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MICHAEL E. PORTER

JENS DEERBERG-WITTRAM

THOMAS W. FEELEY

Martini Klinik: Prostate Cancer Care 2019

"If I were a patient with a severe disease, I would like to find a specialized clinic with high-volume physicians and surgeons who can provide me accurate information about outcomes I could expect from the treatment they provide"

— Hartwig Huland, M.D., Professor, Co-Founder, and Medical Director, Martini Klinik

Since its establishment in 2005, Hamburg's Martini Klinik had single-mindedly focused on prostate cancer care with a commitment to measure long term health outcomes for every patient. A wholly owned subsidiary of the University Hospital Hamburg, Martini Klinik was a "hospital in a hospital" in close proximity to other medical departments and services. By 2019, Martini Klinik had become the largest prostate cancer treatment program in the world with 8,000 outpatient cases and more than 2, 500 surgical cases annually. Patients came from all over Germany and from around the world. A new and expanded facility was under construction to have the capacity to manage more patients with prostate cancer.

Overview of the German Health Care System

Government-mandated universal coverage had been a major principle of the German health care system since the introduction of public health plans in 1883. In the early 1970s, however, steadily rising costs began to threaten universal access for all citizens. Over the last 35 years, reformers had sought to rein in spending growth through capitation models, global budgets, restriction of services, and the introduction of co-payments. Despite these efforts however, health care costs had risen to 11.3 percent of the gross domestic product (GDP) in 2018 up from 9.8 percent in 2000, behind only France, Switzerland, and the United States.[1] The costs of health care in Germany were high and constantly rising due to new drugs, new technologies, price inflation, legislative directives, and the effects of aging, chronic disease, and immigration. Cost pressures had led to declining reimbursement, and pressure to raise productivity that had resulted in more difficult working conditions for doctors and nurses.

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In 2019, anyone residing in Germany was required to have health insurance covering outpatient care and hospitalization. Health insurance in Germany was provided through a public statutory health plan or through a smaller private system. About 10.6 percent of Germans were insured through one of 47 private health plans. By law, only higher-income individuals, civil servants, and the self-employed were allowed to purchase private insurance. Private plans did not participate in the risk-pooling system and set premiums based on actuarial principles, making them less costly for younger and healthier subscribers but far more expensive for older and less healthy subscribers.

In 2017, 87.2 percent of Germans were members of one of 113 statutory plans with each plan providing essentially the same services with premiums set at 14.6 percent of an individual's monthly income up to $5100 (7.3 percent from the employer and 7.3 percent from the employee). Co-payments of $13 per inpatient treatment day and up to $13 for drugs or physical therapy sessions were the responsibility of plan members, but capped at 1-2 percent of gross income per year. [2] All statutory plans were required to participate in a risk-pooling system which involved supplementary payments for subscribers with any of 80 chronic conditions.

Roughly a third of publicly insured patients purchased additional private health insurance which offered access to treatment by senior physicians, single or double rooms in the hospital, and more comprehensive outpatient services such as physical therapy, alternative medicine, and others.

Germans had free choice of providers, and could seek care in any hospital and access outpatient specialists either directly or through a referral from their primary care physician. The system was characterized by a sharp separation of outpatient and inpatient care. There were 1,948 hospitals in Germany in 2017, 29 percent of which were publicly owned and accounted for 48 percent of hospital beds. An additional 35 percent of hospitals were not-for-profit entities owned by foundations or churches that also supported their hospitals when they ran deficits. The remaining 36 percent were for-profit. One third of all German hospitals were reporting financial losses in 2017.

In 2015, Germany had 255 hospital discharges per 1,000 citizens compared to 125 for the U.S. and 156 for the average nation in the Organization for Economic Cooperation and Development (OECD) . Germany had 8.1 hospital beds per 1,000 people in 2015 compared to 2.8 for the U.S. and an OECD average of 4.7.[3] This oversupply of beds had increased competition among hospitals to become more efficient in the face of rising costs and stagnant reimbursement rates.

Hospitals were typically organized into traditional departments by medical specialty that were led by a chief physician who had the ultimate authority. Inpatient physicians were mostly salaried employees. Within the same hospital or department there were often large income differences depending on the doctor's specialization and individual contract.

All hospitals were licensed through regional government hospital plans, which provided some targeted financial assistance to both public and private entities for hospital construction and ongoing maintenance of facilities. Financial constraints of regional governments led to a backlog of investment requests, particularly in publicly owned hospitals.

Hospital reimbursement took place through a heavily procedure based Diagnosis Related Group (DRG) system. Payments for a given DRG were the same for all hospitals as well as for public and private patients. DRGs involved a risk-adjusted price covering the entire inpatient stay including doctors' services and all other costs. Readmissions for the same medical condition within 30 days were generally not reimbursed. Private patients could be charged additional fees for treatment by the chief physician and for preferred rooms.

Most of the 18,356 outpatient physicians in 2016 were licensed through one of 17 regional outpatient physician organizations. New outpatient physician offices required approval unless they were solely designated to treat private patients. Both public and private patients could visit as many physicians as they desired. For public patients, outpatient physicians typically worked under budgets depending on the size of their practice. Since the overall budget for outpatient care was fixed, the actual service fees decreased when volume went up. Many doctors tended to avoid high acuity or complex public patients who required frequent follow-up. Private health plans applied traditional fee-for-service reimbursement to outpatient care without budget restrictions. The net result was significantly higher reimbursement for private outpatients.

Starting in 2004, hospitals were allowed to employ outpatient physicians and operate outpatient clinics, but few hospitals had done so in part because they feared alienating the independent outpatient physicians on whom they depended for referrals. Hospitals also had to obtain licenses for outpatient care from the regional physician organizations, which typically disallowed such requests because hospital provision of outpatient care tended to lower demand for independent outpatient providers. Some hospitals were beginning to buy licensed outpatient physician practices from physicians and employ them in hospital outpatient clinics.

Hospitals had been required to adopt quality management systems beginning in 2000. Bi-annual, publicly available, quality reports had been mandated since 2005, as well as participation in external quality benchmarking. Quality reports included structural measures, process measures, and limited risk adjusted outcome measures at the department level. By 2018 quality reports had covered 250 indicators in 30 specialties. Hospitals reporting below average results on any given measure were required to explain differences to the data-gathering agency, but peer review or quality improvement was not required. No auditing was done to ensure reported data was accurate or complete.[4] Quality metrics formed the basis of certification of German cancer centers which were certified based on the type of cancer treated. OnkoZert, an independent certification institute audited centers using annual peer audits of process and structural measures on behalf of the German Cancer Society who managed the certification system of cancer centers in Germany. By 2017 there were over 1000 organ specific cancer centers certified throughout Germany of which 97 were prostate cancer centers. [5], [6]

Prostate Cancer

The prostate, a small, walnut-sized gland in the male reproductive system, was the most common site of non-skin cancer in men. According the American Cancer Society, there were an estimated 174,650 new prostate cancer diagnoses and 32,620 deaths in 2018.[7] Despite its incidence, prostate cancer was often slow-growing and not fatal for most patients. In 2012, an American male had a 16 percent chance of developing clinically relevant prostate cancer in his lifetime, but only a 2.9 percent risk of dying from it. This understated the actual prevalence, since many more cases went undiagnosed during the patient's lifetime. Autopsies detected prostate cancer in 80 percent of men over the age of 80, most of them clinically insignificant. Patients whose relatives had prostate cancer faced a higher risk of developing clinically significant tumors themselves, suggesting a genetic component to the disease. Behavioral factors, such as high-fat diets, also appeared to increase risk.

The extent of spread of the tumor (Stage I to Stage IV) at diagnosis was the strongest predictor of prostate cancer survival. Patients with cancer localized to the prostate or with only regional spread experienced five-year disease-specific survival of over 97 percent. For those with distant metastases (Stage IV), only 32 percent survived their disease.

Prostate cancer rarely showed clinical symptoms in its early stages. The amount of prostate-specific antigen in the blood (PSA) had become a primary tool for early detection of prostate cancer especially in the US. However, PSA had a high rate of false positives. Only 30 percent of patients with an elevated PSA level had prostate cancer. An elevated PSA could be due to infection or benign growth of the prostate (prostatic hyperplasia). As a result, many specialty societies did not recommend PSA screening, since the test had resulted in over diagnosis and overtreatment. Despite controversies about the use of PSA as a screening tool, there was a general agreement that, with this marker, prostate cancer was detected years before clinical appearance (palpable tumor by digital rectal examination), resulting in a significantly higher rate of cancer detection in a curable stage.

About 30 percent of PSA detected prostate cancers were considered insignificant and did not need immediate treatment. This is the reason why active surveillance had been offered to many patients with early stage disease to avoid overtreatment. In its later stages, after the cancer had spread beyond the capsule of the prostate gland, symptoms included trouble urinating, blood in the urine or semen, and bone pain or tenderness due to metastasis.

Many symptoms associated with prostate cancer could also result from other prostate problems like infection or prostatic hyperplasia, and biopsies were needed for accurate diagnosis. Since localized prostate cancer was a disease that appeared in several different locations throughout the prostate gland, multiple biopsies were usually needed to determine if prostate cancer was present. After many years of evaluation, there had been a recent increase in the use of a new form of magnetic resonance imaging (MRI) called multi-parametric MRI in patients with elevated PSA to identify those who needed a biopsy. Conventional computerized tomography (CT) and MRI scanning were used to detect spread of disease. Molecular imaging technologies had also been employed to further diagnose and guide the treatment of prostate cancer including radio imaging bone scans, the prostate-specific membrane antigen study (PSMA), and positron emission tomography (PET) scanning in conjunction with CT scanning (PET-CT). The real value of the PSA test had become as an after treatment indicator of early cancer recurrence and as a monitor the response to therapy.

Prostate Cancer Treatment

In the late 1970s, the principle treatment for prostate cancer was radical prostatectomy, a complete removal of the prostate gland itself. The procedure cured localized prostate cancer, but patients were nearly always rendered impotent, and many also suffered from urinary incontinence. Prostate cancer treatment choices had been described as "to love or to live". Surgery could also be fatal due to high rates of blood loss during the procedure.

Surgical techniques had also evolved over time. In 1982, Patrick Walsh at Johns Hopkins University Hospital detected the nerves (Nervi eregentes) in close proximity to both sides of the prostate which ran from there to the corpora cavernosa of the penis to enable erection. On that basis he developed the nerve-sparing prostatectomy, a procedure that detected and spared these critical nerves.[8] Also, a better understanding of anatomy resulted in less blood loss and better preservation of the urinary sphincter which improved continence rates. Due to considerably improved postoperative potency, the nerve-sparing technique was applied either as a unilateral or bilateral approach as long as the survival rate was not compromised. However, nerve-sparing surgery was always a balancing act between the ambition to preserve as much quality of life as possible and the risk of compromising cancer control by leaving residual tumor behind if the cancer had infiltrated the preserved neurovascular tissue.[9]

Prostatectomy was a technically challenging procedure. Studies had shown that an experience of approximately 250 cases for an individual surgeon was critical to achieving favorable outcomes. High-

volume surgeons had lower rates of surgical complications, incontinence, impotence, and a better disease-specific survival.[10]

More recent innovations included the introduction of laparoscopic prostatectomy in 1991 and robotic-assisted surgery in 2001. Laparoscopic surgery was performed through small incisions with an endoscope. In robotic surgery, the surgeon controlled the laparoscopic instruments using a joystick, seeking greater precision and better preservation of the nerves associated with the prostate. Robotic surgery required similar experience and skill as conventional prostatectomy, and only robotic surgeons with high case volumes and good technical skills were able to achieve outcomes comparable to experienced conventional surgeons. There was some evidence that robotic surgery could lead to some favorable outcomes in subgroups of patients like the obese who had reduced blood loss and shorter lengths of stay. Robotic surgery had spread the most rapidly in the United States based on patient interest, and more than 80 percent of U.S. prostatectomy patients had robot-assisted surgery.

Long term side effects of prostate cancer surgery were erectile dysfunction and urinary incontinence. Erection problems occurred in up to 80 percent of patients. Minor degrees of urinary incontinence after surgery occurred in 50 percent of men. About 5 percent had more severe problems. Many radical prostatectomy patients suffered from urinary incontinence and erectile dysfunction for the rest of their lives.

The most common alternate treatment to surgical prostatectomy was the application of radiation to destroy tumor tissue. There were four types of radiation therapy:

1. External beam radiation therapy that involved traditional x-rays (photons) as the energy source
2. High-dose brachytherapy, a treatment in which the physician placed several radioactive rods in the tumor tissue for roughly half an hour
3. Low-dose brachytherapy, where small radioactive pellets were permanently implanted into the tumor tissue
4. Proton therapy that used protons as the energy source but was limited to programs with expensive dedicated proton therapy facilities.

Radiation therapy was used for patients not wanting to undergo surgery or who were poor candidates for surgery due to age and co-morbid conditions. The most common short term side effects from external beam radiation therapy were bladder inflammation, diarrhea, and sore skin in the genital area. Brachytherapy caused similar short term side effects. Radiation therapy also resulted in the complete inability to urinate in up to 15 percent of patients. From 1 to 14 percent of patients reported urine leakage or incontinence 3 to 5 years after radiation therapy. Forty to 70 percent of patients receiving external beam radiation therapy and 15 to 40 percent receiving brachytherapy reported erectile dysfunction. Bowel problems were a rare side effect of radiation therapy.

Alternatives to prostatectomy and radiation were active surveillance for patients with low risk localized tumors and focal therapy when the prostate cancer was confined to one small area. Focal therapy involved the removal of just the part of the prostate that was cancerous. Magnetic resonance imaging (MRI) was needed to select candidates for focal therapy. However, this treatment was under evaluation since prostate cancer was commonly a multifocal disease. Up to 30 percent of patients with low risk localized prostate cancer were enrolled in active surveillance programs. The remaining patients with localized prostate cancer either underwent surgery (70 percent), radiation therapy (20 percent), or received other treatment.

Patients with cancer that had spread beyond the prostate generally received hormone depletion therapy to slow tumor growth and chemotherapy to destroy the rapidly growing tissue. Local therapy by surgery or radiation was often performed in such advanced stages, because studies had shown that improved outcomes though treatment by itself was not curative. Next generation hormone depletion medications and selected chemotherapies were available to prolong treatment response if the tumor stopped responding to first-line hormone depletion.

Prostate Cancer Care in Germany

Over 90 percent of prostate cancer cases in Germany were detected through routine checkups provided for men over age 45. Checkups were conducted by primary care physicians or urologists, and included a digital rectal examination, physical examination of the genitals, palpation of the inguinal lymph nodes, and, in some patients, a trans-rectal ultrasound. If the rectal exam revealed a large prostate or a hard or uneven surface, statutory plans covered prostate specific antigen (PSA) testing and, if indicated, prostate biopsies by a urologist. Private health plans covered PSA testing for all men over 45 but it was not used for screening in the majority of men in statutory plans due to a lack of reimbursement.

Diagnosis was challenging because prostate cancer normally grew at multiple points within the prostate which was hard to detect with conventional imaging. This meant that an accurate diagnosis required samples from multiple regions of the prostate. Most urologists collected six to ten samples from a given patient. Multi-parametric MRI was introduced to detect suspicious lesions prior to biopsy providing the opportunity to perform targeted biopsies in addition to random biopsies. X-ray imaging of the skeleton or a CT scan were used to determine whether the cancer had spread. Typical time from exam to confirmation of diagnosis was four weeks.

The referring doctor recommended the treatment modality based on the patient's age, cancer stage, and comorbidities. Typically, younger and healthier patients underwent surgery and older patients with comorbidities received radiation therapy. The indication for surgery versus radiation therapy was often not clear, and for many cases doctors decided based on personal experience and preference. Patients were referred to the urology department of a hospital for radical prostatectomy, or to a radiation therapy center. Radiation therapy centers were either part of a hospital radiology department or an independent facility run by a group of radiation therapists in private practice. While there were 2 proton therapy centers in Germany, prostate cancer patients were rarely referred since it was not reimbursed by any health plan.

In 2005, 30 percent of prostatectomies in Germany had used the nerve-sparing approach. By 2011, this proportion had risen to 55 percent. As of 2010, 72 percent of prostatectomies were performed using an open surgical approach, 11 percent used the traditional laparoscopic technique, and 17 percent used the robotic-assisted laparoscopic approach. The average surgical length of stay in Germany was 12.5 days. Following surgery, 11.3 percent of German prostatectomy patients received hormone depletion therapy and 18.3 percent radiation therapy.[11] In 2017, 410 German hospitals had performed prostatectomies, with two or more surgeons typically operating per center. Half of these hospitals had total volumes below 30 cases per year in contrast to Martini Klinik that performed nearly 2500 (**Exhibit 1**).

Radical prostatectomy was reimbursed at $10,219 for most patients and $16,909 for patients with co-morbidities. DRG rates in Germany were calculated based on audited cost data of the average hospital. DRG reimbursement sought to cover costs but were not meant to result in a profit. The DRG payment included surgery, nursing, and all doctors' fees. Reimbursement was the same for open, laparoscopic, and robot-assisted laparoscopic surgery.[12] Reimbursement of prostatectomies for

patients with private health insurance was 30-40% higher than for public insurance because of care by senior physicians and premium rooms. For robotic-assisted surgery, a 2010 study had found that the direct costs for surgery, depreciation and maintenance of the robotic device and surgical supply alone was around $9,000 for an average case.[13]

Overview of Martini Klinik

Hartwig Huland became interested in prostate cancer treatment as a resident working under Dr. Thomas Stamey at Stanford University Hospital in 1974. Inspired by Stamey's principles of how to organize an academic urology department, Huland returned to Germany to train in urology at University Hospital Hamburg, one of Germany's leading medical centers, where he later joined the faculty. Huland became chairman of Urology at the University Hospital Berlin-Steglitz in 1988. In 1992, by then one of Europe's leading urologists, he was appointed the urology chair at University Hospital Hamburg. Over the next decade, Huland and his colleagues built a reputation for high quality care. The number of radical prostatectomies performed at University Hospital Hamburg rose from 69 in 1992 to 679 in 2004, the largest annual case volume in Germany at the time.

In 2003, Huland, along with Martini Klinik co-founder Markus Graefen, set out to establish a center dedicated solely to prostate cancer care. Martini Klinik, named after a popular neighborhood physician at the end of the 19th century, was launched in 2005 as a wholly owned subsidiary of the University Hospital Hamburg located on the Hamburg campus (**Exhibit 2**). Huland gave up his department chairmanship in 2008 to dedicate himself full-time to the Klinik and to prostate cancer care. By 2018, the Klinik saw about 8, 000 prostate cancer patients as inpatients and outpatients and performed nearly 2,500 radical prostatectomies annually, representing 10% of total German prostatectomy volume.[14] Between 2005 and 2011, Martini Klinik's case volume grew annually by 18.5 percent compared to overall prostatectomy volume growth in Germany of 1.1 percent.

Martini Klinik had 12 faculty members including seven full professors of urology, three assistant professors, and two staff urologists. In 2018, Martini faculty published more than 80 peer-reviewed scientific papers making it the most prolific unit among all University Hospital Hamburg clinical departments. Martini Klinik was leading the project on prostate cancer at the International Cancer Genome Consortium (ICGC), a worldwide initiative to elucidate the genomic changes present in cancers that contributed to the burden of disease throughout the world.

Each faculty member performed between 200 and 250 prostatectomies per year. A junior faculty member trained at Martini Klinik became full faculty after two to three years. One University urologist rotated at Martini Klinik for 12 months for training in prostate cancer treatment. Martini Klinik also trained up to 18 residents and fellows a year.

In addition to general diagnosis and treatment, each Martini faculty member focused on a particular aspect of prostate cancer care such as robotic surgery, quality management, or treatment of erectile dysfunction. One faculty member had specialized in new imaging techniques to detect prostate cancer in its early stages. Another faculty member led Martini Klinik's clinical trial center, which also employed an internist and four study nurses to enroll patients with advanced prostate cancer in new drug trials. (**Exhibit 3**)

Faculty members received a base salary and a bonus based on the number of surgeries they performed, quality metrics, and scientific productivity. However, bonuses were pooled and distributed equally**.** Faculty and staff satisfaction was high, and only one faculty member had left Martini Klinik for a position as head of a urology department in a university hospital. New physicians typically joined

Martini as junior faculty members. After a two-year period, they could become full faculty members with equal salary and voting rights. Policies and practices were determined by consensus among the twelve physicians.

Martini Klinik had recently begun to include associated faculty as part of the Klinik team. Associated faculty were trained in other specialties involved in the prostate cancer care process including medical oncology, radiation therapy, radiology, anesthesiology, psycho-oncology, and pathology . All associated faculty members were specialists in their field and based in their hospital department providing a link between the Klinik and the University Hospital. Associated faculty had become more important as the clinic increased its number of patients. By 2019, the associated radiologist was reading films on site in the Klinik, the medical oncologist had an office in the Klinik and saw patients there. The associated anesthesiologist was based in the operating room at the Klinik.

The Klinik was located in a stand-alone five-story building on the University Hospital campus. The outpatient clinic and doctors' offices were located on the first floor. Three hospital wards with 71 beds, were located on the 2nd and 4th floor of which 30 were single rooms and 41 were double rooms. The wards were fully utilized. Five operating rooms and a 6 bed recovery room were located on the 3rd floor. Fourof the ORs were equipped with DaVinci Xi robot systems. Every working day up to twelve prostatectomies were performed in the five fully utilized ORs. The clinical trial center, outcome study group, and administrative offices were located on the fourth floor.

Martini Klinik employed 95 nurses, each qualified and specialized in prostate cancer care. A detailed care manual covered care plans such as catheter and drainage handling, bladder cleaning, patient mobilization, and continence training. Checklists were used for technically challenging procedures.

Care Process

Three-quarters of patients were referred to Martini Klinik by outpatient urologists following a diagnosis of prostate cancer. The other quarter sought a second opinion after receiving a diagnosis and treatment plan elsewhere.

A central patient administration unit scheduled all patients. Each new patient was assigned to a faculty member who was responsible for the patient over the whole care cycle, including initial examination, pre-operative care, surgery, and post-operative care. Unlike other hospitals, where outpatient clinics were typically run by junior doctors, all Martini faculty members devoted one full working day a week to outpatient visits. The average patient was seen within two weeks after seeking an appointment.

A patient's visit began with physical and trans-rectal ultrasound examinations. All medical records and prior tests were carefully reviewed, and additional biopsies or radiological exams were performed if needed. Martini urologists typically took between 10 and 14 biopsies per patient like most practices. The initial visit averaged 45 minutes. Each patient was discussed by all faculty in a weekly tumor board of dedicated prostate cancer specialists from surgery, radiation therapy, oncology, radiology, nuclear medicine, and pathology. Surgery was recommended only if all participating specialists agreed on that as the treatment of choice. Six percent of the 5000 patients who were originally referred for surgery were ultimately recommended radiation therapy or watchful waiting. Of those 300 patients, approximately 200 were referred annually to the University Hospital Hamburg for external beam radiation therapy and 50 for brachytherapy. The remaining patients received either watchful waiting or radiation therapy in their home community.

Physicians asked the patients to actively include spouses in meetings when treatment options were discussed, since treatment could significantly affect lifestyle. One faculty member described the goal to provide counseling for each patient exactly the way one would counsel their own father.

Surgery was typically scheduled within four to six weeks after the first visit. Patients with risk factors and all patients over age 70 received a cardiac evaluation including stress-ECG and echocardiography to identify patients at risk of cardiac complications. Prior to arrival at the hospital for surgery, patients received a package with detailed information about the care process, the care team, facilities, and an overview of the questionnaires used to document outcomes of care.

On the day of admission basic demographic information was collected at the admission center. The patient next met with a urology resident, who conducted a pre-surgical physical and ultrasound exam and explained the surgery process. The anesthesiologist then met with the patient, discussed anesthesia options, provided sleeping medication for the night before the surgery, and a sedative for the next day. Anesthesiologists were employed by University Hospital Hamburg, with one experienced anesthesiology consultant fully seconded to Martini Klinik as an associated faculty member. Anesthesiology residents rotated through the Klinik. The patient also met with the operating room nurse to discuss particular operating room and bedding needs for patients with comorbidities, prior surgeries, or orthopedic problems, as well as to make sure the patient had a familiar face in the operating room. Every patient was seen by a psychologist. These meetings lasted between 5 and 60 minutes. If a patient showed signs of anxiety or depression, surgery was postponed and psychological counseling or medication was provided. Finally, the assigned faculty surgeon met with the patient during ward rounds the evening before surgery.

Prostatectomies typically lasted 2 to 3 hours. The patient always received a urinary catheter to support healing of the surgical connection between the urethra and bladder. The rate of nerve-sparing had increased steadily. Since 2011, the nerve-sparing technique had been used in more than 90 percent of Martini cases. The remaining patients could not have a nerve sparing approach due to the extent of tumor invasion in the tissue around the nerves that needed to be spared.

After surgery, the patient was transferred to the recovery room for approximately two hours and then to his hospital room. In the three to four days following surgery, the nurses on the ward focused on getting the patient mobile and restoring normal urinary and bowel function, following a detailed checklist. Physicians monitored pain level and complications like pulmonary emboli, infections, and deep vein thrombosis. The drain inserted during surgery was removed 2-3 days post-operatively. The urinary catheter was usually removed 5-10 days post-operatively. The patient was typically discharged after five days, following a wrap-up meeting between the patient and surgeon. At discharge each patient received an information brochure covering different aspects of post-operative management. During this meeting the surgeon also informed the patient about the pathologic results of the removed tumor.

About 20 percent of patients requested psychological counseling after surgery. Patient concerns mostly related to incontinence and impotency and their potential impact on quality of life. Some patients were also still struggling with their cancer diagnosis. Patients showing symptoms of depression were evaluated further and, if needed, outpatient psychotherapy was initiated. Close to discharge, a Martini Klinik social worker helped patients arrange home care, particularly if they were living alone At discharge, patients were always provided with a letter for the referring urologist detailing the diagnosis and therapy as well as next steps for recovery. One week later a comprehensive doctor's letter including all detailed diagnostic data and imaging results was sent to referring doctors.

Brachytherapy treatment was performed by Martini Klinik faculty together with University Hospital Hamburg radiation therapists. External beam treatments were performed at the University Hospital Hamburg radiation therapy department. Approximately 8 percent of prostatectomy patients received radiation therapy in addition to surgery when some cancer remained after the operation. These treatments were also administered at the radiation therapy department. Another 3 percent of patients began radiation therapy months or years after the operation because of indications of relapse.

Depending on their clinical stage, patients could also receive either standard hormone depletion therapy or chemotherapy. These were mostly delivered by private practice urologists, although Martini Klinik offered both treatments. Some patients with metastatic prostate cancer who did not respond to hormone depletion therapy or radiation were treated with new chemotherapeutic drugs at Martini Klinik's clinical trial center. Standard chemotherapy or palliative care for terminally ill patients was administered at the Hamburg oncology department. Every Wednesday and Friday, a faculty member who specialized in the treatment of advanced prostate cancer held a full-day outpatient clinic for patients with metastatic prostate cancer together with the associated faculty oncologist. Aftercare of prostate cancer patients was generally performed by urologists in private practice. However, some patients preferred annual appointments at Martini Klinik for follow-up visits.

To coordinate the clinical care process the Martini Klinik team met frequently. All faculty and residents convened at 7:15 am each morning for a meeting where physicians presented their most challenging cases from the day before. Junior residents were asked to comment on the coming day's more difficult cases including a review of the MRI of the prostate by an associated faculty uro-radiologist. Martini Klinik faculty, the internist at the clinical trial center, a university radiation therapist and a university oncologist met every Wednesday for a tumor board meeting. At this meeting, all participating doctors came to a consensus on each patient's treatment plan before care would proceed, including non-surgical therapy if needed. Every Friday, all Martini faculty, the radiation therapist, oncologist, and uro-pathologist led a pathology conference to discuss complex cases where surgery had failed to completely remove the tumor. An agreement was reached on adjuvant or palliative treatment. Complications such as, significant bleeding, infections, deep venous thrombosis, pulmonary embolus, and others were discussed by faculty at the monthly morbidity and mortality conference. **Exhibit 4** shows the regular meeting schedule of Martini Klinik.

Universal Outcomes Measurement

In 1994, Huland together with Markus Graefen, the co-founders of Martini Klinik, initiated collection of clinical, administrative, and outcome data for every patient treated. Data collection started with a simple excel file that had initially been populated by Graefen, mostly late in the evening. In 1996 Graefen, together with an external consultant, developed a database called "Martini Data" that combined clinical and administrative data with comprehensive medical outcomes. Initially, every patient had been asked to fill out a 13-page quality of life survey for cancer patients (QLQ-C30) to document emotional state and general quality of life, as well as the International Index of Erectile Function (IIEF-5) questionnaire to determine preoperative urinary and sexual function.

In 2012 Professor Huland had led the development of a localized prostate cancer measure set as one of the first four standardized outcome measure sets being created by the newly formed International Consortium for Health Outcomes Measurement (ICHOM). This non-profit had been formed in 2012 as a partnership between Harvard Business School, the Boston Consulting Group and The Karolinska Institute with the goal of driving sustained improvement in the value of health care by defining global standard outcome sets of outcomes that matter to patients, and to enable adoption, implementation, reporting and benchmarking of patient outcomes worldwide.[15]

To initiate the ICHOM process Huland convened an international working group of 28 leading urologists, radiation therapists, oncologists, and patient representatives who aimed to develop 10-15 outcomes measures and related risk factors that were meaningful to patients and clinicians who treat prostate cancer. They used a structured, consensus-driven, modified Delphi method that included teleconferences and surveys over a 7 month period. The ultimate measure set had 30 data elements in several distinct categories consisting of survival and disease control, patient reported functional health status, and acute complications, The baseline clinical characteristics of the patient and the type of treatment received were also included **(Exhibit 5)**[16] A similar measure set for advanced prostate cancer was developed and published by ICHOM and their collaborators in 2015 [17] With two measure sets that addressed all the patients seen in Martini-Klinik they proceeded to change the outcomes they collected to reflect the pre- and postoperative measurements recommended in both standardized outcome measure sets.

Baseline information on every patient included demographics, co-morbidities, tumor stage and characteristics, laboratory data, and functional status assessed by a survey tool designed to address functional recovery, the EPIC-26. [a] Tissue samples as well as urine, semen, and blood specimens were stored for all patients. Information about surgery was also collected including blood loss, pathology, and information about whether the surgical margins were free of disease. Postoperatively all patients were followed for life. One week after removing the urinary catheter, patients were asked to fill in a 4 question survey measuring early urinary function. Six months after surgery patients received an e-mail link to a web-based 30 question survey about complications they may have experienced. These complications utilized a comprehensive standardized classification of surgical complications that graded post-surgical complications into five grades of severity known as the Clavien-Dindo Classification.[18] At six months functional status was again assessed using the EPIC-26. Every year for the first 10 years patients were surveyed about functional status (EPIC-26) and oncology status. After 10 years patients were only surveyed annually about oncologic outcomes. (**Exhibit 6)**

Due to the ever increasing numbers patients being followed, by 2018, Martini Klinik was conducting over 2,000 surveys per month. Return rates in the first three years had started at 75 percent and risen to 85 percent with the introduction of reminders. Surveys had originally been sent to patients by letter, but in 2014 the Klinik had implemented the web-based survey and almost all of the recent patients were using the web-based survey tool. By 2018, data sets for more than 28,000 prostate cancer patients were available. In 2018, Martini Data was not yet fully integrated with the electronic medical record of University Hospital Hamburg. This resulted in considerable reproduction of effort to enter basic information in two locations. In 2019, the University Hospital Hamburg, had begun the process of selecting a vender for a new system wide electronic medical record. Professor Graefen expressed hope that a new electronic record could fully integrate with Martini Data in the future.

Collecting and analyzing outcomes had required a dedicated team. Since 2014 the outcome study group had grown to a group of five members: an IT-programmer, a biostatistician, and three documentation assistants. The database, with its large amount of follow-up clinical data was one of the reasons for starting a research fellowship program. Fellows were responsible for research, publications, and presentations at national and international meetings. In addition, fellows received training in biostatistics and data analysis. To enhance these aspects of the program a collaboration was created

[a] Extended Prostate Index Composite (EPIC) survey. This survey tool that had been developed by the University of Michigan used 26 questions in five domains to measure functional recovery. The five domains were continence, bladder irritation, rectal discomfort, virility, and hormone therapy side effects.

with the University of Montreal to improve the team's ability to assemble and analyze larger and larger data sets due to the fact that all patients were followed for life.

As newer methods for evaluating cancer biology like molecular diagnostics and genomics had emerged the Martini Klinik team were able to link the outcome data collected on every patient with these new diagnostic tools. Techniques such as high throughput gene sequencing and tissue microarrays were now being utilized to collect genetic and molecular data for every tumor sample. By collecting information about the gene activation patterns of different patients, researchers at Martini Klinik were able to link genetic and molecular data with patient outcomes. This research had the potential to improve future treatments by revealing the links between genetic mutations, molecular indicators, and the growth and spread of prostate tumors. The data had helped Martini faculty members better understand the biology of the tumor and to develop nomograms that showed the statistical relationship between patient characteristics, biological characteristics, and the probability for aggressive growth and metastasis. They then were able apply them to predict the prognosis of a particular tumor and determine the probability of lymph node involvement prior to surgery in order to plan an individualized surgical approach. The database was also used to inform patients prior to surgery about the expected oncological outcome and probable functional results like incontinence and impotence.

Beyond Martini Klinik, the collecting and reporting of outcomes had demonstrated dramatic differences in prostate cancer outcomes in Germany. In 2012, a study based on a patient-survey by the largest German public health plans reported surgical complication rates after prostatectomies and other functional outcomes at German hospitals Martini Klinik complication rates were much lower than the German average. 4.5 percent of patients complained of severe urinary incontinence (>5 pads/day) compared to 0.4 percent of Martini Klinik patients. In the study 34.7 percent of Martini Klinik patients reported severe erectile dysfunction one year after operation compared to 75.5 percent for average German public health plan patients.[19]

Standardized outcome measurement using ICHOM measures had begun to spread to other programs in Germany and internationally. The German Cancer Society chose to use ICHOM measures in the certification process for German prostate cancer treatment centers. In 2019 there were 112 certified prostate cancer centers. Beginning in 2019, all newly registered centers were required to measure and report patient reported outcomes using the EPIC-26. For established centers it also became mandatory to measure and report, however centers could write a letter of why they were failing to do this and the plan to enable their reporting. By 2020 all centers would have to meet reporting requirements or lose cancer center certification.

Internationally, the prostate cancer patient advocacy group, Movember, had also initiated an international study of prostate cancer outcomes in over 80 centers in 14 countries using ICHOM measures.[14] This international benchmarking effort in prostate cancer had been adding participating centers annually.

Process Improvement

Every six months, Martini held a 3-hour quality review meeting to analyze outcomes at the individual surgeon level. Every urologist that performed surgeries, including faculty members, junior faculty, and the university urologists, participated. A biostatistician from the outcome study group prepared a roughly 80-slide presentation that reviewed the data and framed the discussion. Reports included basic information like case volume per surgeon, patients' average age and BMI broken down by tumor stage. Data related to surgery such as average blood loss, positive surgical margins, blood

consumption, the removal of lymph nodes, and the ability to spare nerves were reported by the physician. Information about patients' continence, erectile function, ability to have sexual intercourse, general health, and quality of sphincter control were discussed based on patient reported outcomes. Outcomes for the previous six months were compared with the results of earlier years. Traditional open surgery was compared with the robot-assisted approach and led to the publication of the Klinik's analysis of over 10,000 patients treated with the two approaches. This study found small outcome advantages with the robotic approach (lower blood loss, faster removal of urinary catheter postoperatively).[20] Despite the fact that the main oncologic and functional outcomes were similar with each technique, Professor Huland felt that future refinements in robotic technology, such as the inclusion of haptics to enable sensing of tissue density, would ultimately lead to better outcomes with the use of robotic technology.

Highly experienced surgeons were able to achieve functionality and quality of life while achieving a high percentage (>95 percent) of fully extracted tumors with negative surgical margins. Outcome performance data played a role in decisions about whether to promote younger surgeons to faculty status. Surgeons had individual counseling about their outcomes by the department chair. Those with higher than expected complication rates were asked to assist in operations with more experienced surgeons, while faculty members with excellent results were tasked with observing those with less strong results perform their next operations.

Professor Huland, the most experienced surgeon, for a long time had high negative surgical margin rates of about 95 percent in tumors confined to the prostate while achieving excellent functional results. When his rate of positive surgical margins rose from 5 to 8 percent in 2011, Huland participated in the same quality improvement regimen as his junior faculty members. After training with those faculty members achieving better surgical margins, Huland's positive surgical margin rate dropped to 3.5 percent.

Regular meetings were an essential part of care improvement. Every Monday a resident lecture reviewed recent prostate cancer care literature chosen by the faculty member in charge of continuing education. Each faculty member was also tasked with reading different leading medical journals on a rotating basis, allowing the physicians to cover 27 journals every nine weeks. Every Tuesday, the faculty gathered for a literature review meeting, during which one of the faculty presented. Faculty members also selected an "article of the month", which was translated into German and provided to all Martini Klinik referring physicians and posted on the Martini website. Monthly morbidity and mortality conferences reviewed patients with complications and the associated literature on the topic.

The last Wednesday of every month, an interdisciplinary uro-oncological tumor board was held for outpatient urologists to discuss difficult cases together with Martini Klinik faculty, university radiation therapists, oncologists, and pathologists. The meeting aimed to improve the urologists' diagnostic skills and treatment recommendations. Of the 25 physicians participating, half were urologists in private practice and half were physicians from the University Hospital Hamburg and Martini Klinik. A detailed agenda of the meeting topics was developed six months in advance and distributed to outpatient urologists.

Martini Klinik created a continuous patient education program in 2018, starting with a preoperative seminar for nutritional, physical, and mental preparation for prostate cancer surgery. Every week on Thursday inpatients and outpatients were invited to join a seminar on obtaining continence and erectile function after surgery. Once a month there was a course for nutrition designed to prevent cancer recurrence. Every two years, Martini Klinik invited referring doctors from all over Germany to the Martini Seminar where faculty members presented and discussed medical outcomes and recent scientific data coming from the Martini Klinik.

Clinical Improvement

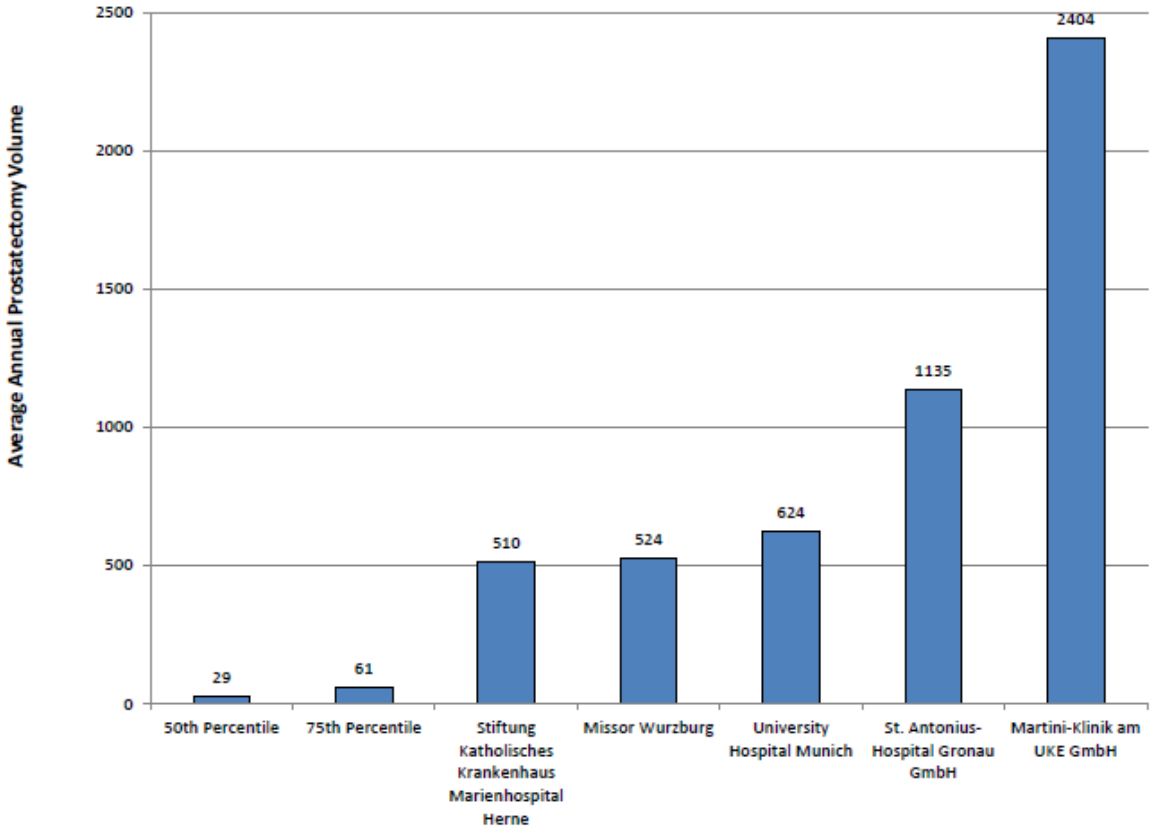
Martini Klinik staff had adopted a number of new surgical techniques over time. For example, in 1994 anesthesiologists began using low volume intravenous fluid replacement intraoperatively after finding that it reduced intraoperative blood loss. In 2004, Huland introduced intraoperative frozen-section analysis of the whole neurovascular tissue-adjacent circumference of the prostate (NeuroSAFE). This laborious intraoperative processing of the removed prostate by the uro-pathology department enabled more precise excision of prostate tissue and better preservation of adjacent nerves. The pathology department had employed two pathologists and four technicians to perform the NeuroSafe analysis. By regularly applying NeuroSAFE during surgery, Martini Klinik faculty were able to increase the percentage of nerve-sparing surgery from 81 percent in 2005 to 93.7 percent in 2011. In the same period, average positive surgical margins for all tumor stages went down from 22% to 15%.[21]

In 2007, a paper published by a group of Korean radiologists was discussed at the literature review meeting. The findings in this publication suggested that the amount of urethral sphincter muscle covered by the prostatic apex varied widely from patient to patient. The authors also demonstrated a strong correlation between postsurgical incontinence and loss of sphincter muscle during surgery.[22] Martini faculty member Thorsten Schlomm decided to adjust his surgical technique to preserve more intra-prostatic muscle. By 2008 he had developed a new approach in which he carefully peeled the prostate off the associated muscle. Schlomm's new technique had already resulted in better results by July 2008, with patients registering one-week urinary continence rates that were 40 percent better than predicted. These outcomes were reviewed at the clinic's regular six month quality review meeting in August 2008. Schlomm explained his new procedure, which he called full-length urethra preservation (FFLU). Huland and Graefen, observed Schlomm's new technique. By mid-August 2008, Huland switched to FFLU, and Graefen followed in late September 2008 after a short introduction phase involving five to ten cases. Within a few weeks of adopting the technique, all three surgeons' one-week urinary continence rates rose from 50 percent to 70 percent. By the end of 2008, all Martini faculty members had adopted the FFLU technique. Their already high one-year continence rate of 94.7 percent climbed further to 96.9 percent.[23]

Future Directions

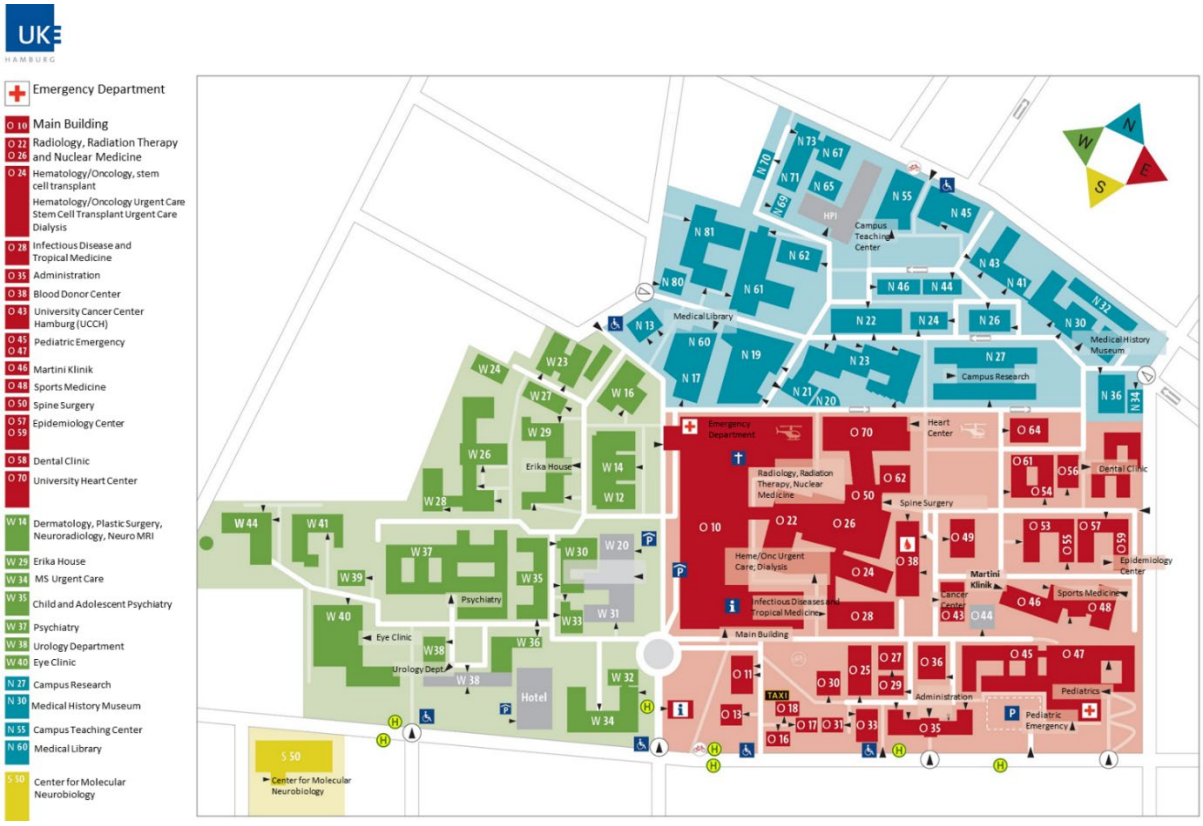
To increase capacity, Martini Klinik decided to create a new building scheduled to open in 2022. Planning for this new building with 8 operating rooms was completed and the construction began in the spring 2019. The building was designed as an integrated practice unit (IPU) for patients with prostate cancer. The new center provided opportunities for new staff and services. There would be space for the new associated faculty members, new MRI facilities to enable new techniques like guided biopsies and focal therapies, and a telemedicine center to facilitate second opinions, treatment options discussions, and patient counseling. Patient space was also planned for a complementary medicine education center, nutrition education, and rooms for physical activities. New research space included laboratories for a Martini Institute for basic science to develop new tools for the treatment of advanced prostate cancer and expansion of the clinical study center due to an increasing number of Martini Klinik patients on clinical trials as well as cooperation with other national and international partners.

Exhibit 1 Prostatectomy Case Volume in German Urological Departments, 2017



Source: Casewriter, based on company documents.

Exhibit 2 Site map of Hamburg University Medical Center, Martini Klinik and Cooperating Departments



Source: Martini Klinik company documents.

Exhibit 3 Martini-Klinik Faculty Urologists and Their Areas of Focus

Name	Year Joined	Role
Hartwig Huland	2005	Founder Martini-Klinik
Professor Urology		Coordination Basic Science
Markus Graefen	2005	Founder Martini-Klinik
Professor Urology		Data Management
Hans Heinzer	2007	Salvage surgery
Professor Urology		Organization Events
Alexander Haese	2008	Robot-assisted surgery
Professor Urology		Serum and urine markers
Georg Salomon	2008	Imaging techniques
Professor Urology		Focal therapy
Thomas Steuber	2008	Therapy of advanced cancer
Professor Urology		Clinical trials
Imke Thederan	2008	Complementary medicine
Urologist		OR - Coordination
Mentoring of residents		
Uwe Michl	2010	Quality management
Urologist		
Lars Budäus	2013	MRI-guided biopsies
Assistant Professor Urology		
Derya Tilki	2015	Coordination of outcome studies
Professor Urology		Mentoring of research fellows
Hendrik Isbarn	2017	Treatment of erectile dysfunction
Assistant Professor Urology		
Tobias Maurer	2018	Radio-guided surgery
Assistant Professor Urology		

Source: Casewriter, based on company documents.

Exhibit 4 Meeting Schedule of Martini Klinik

Meeting	Topic	Participants	When
Morning conference	Last day's surgical cases,current patients on ward,scheduled surgeries of the day	MK faculty and staff	7:15 am, daily
Resident lecture	Resident presenting a topic on prostate cancer from recent literature	MK faculty and staff	Every Monday morning
Tumor board	Discussion of treatment plan for all MK patients prior to admission	MK faculty and staff, medical oncologist, radiation oncologist, clinical trial center representative	Every Wednesday
Pathology conference	Discussion of all patients with unexpected pathologic findings (positive lymph nodes, positive margins)	MK faculty and staff, uro-pathologist, medical oncologist, radiation oncologist	Every Friday
Radiology conference	Discussion of new cases scheduled for surgery	MK faculty and staff, uro-radiologist	Every Tuesday, Wednesday, and Thursday
Nuclear medicine conference (PSMA-PET)	Discussion of locally advanced and metastasized cases	MK faculty and staff, nuclear medicine radiologists	Every Thursday
Advanced prostate cancer clinic	Discussion of patients with advanced prostate cancer	MK faculty leading clinical trial center, oncologist	Every Wednesday and Friday
Literature review	Discussion of recent relevant articles in leading journals	MK faculty and staff	Every Tuesday
Interdisciplinary uro-oncological tumor board	Discussion of difficult cases from outpatient urologists and MK faculty	MK faculty and staff, outpatient urologists, oncologist, radiation oncologist	Last Wednesday of every month
Morbidity and mortality conference	Discussion of all cases with complications	MK faculty and staff, nurses, quality management, radiation oncologist, pathologist, oncologist	Monthly
Quality Review	Comparison of outcomes of MK surgeons	MK faculty, junior faculty, seconded urologist	Every 6 months
Martini Seminar	MK outcomes and current research	Outside urologists	Bi-annually

Source: Casewriter, based on company documents.

Exhibit 5 ICHOM Standard Set for Localized Prostate Cancer

	Measure	*Details*	*Measurement Timing*	*Data Source*
Baseline	Age	Birthdate	Before Treatment	Patient Reported
	Body Mass Index	Height & Weight		Clinical Data
	Date of Diagnosis	Date of Diagnosis		
	Charlson Score[a]	Patient reported		Patient Reported
	PSA	Most recent before diagnosis		Clinical Data
	AJCC Clinical Stage[b]	cT,cN & cM category		
	Number of biopsy cores involved	Cores taken/cores positive		
	Greatest % involvement of biopsy cores	Greatest % involvement of biopsy cores		
	Biopsy Gleason Score[c]	Highest Primary and Secondary Gleason Grade		
	AJCC Pathologic Stage[d]	pT and pN category	Following Surgery	
	Margin Status	Negative/Positive (if positive focal or multifocal)		
	Prostatectomy Gleason Score	Highest Primary and Secondary Gleason Grade		
Acute Complications (Within 6 months of Treatment	Surgery Patients: Clavien Classification[e]	Presence or Absence of Grade 3 or Greater	6 Months After Treatment	Clinical or Patient Reported
	Radiation Patients: CTCAE Classification[f]	Presence or Absence of Grade 3 or Greater Including Name of Event		
Survival & Disease Control	Overall Survival	Date of Death	Annually Until Death	Administrative Data
	Cause-Specific Survival	Was cause prostate Ca on Death Certificate?		
	Metastasis-Free Survival	Date of Metastatic Disease and How Diagnosed		Clinical or Patient Reported
	Biochemical Recurrence-Free Survival	Date of PSA Recurrence		

[a] Charlson Co-morbidity Index is a weighted index to predict risk of death within 1 year of hospitalization for patients with specific comorbid conditions.

[b] The AJCC (American Joint Commission on Cancer) staging system is a classification system developed for describing the extent of disease progression in cancer patients. cT,cN & cM refers to clinical evaluation of the tumor size, number of involved lymph nodes, and whether the tumor has metastasized

[c] Gleason Score is a grading system to determine the aggressiveness of a prostate cancer and in a range of 6-10 higher scores are more invasive

[d] The AJCC (American Joint Commission on Cancer) staging system is a classification system developed for describing the extent of disease progression in cancer patients. pT and pN refer to the pathology of the tumor on lymph nodes

[e] Clavien Classification is a scoring system for post-operative complications that rate the severity of the complication. Scores are 1-5 with 5 the most severe

[f] CTCAE Classification refers to the Common Terminology Criteria for Adverse Events system for grading adverse events in cancer therapy on a scale of 1-5 with 5 the most severe.

Patient Reported Health Status	Urinary Incontinence Scores	EPIC-26[g]	At Baseline, 6 Months After Treatment and Then Annually for 10 Years	Patient Reported
	Urinary Irritative/Obstructive Scores	EPIC-26		
	Bowel Symptom Scores	EPIC-26		
	Sexual Symptom Scores	EPIC-26		
	Hormone Symptom Scores (Pts on ADT)	EPIC-26		

Source: Adapted from Martin NE, Massey L, Stowell C, et al: Defining a standard set of patient-centered outcomes for men with localized prostate cancer. Eur Urol 2015 67:460-467. https://www.ncbi.nlm.nih.gov/pubmed/25234359 PMID: 25234359.

[g] EPIC-26 The Extended Prostate Index Composite Survey. A tool that uses 26 questions in five domains to measure functional recovery. The five domains are continence, bladder irritation, rectal discomfort, virility, and hormone therapy side effects.

Exhibit 6 Adaption of ICHOM Data Collection by the Martini Klinik

Time Collected	Data Type	Outcomes Assessed
Preoperatively	Clinical history, labs, Disease Stage, Gleason Score, Charlson Co-morbidity score, EPIC 26	Baseline
Operative	Operative findings	Pathology, Gleason score, blood loss, margins
1 week postoperatively*	4 question survey about early continence*	Early urinary continence*
6 months postoperatively	Clinical and patient reports for Clavien Grades >III EPIC-26	Post-operative complications Patient reported functional outcomes: • Bladder function • Rectal function • Erectile function • Hormone therapy complications
Yearly postoperatively for first 10 years	EPIC 26	Patient reported functional outcomes as above
Yearly for life	Brief 7 question survey	Oncologic Outcomes

Source: Adapted from Das Martini-Prinzip. Hartwig Huland (Ed.), Markus Graefen (Ed.), Jens Deerberg-Wittram (Ed.)

Note: * The one week assessment of urinary continence was not part of the ICHOM measure set but done at this time so surgeon could recall specifics of the case.

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