with her BCG cystitis without evidence of cancer recurrence. Notably, she was admitted after TURBT 5 for 2 days and transfused 2 units of blood (prbcs). Despite this pathology and her complications from both BCG treatment and TURBT 5, she underwent more maintenance BCG on March 29, 2010, and April 12, 2010, with continued BCG cystitis. Due to persistent suspicions of recurrent bladder cancer, she underwent another TURBT (referred to as "TURBT 6") on May 25, 2010, with "extensive resection". The pathology from TURBT 6 was again benign.

Over the summer of 2010, Mrs. Dyer's urinary quality of life worsened considerably, and she saw Dr. Brent Inman at Duke University Medical Center who recommended radical cystectomy due to the patient's severe, irreversible BCG cystitis. Per Dr. Inman, her symptoms can be described as follows: "She continues to have very severe bladder symptoms, including occasional fevers and chills, incontinence, very poor bladder capacity, urinator frequency, and even required blood transfusions for bleeding." (Inman Deposition, p. 65). Thus, on December 6, 2010, she underwent a radical cystectomy and ileal conduit urinary diversion. During this procedure, it was noted that Mrs. Dyer previously underwent a hysterectomy, so the bladder and pelvic lymph nodes were removed. Pathology from the bladder removal surgery revealed no cancer in the bladder, and showed "radiation associated damage," which likely reflected the six TURBTs, two mitomycin installations, and 11 BCG installments all within a year's time that irreversibly damaged Mrs. Dyer's bladder.

E. Post Bladder Cancer Medical History

Mrs. Dyer appeared to have done well with her ileal conduit urinary diversion for some time until she began to have a worsening, symptomatic parastomal hernia. This required a small bowel resection and repair of her parastomal hernia on May 24, 2023. Additionally, she has had recurrent urinary tract infections, which can occur in the setting of a urinary diversion and can lead to periodic hospitalizations. She also complains of fibromyalgia and depression because of the bladder cancer diagnosis, but it appears these pre-existed her bladder cancer and were treated for beginning in the 1990s. Additionally, she has a known family history of depression, as her sister testified that their father suffered from depression and expressed suicidal ideations, and their mother also suffered from depression. Such a strong family history as well as a personal history of depression that predated her bladder cancer diagnosis likely explains these conditions.

In considering whether any relationship exists between Mrs. Dyer's bladder cancer and depression she attributes to her bladder cancer diagnosis, I am relying on the opinions of the United States' forensic neuropsychiatrist, Dr. Harold Burzstajn who has concluded to a reasonable degree of forensic neuropsychiatric certainty that Mrs. Dyer does not suffer from a psychiatric disorder caused by her bladder cancer. She is now more than 15 years out from her non-muscle invasive bladder cancer diagnosis. In my clinical practice patients undergo cancer surveillance with annual CT scans until they are 10 years out from there diagnosis, at which point they are graduated from routine CT screening.

IV. Opinions

My opinions regarding potential causes of Mrs. Dyer developing bladder cancer have been formed by building a differential etiology of competing risks. This differential diagnosis is something that I do daily as a clinician, where I observe signs and symptoms in a patient to formulate potential diagnoses that could be the cause of the aforementioned signs and symptoms. In a similar manner when assessing risk factors for developing bladder cancer, I incorporate the patient's known risk factors, weighted by their relative risk associated with bladder cancer, in order to provide an opinion on the factors most likely responsible for causing their bladder cancer.

A. Differential Etiology/ Diagnosis

Mrs. Dyer was diagnosed with muscle invasive bladder cancer in 2009 in her 50s. This was approximately 35 years after her residency at Camp Lejeune, and approximately 35 years after her last exposure to cigarette smoking.

Smoking: The primary known risk factor for developing bladder cancer in this patient is cigarette smoking. While Mrs. Dyer only smoked ¼ pack per day for two years, as previously

mentioned even a short interval of daily inhalation of cigarette smoke increases one's lifetime bladder cancer risk with an odds ratio greater than 1. If each cigarette is smoked for 5-6 minutes a ¼ pack (5 cigarettes) translates to 30 minutes of daily smoke inhalation for two years. I thus cannot rule out Mrs. Dyer's smoking history as a risk factor for developing bladder cancer.

Occupation: Mrs. Dyer had several different types of jobs, including as a licensed nail technician, a bank teller, and a security guard. There is no data to suggest the occupations of bank teller or security guard are associated with increased risk. There is some data to suggest that hairdressers have increased risk of bladder cancer. At the time of those publications, the occupation of beautician incorporated both hairdressing and manicure. However, very little has been published specifically on nail technician occupational risk. While there is evidence of increased toxin exposure in the urine of nail technicians, one study of female manicurists and cosmetologists in California did not identify an increased risk of bladder cancer.(44,45) Taken together there is insufficient evidence to link nail technician occupation as a risk factor for developing bladder cancer. I therefore can rule out Mrs. Dyer's occupations as a risk factor.

Family History: Another risk factor for bladder cancer that likely is not a factor in this particular case is familial risk. While Mrs. Dyer has a family history of breast cancer in her maternal grandmother, she has no clear history of bladder cancer or bladder cancer associated malignancies. I can rule out Mrs. Dyer's family history as a risk factor for bladder cancer.

Inflammation: She has no evidence of congenital genitourinary issues, chronic urinary tract infections, or chronic foley catheter—negating these as likely causative factors. I can rule out inflammation as a risk factor.

Body Mass Index (BMI): Mrs. Dyer was documented as having a body mass index of 40.45 kg/ m^2 on October 19, 2021. This would be consistent with morbid obesity. A normal healthy

weight is considered a BMI of 18.5-24.9 and any BMI above 25 is considered overweight, with a BMI above 30 obese and above 40 morbidly obese. As previously discussed, it appears that there is a dose response relationship where the relative risk of developing bladder cancer increases as BMI increases.(32,33) I therefore would rule in elevated BMI as a potential risk factor for bladder cancer.

***Environmental*:** Mrs. Dyer allegedly resided at Camp Lejeune from January 1958 to January 1973. As discussed above, I am relying on the United States' general causation experts, Dr. Goodman and Dr. Shields, and the United States' risk assessment experts, Dr. LaKind and Dr. Bailey. There is insufficient evidence to conclude that Mrs. Dyer's potential exposure to TCE, PCE, benzene, vinyl chloride, and 1,2-tDCE from tap water during her time at Camp Lejeune is causally associated with his bladder cancer. Thus, I am able to rule out exposure to Camp Lejeune water as a risk factor for Mrs. Dyer's bladder cancer.

However, Dr. McCarthy, a local treating urologist in the area where Mrs. Dyer lives, testified in his deposition about abnormally high rates of urologic cancer in Southeast North Carolina.

> "I have seen over 6,000 cancer patients in this area in the last 16 years, and so, we are always trying to understand why we have such a high instance of urological cancer in this area. And I did things that can contribute and counsel generalized patients on what they can do to try to minimize those exposures." (McCarthy Deposition, p. 24.)
>
> "Yes, Southeast North Carolina, about a 13 higher percent cancer ratio than the rest of the state, and so we, throughout our training and afterwards, have always tried to identify maybe what particular things

people are being exposed to and try to decrease them, especially after they have been diagnosed with cancer." (McCarthy Deposition, p. 25.)

"The one that's gotten the most play around this area has been the Chemours Plant, which I have gotten into the Cape Fear River, which sources as lot of the water locally." (McCarthy Deposition, p 28.)

Dr. McCarthy, the local treating physician testified to this. I do not practice urology in that area, but I have no way to dispute this testimony. I therefore cannot rule out her living in Southeast North Carolina as a potential risk factor.

Idiopathy: Despite multiple potential risk factors for development of bladder cancer, idiopathy remains the strongest associated cause of Mrs. Dyer's bladder cancer. Dr. Longo argues that Mrs. Dyer' age and gender are both indicative of "significant toxic exposure." (Dr. Longo Report- pg. 23.) However, there is no data to suggest that patients diagnosed younger are more likely to have known risk factors than patients diagnosed older. In fact, it is far more likely that an older patient will have more identifiable risk factors than a younger patient, and therefore not be considered an idiopathic case of bladder cancer. In my bladder cancer clinical practice, the vast majority of patients who are young (i.e., under 50 years old) are non-smokers, with no known occupational exposures, and no known family history. My research group at Johns Hopkins is actively investigating this group of individuals, but as a generally rule they fall into the idiopathic category when understanding their bladder cancer risk.

B. Conclusions regarding differential etiology

Given what is known about these competing risk factors, my opinion to a reasonable degree of medical certainty is that idiopathy is the most likely contributing risk of her bladder

cancer, with a possibility of her cigarette smoking history, morbid obesity playing contributing roles, and environmental exposure from living in Southeast North Carolina.

C. Prognosis

Mrs. Dyer experienced an unfortunate situation where she was diagnosed with high grade non-muscle invasive bladder cancer, and underwent six TURBTS and eleven BCG treatments over the course of the subsequent year. The second and third TURBTs were close together with just a few days between them, and the BCG therapies were begun to quickly after her third TURBT. In his deposition testimony, Dr. Inman stated that Mrs. Dyer did not receive standard of care bladder cancer management at several junctures in Mrs. Dyer's care and I concur.

When Mrs. Dyer began to experience systemic flu-like symptoms combined with severe, debilitating lower urinary tract symptoms, BCG should have been stopped. Her symptoms were severe enough that Dr. Lovett actually initiated INH therapy, which is a treatment given for disseminated BCGosis—a life threatening systemic infection like side effect of BCG. However, the INH was given in conjunction with BCG, a decision that falls well outside of the standard of care. If INH is given for BCG cystitis or BCGosis, then BCG should be stopped.

Additionally, Mrs. Dyer underwent six TURBTs in the course of a single year, and the last 3 were likely unnecessary. As Dr. Inman noted in his deposition, the pathology from these TURBTs demonstrates that the bladder was experiencing a severe reaction to BCG, termed BCG cystitis. An in-office biopsy could have demonstrated that the erythema in the bladder was simply treatment effect. Yet, she was taken for a fourth TURBT on November 11, 2009. Despite that TURBT showing benign pathology, she was taken back again to the operating room for a fifth TURBT on March 6, 2010, due to erythema without a biopsy first. Six grams of tissue were removed, Mrs. Dyer was admitted, and the TURBT resulted in the rare complication

of an overnight admission and the need for her to receive two units of packed red blood cells—highly unusual for these types of surgeries. And yet when that pathology was also benign, the urologist again took her for a sixth TURBT on May 25, 2010, where an extensive resection was done for what was clearly a reaction to the continued use of BCG—not recurrent cancer.

Taken together, Mrs. Dyer's bladder likely could not tolerate the significant amount of surgical and medical therapy in such a short time. She unnecessarily underwent three surgeries (TURBT Nos. 4,5,6), and should never have continued maintenance BCG, much less the combination of BCG with INH. As a result of this overtreatment, she underwent a radical cystectomy and ileal conduit urinary diversion, which was ultimately complicated thirteen years later by a parastomal hernia requiring repair. While parastomal hernias are quite common after ileal conduit urinary diversions, they almost always can be managed with conservative measures, including hernia belts and weight loss. The largest risk factor for parastomal hernias is obesity, and weight loss is in particular associated with a reduction in symptoms.

Additionally, her bladder symptoms which were a complication of her treatments, could have been avoided if her urologist had allowed time for her bladder to heal between TURBTs, not given her BCG when she had active gross hematuria, stopped the BCG when symptoms developed, and not undertaken unnecessary TURBTs when there was clearly bladder inflammation from the BCG without evidence of cancer on multiple urine tests. Her cystectomy was not the result of her bladder cancer but was due to a complication of her cancer treatments that could have and would have been avoided had Dr. Lovett stopped Mrs. Dyer's BCG treatments in November or December of 2009. For context, I manage more than 50 newly diagnosed bladder cancer patients each year who receive BCG. I have managed BCG cystitis many times in my career. I have never performed a cystectomy solely for BCG cystitis because

with cessation of the BCG, and bladder rest, the symptoms either resolve or are reduced significantly. Her prognosis from the standpoint of long-term cancer control is excellent, as her risk of having a distant recurrence now with over 10 years of durable complete response is under 1%. While the radical cystectomy addressed those local symptoms, it came at the cost of long-term complications such as a parastomal hernia and recurrent urinary tract infections. At this point, I would estimate a 20-30% risk of a subsequent complication requiring surgical intervention due to the combination of her 2010 surgery and 2023 parastomal hernia repair.

V. Conclusion

In conclusion, it is my opinion that 1) Mrs. Dyer did have a pathologically confirmed diagnosis of non-muscle invasive bladder cancer. 2) Her bladder cancer was most likely caused by a combination the idiopathic nature of bladder cancer with possible contributing risk factors of a short-term smoking history, an elevated BMI, and environmental exposure in Southeast North Carolina, and her bladder cancer was unlikely caused by exposure to water at Camp Lejeune.

These are my opinions as of the date of this report. These opinions are based upon my training and experience, my review of the case-specific records or materials, and my review of the medical literature. As further information is acquired, I reserve the right to amend, alter, or supplement my opinions as appropriate. All my opinions are made to a reasonable degree of medical certainty.

Sincerely,

Max Kates, MD
Associate Professor of Urology and Oncology
Director, Division of Urologic Oncology
Director, Bladder Cancer Program
James Buchanan Brady Urological Institute
The Johns Hopkins Medical Institutions
600 N. Wolfe Street / Marburg 401c
Baltimore, Maryland 21287

Scholarly References

1. Max Kates, Trinity Bivalacqua. Campbell-Walsh Urology- Tumors of The Urinary Bladder. 2020. 3073–3090 p.

2. Siegel RL, Giaquinto AN, Jemal A. Cancer statistics, 2024. CA Cancer J Clin. 2024 Jan;74(1):12–49.

3. American Cancer Society. Cancer Facts & Figures 2017. Cancer Facts & Figures 2017 [Internet]. 2017;1. Available from: https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2017.html

4. Chappidi MR, Kates M, Tosoian JJ, Johnson MH, Hahn NM, Bivalacqua TJ, et al. Evaluation of gender-based disparities in time from initial haematuria presentation to upper tract urothelial carcinoma diagnosis: analysis of a nationwide insurance claims database. BJU Int. 2017;120(3).

5. Hemelt M, Yamamoto H, Cheng KK, Zeegers MPA. The effect of smoking on the male excess of bladder cancer: A meta-analysis and geographical analyses. Int J Cancer [Internet]. 2009 Jan 15 [cited 2018 Apr 18];124(2):412–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18792102

6. Hartge P, Harvey EB, Linehan WM, Silverman DT, Sullivan JW, Hoover RN, et al. Unexplained excess risk of bladder cancer in men. J Natl Cancer Inst. 1990;82(20):1636–40.

7. Karagas MR, Park S, Warren A, Hamilton J, Nelson HH, Mott LA, et al. Gender, smoking, glutathione-S-transferase variants and bladder cancer incidence: a population-based study. [cited 2018 Apr 15]; Available from: https://ac.els-cdn.com/S0304383504007815/1-s2.0-S0304383504007815-main.pdf?_tid=abdfb101-114b-46b0-a9f0-6b0138579e98&acdnat=1523907926_a174632de72db6a86aee087932aa9902

8. ZHANG Y. Understanding the Gender Disparity in Bladder Cancer Risk: The Impact of Sex Hormones and Liver on Bladder Susceptibility to Carcinogens. Journal of Environmental Science and Health, Part C [Internet]. 2013 Jan [cited 2018 Apr 15];31(4):287–304. Available from: http://www.tandfonline.com/doi/abs/10.1080/10590501.2013.844755

9. Scosyrev E, Noyes K, Feng C, Messing E. Sex and racial differences in bladder cancer presentation and mortality in the US. Cancer [Internet]. 2009 Jan 1 [cited 2018 Apr 16];115(1):68–74. Available from: http://doi.wiley.com/10.1002/cncr.23986

10. Aydin Mungan N, Kiemeney LALM, Van Dijck JAAM, Van Der Poel HG, Witjes JA. GENDER DIFFERENCES IN STAGE DISTRIBUTION OF BLADDER CANCER. [cited 2018 Apr 15]; Available from: https://ac.els-cdn.com/S0090429599004811/1-s2.0-S0090429599004811-main.pdf?_tid=c44e76b4-8fb8-4874-85c5-7a57da540d1d&acdnat=1523912106_96ecfcd3643e1fc8f1dc830ec01e9da2

11. Kiemeney LALM. Hereditary bladder cancer. Scand J Urol Nephrol [Internet]. 2008 Jan 31 [cited 2018 Apr 25];42(sup218):110–5. Available from: http://www.tandfonline.com/doi/full/10.1080/03008880802283755

12. Pietzak EJ, Whiting K, Srinivasan P, Bandlamudi C, Khurram A, Joseph V, et al. Inherited Germline Cancer Susceptibility Gene Variants in Individuals with Non-Muscle-Invasive Bladder Cancer. Clinical Cancer Research. 2022;

13. Downes MR, Hartmann A, Shen S, Tsuzuki T, Van Rhijn BWG, Bubendorf L, et al. Comparison of Bladder Cancer Grading System Performance [Internet]. 2023. Available from: http://links.lww.

14. Soualhi A, Rammant E, George G, Russell B, Enting D, Nair R, et al. The incidence and prevalence of upper tract urothelial carcinoma: a systematic review. BMC Urol. 2021;21(1).

15. Tomiyama E, Fujita K, Hashimoto M, Adomi S, Kawashima A, Minami T, et al. Comparison of molecular profiles of upper tract urothelial carcinoma vs. urinary bladder cancer in the era of targeted therapy: a narrative review. Vol. 11, Translational Andrology and Urology. 2022.

16. Islami F, Stoklosa M, Drope J, Jemal A. Global and Regional Patterns of Tobacco Smoking and Tobacco Control Policies. Eur Urol Focus [Internet]. 2015 Aug 1 [cited 2018 Apr 18];1(1):3–16. Available from: https://www.sciencedirect.com/science/article/pii/S2405456915000024

17. Cumberbatch MG, Rota M, Catto JWF, La Vecchia C. The Role of Tobacco Smoke in Bladder and Kidney Carcinogenesis: A Comparison of Exposures and Meta-analysis of Incidence and Mortality Risks. Eur Urol [Internet]. 2016 Sep 1 [cited 2018 Apr 18];70(3):458–66. Available from: https://www.sciencedirect.com/science/article/pii/S0302283815005485?via%3Dihub#bib0455

18. Marcus PM, Hayes RB, Vineis P, Garcia-Closas M, Caporaso NE, Autrup H, et al. Cigarette smoking, N-acetyltransferase 2 acetylation status, and bladder cancer risk: a case-series meta-analysis of a gene-environment interaction. Cancer Epidemiol Biomarkers Prev [Internet]. 2000 May 1 [cited 2018 Apr 18];9(5):461–7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/10815690

19. Boffetta P. Tobacco smoking and risk of bladder cancer. In: Scandinavian Journal of Urology and Nephrology. 2008. p. 45–54.

20. Beatrici E, Labban M, Filipas DK, Stone B V., Reis LO, Dagnino F, et al. Smoking characteristics and years since quitting smoking of US adults diagnosed with lung and bladder cancer: A national health and nutrition examination survey analysis. International Braz J Urol. 2024;50(2):199–208.

21. Li Y, Tindle HA, Hendryx MS, Xun P, He K, Liang X, et al. Smoking cessation and the risk of bladder cancer among postmenopausal women. Cancer Prevention Research. 2019 May 1;12(5):305–13.

22. Cumberbatch MGK, Cox A, Teare D, Catto JWF. Contemporary Occupational Carcinogen Exposure and Bladder Cancer. JAMA Oncol [Internet]. 2015 Dec 1 [cited 2018 Apr 21];1(9):1282. Available from: http://oncology.jamanetwork.com/article.aspx?doi=10.1001/jamaoncol.2015.3209

23. Latifovic L, Villeneuve PJ, Parent MÉ, Kachuri L, McCrate F, Dewar R, et al. Silica and asbestos exposure at work and the risk of bladder cancer in Canadian men: A population-based case-control study. BMC Cancer [Internet]. 2020 Mar 3 [cited 2024 Aug 17];20(1):1–13. Available from: https://link.springer.com/articles/10.1186/s12885-020-6644-7

24. Shala NK, Stenehjem JS, Babigumira R, Liu FC, Berge LAM, Silverman DT, et al. Exposure to benzene and other hydrocarbons and risk of bladder cancer among male offshore petroleum workers. British Journal of Cancer 2023 129:5 [Internet]. 2023 Jul 18 [cited 2024 Aug 17];129(5):838–51. Available from: https://www.nature.com/articles/s41416-023-02357-0

25. Occupational exposure to chemical and petrochemical industries and bladder cancer risk in four western Canadian provinces - ProQuest [Internet]. [cited 2024 Aug 17]. Available from: https://www.proquest.com/docview/216611507?fromopenview=true&pq-origsite=gscholar&sourcetype=Scholarly%20Journals

26. Baena AV, Allam MF, Díaz-Molina C, Del Castillo AS, Abdel-Rahman AG, Navajas RFC. Urinary bladder cancer and the petroleum industry: A quantitative review. European Journal of Cancer Prevention [Internet]. 2006 Dec [cited 2024 Aug 17];15(6):493–7. Available from: https://journals.lww.com/eurjcancerprev/fulltext/2006/12000/urinary_bladder_cancer_and_the_petroleum_industry_.6.aspx

27. Olfert SM, Felknor SA, Delclos GL. An Updated Review of the Literature: Risk Factors for Bladder Cancer with Focus on Occupational Exposures. I Review Article. 2006.

28. Miyakawa M, Tachibana M, Miyakawa A, Yoshida K, Shimada N, Murai M, et al. Re-evaluation of the latent period of bladder cancer in dyestuff-plant workers in Japan. International Journal of Urology. 2001 Jan 1;8(8):423–30.

29. Nieder AM, Porter MP, Soloway MS. Radiation Therapy for Prostate Cancer Increases Subsequent Risk of Bladder and Rectal Cancer: A Population Based Cohort Study. J Urol [Internet]. 2008 Nov 1 [cited 2018 May 2];180(5):2005–10. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0022534708018417

30. Brenner DJ, Curtis RE, Hall EJ, Ron E. Second malignancies in prostate carcinoma patients after radiotherapy compared with surgery. Cancer. 2000 Jan 15;88(2):398–406.

31. Post RS van der, Kiemeney LA, Ligtenberg MJL, Witjes JA, Kaa CAH van de, Bodmer D, et al. Risk of urothelial bladder cancer in Lynch syndrome is increased, in particular among MSH2 mutation carriers. J Med Genet [Internet]. 2010 Jul 1;47(7):464. Available from: http://jmg.bmj.com/content/47/7/464.abstract

32. Choi JB, Lee EJ, Han KD, Hong SH, Ha US. Estimating the impact of body mass index on bladder cancer risk: Stratification by smoking status. Sci Rep [Internet]. 2018 Dec 17 [cited 2018 Apr 29];8(1):947. Available from: http://www.nature.com/articles/s41598-018-19531-7

33. Zhao L, Tian X, Duan X, Ye Y, Sun M, Huang J, et al. Association of body mass index with bladder cancer risk: a dose-response meta-analysis of prospective cohort studies. Oncotarget [Internet]. 2017 May 16 [cited 2018 Apr 29];8(20):33990–4000. Available from: http://www.oncotarget.com/fulltext/16722

34. Hektoen HH, Robsahm TE, Andreassen BK, Stenehjem JS, Axcrona K, Mondul A, et al. Lifestyle associated factors and risk of urinary bladder cancer: A prospective cohort study from Norway. Cancer Med. 2020 Jun 1;9(12):4420–32.

35. Bernardo C, Cunha MC, Santos JH, da Costa JMC, Brindley PJ, Lopes C, et al. Insight into the molecular basis of Schistosoma haematobium-induced bladder cancer through urine proteomics. Tumor Biology [Internet]. 2016 Aug 7 [cited 2018 Apr 29];37(8):11279–87. Available from: http://link.springer.com/10.1007/s13277-016-4997-y

36. Vermeulen SH, Hanum N, Grotenhuis AJ, Castaño-Vinyals G, van der Heijden AG, Aben KK, et al. Recurrent urinary tract infection and risk of bladder cancer in the Nijmegen bladder cancer

study. Br J Cancer [Internet]. 2015 Feb 3 [cited 2018 May 2];112(3):594–600. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25429525

37. West DA, Cummings JM, Longo WE, Virgo KS, Johnson FE, Parra RO. Role of chronic catheterization in the development of bladder cancer in patients with spinal cord injury. Urology [Internet]. 1999 Feb [cited 2018 Apr 25];53(2):292–7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/9933042

38. Ho CH, Sung KC, Lim SW, Liao CH, Liang FW, Wang JJ, et al. Chronic Indwelling Urinary Catheter Increase the Risk of Bladder Cancer, Even in Patients Without Spinal Cord Injury. Medicine [Internet]. 2015 Oct [cited 2018 Apr 25];94(43):e1736. Available from: http://www.ncbi.nlm.nih.gov/pubmed/26512566

39. Hird AE, Saskin R, Liu Y, Lee Y, Ajib K, Matta R, et al. Association between chronic bladder catheterisation and bladder cancer incidence and mortality: A population-based retrospective cohort study in Ontario, Canada. BMJ Open. 2021 Sep 2;11(9).

40. Böthig R, Kowald B, Fiebag K, Balzer O, Tiburtius C, Thietje R, et al. Bladder management, severity of injury and period of latency: a descriptive study on 135 patients with spinal cord injury and bladder cancer. Spinal Cord. 2021 Sep 1;59(9):971–7.

41. Burger M, Catto JWF, Dalbagni G, Grossman HB, Herr H, Karakiewicz P, et al. Epidemiology and Risk Factors of Urothelial Bladder Cancer. Eur Urol. 2013 Feb 1;63(2):234–41.

42. Holzbeierlein JM, Bixler BR, Buckley DI, Chang SS, Holmes R, James AC, et al. Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline: 2024 Amendment. Vol. 211, The Journal of urology. 2024.

43. Abdollah F, Gandaglia G, Thuret R, Schmitges J, Tian Z, Jeldres C, et al. Incidence, survival and mortality rates of stage-specific bladder cancer in United States: A trend analysis. Cancer Epidemiol. 2013;37(3).

44. Varshavsky JR, Morello-Frosch R, Harwani S, Snider M, Petropoulou SSE, Park JS, et al. A pilot biomonitoring study of cumulative phthalates exposure among vietnamese american nail salon workers. Int J Environ Res Public Health. 2020;17(1).

45. Quach T, Doan-Billing PA, Layefsky M, Nelson D, Nguyen KD, Okahara L, et al. Cancer incidence in female cosmetologists and manicurists in California, 1988-2005. Am J Epidemiol. 2010;172(6).

CURRICULUM VITAE
The Johns Hopkins University School of Medicine

Max Kates Date of this version: April 8, 2025

DEMOGRAPHIC AND PERSONAL INFORMATION

Current Appointments

University

2018-present R. Christian B. Evensen Professor of Urology
Associate Professor, Urology and Oncology
Director, Bladder Cancer Program
Director, Division of Urologic Oncology
Johns Hopkins Hospital
Baltimore, MD

Hospital

2018-present Attending Physician, Johns Hopkins Hospital

Personal Data

Urological Surgery
James Buchanan Brady Urological Institute
The Johns Hopkins Medical Institutions
600 N. Wolfe Street / Marburg 401c
Baltimore, Maryland 21287
Office: (410) 614-0009
Fax: (410) 502-7711
Mkates@jhmi.edu

Education and Training

Undergraduate

2006 B.A. Wesleyan University, Middletown, CT; graduated High Distinction

Doctoral/graduate

2012 M.D, Mount Sinai School of Medicine, New York, NY

Postdoctoral

2010-2011 Doris Duke Clinical Research Fellow, Columbia University College of Physicians and Surgeons, New York, NY (Mentor: James McKiernan_
2012-2013 Intern, General Surgery, Johns Hopkins Hospital, Baltimore, MD
2013-2018 Resident, Urologic Surgery, Johns Hopkins Hospital, Baltimore, MD
2018-2020 Society of Urologic Oncology Fellow, Johns Hopkins Hospital, Baltimore, MD

Professional Experience

2006 – 2007 Research Assistant, Harvard Medical School, Department of Health Policy
2018-2022 Assistant Professor, Urology, Johns Hopkins University School of Medicine
2022-present Associate Professor, Urology, Johns Hopkins University School of Medicine
2023-present Director, Division of Urologic Oncology, Brady Urologic Institute

RECOGNITION

Awards, Honors

2002	National Association of Secondary School Principals Leader Award
2004	Mount Sinai School of Medicine Humanities and Medicine Scholar
2005	Finalist, Truman Scholar
2006	Team Captain, Wood Memorial Award, Wesleyan University Tennis Team
2011	Oral Presentation Award, Mount Sinai Medical Student Research Day
2011	Gold Humanism Honor Society, Mount Sinai School of Medicine
2011	Alpha Omega Alpha (AΩA) Honor Medical Society, Mount Sinai School of Medicine
2012	Harold Lamport Biomedical Research Award
2012	Distinction in Research, Mount Sinai School of Medicine
2014	Johns Hopkins Walter and Lucille Rubin Research Award
2015	Bladder Cancer Advocacy Network (BCAN) John Quale Travel Fellow
2015	Johns Hopkins Septembeard Research Scholar Award
2015	AUA Urology Care Foundation Russell W Scott Resident Scholar
2016	Society of Urologic Oncology Annual Meeting 1st prize Poster Award
2016	Mid-Atlantic AUA Resident Essay Prize
2016, 2017	Best Reviewer Urologic Oncology: Seminars and Original Investigations
2018	American Urological Association Annual Meeting 1st prize Poster Award
2021	Reviewer of the Month, European Urology

PUBLICATIONS
Peer Reviewed Original Research (Published)

1. **Kates M**, Perez X, Gribetz J, Swanson SJ, McGinn T, Wisnivesky JP. Validation of a model to predict perioperative mortality from lung cancer resection in the elderly. Am J Respir Crit Care Med. 2009 Mar 1;179(5):390-5. doi: 10.1164/rccm.200808-1342OC. Epub 2008 Nov 21. PubMed PMID: 19029001.
2. **Kates M,** Swanson S, Wisnivesky JP. Survival following lobectomy and limited resection for the treatment of stage I non-small cell lung cancer<=1 cm in size: a review of SEER data. Chest. 2011 Mar;139(3):491-496. doi: 10.1378/chest.09-2547. Epub 2010 Jun 24. PubMed PMID: 20576736.
3. **Kates M**, Badalato G, Pitman M, McKiernan J. Persistent overuse of radical nephrectomy in the elderly. Urology. 2011 Sep;78(3):555-9. doi: 10.1016/j.urology.2011.02.066. Epub 2011 Jul 20. PubMed PMID: 21777962.
4. **Kates M**, Badalato GM, McKiernan JM. Renal functional outcomes after surgery for renal cortical tumors. Curr Opin Urol. 2011 Sep;21(5):351-5. doi: 10.1097/MOU.0b013e32834962e9. Review. PubMed PMID: 21730853.
5. **Kates M**, Badalato GM, Pitman M, McKiernan JM. Increased risk of overall and cardiovascular mortality after radical nephrectomy for renal cell carcinoma 2 cm or less. J Urol. 2011 Oct;186(4):1247-53. doi: 10.1016/j.juro.2011.05.054. Epub 2011 Aug 17. PubMed PMID: 21849201.
6. Korets R, Graversen JA, **Kates M,** Mues AC, Gupta M. Post-percutaneous nephrolithotomy systemic inflammatory response: a prospective analysis of preoperative urine, renal pelvic urine and stone cultures. J Urol. 2011 Nov;186(5):1899-903. doi: 10.1016/j.juro.2011.06.064. Epub 2011 Sep 23. PubMed PMID: 21944106.

7. Sadeghi N, Badalato GM, **Kates M,** McKiernan JM. Management of residual non-retroperitoneal disease following chemotherapy for germ cell tumor. Urol Oncol. 2011 Nov-Dec;29(6):837-41. doi: 10.1016/j.urolonc.2011.02.019. Epub 2011 Apr 13. Review. PubMed PMID: 21489835.
8. Badalato GM, **Kates M**, Wisnivesky JP, Choudhury AR, McKiernan JM. Survival after partial and radical nephrectomy for the treatment of stage T1bN0M0 renal cell carcinoma (RCC) in the USA: a propensity scoring approach. BJU Int. 2012 May;109(10):1457-62. doi: 10.1111/j.1464-410X.2011.10597.x. Epub 2011 Sep 20. PubMed PMID: 21933334.
9. **Kates M**, Korets R, Sadeghi N, Pierorazio PM, McKiernan JM. Predictors of locally advanced and metastatic disease in patients with small renal masses. BJU Int. 2012 May;109(10):1463-7. doi: 10.1111/j.1464-410X.2011.10553.x. Epub 2011 Sep 20. PubMed PMID: 21933329.
10. **Kates M,** Lavery HJ, Brajtbord J, Samadi D, Palese MA. Decreasing rates of lymph node dissection during radical nephrectomy for renal cell carcinoma. Ann Surg Oncol. 2012 Aug;19(8):2693-9. doi: 10.1245/s10434-012-2330-6. Epub 2012 Apr 20. PubMed PMID: 22526899.
11. Sadeghi N, Badalato GM, Hruby G, **Kates M**, McKiernan JM. The impact of perioperative blood transfusion on survival following radical cystectomy for urothelial carcinoma. Can J Urol. 2012 Oct;19(5):6443-9. PubMed PMID: 23040626.
12. Pitman M, Korets R, **Kates M,** Hruby GW, McKiernan JM. Socioeconomic and clinical factors influence the interval between positive prostate biopsy and radical prostatectomy. Urology. 2012 Nov;80(5):1027-32. doi: 10.1016/j.urology.2012.01.008. PubMed PMID: 23107396.
13. **Kates M**, Badalato GM, Gupta M, McKiernan JM. Secondary bladder cancer after upper tract urothelial carcinoma in the US population. BJU Int. 2012 Nov;110(9):1325-9. doi: 10.1111/j.1464-410X.2012.11108.x. Epub 2012 May 7. PubMed PMID: 22564365.
14. Badalato GM, Gaya JM, Hruby G, Patel T, **Kates M**, Sadeghi N, Benson MC, McKiernan JM. Immediate radical cystectomy vs conservative management for high grade cT1 bladder cancer: is there a survival difference?. BJU Int. 2012 Nov;110(10):1471-7. doi: 10.1111/j.1464-410X.2012.11116.x. Epub 2012 Apr 4. PubMed PMID: 22487512.
15. Joice GA, Deibert CM, **Kates M**, Spencer BA, McKiernan JM. "Never events": Centers for Medicare and Medicaid Services complications after radical cystectomy. Urology. 2013 Mar;81(3):527-32. doi: 10.1016/j.urology.2012.09.050. Epub 2013 Jan 3. PubMed PMID: 23290151.
16. **Kates M**, Whalen MJ, Badalato GM, McKiernan JM. The effect of race and gender on the surgical management of the small renal mass. Urol Oncol. 2013 Nov;31(8):1794-9. doi: 10.1016/j.urolonc.2012.05.005. Epub 2012 Jun 9. PubMed PMID: 22687567.
17. Tsao CK, Small AC, **Kates M**, Moshier EL, Wisnivesky JP, Gartrell BA, Sonpavde G, Godbold JH, Palese MA, Hall SJ, Oh WK, Galsky MD. Cytoreductive nephrectomy for metastatic renal cell carcinoma in the era of targeted therapy in the United States: a SEER analysis. World J Urol. 2013 Dec;31(6):1535-9. doi: 10.1007/s00345-012-1001-3. Epub 2012 Dec 8. PubMed PMID: 23223962; PubMed Central PMCID: PMC4744480.
18. Patel HD, **Kates M**, Pierorazio PM, Hyams ES, Gorin MA, Ball MW, Bhayani SB, Hui X, Thompson CB, Allaf ME. Survival after diagnosis of localized T1a kidney cancer: current population-based practice of surgery and nonsurgical management. Urology. 2014 Jan;83(1):126-32. doi: 10.1016/j.urology.2013.08.088. Epub 2013 Nov 16. PubMed PMID: 24246317; PubMed Central PMCID: PMC3892770.
19. **Kates M**, Gorin MA, Deibert CM, Pierorazio PM, Schoenberg MP, McKiernan JM, Bivalacqua TJ. In-hospital death and hospital-acquired complications among patients undergoing partial cystectomy for bladder cancer in the United States. Urol Oncol. 2014 Jan;32(1):53.e9-14. doi: 10.1016/j.urolonc.2013.08.024. Epub 2013 Nov 13. PubMed PMID: 24239467.

20. Gorin MA, **Kates M**, Mullins JK, Pierorazio PM, Matlaga BR, Schoenberg MP, Bivalacqua TJ. Impact of hospital volume on perioperative outcomes and costs of radical cystectomy: analysis of the Maryland Health Services Cost Review Commission database. Can J Urol. 2014 Feb;21(1):7102-7. PubMed PMID: 24529009.
21. Patel HD, **Kates M**, Pierorazio PM, Allaf ME. Race and sex disparities in the treatment of older patients with T1a renal cell carcinoma: a comorbidity-controlled competing-risks model. Urol Oncol. 2014 Jul;32(5):576-83. doi: 10.1016/j.urolonc.2014.01.002. Epub 2014 Mar 12. PubMed PMID: 24629500; PubMed Central PMCID: PMC4062588.
22. Patel HD, **Kates M**, Pierorazio PM, Gorin MA, Jayram G, Ball MW, Hyams ES, Allaf ME. Comorbidities and causes of death in the management of localized T1a kidney cancer. Int J Urol. 2014 Nov;21(11):1086-92. doi: 10.1111/iju.12527. Epub 2014 Jun 16. PubMed PMID: 24931430.
23. McKiernan JM, Holder DD, Ghandour RA, Barlow LJ, Ahn JJ, **Kates M**, Badalato GM, Roychoudhury A, Decastro GJ, Benson MC. Phase II trial of intravesical nanoparticle albumin bound paclitaxel for the treatment of nonmuscle invasive urothelial carcinoma of the bladder after bacillus Calmette-Guérin treatment failure. J Urol. 2014 Dec;192(6):1633-8. doi: 10.1016/j.juro.2014.06.084. Epub 2014 Jul 1. PubMed PMID: 24996128.
24. Patel HD, **Kates M**, Pierorazio PM, Allaf ME. Balancing cardiovascular (CV) and cancer death among patients with small renal masses: modification by CV risk. BJU Int. 2015 Jan;115(1):58-64. doi: 10.1111/bju.12719. Epub 2014 Jul 27. PubMed PMID: 24589376; PubMed Central PMCID: PMC4153794.
25. **Kates M**, Tosoian JJ, Trock BJ, Feng Z, Carter HB, Partin AW. Indications for intervention during active surveillance of prostate cancer: a comparison of the Johns Hopkins and Prostate Cancer Research International Active Surveillance (PRIAS) protocols. BJU Int. 2015 Feb;115(2):216-22. doi: 10.1111/bju.12828. Epub 2014 Aug 16. PubMed PMID: 24904995.
26. Patel HD, Ball MW, Cohen JE, **Kates M,** Pierorazio PM, Allaf ME. Morbidity of urologic surgical procedures: an analysis of rates, risk factors, and outcomes. Urology. 2015 Mar;85(3):552-9. doi: 10.1016/j.urology.2014.11.034. PubMed PMID: 25733265; PubMed Central PMCID: PMC4349385.
27. **Kates M**, Singh A, Matsui H, Steinberg GD, Smith ND, Schoenberg MP, Bivalacqua TJ. Tissue-engineered urinary conduits. Curr Urol Rep. 2015 Mar;16(3):8. doi: 10.1007/s11934-015-0480-3. Review. PubMed PMID: 25677229.
28. **Kates M,** Ball MW, Patel HD, Gorin MA, Pierorazio PM, Allaf ME. The financial impact of robotic technology for partial and radical nephrectomy. J Endourol. 2015 Mar;29(3):317-22. doi: 10.1089/end.2014.0559. Epub 2014 Oct 10. PubMed PMID: 25167378.
29. Gandhi NM, Baras A, Munari E, Faraj S, Reis LO, Liu JJ, **Kates M**, Hoque MO, Berman D, Hahn NM, Eisenberger M, Netto GJ, Schoenberg MP, Bivalacqua TJ. Gemcitabine and cisplatin neoadjuvant chemotherapy for muscle-invasive urothelial carcinoma: Predicting response and assessing outcomes. Urol Oncol. 2015 May;33(5):204.e1-7. doi: 10.1016/j.urolonc.2015.02.011. Epub 2015 Mar 23. PubMed PMID: 25814145; PubMed Central PMCID: PMC4507518.
30. Joice GA, **Kates M,** Bivalacqua TJ. Reply: To PMID 26142586. Urology. 2015 Jul;86(1):78-9. doi: 10.1016/j.urology.2015.01.052. PubMed PMID: 26142587.
31. Joice GA, **Kates M,** Sopko NA, Hannan JL, Bivalacqua TJ. Sickle Cell Disease in Priapism: Disparity in Care?. Urology. 2015 Jul;86(1):72-7. doi: 10.1016/j.urology.2015.01.050. PubMed PMID: 26142586.
32. Deibert CM, **Kates M,** McKiernan JM, Spencer BA. National estimated costs of never events following radical prostatectomy. Urol Oncol. 2015 Sep;33(9):385.e1-6. doi: 10.1016/j.urolonc.2014.08.002. Epub 2015 Mar 11. PubMed PMID: 25770748.
33. Lascano D, Pak JS, **Kates M**, Finkelstein JB, Silva M, Hagen E, RoyChoudhury A, Bivalacqua TJ, DeCastro GJ, Benson MC, McKiernan JM. Validation of a frailty index in patients

undergoing curative surgery for urologic malignancy and comparison with other risk stratification tools. Urol Oncol. 2015 Oct;33(10):426.e1-12. doi: 10.1016/j.urolonc.2015.06.002. Epub 2015 Jul 9. PubMed PMID: 26163940; PubMed Central PMCID: PMC4584178.

34. Sopko NA, **Kates M**, Bivalacqua TJ. Use of regenerative tissue for urinary diversion. Curr Opin Urol. 2015 Nov;25(6):578-85. doi: 10.1097/MOU.0000000000000223. Review. PubMed PMID: 26383039.
35. **Kates M**, Sopko NA, Matsui H, Drake CG, Hahn NM, Bivalacqua TJ. Immune checkpoint inhibitors: a new frontier in bladder cancer. World J Urol. 2016 Jan;34(1):49-55. doi: 10.1007/s00345-015-1709-y. Epub 2015 Oct 20. Review. PubMed PMID: 26487055.
36. **Kates M**, Sopko NA, Han M, Partin AW, Epstein JI. Importance of Reporting the Gleason Score at the Positive Surgical Margin Site: Analysis of 4,082 Consecutive Radical Prostatectomy Cases. J Urol. 2016 Feb;195(2):337-42. doi: 10.1016/j.juro.2015.08.002. Epub 2015 Aug 8. PubMed PMID: 26264998.
37. Kryvenko ON, Diaz M, Matoso A, **Kates M,** Cohen J, Swanson GP, Epstein JI. Prostate-specific Antigen Mass Density--A Measure Predicting Prostate Cancer Volume and Accounting for Overweight and Obesity-related Prostate-specific Antigen Hemodilution. Urology. 2016 Apr;90:141-7. doi: 10.1016/j.urology.2015.11.042. Epub 2016 Jan 7. PubMed PMID: 26773349.
38. Kaye DR, Canner JK, **Kates M**, Schoenberg MP, Bivalacqua TJ. Do African American Patients Treated with Radical Cystectomy for Bladder Cancer have Worse Overall Survival? Accounting for Pathologic Staging and Patient Demographics Beyond Race Makes a Difference. Bladder Cancer. 2016 Apr 27;2(2):225-234. doi: 10.3233/BLC-150041. PubMed PMID: 27376141; PubMed Central PMCID: PMC4927827.
39. Baras AS, Drake C, Liu JJ, Gandhi N, **Kates M**, Hoque MO, Meeker A, Hahn N, Taube JM, Schoenberg MP, Netto G, Bivalacqua TJ. The ratio of CD8 to Treg tumor-infiltrating lymphocytes is associated with response to cisplatin-based neoadjuvant chemotherapy in patients with muscle invasive urothelial carcinoma of the bladder. Oncoimmunology. 2016 May;5(5):e1134412. doi: 10.1080/2162402X.2015.1134412. eCollection 2016 May. PubMed PMID: 27467953; PubMed Central PMCID: PMC4910705.
40. Chappidi MR, **Kates M**, Patel HD, Tosoian JJ, Kaye DR, Sopko NA, Lascano D, Liu JJ, McKiernan J, Bivalacqua TJ. Frailty as a marker of adverse outcomes in patients with bladder cancer undergoing radical cystectomy. Urol Oncol. 2016 Jun;34(6):256.e1-6. doi: 10.1016/j.urolonc.2015.12.010. Epub 2016 Feb 15. PubMed PMID: 26899289; PubMed Central PMCID: PMC4875870.
41. Liu JJ, Mullane P, **Kates M**, Gandhi N, Schoenberg MP, Drake C, Hahn NM, Frank S, Bivalacqua TJ. Infectious complications in transfused patients after radical cystectomy. Can J Urol. 2016 Aug;23(4):8342-7. PubMed PMID: 27544556.
42. Patel HD, Gorin MA, Gupta N, **Kates M**, Johnson MH, Pierorazio PM, Allaf ME. Mortality trends and the impact of lymphadenectomy on survival for renal cell carcinoma patients with distant metastasis. Can Urol Assoc J. 2016 Nov-Dec;10(11-12):389-395. doi: 10.5489/cuaj.1999. PubMed PMID: 28096912; PubMed Central PMCID: PMC5167593.
43. Chappidi MR, **Kates M**, Johnson MH, Hahn NM, Bivalacqua TJ, Pierorazio PM. Lymph node yield and tumor location in patients with upper tract urothelial carcinoma undergoing nephroureterectomy affects survival: A U.S. population-based analysis (2004-2012). Urol Oncol. 2016 Dec;34(12):531.e15-531.e24. doi: 10.1016/j.urolonc.2016.06.013. Epub 2016 Jul 27. PubMed PMID: 27476032; PubMed Central PMCID: PMC5124513.
44. **Kates M**, Ball MW, Chappidi MR, Baras AS, Gordetsky J, Sopko NA, Brant A, Pierorazio PM, Epstein JI, Schoenberg MP, Bivalacqua TJ. Accuracy of urethral frozen section during radical cystectomy for bladder cancer. Urol Oncol. 2016 Dec;34(12):532.e1-532.e6. doi: 10.1016/j.urolonc.2016.06.014. Epub 2016 Jul 16. PubMed PMID: 27432433.

45. Brant A, **Kates M**, Chappidi MR, Patel HD, Sopko NA, Netto GJ, Baras AS, Hahn NM, Pierorazio PM, Bivalacqua TJ. Pathologic response in patients receiving neoadjuvant chemotherapy for muscle-invasive bladder cancer: Is therapeutic effect owing to chemotherapy or TURBT?. Urol Oncol. 2017 Jan;35(1):34.e17-34.e25. doi: 10.1016/j.urolonc.2016.08.005. Epub 2016 Sep 14. PubMed PMID: 27639777.
46. Chappidi MR, **Kates M**, Stimson CJ, Bivalacqua TJ, Pierorazio PM. Quantifying Nonindex Hospital Readmissions and Care Fragmentation after Major Urological Oncology Surgeries in a Nationally Representative Sample. J Urol. 2017 Jan;197(1):235-240. doi: 10.1016/j.juro.2016.07.078. Epub 2016 Jul 25. PubMed PMID: 27460756; PubMed Central PMCID: PMC5161702.
47. Gorin MA, Rowe SP, Hooper JE, **Kates M**, Hammers HJ, Szabo Z, Pomper MG, Allaf ME. PSMA-Targeted ^{18}F-DCFPyL PET/CT Imaging of Clear Cell Renal Cell Carcinoma: Results from a Rapid Autopsy. Eur Urol. 2017 Jan;71(1):145-146. doi: 10.1016/j.eururo.2016.06.019. Epub 2016 Jun 28. PubMed PMID: 27363386; PubMed Central PMCID: PMC5516900.
48. Matsui H, Sopko NA, Hannan JL, Reinhardt AA, **Kates M,** Yoshida T, Liu X, Castiglione F, Hedlund P, Weyne E, Albersen M, Bivalacqua TJ. M1 Macrophages Are Predominantly Recruited to the Major Pelvic Ganglion of the Rat Following Cavernous Nerve Injury. J Sex Med. 2017 Feb;14(2):187-195. doi: 10.1016/j.jsxm.2016.12.012. PubMed PMID: 28161077; PubMed Central PMCID: PMC5298795.
49. Chappidi MR, Chalfin HJ, Johnson DJ, **Kates M,** Sopko NA, Johnson MH, Liu JJ, Frank SM, Bivalacqua TJ. Longer average blood storage duration is associated with increased risk of infection and overall morbidity following radical cystectomy. Urol Oncol. 2017 Feb;35(2):38.e17-38.e24. doi: 10.1016/j.urolonc.2016.09.005. Epub 2016 Oct 19. PubMed PMID: 27771280; PubMed Central PMCID: PMC5222715.
50. Chappidi MR, **Kates M**, Stimson CJ, Johnson MH, Pierorazio PM, Bivalacqua TJ. Causes, Timing, Hospital Costs and Perioperative Outcomes of Index vs Nonindex Hospital Readmissions after Radical Cystectomy: Implications for Regionalization of Care. J Urol. 2017 Feb;197(2):296-301. doi: 10.1016/j.juro.2016.08.082. Epub 2016 Aug 18. PubMed PMID: 27545575; PubMed Central PMCID: PMC5241219.

51. Chappidi MR, **Kates M**, Bivalacqua TJ. Author Reply. Urology. 2017 Apr;102:158. doi: 10.1016/j.urology.2016.10.066. Epub 2017 Jan 26. PubMed PMID: 28131434.
52. Chappidi MR, **Kates M,** Brant A, Baras AS, Netto GJ, Pierorazio PM, Hahn NM, Bivalacqua TJ. Assessing Cancer Progression and Stable Disease After Neoadjuvant Chemotherapy for Organ-confined Muscle-invasive Bladder Cancer. Urology. 2017 Apr;102:148-158. doi: 10.1016/j.urology.2016.10.064. Epub 2017 Jan 16. PubMed PMID: 28104421; PubMed Central PMCID: PMC5376379.
53. Sopko NA, Matsui H, Lough DM, Miller D, Harris K, **Kates M**, Liu X, Billups K, Redett R, Burnett AL, Brandacher G, Bivalacqua TJ. Ex Vivo Model of Human Penile Transplantation and Rejection: Implications for Erectile Tissue Physiology. Eur Urol. 2017 Apr;71(4):584-593. doi: 10.1016/j.eururo.2016.07.006. Epub 2016 Jul 16. PubMed PMID: 27432525.
54. Chappidi MR, **Kates M**, Sopko NA, Joice GA, Tosoian JJ, Pierorazio PM, Bivalacqua TJ. Erectile Dysfunction Treatment Following Radical Cystoprostatectomy: Analysis of a Nationwide Insurance Claims Database. J Sex Med. 2017 Jun;14(6):810-817. doi: 10.1016/j.jsxm.2017.04.002. Epub 2017 Apr 29. PubMed PMID: 28460994.
55. **Kates M**, Nirschl T, Sopko NA, Matsui H, Kochel CM, Reis LO, Netto GJ, Hoque MO, Hahn NM, McConkey DJ, Baras AS, Drake CG, Bivalacqua TJ. Intravesical BCG Induces CD4$^+$ T-Cell Expansion in an Immune Competent Model of Bladder Cancer. Cancer Immunol Res. 2017 Jul;5(7):594-603. doi: 10.1158/2326-6066.CIR-16-0267. Epub 2017 Jun 6. PubMed PMID: 28588015; PubMed Central PMCID: PMC5536898.

56. **Kates M,** Chappidi MR, Brant A, Milbar N, Sopko NA, Meyer C, Terezakis SA, Herman JM, Efron JE, Safar B, Tran PT, Ahuja N, Pierorazio PM, Bivalacqua TJ. High dose-rate Intra-Operative Radiation Therapy During High Risk Genitourinary Surgery: Initial Observations and a Proposal for its Study in Bladder Cancer. Bladder Cancer. 2017 Jul 27;3(3):191-199. doi: 10.3233/BLC-170104. PubMed PMID: 28824947; PubMed Central PMCID: PMC5545919.
57. Pederzoli F, Chappidi MR, Collica S, **Kates M**, Joice GA, Sopko NA, Montorsi F, Salonia A, Bivalacqua TJ. Analysis of Hospital Readmissions After Prosthetic Urologic Surgery in the United States: Nationally Representative Estimates of Causes, Costs, and Predictive Factors. J Sex Med. 2017 Aug;14(8):1059-1065. doi: 10.1016/j.jsxm.2017.06.003. Epub 2017 Jul 12. PubMed PMID: 28709874.
58. Chappidi MR, **Kates M**, Tosoian JJ, Johnson MH, Hahn NM, Bivalacqua TJ, Pierorazio PM. Evaluation of gender-based disparities in time from initial haematuria presentation to upper tract urothelial carcinoma diagnosis: analysis of a nationwide insurance claims database. BJU Int. 2017 Sep;120(3):377-386. doi: 10.1111/bju.13878. Epub 2017 May 17. PubMed PMID: 28418183.
59. Milbar N, **Kates M**, Chappidi MR, Pederzoli F, Yoshida T, Sankin A, Pierorazio PM, Schoenberg MP, Bivalacqua TJ. Oncological Outcomes of Sequential Intravesical Gemcitabine and Docetaxel in Patients with Non-Muscle Invasive Bladder Cancer. Bladder Cancer. 2017 Oct 27;3(4):293-303. doi: 10.3233/BLC-170126. PubMed PMID: 29152553; PubMed Central PMCID: PMC5676758.
60. **Kates M**, Date A, Yoshida T, Afzal U, Kanvinde P, Babu T, Sopko NA, Matsui H, Hahn NM, McConkey DJ, Baras A, Hanes J, Ensign L, Bivalacqua TJ. Preclinical Evaluation of Intravesical Cisplatin Nanoparticles for Non-Muscle-Invasive Bladder Cancer. Clin Cancer Res. 2017 Nov 1;23(21):6592-6601. doi: 10.1158/1078-0432.CCR-17-1082. Epub 2017 Aug 14. PubMed PMID: 28808039; PubMed Central PMCID: PMC6487844.
61. Campbell SP, Baras AS, Ball MW, **Kates M**, Hahn NM, Bivalacqua TJ, Johnson MH, Pomper MG, Allaf ME, Rowe SP, Gorin MA. Low levels of PSMA expression limit the utility of ^{18}F-DCFPyL PET/CT for imaging urothelial carcinoma. Ann Nucl Med. 2018 Jan;32(1):69-74. doi: 10.1007/s12149-017-1216-x. Epub 2017 Oct 24. PubMed PMID: 29067547; PubMed Central PMCID: PMC5881395.
62. Semerjian A, Milbar N, **Kates M**, Gorin MA, Patel HD, Chalfin HJ, Frank SM, Wu CL, Yang WW, Hobson D, Robertson L, Wick E, Schoenberg MP, Pierorazio PM, Johnson MH, Stimson CJ, Bivalacqua TJ. Hospital Charges and Length of Stay Following Radical Cystectomy in the Enhanced Recovery After Surgery Era. Urology. 2018 Jan;111:86-91. doi: 10.1016/j.urology.2017.09.010. Epub 2017 Oct 13. PubMed PMID: 29032237.
63. Yoshida T, Sopko NA, **Kates M**, Liu X, Joice G, McConkey DJ, Bivalacqua TJ. Three-dimensional organoid culture reveals involvement of Wnt/β-catenin pathway in proliferation of bladder cancer cells. Oncotarget. 2018 Feb 16;9(13):11060-11070. doi: 10.18632/oncotarget.24308. eCollection 2018 Feb 16. PubMed PMID: 29541396; PubMed Central PMCID: PMC5834271.
64. Yoshida T, **Kates M**, Sopko NA, Liu X, Singh AK, Bishai WR, Joice G, McConkey DJ, Bivalacqua TJ. Ex vivo culture of tumor cells from N-methyl-N-nitrosourea-induced bladder cancer in rats: Development of organoids and an immortalized cell line. Urol Oncol. 2018 Apr;36(4):160.e23-160.e32. doi: 10.1016/j.urolonc.2017.11.024. Epub 2017 Dec 26. PubMed PMID: 29288005.
65. Chalfin HJ, **Kates M**, van der Toom EE, Glavaris S, Verdone JE, Hahn NM, Pienta KJ, Bivalacqua TJ, Gorin MA. Characterization of Urothelial Cancer Circulating Tumor Cells with a Novel ion-Free Method. Urology. 2018 May;115:82-86. doi: 10.1016/j.urology.2018.01.036. Epub 2018 Feb 9. PubMed PMID: 29432873.
66. Ooki A, Begum A, Marchionni L, VandenBussche CJ, Mao S, **Kates M**, Hoque MO. Arsenic promotes the COX2/PGE2-SOX2 axis to increase the malignant stemness properties of

urothelial cells. Int J Cancer. 2018 Jul 1;143(1):113-126. doi: 10.1002/ijc.31290. Epub 2018 Feb 14. PubMed PMID: 29396848; PubMed Central PMCID: PMC5938132.

67. Liao RS, Gupta M, Schwen ZR, Patel HD, **Kates M**, Johnson MH, Hahn NM, McConkey D, Bivalacqua TJ, Pierorazio PM. Comparison of Pathological Stage in Patients Treated with and without Neoadjuvant Chemotherapy for High Risk Upper Tract Urothelial Carcinoma. J Urol. 2018 Jul;200(1):68-73. doi: 10.1016/j.juro.2017.12.054. Epub 2018 Jan 4. PubMed PMID: 29307680.
68. Ooki A, VandenBussche CJ, **Kates M,** Hahn NM, Matoso A, McConkey DJ, Bivalacqua TJ, Hoque MO. CD24 regulates cancer stem cell (CSC)-like traits and a panel of CSC-related molecules serves as a non-invasive urinary biomarker for the detection of bladder cancer. Br J Cancer. 2018 Oct;119(8):961-970. doi: 10.1038/s41416-018-0291-7. Epub 2018 Oct 17. PubMed PMID: 30327565; PubMed Central PMCID: PMC6203855.
69. Joice GA, Chappidi MR, Patel HD, **Kates M**, Sopko NA, Stimson CJ, Pierorazio PM, Bivalacqua TJ. Hospitalisation and readmission costs after radical cystectomy in a nationally representative sample: does urinary reconstruction matter?. BJU Int. 2018 Dec;122(6):1016-1024. doi: 10.1111/bju.14448. Epub 2018 Jul 26. PubMed PMID: 29897156.
70. **Kates M**, Nirschl TR, Baras AS, Sopko NA, Hahn NM, Su X, Zhang J, Kochel CM, Choi W, McConkey DJ, Drake CG, Bivalacqua TJ. Combined Next-generation Sequencing and Flow Cytometry Analysis for an Anti-PD-L1 Partial Responder over Time: An Exploration of Mechanisms of PD-L1 Activity and Resistance in Bladder Cancer. Eur Urol Oncol. 2019 Feb 26;. doi: 10.1016/j.euo.2019.01.017. [Epub ahead of print] PubMed PMID: 31411999.
71. Pederzoli F, Murati Amador B, Samarska I, Lombardo KA, **Kates M,** Bivalacqua TJ, Matoso A. Diagnosis of urothelial carcinoma in situ using blue light cystoscopy and the utility of immunohistochemistry in blue light-positive lesions diagnosed as atypical. Hum Pathol. 2019 Aug;90:1-7. doi: 10.1016/j.humpath.2019.04.018. Epub 2019 May 6. PubMed PMID: 31071342; PubMed Central PMCID: PMC6696917.
72. Chalfin HJ, Glavaris SA, Gorin MA, **Kates MR**, Fong MH, Dong L, Matoso A, Bivalacqua TJ, Johnson MH, Pienta KJ, Hahn NM, McConkey DJ. Circulating Tumor Cell and Circulating Tumor DNA Assays Reveal Complementary Information for Patients with Metastatic Urothelial Cancer. Eur Urol Oncol. 2019 Sep 25;. doi: 10.1016/j.euo.2019.08.004. [Epub ahead of print] PubMed PMID: 31563523.
73. Gupta M, Milbar N, Tema G, Pederzoli F, Chappidi M, **Kates M,** VandenBussche CJ, Bivalacqua TJ. Impact of intravesical therapy for non-muscle invasive bladder cancer on the accuracy of urine cytology. World J Urol. 2019 Oct;37(10):2051-2058. doi: 10.1007/s00345-018-02624-3. Epub 2019 Jan 23. PubMed PMID: 30671639.
74. Yoshida T, Sopko NA, **Kates M**, Liu X, Joice G, Mcconkey DJ, Bivalacqua TJ. Impact of spheroid culture on molecular and functional characteristics of bladder cancer cell lines. Oncol Lett. 2019 Nov;18(5):4923-4929. doi: 10.3892/ol.2019.10786. Epub 2019 Aug 29. PubMed PMID: 31612003; PubMed Central PMCID: PMC6781760.
75. Joice GA, Tema G, Semerjian A, Gupta M, Bell M, Walker J, **Kates M,** Bivalacqua TJ. Evaluation of Incisional Negative Pressure Wound Therapy in the Prevention of Surgical Site Occurrences After Radical Cystectomy: A New Addition to Enhanced Recovery After Surgery Protocol. Eur Urol Focus. 2019 Nov 5;. doi: 10.1016/j.euf.2019.09.016. [Epub ahead of print] PubMed PMID: 31704281.
76. Brant A, Daniels M, Chappidi MR, Joice GA, Sopko NA, Matoso A, Bivalacqua TJ, **Kates** M. Prognostic implications of prostatic urethral involvement in non-muscle-invasive bladder cancer. World J Urol. 2019 Dec;37(12):2683-2689. doi: 10.1007/s00345-019-02673-2. Epub 2019 Mar 8. PubMed PMID: 30850856.
77. Daniels MJ, Barry E, Schoenberg M, Lamm DL, Bivalacqua TJ, Sankin A, **Kates** M. Contemporary oncologic outcomes of second induction course BCG in patients with

nonmuscle invasive bladder cancer. Urol Oncol. 2020 Jan;38(1):5.e9-5.e16. doi: 10.1016/j.urolonc.2019.05.018. Epub 2019 Jun 27. PubMed PMID: 31255541.

78. Becker REN, **Kates MR**, Bivalacqua TJ. Identification of Candidates for Salvage Therapy: The Past, Present, and Future of Defining Bacillus Calmette-Guérin Failure. Urol Clin North Am. 2020 Feb;47(1):15-21. doi: 10.1016/j.ucl.2019.09.004. Review. PubMed PMID: 31757296.
79. Daniels MJ, Barry E, Milbar N, Schoenberg M, Bivalacqua TJ, Sankin A, **Kates M**. An evaluation of monthly maintenance therapy among patients receiving intravesical combination gemcitabine/docetaxel for nonmuscle-invasive bladder cancer. Urol Oncol. 2020 Feb;38(2):40.e17-40.e24. doi: 10.1016/j.urolonc.2019.07.022. Epub 2019 Aug 28. PubMed PMID: 31473090.
80. Hassan O, Murati Amador B, Lombardo KA, Salles D, Cuello F, Marwaha AS, Daniels MJ, **Kates M**, Bivalacqua TJ, Matoso A. Clinical significance of urothelial carcinoma ambiguous for muscularis propria invasion on initial transurethral resection of bladder tumor. World J Urol. 2020 Feb;38(2):389-395. doi: 10.1007/s00345-019-02782-y. Epub 2019 Apr 27. PubMed PMID: 31030230; PubMed Central PMCID: PMC6815684.
81. **Kates M**, Matoso A, Choi W, Baras AS, Daniels MJ, Lombardo K, Brant A, Mikkilineni N, McConkey DJ, Kamat AM, Svatek RS, Porten SP, Meeks JJ, Lerner SP, Dinney CP, Black PC, McKiernan JM, Anderson C, Drake CG, Bivalacqua TJ. Adaptive Immune Resistance to Intravesical BCG in Non-Muscle Invasive Bladder Cancer: Implications for Prospective BCG-Unresponsive Trials. Clin Cancer Res. 2020 Feb 15;26(4):882-891. doi: 10.1158/1078-0432.CCR-19-1920. Epub 2019 Nov 11. PubMed PMID: 31712383.
82. Chappidi MR, Stimson CJ, **Kates M**, Odisho AY, Bivalacqua TJ. A Nationally Representative Study of Nonindex Hospital Readmissions following Radical Prostatectomy: Implications for Bundled Payment Models. J Urol. 2020 Mar;203(3):546-553. doi: 10.1097/JU.0000000000000522. Epub 2019 Sep 3. PubMed PMID: 31479405.
83. Steinberg RL, Thomas LJ, Brooks N, Mott SL, Vitale A, Crump T, Rao MY, Daniels MJ, Wang J, Nagaraju S, DeWolf WC, Lamm DL, **Kates M,** Hyndman ME, Kamat AM, Bivalacqua TJ, Nepple KG, O'Donnell MA. Multi-Institution Evaluation of Sequential Gemcitabine and Docetaxel as Rescue Therapy for Nonmuscle Invasive Bladder Cancer. J Urol. 2020 May;203(5):902-909. doi: 10.1097/JU.0000000000000688. Epub 2019 Dec 10. PubMed PMID: 31821066.
84. DeCastro GJ, Sui W, Pak JS, Lee SM, Holder D, **Kates M**, Virk RK, Drake CG, Anderson CB, James B, Abate-Shen CT, McKiernan JM. A Phase I Trial of Intravesical Cabazitaxel, Gemcitabine and Cisplatin for the Treatment of Nonmuscle Invasive bacillus Calmette-Guérin Unresponsive or Recurrent/Relapsing Urothelial Carcinoma of the Bladder. J Urol. 2020 Aug;204(2):247-253.
85. Becker REN, Meyer AR, Brant A, Reese AC, Biles MJ, Harris KT, Netto G, Matoso A, Hoffman-Censits J, Hahn NM, Choi W, McConkey D, Pierorazio PM, Johnson MH, Schoenberg MP, **Kates M**, Baras A, Bivalacqua TJ. Clinical Restaging and Tumor Sequencing are Inaccurate Indicators of Response to Neoadjuvant Chemotherapy for Muscle-invasive Bladder Cancer. Eur Urol. 2020 Aug 17:S0302-2838(20)30564-9
86. Lombardo KA, Murati Amador B, Parimi V, Hoffman-Censits J, Choi W, Hahn NM, **Kates M**, Bivalacqua TJ, McConkey D, Hoque MO, Matoso A. Urothelial Carcinoma In Situ of the Bladder: Correlation of CK20 Expression With Adaptive Immune Resistance, Response to BCG Therapy, and Clinical Outcome. Appl Immunohistochem Mol Morphol. 2020 Aug 28.
87. Cheaib JG, Claus LE, Patel HD, **Kates M**, Matoso A, Hahn NM, Bivalacqua TJ, Hoffman-Censits JH, Pierorazio PM. Site of metastatic recurrence impacts prognosis in patients with high-grade upper tract urothelial carcinoma. Urol Oncol. 2021 Jan;39(1):74.e9-74.e16
88. Date AA, **Kates M (Co-1st author)**, Yoshida T, Babu T, Afzal U, Kanvinde P, Baras A, Anders N, He P, Rudek M, Hanes J, Bivalacqua TJ, Ensign LM. Preclinical evaluation of a hypotonic

docetaxel nanosuspension formulation for intravesical treatment of non-muscle-invasive bladder cancer. Drug Deliv Transl Res. 2020 Nov 8

89. Kardos J, Rose TL, Manocha U, Wobker SE, Damrauer JS, Bivalaqua TJ, **Kates M**, Moore KJ, Parker JS, Kim WY. Development and validation of a NanoString BASE47 bladder cancer gene classifier. PLoS One. 2020 Dec 17;15(12):e0243935.
90. Hoffman-Censits J, Choi W, Bivalacqua TJ, Pierorazio P, **Kates M**, Lombardo K, Parini V, McConkey D, Trabulsi EJ, Hahn N, Matoso A. Small Cell Bladder Cancer Response to Second-line and Beyond Checkpoint Inhibitor Therapy: Retrospective Experience. Clin Genitourin Cancer. 2020 Nov 12:S1558-7673(20)30251-2.
91. Hoffman-Censits JH, Lombardo KA, Parimi V, Kamanda S, Choi W, Hahn NM, McConkey DJ, McGuire BM, Bivalacqua TJ, **Kates M**, Matoso A. Expression of Nectin-4 in Bladder Urothelial Carcinoma, in Morphologic Variants, and Nonurothelial Histotypes. Appl Immunohistochem Mol Morphol. 2021 April 23.
92. Steinberg RL, Packiam VT, Thomas LJ, Brooks N, Vitale A, Mott SL, Crump T, Wang J, DeWolf WC, Lamm DL, **Kates M**, Hyndman ME, Kamat AM, Bivalacqua TJ, Nepple KG, O'Donnell MA. Intravesical sequential gemcitabine and docetaxel versus bacillus calmette-guerin (BCG) plus interferon in patients with recurrent non-muscle invasive bladder cancer following a single induction course of BCG. Urol Oncol 2021 Jun 3.
93. Choi W, Lombardo K, Patel S, Epstein G, Feng M, Gabrielson A, Hahn N, Hoffman-Censits J, McConkey D, Bivalacqua T, Matoso A, **Kates M**. A Molecular Inquiry into the Role of Antibody Drug Conjugates in BCG Exposed NMIBC. Eur Urol 2021 *In Press*
94. **Kates M**, Mansour AM, Lamm DL, Shore N, Maulhardt H, Wendt A, Verco J, Marin A, Dewnani K, Verco S, diZerega GS. Phase 1/2 Trial Results of a Large Surface Area Microparticle Docetaxel for the Treatment of High-Risk Non-muscle Invasive Bladder Cancer. J Urol. 2022.
95. Fletcher SA, Bivalacqua TJ, Brawley OW, **Kates M.** Race, ethnicity, and gender reporting in North American clinical trials for BCG-unresponsive non-muscle invasive bladder cancer. Urol Oncol. 2022 May;40(5):195.e13-195.e18. doi: 10.1016/j.urolonc.2021.11.015. Epub 2021 Dec 20. PMID: 34949513.
96. Chappidi MR, Yang H, Meng MV, Bivalacqua TJ, Daneshmand S, Holzbeierlein JM, Kaimakliotis HZ, Konety B, Liao JC, Pohar K, Steinberg GD, Taylor JM, Tyson MD, Willard B, Lotan Y, Porten SP, **Kates M.** Utility of Blue Light Cystoscopy for Post-bacillus Calmette-Guérin Bladder Cancer Recurrence Detection: Implications for Clinical Trial Recruitment and Study Comparisons. J Urol. 2022 Mar;207(3):534-540. doi: 10.1097/JU.0000000000002308. Epub 2021 Oct 25. PMID: 34694916.
97. Gabrielson AT, Daniels MJ, Rowe J, Alam R, Lee EJ, Matoso A, De Felice A, Hahn N, Hoffman-Censits J, Bivalacqua TJ, **Kates M.** Residual CIS after neoadjuvant chemotherapy and radical cystectomy for muscle invasive bladder cancer: Implications for neoadjuvant trials. Urol Oncol. 2022 Apr;40(4):164.e9-164.e16. doi: 10.1016/j.urolonc.2021.11.021. Epub 2022 Jan 16. PMID: 35045949.
98. Patel SH, Wang S, Metcalf MR, Gupta N, Gabrielson A, Lee E, Rostom M, Pierorazio P, Smith A, Hahn N, Schoenberg M, **Kates M**, Hoffman-Censits J, Bivalacqua TJ. Safety and Efficacy of Reproductive Organ-Sparing Radical Cystectomy in Women With Variant Histology and Advanced Stage. Clin Genitourin Cancer. 2022 Feb;20(1):60-68. doi: 10.1016/j.clgc.2021.11.005. Epub 2021 Nov 15. PMID: 34896022.
99. Lombardo KA, Obradovic A, Singh AK, Liu JL, Joice G, **Kates M**, Bishai W, McConkey D, Chaux A, Eich ML, Rezaei MK, Netto GJ, Drake CG, Tran P, Matoso A, Bivalacqua TJ. BCG invokes superior STING-mediated innate immune response over radiotherapy in a carcinogen murine model of urothelial cancer. J Pathol. 2022 Feb;256(2):223-234. doi: 10.1002/path.5830. Epub 2021 Dec 10. PMID: 34731491; PMCID: PMC8738146.

100. Ahmadi H, Ladi-Seyedian SS, Konety B, Pohar K, Holzbeierlein JM, **Kates M,** Willard B, Taylor JM, Liao JC, Kaimakliotis HZ, Porten SP, Steinberg GD, Tyson MD, Lotan Y, Daneshmand S; Blue Light Cystoscopy with Cysview Registry Group. Role of blue-light cystoscopy in detecting invasive bladder tumours: data from a multi-institutional registry. BJU Int. 2022 Jul;130(1):62-67. doi: 10.1111/bju.15614. Epub 2021 Oct 26. PMID: 34637596.
101. Mi H, Bivalacqua TJ, **Kates M**, Seiler R, Black PC, Popel AS, Baras AS. Predictive models of response to neoadjuvant chemotherapy in muscle-invasive bladder cancer using nuclear morphology and tissue architecture. Cell Rep Med. 2021 Aug 27;2(9):100382. doi: 10.1016/j.xcrm.2021.100382. PMID: 34622225; PMCID: PMC8484511.
102. Patel HD, Patel SH, Blanco-Martinez E, Kuzbel J, Chen VS, Druck A, Koehne EL, Patel PM, Doshi CP, Hahn NM, Hoffman-Censits JH, Berg S, Bivalacqua TJ, **Kates M**, Quek ML. Four versus 3 Cycles of Neoadjuvant Chemotherapy for Muscle-Invasive Bladder Cancer: Implications for Pathological Response and Survival. J Urol. 2022 Jan;207(1):77-85. doi: 10.1097/JU.0000000000002189. Epub 2021 Aug 27. PMID: 34445890.
103. Chevli KK, Shore ND, Trainer A, Smith AB, Saltzstein D, Ehrlich Y, Raman JD, Friedman B, D'Anna R, Morris D, Hu B, Tyson M, Sankin A, **Kates M**, Linehan J, Scherr D, Kester S, Verni M, Chamie K, Karsh L, Cinman A, Meads A, Lahiri S, Malinowski M, Gabai N, Raju S, Schoenberg M, Seltzer E, Huang WC. Primary Chemoablation of Low-Grade Intermediate-Risk Nonmuscle-Invasive Bladder Cancer Using UGN-102, a Mitomycin-Containing Reverse Thermal Gel (Optima II): A Phase 2b, Open-Label, Single-Arm Trial. J Urol. 2022 Jan;207(1):61-69. doi: 10.1097/JU.0000000000002186. Epub 2021 Aug 26. PMID: 34433303; PMCID: PMC8667793.
104. Lowe AW, Macura KJ, **Kates M**, Lotan T, Haffner MC, Rowe SP. Prostate multi-parametric magnetic resonance imaging appearance of diffuse adenosis of the peripheral zone (DAPZ). Urol Case Rep. 2022 Aug 2;45:102178.
105. Alam R, Patel SH, **Kates MR**, Singla N, Pavlovich CP, Allaf ME, Bivalacqua TJ, Pierorazio PM. Differential changes in self-reported quality of life in elderly populations after diagnosis of a genitourinary malignancy. Urol Oncol. 2022 Oct;40(10):455.e1-455.e10.
106. Singh SM, Liu JL, Sedaghat F, Wethington SL, Atallah C, **Kates M**. Tubo-ovarian abscess: A potential mimicker of urachal malignancy. Urol Case Rep. 2022 Aug 18;45:102191.
107. Stabinska J, Singh A, Haney NM, Li Y, Sedaghat F, **Kates M**, McMahon MT. Noninvasive assessment of renal dynamics and pH in a unilateral ureter obstruction model using DCE MR-CEST urography. Magn Reson Med. 2023 Jan;89(1):343-355. doi: 10.1002/mrm.29436. Epub 2022 Sep 11.
108. Alsyouf M, Ladi-Seyedian SS, Konety B, Pohar K, Holzbeierlein JM, **Kates M**, Willard B, Taylor JM, Liao JC, Kaimakliotis HZ, Porten SP, Steinberg GD, Tyson MD, Lotan Y, Daneshmand S; Blue Light Cystoscopy with Cysview Registry Group. Is a restaging TURBT necessary in high-risk NMIBC if the initial TURBT was performed with blue light? Urol Oncol. 2023 Feb;41(2):109.e9-109.e14.
109. Bo S, Stabinska J, Wu Y, Pavuluri KD, Singh A, Mohanta Z, Choudhry R, **Kates M**, Sedaghat F, Bhujwalla Z, Pomper MG, McMahon MT. Exploring the potential of the novel imidazole-4,5-dicarboxyamide chemical exchange saturation transfer scaffold for pH and perfusion imaging. NMR Biomed. 2023 Jun;36(6):e4894.
110. Alam R, Gabrielson AT, Rabinowitz MJ, **Kates M**, Di Carlo HN. Abdominal Mass in a Phenotypic Female with 46,XY Differences in Sex Development. Urology. 2023 Mar;173:e13-e16.
111. Hahn NM, O'Donnell MA, Efstathiou JA, Zahurak M, Rosner GL, Smith J, **Kates MR**, Bivalacqua TJ, Tran PT, Song DY, Baras AS, Matoso A, Choi W, Smith KN, Pardoll DM, Marchionni L, McGuire B, Grace Phelan M, Johnson BA 3rd, O'Neal T, McConkey DJ, Rose TL, Bjurlin M, Lim EA, Drake CG, McKiernan JM, Deutsch I, Anderson CB, Lamm DL, Geynisman DM, Plimack ER, Hallman MA, Horwitz EM, Al-Saleem E, Chen DYT, Greenberg

RE, Kutikov A, Guo G, Masterson TA, Adra N, Kaimakliotis HZ. A Phase 1 Trial of Durvalumab in Combination with Bacillus Calmette-Guerin (BCG) or External Beam Radiation Therapy in Patients with BCG-unresponsive Non-muscle-Invasive Bladder Cancer: The Hoosier Cancer Research Network GU16-243 ADAPT-BLADDER Study. Eur Urol. 2023 Jun;83(6):486-494.

112. Parimi V, Choi W, Feng M, Fong M, Hoffman-Censits J, **Kates M**, Lombardo KA, Comperat E, McConkey DJ, Hahn NM, Esteves RS, Matoso A. Comparison of clinicopathological characteristics, gene expression profiles, mutational analysis, and clinical outcomes of pure and mixed small-cell carcinoma of the bladder. Histopathology. 2023 Jun;82(7):991-1002
113. Agrawal P, Rostom M, Alam R, Florissi I, Biles M, Rodriguez K, Hahn NM, Johnson BA 3rd, Matoso A, Smith A, Bivalacqua TJ, **Kates M**, Hoffman-Censits J, Patel SH. Clinicopathologic and Survival After Cystectomy Outcomes in Squamous Cell Carcinoma of the Bladder. Clin Genitourin Cancer. 2023 Dec;21(6):631-638.e1.
114. Feng M, Matoso A, Epstein G, Fong M, Park YH, Gabrielson A, Patel S, Czerniak B, Compérat E, Hoffman-Censits J, **Kates M**, Kim S, McConkey D, Choi W. Identification of Lineage-specific Transcriptional Factor-defined Molecular Subtypes in Small Cell Bladder Cancer. Eur Urol. 2023 Jun 27:S0302-2838(23)02830-0.
115. VandenBussche CJ, Heaney CD, **Kates M,** Hooks JJ, Baloga K, Sokoll L, Rosenthal D, Detrick B. Urinary IL-6 and IL-8 as predictive markers in bladder urothelial carcinoma: A pilot study. Cancer Cytopathol. 2024 Jan;132(1):50-59
116. Gore JL, Follmer K, Reynolds J, Nash M, Anderson CB, Catto JWF, Chamie K, Daneshmand S, Dickstein R, Garg T, Gilbert SM, Guzzo TJ, Kamat AM, **Kates MR**, Lane BR, Lotan Y, Mansour AM, Master VA, Montgomery JS, Morris DS, Nepple KG, O'Neil BB, Patel S, Pohar K, Porten SP, Riggs SB, Sankin A, Scarpato KR, Shore ND, Steinberg GD, Strope SA, Taylor JM, Comstock BA, Kessler LG, Wolff EM, Smith AB. Interruptions in bladder cancer care during the COVID-19 public health emergency. Urol Oncol. 2023 Dec 11:S1078-1439(23)00362-9.
117. Dong L, Feng M, Kuczler MD, Horie K, Kim CJ, Ma Z, Lombardo K, Lyons H, Amend SR, **Kates M**, Bivalacqua TJ, McConkey D, Xue W, Choi W, Pienta KJ. Tumour tissue-derived small extracellular vesicles reflect molecular subtypes of bladder cancer. J Extracell Vesicles. 2024 Feb;13(2):e12402.
118. Ladi-Seyedian SS, Ghoreifi A, Konety B, Pohar K, Holzbeierlein JM, Taylor J, **Kates M**, Willard B, Taylor JM, Liao JC, Kaimakliotis HZ, Porten SP, Steinberg GD, Tyson MD, Lotan Y, Daneshmand S, Blue Light Cystoscopy With Cysview Registry Group. Racial Differences in the Detection Rate of Bladder Cancer Using Blue Light Cystoscopy: Insights from a Multicenter Registry. Cancers (Basel). 2024 Mar 24;16(7):1268.
119. Rana Z, Kamran SC, Shetty AC, Sutera P, Song Y, Bazyar S, Solanki AA, Simko JP, Pollack A, McConkey D, **Kates M**, Siddiqui MM, Hiken J, Earls J, Messina D, Mouw KW, Miyamoto D, Shipley WU, Michaelson MD, Zietman A, Coen JJ, Dahl DM, Jani AB, Souhami L, Chang BK, Lee RJ, Pham H, Marshall DT, Shen X, Pugh SL, Feng FY, Efstathiou JA, Tran PT, Deek MP. Prognostic Significance of Immune Cell Infiltration in Muscle-invasive Bladder Cancer Treated with Definitive Chemoradiation: A Secondary Analysis of RTOG 0524 and RTOG 0712. Eur Urol Oncol. 2024 Apr 18:S2588-9311(24)00095-6. doi: 10.1016/j.euo.2024.03.015.
120. Patel SH, Gabrielson AT, Chan S, Schwartz D, Collins C, Singla N, Trock B, Bivalacqua TJ, Hahn N, **Kates MR**. A Phase II Trial of Intravesical Gemcitabine and Docetaxel in the Treatment of Bacillus Calmette-Guérin–Naïve Nonmuscle-Invasive Urothelial Carcinoma of the Bladder. J Urol. 2024 Jul;212(1):95-103
121. Rezaee ME, Mahon KM, Trock BJ, Nguyen TE, Smith AK, Hahn NM, Patel SH, Kates M. ERAS for Ambulatory TURBT: Enhancing Bladder Cancer Care (EMBRACE) randomised controlled trial protocol. BMJ Open. 2024 Jun 10;14(6):e076763.

122. Chang E, Hahn NM, Lerner SP, Fallah J, Agrawal S, Kamat AM, Bhatnagar V, Svatek RS, Jaigirdar AA, Bross P, Shore N, **Kates M,** Sachse K, Brewer JR, O'Donnell MA, Steinberg GD, Viviano CJ, Bloomquist E, Ribal MJ, Galsky MD, Oliver R, Black PC, Al-Ahmadie H, Brothers K, Pohar K, Dinney CP, Feng Z, Downs TM, Porten SP, Smith AB, Bangs R, Psutka SP, Agarwal N, Amiri-Kordestani L, Suzman DL, Pazdur R, Kluetz PG, Weinstock C. Advancing Clinical Trial Design for Non-Muscle Invasive Bladder Cancer. Bladder Cancer. 2023 Sep 25;9(3):271-286. doi: 10.3233/BLC-230056. PMID: 38993184; PMCID: PMC11181701.
123. Johnson Iii BA, Teply BA, Kagemann C, McGuire B, Lombardo K, Jing Y, Langbo W, Epstein JI, Netto GJ, Baras AS, Matoso A, McConkey DJ, Gupta A, Ahuja N, Ross AE, Pierorazio PM, Comperat E, Hoffman-Censits J, Singla N, Patel SH, **Kates M**, Choi W, Bivalacqua TJ, Hahn NM. Neoadjuvant Cisplatin, Gemcitabine, and Docetaxel in Sarcomatoid Bladder Cancer: Clinical Activity and Whole Transcriptome Analysis. Bladder Cancer. 2024 Jun 18;10(2):133-143. doi: 10.3233/BLC-240008. PMID: 39131872; PMCID: PMC11308648.
124. Su ZT, Florissi IS, Mahon KM, Li T, Rezaee ME, Singla N, Patel SH, Townsend JP, **Kates MR**. Varying the intensity of cystoscopic surveillance for high-risk non-muscle-invasive bladder cancer. BJU Int. 2025 Jan;135(1):148-155. doi: 10.1111/bju.16521. Epub 2024 Aug 29. PMID: 39210627.
125. Michel KF, Slinger M, Stambakio H, Talwar R, Luckenbough AN, **Kates M**, Patel SH, Keele LJ, Bivalacqua TJ. Comparison of Apixaban Versus Enoxaparin for Venous Thromboembolism Prevention After Radical Cystectomy: The CARE Trial. Eur Urol Focus. 2024 Oct 22:S2405-4569(24)00189-5. doi: 10.1016/j.euf.2024.10.002. Epub ahead of print. PMID: 39443196.
126. Prasad SM, Shishkov D, Mihaylov NV, Khuskivadze A, Genov P, Terzi V, **Kates M**, Huang WC, Louie MJ, Raju S, Burger B, Meads A, Schoenberg M. Primary Chemoablation of Recurrent Low-Grade Intermediate-Risk Nonmuscle-Invasive Bladder Cancer With UGN-102: A Single-Arm, Open-Label, Phase 3 Trial (ENVISION). J Urol. 2025 Feb;213(2):205-216. doi: 10.1097/JU.0000000000004296. Epub 2024 Oct 24. PMID: 39446087.
127. Baraban EG, Vlachou E, Patel S, **Kates M**, Johnson B, Smith A, Shenderov E, Sharma S, Denmeade SR, Brame A, Han M, De Marzo AM, Matoso A, Hoffman-Censits J. Nectin-4 Expression in Prostatic Adenocarcinoma: An Immunohistochemical Study. Prostate. 2025 Apr;85(5):443-447. doi: 10.1002/pros.24846. Epub 2025 Jan 2. PMID: 39748460.
128. Johnson BA 3rd, Parimi V, Kamanda S, Corney DC, Choi W, Hoffman-Censits J, **Kates M**, McConkey DJ, Hahn NM, Matoso A. Sarcomatoid areas of urothelial carcinoma are enriched for CD163-positive antigen-presenting cells. J Pathol Clin Res. 2025 Mar;11(2):e70021. doi: 10.1002/2056-4538.70021. PMID: 39971624; PMCID: PMC11839278.

Other Publications
Review Articles

1. Sadeghi N, Badalato GM, **Kates M**, McKiernan JM. Management of residual non-retroperitoneal disease following chemotherapy for germ cell tumor. Urol Oncol. 2011 Nov-Dec;29(6):837-41.
2. **Kates M**, Badalato GM, McKiernan JM. Renal functional outcomes after surgery for renal cortical tumors. Curr Opin Urol. 2011 Sep;21(5):351-5.
3. **Kates M,** Matlaga BR. Stones in the elderly. Current Geriatrics Reports. 2014;3(1):14-8.
4. **Kates M**, Singh A, Matsui H, Steinberg GD, Smith ND, Schoenberg MP, Bivalacqua TJ. Tissue Engineered Urinary Conduits. Current Urology Reports. 2015; 16 (3):480-485.
5. Sopko NA, **Kates M**, Bivalacqua TJ. Use of regenerative tissue for urinary diversion. Curr.Opin.Urol. 2015;25 578-85.
6. **Kates M**, Sopko NA, Matsui H, Drake CG, Hahn NM, Bivalacqua TJ. Immune checkpoint inhibitors: a new frontier in bladder cancer. World J.Urol. 2015.
7. **Kates M,** Drake C. Immunotherapy for Prostate Cancer: Why Now. Urology Practice. *In Press*

8. Patel HD, **Kates M**, Allaf ME. Adjuvant Therapy for Urothelial and Renal Cell Carcinoma. Eur Urol Focus. 2020 Jan 15;6(1):3-6. doi: 10.1016/j.euf.2019.04.007. Epub 2019 Apr 26. PubMed PMID: 31031041.
9. Becker R, **Kates MR**, Bivalacqua TJ. Identification of Candidates for Salvage Therapy: The Past, Present, and Future of Defining Bacillus Calmette-Guérin Failure. *Urol Clin North Am*. 2020;47(1):15–21.
10. for bladder cancer. Nat Rev Urol. 2019 Oct;16(10):599-612. doi:10.1038/s41585-019-0220-4. Epub 2019 Aug 21. Review. PubMed PMID: 31434998.
11. Joice GA, Bivalacqua TJ, **Kates M**. Optimizing pharmacokinetics of intravesical chemotherapy
12. Yoshida T, **Kates M**, Fujita K, Bivalacqua TJ, McConkey DJ. Predictive biomarkers for drug response in bladder cancer. Int J Urol. 2019 Nov;26(11):1044-1053. doi: 10.1111/iju.14082. Epub 2019 Aug 1. Review. PubMed PMID: 31370109.
13. Gupta M, **Kates M,** Bivalacqua TJ. Immunotherapy in nonmuscle invasive bladder cancer: current and emerging treatments. Curr Opin Oncol. 2019 May;31(3):183-187.doi: 10.1097/CCO.0000000000000533. PubMed PMID: 30893148
14. Joice GA, Bivalacqua TJ, **Kates M**. Optimizing pharmacokinetics of intravesical chemotherapy for bladder cancer. *Nat Rev Urol*. 2019;16(10):599–612.
15. Patel SH, Metcalf M, Bivalacqua TJ, **Kates M.** Plastic exposure and urological malignancies - an emerging field. Nat Rev Urol. 2020 Dec;17(12):653-654
16. Bo S, Sedaghat F, Pavuluri K, Rowe SP, Cohen A, **Kates M**, McMahon MT. Dynamic Contrast Enhanced MRCEST Urography: An Emerging Tool in the Diagnosis and Management of Upper Urinary Tract Obstruction. *Tomography* 2021. Mar2;7(1) 80-94
17. **Kates M**, Chu X, Hahn N, Pietzak E, Smith A, Shevrin DH, Crispen P, Williams SB, Daneshmand S, Packiam VT, Porten S, Westerman ME, Wagner LI, Carducci M. Background and Update for ECOG-ACRIN EA8212: A Randomized Phase 3 Trial of Intravesical Bacillus Calmette-Guérin (BCG) Versus Intravesical Docetaxel and Gemcitabine Treatment in BCG-naïve High-grade Non-muscle-invasive Bladder Cancer (BRIDGE). Eur Urol Focus. 2023 Jul;9(4):561-563
18. Sepehri S, Rezaee ME, Su ZT, **Kates M**. Strategies to Improve Clinical Outcomes and Patient Experience Undergoing Transurethral Resection of Bladder Tumor. Curr Urol Rep. 2024 Oct 11;26(1):13. doi: 10.1007/s11934-024-01243-3. PMID: 39390270

Book Chapters

1. Badalato GM, **Kates M.** Sadeghi N, and McKiernan JM. Renal Cortical Neoplasms and Associated Renal Functional Outcomes, *Diseases of Renal Parenchyma*. 2012. Prof. Manisha Sahay (Ed.), ISBN: 978-953-51-0245-8, InTech.
2. **Kates M**, Carter H.B., Macura, K. MRI and Active Surveillance, *MRI of the Prostate*. 2016, Thieme Publishers
3. **Kates M**, Bivalacqua TB. Tumors of the Urinary Bladder, *Campbell-Walsh-Wein Urology, 2020*
4. Gabrielson A, Christopher VandenBussche, **Kates M.** Urine Cytology in the Clinical Management of Bladder Cancer. *Comprehensive Diagnostic Approach to Bladder Cancer, 2021, Straive Publishers*

Invited Editorials:

1. **Kates MR**, Wisnivesky JP. Author reply to a letter. *American Journal of Respiratory and Critical Care Medicine.* 2009. 180: 794-5
2. **Kates M,** McKiernan J. Reply to editorial. 2012 *Urology.78:*560

3. **Kates M**, Bivalacqua TB. Editorial. 2018. J Urol. 2018 Nov;200(5):1011-1012
4. **Kates M**. Editorial Comment. J Urol. 2019 Jul 9
5. Chappidi MR, Stimson CJ, **Kates M**, Odisho AY, Bivalacqua TJ. Reply by Authors. J Urol. 2020 Mar;203(3):552-553. Epub 2019 Nov 26. PubMed PMID: 31769720.
6. Patel SH, **Kates M.** Open Versus Robot-assisted Radical Cystectomy: Is Standardization Without Randomization Possible? Eur Urol. 2021 Jan 20:S0302-2838(21)00009-9.
7. Rodriguez K, **Kates M**. Novel intravesical gemcitabine delivery system (TAR-200) for neoadjuvant treatment of MIBC: context is everything. Nat Rev Urol. 2022 Oct;19(10):579-580..
8. Solanki AA, **Kates MR**, Tran PT. Paving the Road to the Future of Chemoradiotherapy in Muscle-invasive Bladder Cancer: 10-year Follow-up of BC2001. Eur Urol. 2022 Sep;82(3):280-282.
9. **Kates M**. Doing Less with More: Towards a New Paradigm of Non-muscle-invasive Bladder Cancer Care. Eur Urol Focus. 2023 Jul;9(4):555-556.

FUNDING

EXTRAMURAL Funding

Current

2021-2026 Title: A study of intravesical enfortumab vedotin for treatment of patients with non-muscle invasive bladder cancer (NMIBC) [EV-10]
PN22032704
Seagen
$1,124,883.00
Role: PI (2% effort)

2022-2027 Phase 3, Single-Arm, Multicenter Study of UGN-102 as Primary Chemoablative Therapy in Patients with Low grade Non-Muscle-Invasive Bladder Cancer at intermediate Risk of Recurrence
Urogen
$300,000
Role: PI (1% effort)

Previous

2015-2016 "Nanoparticle Approaches to Improving the Immunologic Response to Intravesical Chemotherapy for Non-Muscle Invasive Bladder Cancer"
Russell Scott, Jr. MD Urology Research Fund
Urology Care Foundation and American Urological Association Office of Research
$40,000
PI (50% effort)

2015-2016 "T-cell receptor sequencing in urine as a biomarker for bladder cancer"

Adaptive Biotechnology
$50,000
PI (0% effort)

2018-2022 A Phase 2b, Single-Arm, Multicenter Trial to Evaluate the Efficacy and Safety of UGN-102 as Primary Chemoablative Therapy in Patients with Low Grade (LG) Non-Muscle-Invasive Bladder Cancer (NMIBC) at Intermediate Risk of Recurrence (TC-BC-12)
TC-BC-12
Urogen
$142,749
Role: PI (4% effort)

2019-2024 "Intravesical Cisplatin Chemotherapy and Mechanisms of Resistance for NMIBC"
CSDG-19-001-01
Clinician Scientist Development Grant
American Cancer Society
$729,000
Principal Investigator (50% effort)

2019-2024 Phase 1/2 Trial Evaluating the Safety and Tolerability of NanoDoce® Injection and Intravesical Instillation in Subjects with Urothelial Carcinoma
J18180
US Biotest
$427,458
Role: PI (10% effort)

2022-2024 " Phase 1/2 Study of Modern Immunotherapy in BCG-Relapsing Urothelial Carcinoma of the Bladder- (ADAPT-BLADDER)"
R01 CA235681
Noah Hahn (PI)
$628,148
Role: Co-investigator (5% effort)

INTRAMURAL Funding

Previous

2015-2016 "Establishment of a Multi-Institutional Active Surveillance Research Network"
Johns Hopkins Septembeard Fund
Brady Urological Institute
$25,000
Role: PI (0% effort)

2015-2017 "Nanomedicine Approaches for Improving Intravesical Delivery of Chemotherapeutic Agents."

Greenberg Bladder Cancer Institute Research Fund
Johns Hopkins Greenberg Bladder Cancer Institute
$100,000
Role: co-PI (0% effort)

2014-2015 "Development of a novel intravesical agent that prevents radiation hemorrhagic cystitis"
Walter and Lucille Rubin Award
Brady Urological Institute
$20,000
Role: PI (0% effort)

2020-2022 "A Phase II trial for the use of Intravesical Gemcitabine and Docetaxel (GEMDOCE) in the treatment of BCG naïve Non-muscle invasive Urothelial Carcinoma of the Bladder."
Chad Holiday Pilot Project Fund
Brady Urological Institute
$22,500
Role: PI (0% effort)

CLINICAL ACTIVITIES

Clinical Focus:
I have expertise in all areas of urologic oncology, with a particular emphasis on bladder and prostate cancer surgery. With training in both open and minimally invasive approaches, my surgical philosophy is to assess the unique needs of each patient and develop the right treatment plan for their malignancy. As clinical director of the bladder cancer multidisciplinary clinic, I work with the team at the Johns Hopkins Greenberg Bladder Cancer Institute to deliver a personalized approach to bladder cancer.

Certification

Medical, other state/government licensure
NPI: 1487910600
Maryland License: D0079254 Expiration: 9/30/2024
DEA: FK5267706 Expiration 12/31/2026
Maryland Controlled Dangerous Substance License: M83609 Expiration 4/30/2026

Boards, other specialty certification
2/22 American Board of Urology (Board Certified) #21094 Expiration 2/28/2032

Clinical (Service) Responsibilities
Associate Professor, Attending Surgeon (50% clinical)

Clinical Productivity
FY 23: 12,135 wRVU, 329 outpatient surgeries, 106 inpatient surgeries, >500 procedures

Clinical Draw from outside Local/Regional Area
28% of my patients come from outside the state of Maryland

Clinical Program Building / Leadership

2018 Co-Director, Bladder Cancer Precision Medicine Center of Excellence
This program constitutes one of the first programs of its kind for bladder cancer in the United States, and involves a multidisciplinary clinical team working seamlessly with a translational science team to tailor bladder cancer patient management based on cancer genomics and predictive biomarkers.
2020 Director, Bladder Cancer Program
In this current role I lead the clinical and research aspects of the bladder cancer program in the urology department. Under my leadership from 2020 to 2023, surgical case volumes increased 28%, medical oncology visits increased 56% and we underwent a coordinated expansion of our enterprise into the Washington DC area and Southern Pennsylvania. Our research program also grew between 2020 and 2023, with a 28% increase in patients accrued to clinical trials, and multiple PIs with multi-year extramural funding.
2023 Director, Division of Urologic Oncology
In this current role I oversee a team of 14, including 5 urologic oncology faculty members as well as 2 advanced practice providers, 2 nurses, and 5 administrative assistants. Highlights of my tenure thusfar have included the recruitment of 3 faculty members and the successful fundraising of a $300K urologic oncology innovation fund, which provides early stage "seed" funding for junior faculty and trainees.

Clinical Demonstration Activities to external audience, on or off campus

9/7/19 Resident Preceptorship in Robotic Surgery to national group of urology residents, JHU Blalock building
11/18/19 Presented techniques regarding robotic cystectomy to visiting Chinese delegation, JHU Viragh building

Development of nationally/internationally recognized standard of care
Currently serving as Study Chair on EA8212 BRIDGE, which is a potentially practice changing trial that is randomizing newly diagnosed non-muscle invasive bladder cancer patients to standard of care BCG or Gemcitabine/Docetaxel chemotherapy.

EDUCATIONAL ACTIVITIES

Educational Focus
I am a dedicated educator to the medical students, residents, and fellows I interact with on a daily basis. My educational goals are to train technically sound and emotionally caring physicians and surgeons, and I do that through formal didactics and informal apprentice style teaching in the operating room.

Classroom Instruction

JHMI/Regional
2014-2015 Small Group Instructor, genitourinary pathophysiology for 1st year medical students, Johns Hopkins School of Medicine
2020 Lecturer, "Genes to Society" course for second year medical students
2020-2023 Lecturer, "Approach to hematuria", Bayview internal medicine didactics (3 separate lecturers)
National
NA

International
2023 & 2024 Course Director, "Contemporary Techniques in TURBT" American Urologic Association Annual Meeting, instructional course.

Leading a team of 4 faculty, we present case based didactic discussion regarding best practices in transurethral resection for bladder tumors.

Clinical Instruction

JHMI/Regional

2018-2024 As an Attending Surgeon at Johns Hopkins Hospital, I participate daily in surgical education of the resident and medical students

Mentoring

I spend many hours each week mentoring medical student, resident, and fellows in both clinical urology as well as on their research skills and careers. The following is a brief list of trainees that have spent a dedicated research year or summer with me.

Pre-doctoral Advisees /Mentees

2015-2018 Meera Chappidi (mchappi1@jhmi.edu): [Medical Student] currently urology resident UCSF. I mentored Meera during her dedicated research year. Working on clinical bladder cancer projects, she presented at several national meetings and had multiple first author publications. Co-authored article OR40 OR43 OR49 OR50 OR52 OR54 OR58

2015-2017 Aaron Brant (abrant@jhmi.edu): [Medical Student] Currently urology resident NYUI mentored Aaron in his Persky summer research fellowship between 1st and 2nd year of medical school. His project focused on the role of TURBT in accounting for the complete responses seen after neoadjuvant therapy for bladder cancer. He was able to present his work at several national meetings including the AUA and GU-ASCO, and published his work in *Urologic Oncology* article OR 80

2016-2018 Niv Milbar (nmilbar1@jhmi.edu) : [Medical Student]. Currently plastic surgery resident, NYU. Also Mentored Niv during Persky research fellowship on a project assessing our institutional experience with intravesical gemcitabine/docetaxel. Co-authored article OR59

2018-2019 Marcus Daniels (mdaniel56@jhmi.edu): [Medical Student] Currently radiology resident NYU. Spent a dedicated research year with me to advance his knowledge in clinical and translational research in bladder cancer. Co-authored articles OR81 OR84

2022-present Pranjal Agrawal (pagrawa9@jhmi.edu): [Medical Student] Currently an incoming urology resident at Johns Hopkins. Spent a dedicated Persky summer evaluating opportunistic salpingectomy to prevent ovarian cancer at the time of radical cystectomy.

Post-doctoral Advisees /Mentees

2020-present Sunil Patel [urologic oncology fellow]. Co-authored articles OR93 RA15
2022-present Katherine Mahon [urology resident]
2022-present Tony Su [urology resident]
2023-present Michael Rezzae [urologic oncology fellow]

RESEARCH ACTIVITIES

Research Focus

My research seeks to improve care for patients with urologic disorders by 1) Predicting response to current treatments including intravesical BCG for bladder cancer 2) Developing novel therapies and diagnostic modalities to aid in treating and characterizing disease and 3) Assessing outcomes of failure including surgical complications and staging. As a surgeon with one eye towards the laboratory bench and another towards the patient experience, I hope to be well-adapted to generate important questions and tangible solutions for my patients.

Inventions, Patents, Copyrights

4/22/2020 Co-author [Ensign, L, Hanes J, Date A, Bivalacqua T, Kates M].Method to achieve enhanced delivery to the bladder C1402, pending

ORGANIZATIONAL ACTIVITIES

Institutional Administrative Appointments
NSQIP Collaborative Committee
Robotic Steering Committee
Surgical Instrument Committee
SOM Research Council
ERAS Steering Committee
Wellspan Expansion Committee
Surgical Instrument Committee
Clinical Competency Committee

Editorial Board Appointments

2021-present Consulting Editor, *Urologic Oncology: Seminars and Original Investigations*

Journal peer review activities

2015-present *European Urology*
2015-present *Scientific Reports*
2012-present *Journal of Urology*
2013-present *Urologic Oncology: Seminars and Original Investigations*
2012-present *Urology*
2013-present *BJUI*
2017-present *Clinical Genitourinary Cancer*
2018-present *Bladder Cancer*
2018-present *Journal of Clinical Oncology*
2024-present *New England Journal of Medicine*
2024-present *Journal of Controlled Release*
2024-present *Clinical Cancer Research*

Advisory Committees, Review Groups/Study Sections

2016 Grant Reviewer, Medical Research Council (MRC), United Kingdom 2016
2020 Grant Reviewer, Bladder Cancer Advocacy Network John Quale Fellow, 2020
2021 Grant Reviewer, Swiss National Science Foundation, Switzerland, 2021
2022,2023 Grant Reviewer, Bladder Cancer Advocacy Network Career Development Award

Professional Societies

2012-current Gold Humanism Society

2012-current	Alpha Omega Alpha Honor Society
2012-present	American Urological Association
2018-present	Society of Urologic Oncology
2018-current	International Bladder Cancer Network
2020-present	Mid-Atlantic Section of American Urologic Association, Young Urologist Committee Member
2021-present	Bladder Cancer Advocacy Network, BCAN Think Tank Steering Committee (3yr term 9/2021-8/2024)
2023-present	Committee Chair, BCAN John Quale Travel Fellowship Committee

Invited Talks

JHMI/Regional

5/17 Speaker, "Bladder Cancer" ; Bladder Cancer Awareness Month Lunch n' Learn, Johns Hopkins, Baltimore, MD

5/18 Speaker, "Bladder Cancer"; Bladder Cancer Awareness Month Lunch n' Learn, Johns Hopkins, Baltimore, MD

9/19 Guest Faculty/Moderator, National Resident Preceptorship in Robotic Surgery (JHH Campus) , Baltimore, MD

9/19 Speaker, Adaptive Immune Resistance to Intravesical BCG in Non-Muscle Invasive Bladder Cancer: Implications for Prospective BCG Unresponsive Trials, *Amtrak Alliance Meeting,* Philadelphia, PA

12/20 Speaker, "Muscle Invasive Bladder Cancer: A Guidelines Based Approach" Mid-Atlantic AUA UroBrief Webinar Series.\, virtual

1/21 Speaker, "Bladder Cancer—Management with updates on Chemo/Immunotherapeutic Agents", Mid-Atlantic AUA APP Annual Meeting, virtual

3/23 Speaker- Mid-Atlantic Mondays. "BCG Unresponsive", virtual

9/23 Keynote Speaker, "Updates in NMIBC Trials." Advances in the Management of Prostate, Kidney, and Bladder Cancers 2023, Washington DC

National

10/17 Speaker, AUA Bladder Health Alliance Roundtable, National Bladder Cancer Representative, Linthecum, MD

6/18 Speaker, Biology of Bladder Cancer Workshop, National Cancer Institute, Bethesda, MD

4/20 Speaker, "Updates in Muscle Invasive Bladder Cancer", Empire Urology Series, New York, NY (This talk was given via zoom videoconference)

5/20 Moderator, Bladder Cancer & Urinary Diversion Video Session, American Urological Association Annual Meeting (*This conference was cancelled secondary to the COVID-19 Pandemic)*

8/20 Plenary Speaker: "BCG Unresponsive Bladder Cancer: Time to Recalibrate". Bladder Cancer Advocacy Network Think Tank Virtual Session (2 hr virtual session in lieu of meeting)

10/20 Panelist: New Developments and Therapies. Bladder Cancer Summit for Patients and Families (*This conference was made a virtual event secondary to the COVID-19 Pandemic)*

12/20 Plenary Speaker: "Next Generation Clinical Trial Design for BCG Unresponsive NMIBC, Society of Urologic Oncology Annual Meeting (*This conference was made a virtual event secondary to the COVID-19 Pandemic)*

1/21 *Speaker: What They See in my Pee: Uncovering the Mysteries of Urine Cytology.* Bladder Cancer Advocacy Network Patient Webinar (*This conference was made a virtual event secondary to the COVID-19 Pandemic)*

3/21 Speaker: "Predicting response to BCG". FDA/AUA/GBCI Joint Symposium: Drug Development in NMIBC from Scientific, Regulatory, Clinician, and Patient Perspectives. (*This conference was made a virtual event secondary to the COVID-19 Pandemic)*

5/21 Plenary Speaker: American Urologic Association Annual Meeting, Virtual Kickoff Weekend. Bladder Cancer: Management with Updates on Chemo/Immunotherapeutic Agents

8/21 Plenary speaker: BCG and the Tumor Microenvironment. Bladder Cancer Advocacy Network Think Tank (*This conference was cancelled secondary to the COVID-19 Pandemic)*

10/21 Speaker: *Beyond BCG to exploit immunomodulation for bladder cancer therapy* 7th Leo & Anne Albert Institute Bladder Cancer Symposium, Kansas City, MO.

5/22 Speaker, Montefiore Urology Grand Rounds (virtual)

5/22 Plenary Speaker: "Rescue Therapy and BCG Alternatives in Non-Muscle Invasive Bladder Cancer". American Urologic Association Annual Meeting, Society of Urologic Oncology section, New Orleans, LA.

8/22 Speaker, UPenn Urology Grand Rounds (virtual)

10/22 Speaker: "Biomarkers of GEMDOCE response", Urologic Research Society (URS), Charlottsville, VA

12/22 Plenary Speaker: "The future of BCG Naïve Therapy is intravesical", Society of Urologic Oncology (SUO) Annual Meeting, San Diego, CA

2/23 Plenary Speaker "Next generation therapies in NMIBC", ASCO-GU Annual Meeting, San Francisco, CA

4/23 Plenary Speaker "Optimal Management of cN+ MIBC: PRO local consolidation", SUO at the AUA Annual Meeting, Chicago, IL.

9/23 Speaker, "The Rationale for Chemoablation in IR-NMIBC", Albert Institute Annual Meeting. Denver, CO.

2/24 Plenary Speaker "A New Era in the Perioperative Management of Muscle invasive Bladder Cancer", ASCO-GU Annual Meeting, San Francisco, CA

International

8/18 Speaker, XV Paulista Congress of Urology (Sao Paolo, Brazil). Guest Faculty
Case Discussions
- Prostate Cancer Challenging Clinical Case Discussion - International Panel
- Kidney Cancer Challenging Clinical Case Discussion - International Panel
- Bladder Cancer Challenging Clinical Case Discussion - International Panel
- Complications of cystectomy and bladder cancer recurrence after cystectomy (plenary)

Lectures
- "BCG shortage, BCG failure and emerging intravesical drugs"
- Flourescent light guided cystoscopy – new gold standard? (plenary)
- Cystectomy in the elderly over 75 years - contemporary evaluation (plenary)
- Urothelial bladder carcinoma (pT1) - multiple recurrences after intravesical therapy

6/19 Speaker, Pearl River Urology Hi-Tec Forum (Guangzhou, China). Guest Faculty
- Flourescent Blue Light Guided Cystoscopy—The New Gold Standard?

9/19 Speaker, Uro Onco Litoral (Santos, Brazil). Guest Faculty
Case Discussions
- Bladder Cancer Challenging Clinical Case Discussion - International Panel

Lectures

- "BCG Unresponsive Bladder Cancer: When and How to Avoid Cystectomy"
- Muscle Invasive Bladder Cancer Preservation, who, what, and how?
- Bladder Cancer Lymph Node Dissection in 2019

7/20 Speaker, Association of Urologists of Central American and the Caribbean (Meeting cancelled due to COVID-19 and converted to online format). Guest Faculty. "Trimodal therapy for bladder cancer"

6/21 Speaker, European Association of Urology (EAU) Section of Urological Research (ESUR) Monthly Webinar Series. Speaker, "Understanding the tumor micro-environment in urological cancers to improve immuno-therapy"

10/23 Speaker, Updates on a Phase 2 trial of GemDoce for BCG Naïve NMIBC, and Explorations into Mechanisms of Response. Urologic Research Society, Heidelberg, Germany

10/23 Keynote Speaker and Guest Faculty, 15th Hong Kong Urology Symposium, Hong Kong

- "Sequential intravesical gemcitabine and docetaxel for high risk NMIBC"
- "How to Optimize kidney sparing surgery for UTUC"

Background and Interests

Married - Rena Stern Kates, Esq
Children- Eli (9), Amira (7), Henry (4)
Academic – Student Body President, Alamo Heights High School, San Antonio, Tx
Hobbies – Tennis (former Texas team tennis state champion, former college team captain and #1 player), Gardening, skiing, hiking, travel.