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Aurora Health Care Metro Region Cancer Program Annual Report 2000

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2000 Annual Report

Prostate Cancer
# Cancer Services Report

## Table of Contents

### Metro Region Cancer Service Reports
- William Laffey, MBA - Regional Director of Cancer Services
- Jeffrey Derus, MD - St. Luke’s Medical Center
- William Donegan, MD - Sinai Samaritan Medical Center
- Rakesh Jagetia, MD - West Allis Memorial Hospital
- Jonathan Treisman, MD - Hartford Memorial Hospital
- Lisa Robinson, RHIA, CTR - Regional Clinical Data Registries

### In Depth Reports - Special Focus on Prostate Cancer
- Screening Detection and Prevention - Mark Waples, MD
- Surgical Management - Jeffrey Derus, MD
- Prostate Seed Implants - Mitchell Pincus, MD
- Prostate Seed Implants Behind the Scenes - Steve Belanger, BS, CMD
- Treatment of Incontinence and Sexual Dysfunction - Stuart Fine, MD
- Current Aspects of Hormonal Treatment - Brian Butler, MD, FACS
- Chemotherapy for Prostate Cancer - Ronald Hart, MD
- Pathology of Prostate Cancer - Jorge Pellegrini, MD
- Recent Advances in Prostate Cancer Genetics - Angela Mengelt, MS
- Oncology Program for End of Life Care - Mary Runge, MSN
- Metro Region Research Studies for Prostate Cancer

### Cancer Conferences in the Metro Region

### Regional Activities in Aurora’s Metro Region
- Community Outreach and Events
- Vince Lombardi Cancer Counseling Services
- Support Groups
- 1999 Site Table and Statistical Review
Prostate cancer is the second leading cause of cancer death in men. The five-year survival rate for prostate cancers discovered in the early stages is 100%. If these statements seem conflicting to you, you're not alone. The challenge of education and early detection is one of the reasons for the focus of this year's Metro Region annual report. Many symptoms of prostate cancer may be similar to those caused by benign conditions such as infection or prostate enlargement. A number of men feel that testing for prostate cancer is difficult or uncomfortable, and would rather go untested.

The inherent danger in this 'benign neglect' is that 700 Wisconsin men are expected to die this year from prostate cancer, comparable to the number of deaths expected from breast cancer. While our annual report is often geared toward health professionals, we truly hope that by focusing on this disease site we will continue to spread the message of testing and early detection espoused by Senator Bob Dole at our first annual Men's Health Conference.

Within this report, physicians and Aurora Health Care staff discuss prostate cancer from the viewpoint of detection, screening, medical and surgical treatments, seed implants, pathology, genetic factors and others. We share with you our care, compassion, intellect, technological advances and cutting-edge research. We have treated more cancer patients than ever and continue to enhance our reputation as an outstanding cancer program.

Most importantly, we hope that this annual report will cause additional men to seek early detection of prostate cancer. In that way, the partnership between patient and provider will allow us to maximize our success in cancer treatment.
Looking back on the activities of the cancer committee during the past year, several exciting developments have occurred. On September 26, 2000 we had our first Men's Health Fair at the Italian Community Center. The focus of the health fair was prostate cancer with Senator Bob Dole giving the keynote speech, “Life After Prostate Cancer”. It was a wonderful presentation and over 500 people attended. Other health issues covered at the health fair were hypertension, stroke prevention, glaucoma and coronary arterial disease. Numerous physicians were on hand to answer questions. I would like to thank them for volunteering their time. I would like to give a special thanks to Bob Reitman, Gary Grunau and Ken Sanders for sponsoring the golf outing the previous day and raising money to support the Men's Health Fair and prostate cancer awareness. The health fair was such a success that plans are already in the works for the second annual Men's Health Fair next year.

Last year St. Luke's Medical Center was notified that it received accreditation for its cancer services for a three year period from the American College of Surgeons. In 1999 Marija Weidman was recruited and hired as a new business and market development representative for the cancer services in the metro region. She previously served in other management roles within Aurora and began her new job in January 2000. She is a tremendous asset to the cancer program at St. Luke's and throughout the region.
Several Vince Lombardi Cancer Clinics (VLCC) have opened this past year, with the help of Patty Abella, Regional Manager. West Bend opened their doors in April 2000. Melody Wilson was the guest speaker for the grand opening and over 800 people attended. Another new facility opened in Lakeland in November 1999. We are also looking forward to expanding to Oshkosh, Fond Du Lac, Green Bay, Burlington, and western Waukesha in the future. I would like to congratulate Kerry Twite, RN, CNS on her promotion to regional clinical nurse specialist for all Vince Lombardi clinics and radiation oncology.

The community outreach activities that have taken place throughout the year can be found in the Education Outreach Activities in the annual report. The Vince Lombardi Golf Classic and Ball was, again, a great success. Special thanks for the generosity of the volunteers and the support from the Vince Lombardi Cancer Clinic. The Breast Cancer Race For Cure took place on October 24, 1999. There were approximately 2900 participants who raised over $150,000. Of that money, 25% went to the National Susan G. Komen Foundation for research and 75% went for grant requests in the metropolitan Milwaukee area.

In 2000 we continued our quarterly meetings of the regional cancer committee which consists of representatives from West Allis Memorial Hospital, Sinai Samaritan Medical Center, St. Luke’s Medical Center, and now Hartford Memorial Hospital. The Regional Cancer Committee has continued to work toward integrating the cancer programs throughout the Aurora metro area.

In the fall of 1999, St. Luke’s opened the first operational Gamma Knife in Wisconsin. The Gamma Knife is a state-of-the-art highly technological tool dedicated to performing brain tumor surgery. The Gamma Knife radiosurgery precludes the need for open brain surgery or hospitalization. The patients are treated as outpatients. A new CT simulator is now being employed to allow more precise treatment planning in radiation oncology. St. Luke’s Medical Center will be the first institution in the city to have the new CT simulator and will also be a demonstration site for GE.

It was an honor and pleasure to chair the cancer committee at St. Luke’s. I would like to personally thank the members for their hard work and dedication.
During the past year a number of initiatives have been taken at Sinai Samaritan Medical Center to improve care for cancer patients. A working group was established to implement a tracking system in clinics to remind physicians when their patients are due for routine mammograms and pap smears. In a formative stage is a quality improvement plan that will use the PDSA model (plan, do, study, act) as a framework to improve oncology services. Oza Holmes, RN was on the planning committee for the Susan G. Komen Race for the Cure that was held for the first time in Milwaukee on October 24, 1999 and which was a large success. Seventy-five percent of the funds raised through this event support education and services for breast cancer patients in the greater Milwaukee community.

The nationwide breast cancer prevention trial known as STAR began in July 1999. Sinai Samaritan Medical Center is one of more than 400 recruitment centers across the country. Julie Jensen, RN serves as the coordinator for institutions in Milwaukee and as far north as Green Bay. The research activity at Sinai Samaritan Medical Center is now documented and published in a brochure that lists all active protocols at Aurora hospitals, a project of the committee of research nurses. This ready reference helps physicians make patients aware of additional options for treatment. A modern treatment method that became available to our patients during the year was the Gamma Knife installed at St. Luke’s Medical Center. This equipment permits more effective radiation therapy for brain cancers. Many thanks to Phil Whitton, Regional Manager of radiation oncology for coordinating this effort.

Sinai Samaritan Medical Center contributed to the patient care evaluation study of early stage breast cancers of the American College of Surgeons.
Results at Sinai Samaritan Medical Center will be compared with those from institutions across the nation. The creation of a Vince Lombardi Cancer Clinic at Sinai Samaritan Medical Center was discussed, and we look forward to this development.

The Cancer Committee at Sinai Samaritan Medical Center has gradually taken on a broader look since metro regionalization. A uniform statement describing our cancer committees has been prepared for the bylaws of each metro institution. We enjoy our working relationship with Mr. William Laffey, the Aurora cancer services director, and during this year welcomed the return of Marija Weidman in her new capacity as the cancer services manager for Business and Market Development and the services of Kristin Niendorf and Angela Mengelt, the Aurora genetic counselors.

Barbara Haag-Heitman worked with the site implementation group at Sinai Samaritan Medical Center to streamline screening and diagnostic services for breast cancer patients. Close connections with sister hospitals is also anticipated through a combined cancer registry software system being planned by Lisa Robinson, the Aurora Metro Region clinical data registries supervisor.

2000 was an eventful year, one that saw new things happening and progress being made. It was a privilege for me to work with the talented and dedicated individuals who compose the Cancer Committee at Sinai Samaritan Medical Center. On behalf of the Cancer Committee, I wish to thank all who contribute to the high quality of cancer care at our institution.
A significant number of changes have taken place at West Allis Memorial Hospital over the past year. Most noticeable are the physical changes, with a new Women's Pavilion under construction and a new Radiation Oncology suite in the planning stages. A comprehensive prostate cancer program has been expanded, now having the availability of both prostate seed implantation and cryoablation. Our commitment to excellence in cancer treatment, however, is exemplified not only with building projects and technology, but also in the dedicated and talented professional staffs who provide care, education and treatment. As newly elected Chairman of the Cancer Committee, I am pleased to be able to work more closely with these individuals as we try to meet the challenge of providing high quality cancer care at West Allis Memorial Hospital. I would like to extend the appreciation of the Cancer Committee and the entire organization to Dr. Maury Berger, who chaired the committee for many years before making the decision to relocate his practice outside the Midwest. His dedication to the cancer program will be remembered.

Committee members Dr. Terry Roth and Dr. Craig Evans were instrumental in the metro region's establishment of a committee to explore membership in the American College of Surgeons Oncology Group (ACOSOG). This organization is dedicated to performing prospective, randomized trials evaluating surgical therapies in the management of patients with solid tumor malignancies.
As a result of this leadership, over twenty Aurora physicians have been accepted for membership and awarded the right to participate in the American College of Surgeons Oncology Group national trials for their patients.

Committee members were also most active in the educational component of cancer care. Many members attended presentations given by the Washington, DC based Oncology Roundtable on “Redefining the Patient Experience in Breast Cancer Care”. Other members participated in the Southeastern Wisconsin Cancer Conference on malignant melanoma, and still others volunteered their time at Aurora’s first Annual Men’s Health Conference, answering questions for the 500 attendees in a private, consultation-like setting.

Finally, we were pleased to organize patient care evaluation studies around the topics of brain tumor and hepatocellular carcinoma, and participate in the Public Broadcasting System’s series on End of Life issues. The educational aspects of cancer care, whether in weekly cancer conferences or annual seminars, are most important to our Cancer Committee members. Through these efforts, we afford our patients access to the latest treatments in cancer care and the combined energy of health professionals with varied fields of expertise.
Hartford Memorial Hospital has seen explosive growth, and Hartford Memorial Hospital has been responding with enhancement of services. This includes consolidation of cancer services and the initiation of a formalized cancer program. This new program will enhance the quality of patient care through prevention, early diagnosis, pretreatment evaluation, staging, treatment, rehabilitation, surveillance for recurrent disease, psychosocial support and the hospice concept.

The Cancer Committee offers the opportunity for multidisciplinary collaboration on projects that strive to improve cancer care at the institution. One collaboration has been between Hartford Memorial Hospital and St. Joseph’s Hospital in West Bend. Patients are now being offered Radiation Oncology services at St. Joseph’s and outpatient chemotherapy services at both the new West Bend Vince Lombardi Cancer Clinic as well as the Vince Lombardi Cancer Clinic in Slinger. The medical/surgical unit at Hartford Memorial Hospital was also named the Oncology Unit with Linda Martin as its Director. The cancer registry data will be maintained on a modern database platform.
Tumor board is one of the best ways to integrate disciplines of care for cancer patients. In a community setting, especially with commuter physicians, attendance is a special challenge. Although video conferencing has been proposed, the Hartford Memorial Hospital Cancer Committee has proposed exploring the development of an on-line tumor board, in which physicians and other health professionals can log-on and provide input.

The Hartford community has shown its emotional involvement in the pursuit of cancer treatment in its wonderful turnout for the Relay for Life, an annual event at Hartford High School.

The establishment of a Cancer Committee at Hartford Memorial Hospital has been an exciting development. The next exciting step will be its integration into the Metro Regional Cancer Program.
In October, 2000, the Cancer Registrars of the Metro Region joined their peers at the 25th Anniversary Meeting of the Wisconsin Cancer Registrar's Association. The keynote speaker for the event was April Fritz, RHIA, CTR, a former Milwaukee registrar who currently works for the National Cancer Institute. Ms. Fritz noted the extensive strides made in cancer over the last 25 years. It is hard to believe that in the past, registrars were merely responsible for collecting information on approximately 20 data elements for each cancer patient accessioned into a hospital's tumor registry!

Today the Aurora Metro Region's ACOS approved cancer registries date back 15 years and currently collect well over 170 data elements per patient. More importantly is the fact that this data can be accessed immediately through computerized software and can subsequently be reported out in a variety of combinations and formats. Metro Region physicians, administrators and key personnel may request information from this rich database for purposes of assessing patient outcome, facilitating research, assisting with marketing, administrative planning, and quality benchmark purposes.

In 1999, the registries of Aurora Health Care's Metro Region including Hartford Memorial Hospital, St. Luke's Medical Center (including the main and South Shore campuses), Sinai Samaritan Medical Center, and West Allis Memorial Hospital accessioned 3,001 new cancer cases (See Site Table, page 62), satisfied over 30 requests for data, participated in the American College of Surgeons (ACOS) patient care evaluation (PCE) study on malignant melanoma, and voluntarily submitted abstracts for a quality outcome study. In addition, the registrars routinely coordinate and attend site-specific cancer case conferences, participate in cancer committee meetings and complete physician-assisted quality control studies on 10% of the analytic case load.
In compliance with state statute and ACOS requirements, new cancer cases are submitted to the Wisconsin Cancer Reporting System and year-end data is blinded and submitted to the National Cancer Data Base. Types of information that will be benchmarked for statistical analysis include demographics, family history, diagnostic work-up, tumor assessment, staging including nodal, regional and distant disease status, treatment type, applicable recurrence and subsequent treatment information, as well as yearly lifetime follow-up. All information is kept strictly confidential and only aggregate data is released. It is hoped that beneficial conclusions can be drawn from this in-depth array of longitudinal data.

Dispersed within this year's annual report you will find 5 year data on prostate cancer pulled from the standard data set of the three main campuses (St. Luke's Medical Center, Sinai Samaritan Medical Center and West Allis Memorial Hospital). This standardized data is compared to the national statistics of the National Cancer Data Base (NCDB) from 1995. Also included within this report, but without NCDB comparison, is in-depth or ad hoc data compiled from 1998's ACOS PCE on Prostate Cancer; this information was gathered strictly from our largest institution, St. Luke's Medical Center. Many thanks go out to Marilyn Raciti, RHIT, CPHQ for compiling the prostate study statistics.

It is our hope that you benefit from the in-depth site study reports on prostate cancer that follow. For references on any of the enclosed reports or if you would like to request information from any or all of the Metro Region cancer registries, please feel free to call (414) 649-7290.

Metro Region Clinical Data Registrars

Sharon Collison, RHIT
Christine Doege
Deborah Dries, RHIT
Judith Ferkans, RHIT
Cynthia Ganzel, RN, RHIT
Sheri Hackbarth, RHIA
Jamie Keen
Mary Kissinger, RHIA, CTR
Tracy Miller
Ramona Miranda
Karen Pollock
Marilyn Raciti, RHIT, CPHQ
Lisa Robinson, RHIA, CTR
Jane Seymour, RHIT, CTR
Lisa Stachowiak
Holly Stowe-Behling
Lisa White
Prostate cancer is the most commonly diagnosed malignancy in men and has the second highest rate of mortality behind lung cancer. An incidence rate of 244,000 new cases with 44,000 deaths related to prostate cancer was estimated in 1995. There is greater public awareness of prostate cancer related to an increasing incidence, an aging population and media attention. The etiology of prostate cancer is not particularly well defined. Risk factors include family history, age and race. Prostate cancer is more common and seems to be more aggressive in black men. Conversely, Oriental men have a relatively low rate of prostate cancer that in part may be explained by low dietary fat intake. A brief overview of recent developments in prostate cancer screening and detection will be presented.

Prostate-specific antigen (PSA) has revolutionized the management of prostate cancer. PSA is utilized in early detection, staging and monitoring of prostate cancer patients. The sensitivity of PSA > 4.0 ng/ml for detecting prostate cancer is approximately 80%. However, specificity and positive predictive value for PSA is relatively low with 60% to 80% of patients with PSA values between 4 and 10 proving not to have prostate cancer. A variety of PSA derivatives have been proposed to improve the performance of the test including age-specific PSA, PSA density and PSA velocity. However, there are significant controversies with all of these derivatives. Another approach has been the utilization of new assays of various molecular forms of PSA. Free-to total PSA ratio, PSA complexed with alpha-I antichymotrypsin (cPSA), reverse transcriptase-polymerase chain reaction PSA and a human kallikrein PSA are examples of these new approaches. Further refinement of the PSA derivatives and the new PSA assays will continue to occur resulting in improved performance of this important tumor marker.
Digital Rectal Examination (DRE) is the second tool available for initial detection of prostate cancer. Approximately 20% of patients with prostate cancer will have a normal PSA thus making DRE mandatory in any early detection or screening program. Conversely, the positive predictive value of an abnormal DRE is only approximately 20%. Prostatic stones and BPH nodules are palpable abnormalities that cannot readily be distinguished from prostate cancer without the use of ultrasound and/or biopsy.

Screening for prostate cancer is controversial. Currently, there is no definite evidence that screening for prostate cancer using PSA and digital rectal examination decreases mortality from prostate cancer. Some observers feel PSA screening will go the way of routine chest x-ray screening for lung cancer, whereas others are convinced of the value of prostate cancer screening. There are several natural occurring "experiments" in this country based on different levels of PSA utilization in various geographic areas. Specifically, patients in Utah and the Pacific Northwest have utilized PSA screening to a greater extent than those in Connecticut. Therefore, a comparison of mortality rates from prostate cancer in these regions over time may provide additional insight into the value of screening. Additional support for prostate cancer screening comes from two recent European studies which suggested PSA screening resulted in detection of prostate cancer at an earlier stage than historical controls.

A reasonable approach to early detection in an individual patient is to have an informed consent discussion. Present the patient with the risks and benefits of screening with PSA and digital rectal examination and allow these men to decide whether to undergo investigation. Patients with a family history of prostate cancer and African Americans are at high risk for prostate cancer and should be offered early detection beginning at age 40, whereas other men should be offered early detection at age 50. Both the American Cancer Society and the American Urological Association support this approach.

The histologic diagnosis of prostate cancer is most commonly obtained by transrectal ultrasound guided biopsy of the prostate. Other diagnostic modalities consist of transurethral prostatectomy, transperineal biopsy and as an "incidental" diagnosis at radical cystoprostatectomy performed for bladder cancer. Indications for transrectal ultrasound guided biopsy include an elevated PSA or abnormal digital rectal examination. Transrectal ultrasound guided biopsy of the prostate is carried out under local anesthesia with sampling of all ultrasound and digital rectal examination abnormal areas. Additionally, patients with an elevated PSA undergo systematic sampling of the prostate. Historically, this has involved 1 “sextant” biopsy of the prostate including bilateral sampling of the base, mid-gland and apex of the prostate. However, recent literature has suggested the need for a greater number of biopsies as well as sampling of the deeper zones of the prostate with a variety of new biopsy arrays being advocated.
Preparation for transrectal ultrasound guided biopsy includes an enema and a fluoroquinolone antibiotic. The pathologist plays a critical role for patients with prostate cancer both in making the diagnosis and assigning a Gleason grade to the tumor. The Gleason grade along with PSA and clinical stage provide a basis for predicting the behavior of the cancer. Prostatic intra-epithelial neoplasia is a pre-malignant condition that when present on needle biopsy necessitates careful follow-up.

In summary, detection of prostate cancer involves PSA, DRE and transrectal ultrasound guided biopsy of the prostate. Screening for prostate cancer remains controversial, but additional studies and information are forthcoming. The decision to utilize PSA and DRE should be individualized to each patient.

Race / Ethnicity

The American Cancer Society National Cancer Data Base 1998 Prostate Cancer Report indicates that the proportion of African Americans diagnosed with this disease has increased 34% from 1992-1995 (8.8% to 11.8%). This trend was most evident in all regions of the country except the Midwest which showed little change (0.1%). Data for 1995 at St. Luke's and West Allis Memorial shows a much smaller proportion (2% and 3% respectively) of African Americans diagnosed at those sites while Sinai Samaritan diagnosed a number much greater than the NCDB national and Midwest percentages (SSMC 62%, NCDB national 11.8%, NCDB Midwest 8.2%). According to ACS Cancer Facts & Figures 2000, black Americans have the highest prostate cancer incidence rates in the world.

It should be noted that on a national level there was a fairly substantial percentage (9%) of cases identified as other and unknown. It is also interesting to note that the incidence of prostate cancer diagnosed in Asians at the Metro level was none and at the national level only 1%.

The percentage of Hispanic patients at each of the Metro hospitals varied from 0% to 4.8%, but the average percent for the Metro Region as a whole (2.1%) was just slightly lower than the national percentage rate of 4%. 

![Race](image)
Various tests are used to diagnose and stage prostate cancer. PSA tests, along with DREs, are used to detect the cancer at an early stage. If prostate cancer is confirmed by a biopsy, PSA results are used to help predict prognosis and decide which tests are needed for further evaluation. PSA tests are also used to assist in staging of the disease and making treatment decisions. If indicated, additional diagnostic tests may be recommended to determine the extent of spread of the disease. These may include lymph node dissections, chest x-rays, bone scans, CT scans and MRIs. A table of some of the diagnostic evaluations done at St. Luke's on prostate cancer patients during 1998 follows. Findings are also displayed including percentage of abnormal tests showing cancer.

**Diagnostic Evaluations**

<table>
<thead>
<tr>
<th>Type of Tests</th>
<th>Abnormal Cancer (and %)</th>
<th>Abnormal Not Cancer</th>
<th>Normal</th>
<th>Total Tests Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone Marrow Aspiration</td>
<td>2 (100.0%)</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Bone Scan</td>
<td>14 (13.9%)</td>
<td>17</td>
<td>70</td>
<td>101</td>
</tr>
<tr>
<td>Bone X-ray</td>
<td>2 (15.4%)</td>
<td>3</td>
<td>8</td>
<td>13</td>
</tr>
<tr>
<td>Chest X-ray</td>
<td>11 (10.6%)</td>
<td>8</td>
<td>85</td>
<td>104</td>
</tr>
<tr>
<td>CT of Abdomen</td>
<td>8 (14.8%)</td>
<td>7</td>
<td>39</td>
<td>54</td>
</tr>
<tr>
<td>CT of Pelvis</td>
<td>14 (24.1%)</td>
<td>5</td>
<td>39</td>
<td>58</td>
</tr>
<tr>
<td>IVP</td>
<td>2 (40.0%)</td>
<td>0</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>MRI</td>
<td>2 (33.3%)</td>
<td>1</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Pelvic LN Dissection</td>
<td>2 (10.5%)</td>
<td>1</td>
<td>16</td>
<td>19</td>
</tr>
<tr>
<td>PSA</td>
<td>142 (94.0%)</td>
<td>0</td>
<td>9</td>
<td>151</td>
</tr>
<tr>
<td>Ultrasound of Abdomen</td>
<td>8 (66.7%)</td>
<td>2</td>
<td>2</td>
<td>12</td>
</tr>
</tbody>
</table>

**DIAGNOSIS UNDER AGE 65**

According to the 1998 NCDB Annual Review of Cancer Patient Care, the proportion of patients diagnosed with prostate cancer under age 65 was 21.3% in 1992, increasing to 29.8% in 1995. This important change indicates that patients are being diagnosed with this type of cancer at a younger age. When combined with the shift toward diagnosis at an earlier stage of disease, this may indicate a move in pattern of care to curative intervention rather than palliation or expectant management. Earlier diagnosis may be a result of increased use of PSA testing as a screening mechanism. 1995 data from West Allis Memorial Hospital is comparable to national data with 28.6% of patients diagnosed before age 65. Sinai Samaritan Medical Center diagnosed a slightly lower percentage (23.8%) of patients in that age group while at St. Luke's Medical Center, a greater number (38.1%) of its patients were diagnosed at an age younger than 65 years.
PRESENTING SYMPTOMS
St. Luke's Medical Center — 1998

According to the National Cancer Institute, most men with prostate cancer have no symptoms as this type of cancer can grow quietly for years. When symptoms do occur, they are similar to those caused by other noncancerous disease. Common symptoms include difficulty urinating, a weak stream, a frequent urge to urinate especially at night, pain or burning on urination, and blood in the urine. As can be seen in the accompanying graph, only a small number of patients at St. Luke's presented with symptoms, the most common of which was trouble urinating.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trouble Urinating</td>
<td>124</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Hematuria</td>
<td>153</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Lower Back Pain</td>
<td>153</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

BIOPSIES – PROCEDURE

If prostate cancer is suspected, either because of symptoms or early detection screening, a biopsy is done to confirm that the disease is present. The biopsy is usually performed in the urologist's office. The most common method is the needle core biopsy. During the year 1998 at St. Luke's, 67% of patients having a biopsy had a needle core biopsy.

<table>
<thead>
<tr>
<th>Procedure Type</th>
<th>Number Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incisional</td>
<td>46</td>
</tr>
<tr>
<td>FNA</td>
<td>5</td>
</tr>
<tr>
<td>Needle Core</td>
<td>106</td>
</tr>
<tr>
<td>Sextant</td>
<td>2</td>
</tr>
<tr>
<td>Unknown</td>
<td>1</td>
</tr>
<tr>
<td>Not done</td>
<td>14</td>
</tr>
</tbody>
</table>

BIOPSIES – GUIDANCE

The urologist usually performs the prostate biopsy guided by some type of technique, the most common being ultrasound guidance. With this method, high frequency sound waves create an image or picture on a video screen, assisting the physician in obtaining the biopsy. Multiple tissue specimens are normally taken from different areas of the prostate. Of those patients at St. Luke's for which data is known, 76% had a biopsy using ultrasound guidance in 1998.

<table>
<thead>
<tr>
<th>Guidance Type</th>
<th>Number Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guided</td>
<td>7</td>
</tr>
<tr>
<td>Radiographic</td>
<td>1</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>104</td>
</tr>
<tr>
<td>Not guided</td>
<td>25</td>
</tr>
<tr>
<td>Unknown</td>
<td>37</td>
</tr>
</tbody>
</table>

BIOPSIES – APPROACH

Most prostate cancers develop in the lower portion of the prostate situated closest to the rectum. For this reason the transrectal approach is the most commonly used to obtain biopses. In 1998 at St. Luke's, 84% of patient cases with approaches known had prostate biopsies done transrectally.

<table>
<thead>
<tr>
<th>Approach Type</th>
<th>Number Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transrectal</td>
<td>98</td>
</tr>
<tr>
<td>Transperineal</td>
<td>6</td>
</tr>
<tr>
<td>Transurethral</td>
<td>13</td>
</tr>
<tr>
<td>Unknown</td>
<td>45</td>
</tr>
<tr>
<td>No biopsy</td>
<td>12</td>
</tr>
</tbody>
</table>
Over the past decade, there have been a number of major advances in the diagnosis and treatment of prostate cancer. Through the use of digital rectal examination, prostate specific antigen (PSA) testing and improved biopsy techniques, it is now possible to diagnose prostate cancer in more men at an earlier, more curable stage.

The prostate is one of the male sex glands. Other major sex glands in men are the testicles and the seminal vesicles. Together, these glands secrete fluids to make up the semen. The prostate is about the size of a walnut. It lies just beneath the urinary bladder and surrounds the upper part of the urethra. The urethra is a tube that carries urine from the bladder and semen from the sex glands out through the penis (See Diagram below).

One can feel the prostate by doing a digital rectal exam. Prostate cancer is suspected when the patient has either an abnormal digital rectal examination or elevated PSA. This will ultimately lead to a transrectal ultrasound and biopsy of the prostate to confirm if cancer is indeed present.

The radical retropubic prostatectomy is the most commonly performed surgery for localized prostate cancer, Stages T1 and T2. It involves removal of the entire prostate gland, the seminal vesicles and re-attaching the urethra to the bladder.
The indications for surgical removal of the prostate should be reserved for those men who have localized cancer, who are likely to be cured and who will live long enough to benefit from the treatment. The factors that influence the risk to benefit ratio for surgery include the patient’s age and health, the nature and stage of the cancer, the probability of surgical cure of the cancer and the complications of surgery.

The retropubic approach to radical retropubic prostatectomy was pioneered by Millin in 1947. Over the next decade, the technique was adopted by others; however, it never gained widespread popularity because of the significant complications of bleeding, incontinence and impotence.

Over the past 20 years a series of anatomic discoveries have improved the surgeon’s ability to remove all of the prostate cancer and substantially reduce the peri-operative morbidity, specifically incontinence and impotence. The delineation of the anatomy of the dorsal venous complex and improved hemostasis allows precise anatomic dissection in a bloodless field. The apex of the prostate, urethra and external urinary sphincter are readily identified, minimizing the risk of urinary incontinence.

Over this period of time, another anatomic discovery was made identifying the pelvic nerves and neurovascular bundles in relationship to the prostate which are responsible for male erections. Techniques have been modified to make it possible to preserve sexual function. Before the development of the anatomic approach to radical retropubic prostatectomy with the identification of the neurovascular bundles, virtually all patients were impotent after surgery. It was not until 1982 that the exact location of the neurovascular bundles in relationship to the prostate and the penis were identified. In 1982, Dr. Walsh and Dr. Docker described the anatomy of the pelvic floor, neurovasculature and its importance for erectile function. Since that time, the nerve sparing radical retropubic prostatectomy has been modified and perfected to help preserve erectile function.

Recently, a new device called the Cavermap, a nerve stimulator, has been employed to help identify the neurovascular bundles. This is a nerve stimulator that is used intra-operatively to identify the neurovascular bundles along the posterior aspect of the prostate. We have been using this device for the past 6 to 9 months at St. Luke’s Medical Center with improved preservation of one’s erectile function.

Three factors have been identified that correlate with the return of sexual function. They are the patient’s age, clinical and pathologic stage and the surgical technique (i.e. preservation or excision of the neurovascular bundles). Patients who have the best recovery of sexual function are those who are young and have organ confined disease. These patients see the most benefit from the nerve sparing procedure.

Trends for the future focus on less invasive surgical procedures, laparoscopic radical retropubic prostatectomy and possibly robotics to perform a radical retropubic prostatectomy. These techniques are currently being developed and are not in widespread clinical use. Their use may increase over the next three to five years.
Reference 1

AGE CATEGORY DIAGNOSIS

As can be seen from the graph, the majority of patients at both the Metro level and nationally were diagnosed with prostate cancer between ages 60-69. Of interest is that the age category 70-79 ranks next on a national level by only 1% difference, and at Sinai Samaritan an equal number of patients were diagnosed in that age category. In contrast, St. Luke's and West Allis show a percentage drop of 16% and 9% respectively in that age group. Per Cancer Facts & Figures 2000, and as illustrated in the graph, the incidence of prostate cancer increases with age more rapidly than any other cancer.

TREATMENT FOR LOCAL DISEASE


During 1998 at St. Luke's Medical Center, 87% of patients diagnosed with prostate cancer had local disease. The two most common curative modalities used in the treatment of early stage cancer are the radical retropubic prostatectomy and external beam radiation. At SLMC, one-fourth of the patients diagnosed with local disease in 1998 were treated by radical prostatectomy, the most commonly performed surgery. Overall, 33% of St. Luke's patients had some type of surgery as illustrated in the accompanying graph (74% of those patients had a radical prostatectomy). A small percentage (3%) of patients had surgery in combination with some other type of treatment (hormones and/or radiation). Sixty-four percent (64%) of patients with localized prostate cancer had radiation or a combination of radiation and hormone treatment. It is significant that although radiation implant was used infrequently (<3%) in 1992 and 1995 on a national level, in 1998 at St. Luke's brachytherapy utilization was at 40%. Of note is that only 3% of patients with local disease did not have any treatment.
**TYPE OF SURGICAL TREATMENT**

The radical retropubic prostatectomy is the most commonly performed surgery for prostate cancer. Indications for this surgery include patients who have localized cancer, who are likely to be cured and who will live long enough to benefit from the treatment. As identified in the 1998 NCDB Annual Review of Cancer Patient Care, trends toward diagnosis at earlier stages of disease and younger ages support this type of curative intervention. Published statistics from NCDB show that of those patients having surgery in 1995, 66% had radical prostatectomies. Metro region data compares to national findings with the radical prostatectomy being the most common type of surgery for those patients having surgery. At St. Luke's Medical Center and at West Allis Memorial Hospital, 72% and 53% of the patients had prostatectomies while at Sinai Samaritan Medical Center only 42% had this surgery. Of interest is that 42% of the patients at Sinai had surgery to a site other than the primary. This could be related to the large percentage of patients diagnosed with advanced disease.
Carcinoma of the prostate is the most common cancer in men (244,000 in 1999), and the second leading cause of cancer deaths in men in the United States (after lung cancer). Radical prostatectomy and external beam radiation therapy are the most common curative modalities used in the treatment of early stage prostate carcinoma. Recently, transrectal ultrasound guided brachytherapy has gained popularity as an excellent treatment option for these patients. Interstitial prostate seed implantation is a team effort, requiring radiotherapeutic knowledge, medical physics calculations, and urologic surgical skills. Most patients with localized prostate cancer are eligible for seeds. However, patients with very large or very small glands may not be. Hormone therapy may reduce the large glands enough for implantation. However, those still over 50 cc's have too high a chance of pubic arch interference and/or excessive obstructive urinary symptoms and should not be implanted. Patients with other severe medical problems that could pose unacceptable operative risks or those with life expectancies less than five years are not candidates for seeds. Patients with prior TURP's (transurethral resection of prostate) with large residual defects or those with involved lymph nodes, metastatic or T3 disease should not receive seeds. Brachytherapy should be tailored to the individual patient's prognostic factors. Patients with high Gleason's grades (greater than or equal to 8), high PSA's (greater than or equal to 10), or larger tumors (T2b) should be treated with induction limited external beam radiation therapy. This would include 4500 cGy over five weeks to treat the tissues around the prostate and kill potential microscopic extracapsular extension.
This may also be combined with induction "adjuvant" hormonal ablative therapy. The procedure is done as an outpatient through Same Day Surgery. Patients receive general or spinal anesthesia.

They are placed in an exaggerated lithotomy position and radioactive I-125 or Pd-103 seeds are inserted transperineally with transrectal ultrasound, fluoroscopic, and template guidance. The procedure is based on a preimplant ultrasound volume study done by the urologist and planned by radiation oncology. The implant takes about one hour. Most patients go home that same day without a Foley catheter. Ninety percent of patients will experience an increase in their obstructive and irritative symptoms, such as urgency, dysuria, and frequency. It is usually mild to moderate, but 10 to 20% will have more severe symptoms. These usually last from one to three weeks; however, it can last six to eight weeks and 5% of patients may have longer term duration of six months plus. Five percent of patients may experience prolonged urinary retention and may require intervention.

Incontinence is rare (1 to 2%), but may be increased slightly (5 to 10%) in patients with prior TURP's. Impotence should occur in less than 20% of patients that were potent prior to the implant. Viagra is usually helpful in those patients. Rectal complications are also rare but around 2 to 5% of patients may have some rectal bleeding that is usually self-limited. We have done almost 450 patients since 1994. Our results echo the 10-year national results with an overall 85 to 90% biochemical free survival. Salvage therapy is usually hormonal therapy, as local prostate only failures are rare.

Determination of optimal therapy for clinically organ confined prostate cancer must await results of well controlled prospective studies. However, prostate seeds offer most patients with localized prostate cancer a relatively easy, and effective alternative to surgery or fractionated external beam radiation therapy.
The 1998 NCDB Annual Review of Cancer Patient Care identifies brachytherapy (interstitial implantation / seed implants) as a "growing phenomena." Although this treatment modality was used infrequently in 1992 and 1995, the proportion of patients having seed implants increased on a national level from 1.4% to 2.2%. In comparison, St. Luke's Medical Center had a much higher rate of usage with 8% of its patients having this type of treatment in 1995. Additionally, 11% of patients had brachytherapy in combination with external beam radiation during that year. In 1998 the percentage of patients having brachytherapy increased to 40%, and 9% had combination treatment (seed and external beam). As can be seen in the graph insert, the majority of patients treated with brachytherapy had iodine seed implants. Note that the data depicted in the accompanying graph includes five patients having regional or distant disease who were also treated with beam radiation.
A dosimetrist is used to living behind the scenes. They have intense patient involvement during a person's course of radiation therapy, but not much direct patient contact. Most people undergoing external radiation therapy or radiation implants probably do not even know they exist.

But they do exist. The job of the dosimetrist is to map out the course of treatment using CT data or patient measurements. They calculate the amount of time necessary to treat each treatment field, calculate the doses that critical structures will receive, and in the case of prostate seed implants, they use the information gathered in a volume study to determine the seed placement and seed activity to give an optimal implant.

Prostate seed implant patients will have a volume study performed about one month prior to their implant date. In a volume study, the patient is positioned the same as they will be for the implant itself, and pictures of the prostate are taken using a rectal ultrasound probe. Once a patient has had his volume study, his only job is to wait until his implant date, which can be difficult enough. But, it is now time for the dosimetrist to go to work and plan the implant. The images obtained in the volume study are axial images, similar to if you had sliced the prostate apart every 5mm from top to bottom. These images are fed into a planning computer. The ultimate goal is to deliver the target dose to the prostate itself, and have a minimal dose reaching the bladder and rectum. Certain seed placement guidelines must also be followed. Seeds cannot be placed directly in the middle of the prostate, as they will probably end up in the urethra and lost. Also, the anterior portion of the prostate is close to blood vessels which we try to avoid.
The posterolateral sections of the prostate are close to nerve bundles which control potency. The dose to these bundles should be kept low if potency is still an issue to the patient. The dosimetrist also tries to avoid planning too many seeds in the posterior section of the gland because the rectum abuts the prostate posteriorly and is a critical structure. The seeds cannot be too close together or too far apart or there may be areas that receive too high or too low a dose.

Tailoring the implant to each individual is an art in addition to a science. Since no two people have the same exact prostate, each implant will be different. For a particular patient, the dosimetrist will generally run several different plans and the physician will choose the one he feels is the most optimal. A radiation physicist double-checks the plan for accuracy, and finally, seeds are ordered from a supplier.

On the day of the implant, the dosimetrist will be in surgery an hour before the case is set to begin, loading seeds into the needles in accordance with the plan. He or she will also be present during the surgery directing the physicians as to where each needle will be placed. Once the patient has been implanted, the dosimetrist must account for every seed, whether it was used for the implant or not. He or she will document where each seed was placed and will keep a record of seeds not used. They must therefore be well versed on the regulations of the Nuclear Regulatory Commission in regard to personnel exposure to radioactive materials, seed storage, and proper documentation.

Once the implant has been completed, the dosimetrist still has work to do. Prostate seed implant patients all receive a modified CT scan through the prostate gland about one month after their implant. The dosimetrist will enter this study into the planning computer and generate a dose map showing the exact doses that were actually delivered from the implant. This is very important, since if, for whatever reason, the implant were felt to be inadequate, additional seeds might be added or additional external radiation delivered.

Generally there are always between twenty and forty patients who are in the process of their prostate implant; awaiting their volume study, awaiting their implant, or awaiting their post planning. Those of us working as dosimetrists may only have a passing interaction with any of these patients but are very proud of the work that we do behind the scenes to make each prostate implant a success.
There are two potential side effects that will result from treatment for prostate cancer. Those are incontinence, meaning the involuntary loss of urine and erectile dysfunction or the inability to maintain an erection which is adequate for intercourse.

Radiation therapy, either permanent prostate seed implant or external beam radiation, can result in inflammation. This inflammation can damage the nerves and blood vessels essential for normal erection function. This effect may occur immediately after therapy or may occur gradually over a period of time and this issue must be addressed in any man who is considering therapy for prostate cancer.

Surgery, or the operation commonly known as radical prostatectomy, may also damage the neurovascular bundle; in fact, in some cases the neurovascular bundle may have to be removed in order to remove an extensive cancer that is involving these structures. If possible, the nerve and blood vessels may be spared and this is known as a nerve sparing radical prostatectomy. Even when a nerve sparing radical prostatectomy is performed and even when the most sophisticated technology known as Cavernmapping is used to identify these structures during surgery impotence may occur. The post surgical inflammation and scarring may damage these structures as well, even though they have been identified and spared during a procedure.

In essence loss of potency may result from any treatment for prostate cancer and while it is certainly higher with surgery, it can occur with both radiation and surgery.
Fortunately, we are able to offer patients therapy for this loss of function and a variety of therapies are available. The most commonly used therapy would be oral medication using the drug, Sildenafil (Viagra). It is highly effective in restoring potency in both the radiation and surgical patient. Another mode of therapy is injection therapy, which allows the patient to inject a medication into the penis, which allows the blood vessels to dilate and bring blood flow into the penis. Vacuum erection devices are also useful. In cases where all other measures fail the use of the penile implant is an excellent option for restoring potency.

If any man feels that the quality of his life is diminished by his loss of sexual potency, this function can be restored with one of the methods that have been previously discussed.

The second issue that men must deal with is incontinence. Incontinence is the involuntary loss of urine and there are two types of incontinence which may result from treatment for prostate cancer.

The first is urgency incontinence, which means the loss of urine that is associated with the intense urge to empty one's bladder. This is the type of incontinence that may occur as a result of inflammation to the bladder as a result of radiation therapy. In most instances the irritation of the bladder is temporary; however, in some cases it may be an ongoing problem.

A majority of the time this problem can be addressed using medications which relax the muscle of the bladder wall. In the rare cases when the bladder muscle is severely damaged and conservative treatment with antispasmodics is not affective, the use of an electronic stimulator known as the Interstim has shown promise reducing severe and intractable urgency. This device is similar to a heart pacemaker and is attached to the nerve fibers that stimulate the bladder. Fortunately, the majority of men who are affected by post radiation urgency benefit from simple antispasmodic medications. In extreme cases where the bladder is damaged and is unable to retain any volume of urine, artificial bladders can be created. The most common of which is known as the ileal conduit, which is a bladder constructed out of a portion of the patient's intestines. Other varieties of urinary diversion operations, known as continent urinary diversions.

The second type of incontinence is known as stress incontinence. This type of incontinence is the involuntary loss of urine with coughing, sneezing or straining or simply the passive loss of urine when a man performs any normal activities such as walking, running, etc. This type of incontinence which may occur after radical prostatectomy is a result of poor external urinary sphincter tone. The percent that this occurs after radical prostatectomy varies.
The first treatment is to instruct the patient in exercises to help strengthen this voluntary sphincter muscle combined with some simple medications that are known as decongestants, also known as alpha stimulating drugs.

If simple exercises fail to control urinary incontinence as a result of radical prostatectomy, other options are available which include external clamp devices, which simply compress the man’s urethra and of course, the use of the artificial urinary sphincter.

Once again, the problem of post surgical incontinence can be addressed and resolved in any man who is committed to improve the quality of his life should this problem occur as a result of radical prostatectomy.

In summary, the problems of incontinence and erectile dysfunction that may occur as a result of the therapy for prostate cancer can be corrected with a variety of techniques. No man should feel that he must live with either of these problems, help is available. If either of these problems occurs as a result of treatment for prostate cancer, the patient should seek consultation with a urologist who has experience in dealing with these situations.
Six decades ago Huggins and Hodges established that the initial growth of prostate cancer (CAP) is dependent upon testosterone. Since then the standard primary treatment for metastatic prostate cancer has been androgen suppression in the form of medical or surgical castration. Although such androgen suppression results in tumor responses in more than 80% of patients, it is not curative. Eventually, in all patients who do not die of unrelated causes, the disease progresses, as manifested by rising concentrations of prostate-specific-antigen (PSA), local or distant tumor growth, and symptoms such as bone pain or urinary obstruction.

**Options for Hormonal Therapy**

Several different hormonal suppression approaches can benefit men with various stages of CAP. These include bilateral orchiectomy, estrogen therapy, LHRH agonists, antiandrogens, ketoconazole, and aminoglutethimide.

Benefits of bilateral orchiectomy include ease of the procedure, compliance, its immediacy in lowering testosterone levels, and low cost. Disadvantages include psychological effects, loss of libido, impotence, hot flashes, and osteoporosis.

Estrogens (DES) at a dose of 3 milligrams per day will achieve castrate levels of testosterone. Similar to orchiectomy, estrogens cause a loss of libido and impotence. Gynecomastia can be prevented by low dose radiation to the breasts. However, estrogen is seldom used today because of the risk of serious side effects including myocardial infarction, cerebrovascular accident, and pulmonary embolism.
LHRH agonists, such as leuprolide, goserelin and buserelin will lower testosterone to castrate levels. LHRH agonist can cause impotence, hot flashes and loss of libido. Tumor flare reaction may occur transiently and can be prevented by antiandrogens at low dose for several weeks. The high effectiveness and excellent patient acceptance of these agents have made them the mainstay of treatment at this time. A long term LHRH Implant that can maintain medical castration for up to 30 months in metastatic PCA has been developed.

Antiandrogens of various forms block the peripheral action of testosterone. The pure antiandrogen flutamide may cause diarrhea, breast tenderness, and nausea. There have been case reports of severe hepatic toxicity. Bicalutamide may cause nausea, breast tenderness, hot flashes, loss of libido, and impotence. The steroidal antiandrogen megestrol acetate suppresses androgen production incompletely and is typically not used initially. Long term and/or high dose ketoconazole can induce adrenal insufficiency, pruritis, nail changes and impotence. Aminoglutethimide commonly causes sedation and skin rashes.

Metastatic Disease
In the 1980's it was proposed that the anti tumor effect could be improved by the addition of an antiandrogen to castration. This approach was termed combined androgen blockade (CAB), the fundamental premise of which is that adrenal sources of androgens contribute to CAP progression. Antiandrogens competitively inhibit the binding of testosterone or its metabolite to the androgen receptor in target cells. Many randomized trials have compared some form of CAB with castration alone, but have produced contradictory results. As such CAB remains controversial. A recently updated Prostate Cancer Trial Group meta-analysis including 27 mature trials and over 8000 men with advanced prostate cancer was reported in Lancet. This analysis found that at 5 years CAB was associated with a slight (2%) survival advantage when compared to monotherapy (LHRH agonist alone). This survival advantage is only statistically significant when trials using the steroidal antiandrogen cyproterone acetate are excluded. This small survival advantage must be weighed against the quality of life and economic impact of CAB versus monotherapy. Some studies suggest that patients treated with CAB have a worsened QOL scores versus those on monotherapy primarily due to diarrhea and worse emotional function. Antiandrogens are quite expensive and only variably covered by insurers.

Intermittent Hormonal therapy has been advanced as a both cost effective and side effect limiting approach to the treatment of metastatic disease. The rationale is based on the finding that combined androgen blockade is associated with previously androgen-repressed genetic code for growth factors that stimulate cancer cell growth. If androgens are replaced, the genes remain repressed and the tumor remains androgen dependent. A temporary return of androgens (“off therapy”) continues to suppress the growth factors responsible for androgen independence. More recent clinical work suggests this therapy is best suited toward those with low tumor burden and PSA only disease as opposed to those with overtly symptomatic metastasis.
With our growing numbers of patients on some form of hormonal therapy long term, an emerging discussion of bone density loss is occurring. Treatment of Vitamin D deficiency with 2000 u per day for 12 weeks in metastatic prostate cancer is associated with increasing muscle strength and decreased bone pain. Biphosphonate use to prevent bone loss has demonstrated benefit and is on the rise.

**Neoadjuvant and Adjuvant Hormonal Therapy**

More recently, neoadjuvant and adjuvant application of hormones have been advanced to improve on results for patients with locally advanced or aggressive disease, with data supporting or rejecting hormonal therapy use depending upon patient circumstance.

Neoadjuvant hormonal therapy before radical prostatectomy, while improving node status and surgical margin status of the pathologic specimen, has not demonstrated benefit in biochemical or overall survival. As such the use of neoadjuvant hormonal therapy prior to surgery has fallen out of favor.

A significant survival advantage of early adjuvant hormonal therapy has been demonstrated in patients with node positive disease after radical prostatectomy. Overall and cancer-free survival was improved in those treated with immediate hormonal therapy versus those observed and treated only when symptomatic. The results confirm findings of the Medical Research Council and data from the Mayo Clinic, but conflicts with VACURG data. Future clinical trials will address this issue.

A growing number of studies have demonstrated the benefit of neoadjuvant and adjuvant hormonal therapy with radiotherapy, both external beam and brachytherapy, in selected patients. In high-risk tumors, i.e. T2b or greater, PSA >10 and/or Gleason score >7 an improvement in clinical and PSA free survival has been seen in patients treated with NHT and adjuvant HT with EBRT. LHRH agonist use in this setting continues to grow.

**Second Line Hormonal Therapy**

The Androgen (“flutamide”) withdrawal effect first reported in 1993 is now a well-accepted phenomenon and represents the first line of therapy for any patient failing combined androgen blockade. The observations reawakened the possibility that second and third line hormonal manipulations could be successful. Therefore, the following pathways are considered reasonable: 1) if CAB had been the initial therapy, withdraw the antiandrogen and monitor response. 2) If monotherapy had been the initial therapy, add an antiandrogen, 3) after 1) consider another antiandrogen. Responses in these instances emphasize the heterogeneity of the androgen independent patient. It is also well reconciled that all antiandrogens are not identical in their mechanism of action, despite being of the same drug (nonsteroidal) class. The addition of ketoconazole or aminoglutethimide to antiandrogen withdrawal has demonstrated an increase in PSA response from 20-30% to 50-60%. Prednisone may be symptomatically effective and also reduce PSA. A number of patients are taking PC-SPES whether as primary or second line therapy. A recent publication analyzed the components of this compound and found it to contain a number of estrogenic compounds.
Both its therapeutic effect (decreasing PSA) and its adverse effects (DVT, CHF, gynecomastia) are consistent with this finding.

A great deal of interest has centered on the development of strategies for disease, which no longer responds to hormonal manipulation. Chemotherapeutic agents are being re-investigated with results. Interest in cytostatic (versus cytotoxic) agents which rather than destroy cells manipulate and redirect the cells growth cycles into more disciplined pattern is attractive and ongoing.

Hormonal therapy in the management of prostate cancer represents a diverse group of techniques and compounds with variable effects. The optimal application of both type and timing of therapy to specific patients is an ongoing challenge.

**TREATMENT BY MODALITY**

One of the major trends identified in the NCDB 1998 Annual Review of Patient Care was a greater rate of treatment with curative intent by radical prostatectomy or radiation therapy. As illustrated in the graph, over 60% of patients were treated with either surgery or radiation alone, both at the Metro level and nationally. The exception was at Sinai Samaritan where 29% of patients were treated with surgery or radiation alone. Of interest is that a much larger percentage of patients at Sinai Samaritan (24%) were treated with hormone therapy alone than at St. Luke’s (7%), West Allis Memorial (6%) or at a national level (8%). This could be due to a larger percentage of patients being diagnosed with late stage disease at Sinai Samaritan (37%) compared with St. Luke’s (31%), West Allis (22%) or the National Cancer Data Base (21%). In addition, a large percentage of patients at Sinai Samaritan (24%) had no known treatment.
CHEMOTHERAPY FOR prostate cancer

Ronald D. Hart, MD

For patients whose prostate cancer has spread to the adjacent tissues, or to distant sites, the most commonly used systemic treatment is hormonal. Initially this was accomplished by surgical castration, later by the use of estrogen. More recently the treatments have been based on much less toxic regimens of luteinizing hormone-releasing hormone agonists (such as leuprolide or goserelin) and nonsteroidal antiandrogens, such as flutamide (Eulexin), bicalutamide (Casodex), or nilutamide (Anandron). Antagonists of gonadotropin-releasing hormone (GnRH), such as abarelix are currently under development. None of these treatments are curative however, and sooner or later, the patient will develop symptoms from progressive tumor growth. The best management for this situation is still being defined.

Many consider the combination of mitoxantrone and prednisone to be the standard of care, since two randomized trials have shown a palliative benefit. A significant survival advantage was reported in October 2000 for men with locally advanced prostate cancer who received adjuvant mitoxantrone chemotherapy plus hormone treatment compared with men who received hormone treatment alone.

Estramustine is an estrogen linked to a non-nitrogen mustard. When it is combined with vinblastine or oral etoposide it leads to PSA declines of 50% or more in 45% and 52% of patients respectively. Objective responses are seen in 26% and 33% of these patients. A randomized comparison of vinblastine with or without estramustine showed a trend to improved survival for the combination, and a statistically significant improvement in time to progression.
The most recently developed class of drugs for prostate cancer are the taxanes. The combination of estramustine plus paclitaxel led to a PSA response rate of 52%, and objective responses were observed in 44% of patients with measurable soft-tissue lesions.

The median survival reported in this study of patients with hormone refractory disease was 17 months. In a phase I study of estramustine combined with docetaxel in men with hormone-refractory prostate cancer, 62% of patients treated had a PSA decline of 50% or more; objective responses were observed in 28% of patients. Of the patients with bone pain requiring narcotic medications, 53% discontinued all pain medications for a median of 6 weeks. The median survival reported was approximately 23 months.

The combination of estramustine and docetaxel is now being compared in a randomized trial with the current standard therapy of mitoxantrone and prednisone. This national trial will accept 620 patients over the next 3 years and is available to patients at St. Luke's Medical Center. It will help answer many of the remaining questions for patients with advanced disease.
AJCC STAGE
Data from the 1998 NCDB Annual Review of Prostate Cancer indicates that Stage II disease is diagnosed most frequently, showing an increase of 8.6% from 1992 to 1995. As illustrated in the accompanying graph, 1995 data from St Luke’s Medical Center (SLMC) and West Allis Memorial Hospital (WAMH) compares with national statistics, the majority of cases being diagnosed at Stage II disease. Data from Sinai Samaritan Medical Center (SSMC) for that time frame differs in that the greatest number of patients were diagnosed with more advanced Stage IV disease.

SURVIVAL
Metro Region – 1985-1990
According to the American Cancer Society’s Cancer Facts and Figures of 1992, the five-year relative survival rate for all stages of disease was 74%. Today, the most recent Fact and Figures state that overall five year survival has increased to over 93%. The graph on the right represents relative survival of cancer patients with combined stages of disease who were reported between 1985 and 1990. Results show a comparable benchmark outcome between patients treated in the Metro Region of Aurora Health Care to those reported nationally to the National Cancer Data Base (NCDB).
Pathology

Adenocarcinoma accounts for about 95% of prostatic malignancies. Prostatic carcinomas can be divided into two major categories on the basis of their presumptive site of origin and morphologic appearance:

1) adenocarcinoma of peripheral ("secondary") ducts and acini

2) carcinoma of large "primary" ducts. The majority belong to the first category.

Adenocarcinoma of Peripheral Ducts and Acini

Most of these carcinomas arise in the peripheral zone, whether posteriorly, laterally, or anteriorly, with sparing of the periurethral region except for the late stages of the disease. Grossly, the tumor may be difficult to see but usually can be identified as a gray or yellowish, poorly delineated, firm area. In prostatectomy specimens, multiple tumor foci have been demonstrated in 75 - 85% (multicentricity). The presence of prostatic glands within perineural spaces is common in these tumors and its presence in a needle biopsy specimen is a good predictor of capsular invasion by the tumor.

Carcinoma of Large ("Primary") Ducts

Microscopically, the following types have been recognized: Large (prostatic) duct adenocarcinoma, endometrial-type (endometrioid) adenocarcinoma, primary transitional cell carcinoma and mixed adenocarcinoma-transitional cell carcinoma.

Other Prostatic Carcinomas

Other prostatic carcinomas exist, most of them probably representing variants of adenocarcinoma of the peripheral ducts and acini. These include carcinoma with neuroendocrine features, including small cell carcinoma, mucinous adenocarcinoma, signet ring carcinoma, adenosquamous cell carcinoma, squamous cell carcinoma, adenoid basal cell tumor, basaloid carcinoma, and lymphoepithelioma-like carcinoma.
Immunohistochemical and Other Special Techniques

Two immunohistochemical markers for prostatic epithelium demonstrable in routinely processed material with polyclonal or monoclonal antisera are PAP and PSA. Antikeratin antibody 34BE12 (high molecular keratin) identifies basal cells in the prostatic glands and is therefore of diagnostic use; it is invariably present (although sometimes discontinuously) in benign glands and absent in adenocarcinomas regardless of grade. Information on the chromosomal alterations of prostatic carcinoma is sparse. Allelic loss has been found in about half of the cases. Numerical chromosomal aberrations are associated with advanced disease. Mutations of p53 have been found in a subset of prostatic carcinomas characterized by a highly proliferative pattern and an aggressive behavior.

Prostatic Intraepithelial Neoplasia (PIN)

PIN is the currently preferred term for a process involving prostatic ducts and acini, which has also been described as intraductal or ductalacinar dysplasia. A subsequent consensus conference sponsored by the American Cancer Society concluded that prostatic intraepithelial neoplasia is the most likely precursor of prostatic adenocarcinoma. This association refers to high grade prostatic intraepithelial neoplasia or PIN III. The clinical importance of recognizing high grade prostatic intraepithelial neoplasia is based on its strong association with prostatic carcinoma.

Cytology

In experienced hands, the technique of fine-needle aspiration cytology is very effective in detecting prostatic carcinoma. Poorly and moderately differentiated tumors are diagnosed with ease, but there is some difficulty in identifying lesions at the better differentiated end of the spectrum. The overall accuracy of the needle biopsy according to one study, was 85.6%, and that of the aspirates was 86.6%; when considered together, the accuracy reached the remarkable figure of 95.8%. Despite these facts, aspirations cytology has fallen into disuse (especially in the United States) and largely replaced by the spring-loaded 18-gauge biopsy.

Biopsy, TUR, and Frozen Section

During the last decade the automated spring-loaded 18-gauge biopsy gun has gained in popularity. One author reported a false-negative rate of 12% because of sampling error with needle biopsy of the prostate on a 4-year follow-up. The probability of detecting a carcinoma in a TUR specimen is directly related to the amount of sampling and can reach up to 90% of the carcinomas detected. The accuracy of frozen section for the diagnosis of prostatic carcinoma is high.

Frozen section examination and touch imprints are also useful for the diagnosis of lymph node metastases, but both techniques suffer from a 10% to 15% incidence of false-negative results.

Spread and Metastases

Invasion of the “capsule” (i.e., the outer fibromuscular layer of the prostate) is very common in carcinomas of the prostate. In one series, capsular invasion was found in 90% of specimens from radical prostatectomies in patients with clinical stage A or B disease.
In another study, the probability of tumor having extended outside the prostate into the neurovascular bundles was found to be zero if the "capsular margin" was negative, 12% if it was equivocal, and 60% if it was positive. Advanced tumor may extend into the seminal vesicles, apex (distal aspect) of the gland, prostatic urethra (very rarely), and bladder. Rectal invasion is much less common.

The most common sites of metastatic spread of prostatic carcinoma are the skeletal system and lymph nodes. Bone metastases are usually multiple, but can be solitary. The most common pathway of nodal involvement is to the pelvic chains, from which the tumor spreads to the retroperitoneal nodes. The overall incidence of nodal metastases at the time of diagnosis has been in the neighborhood of 40% in the majority of published series, but it has been considerably lower in most recent studies, suggesting a change in the stage at which prostatic carcinoma is currently diagnosed.

Lumbar spine, sacrum, and pelvis are the most common locations for bone metastases, supposedly as the result of tumor spread via Batson's vertebral venous system. However, any other bone can be involved through the systemic circulation. Lung metastases are not as rare as formerly believed; most of them exhibit a lymphangitic pattern of spread. Prostatic carcinoma also may metastasize to the breast, sometime bilaterally, particularly in patients taking estrogens. Other metastatic sites include liver, adrenal gland, central nervous system (including dura), eye, skin, and unusual locations such as penis, and salivary gland.

In general, the degree of microscopic differentiation of the metastases and of PSA expression follows closely that of the primary tumor.

**Grading**

Microscopic grading of prostatic adenocarcinoma has been found to correlate well with PAP and PSA levels, clinical and pathologic staging, incidence of lymph node and bone metastases, survival rate, and response to therapy. The grading system developed by Gleason in conjunction with the Veterans Administration Cooperative Urologic Research Group has shown a remarkable correlation with mortality rates and is currently preferred to other grading methods proposed over the years. This grading system is based on the degree of glandular differentiation and the growth pattern of the tumor in relation to the stroma as evaluated on low-power examination.

According to Gleason's system, 5 patterns are defined (1-5) and three Gleason Scores are determined: 2-4 Well-differentiated, 5-7 Moderately differentiated, and 8-10 Poorly differentiated. The patterns described are synonymous with grades. If this system is used, the combined grade (pattern) is obtained by adding predominant grade (primary grade or pattern) and the other grade (secondary grade or pattern). The pattern (grade) sum results in the Gleason's score.

As already indicated, the histologic grades correlate with the clinical and pathologic stages; in addition, grading shows good correlation with mortality rates within each clinical stage. By combining grading and staging, the best predictive values are obtained.
**Prognosis**

From the pathologic point of view, many parameters have been evaluated for their ability to predict outcome in patients with prostatic carcinoma, as follows: pathologic stage, microscopic grading, surgical margins, tumor volume, PSA and PAP immunoreactivity, neovascularity, neuroendocrine features, androgen-receptor status, DNA ploidy, chromosomal abnormalities, p53 expression and ras oncogene.

**HISTOLOGIC CELL TYPE**

In its data regarding tumor characteristics of prostate cancer patients, the National Cancer Data Base describes histologic cell type as referring to the type of cell or tissue in which the cancer has formed. Cell types differ in patterns of spread and treatment characteristics. According to the "Textbook of Clinical Oncology," the vast majority of prostate carcinomas are adenocarcinomas. This is further detailed by the National Cancer Institute in its CancerNet Service which indicates that 95% of primary prostate cancers are adenocarcinomas. As can be seen in the accompanying table, metro statistics for 1995 support this and compare almost equally to NCDB data with the exception of Sinai Samaritan Medical Center where approximately 86% of patients were diagnosed with adenocarcinoma.

<table>
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<td>Adenocarcinoma NOS</td>
<td>95.5%</td>
<td>85.7%</td>
<td>95.2%</td>
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<tr>
<td>Acomar cell carcinoma</td>
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<tr>
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<td>Carcinoma in situ</td>
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**TUMOR GRADE**  
*St. Luke's Medical Center – 1998*

The Gleason Grading System is the most commonly used system for grading prostate cancer. After a biopsy the tissue is examined to determine how closely the cancer cells look like normal tissue. Prostate cancers often have areas with differentiated grades, so the pathologist assigns a primary grade and a secondary grade, ranging from 1 through 5, to each of the two largest areas of cancer in the tissue sample. The grades are then added to produce the Gleason score. A score of 2-4 is considered low grade (well-differentiated), 5-7 intermediate grade (moderately differentiated) and 8-10 high grade (poorly differentiated). The higher the grade, the more aggressive the cancer is. Tumor grade is useful as a predictor of outcome. The Gleason grade along with PSA and clinical stage provide a basis for predicting behavior and making treatment decisions.

At St. Luke's Medical Center during the year 1998, the majority of prostate cancers were moderately differentiated (69%) which compares to NCDB data from 1995 (62%). The most commonly performed biopsy done at St. Luke's was the ultrasound needle core biopsy, transrectal approach.

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**AJCC LOCALIZED DISEASE**  
*St. Luke's Medical Center – 1995*

The 1998 NCDB Annual Review of Prostate Cancer indicates that patients are being diagnosed at earlier stages and that the number of patients diagnosed with localized disease (Stages 0, I and II) has increased. The NCDB Review reports an increase of 7.4% in the proportion of patients diagnosed with localized disease from 1992 to 1995. Data from hospitals in the Metro Region for 1995 shows the number of patients diagnosed with local disease comparable to that of the NCDB with the exception of Sinai Samaritan which was 26% lower than the national average (SLMC 68%, SSMC 43%, WAMH 68%, NCDB 69%). The Metro Region average for localized disease was 60%.
Prostate cancer is an important issue in men's health. Each year, over 180,000 new cases are diagnosed and 32,000 deaths are attributed to the disease. Key risk factors for prostate cancer include age and race. Three-quarters of prostate cancers will be diagnosed in men over the age of 65 and the incidence of prostate cancer in African-American men is significantly increased above that of Caucasian men. As with many other cancers, such as breast, ovarian, and colon, another important risk factor for prostate cancer is family history.

The association between increased prostate cancer risks and a positive family history for the disease has been well documented. A case-control study of 691 men with prostate cancer found that men with one, two, and three first-degree relatives with prostate cancer were two, five, and eleven times as likely to develop prostate cancer, respectively, as compared to men with no family history. The risk of developing prostate cancer is further increased when the diagnoses in the family are made at an early age. For example, in studying father/son pairs with prostate cancer, Gronberg et al. assessed cumulative risks to unaffected sons based on this family history and age at diagnosis of the father. Overall, they found the cumulative risk for prostate cancer in sons to be 5%, 15%, and 30% by ages 60, 70, and 80 respectively and the risk to be 25% and 43% by ages 60 and 70 respectively when the father was diagnosed before age 70.

Hereditary prostate cancer is defined as three first-degree relatives with prostate cancer, three generations in the same family line affected with prostate cancer, or two first-degree relatives with prostate cancer under the age of 55. Much effort has been made to define the genetic factors that play a role in these hereditary prostate cancer families. Complex segregation analyses have suggested autosomal dominant inheritance of a rare, highly penetrant allele.
This allele is thought to have a frequency of 0.3% in the general population and account for 9% of all prostate cancers and 40% of prostate cancers under the age of 55. A X-linked or autosomal recessive inheritance has also been suggested by one study as the risk for prostate cancer in individuals with affected brothers was greater than the risk in individuals with affected fathers.

Utilizing high risk prostate cancer families, several groups are now searching for putative prostate cancer predisposing genes. Thus far, no prostate cancer genes have been cloned, but several regions of the genome have been identified as potential candidates for possessing such genes. In 1996, Smith and others performed a genome-wide scan in 66 prostate cancer families with 3 or more first-degree relatives with prostate cancer. They identified a prostate-susceptibility locus, HPC1, on the long arm of chromosome 1 (1q24-25). Since this initial study, other potential loci have been identified including HPCX (Xq27-28), PCAP (1q42.2-43), and HPC20 (20q13) in prostate cancer families and CAPB (1p36) in families with prostate and brain cancers. For each potential locus, confirmation studies have provided conflicting results. Therefore, hereditary prostate cancer appears to possess significant locus heterogeneity with multiple genes each accounting for a small proportion of hereditary prostate cancer families.

Increased risk for prostate cancer has also been associated with other cancer syndromes and modifier genes. The risk for prostate cancer is increased in males with mutations in the hereditary breast and ovarian cancer genes, BRCA1 and BRCA2. Mutations in these genes, however, are infrequently identified in prostate cancer only families and are unlikely to play a significant role in hereditary prostate cancer. An example of a modifier gene that may play a role in prostate cancer risk is the androgen receptor gene (AR) on the X chromosome. The binding of androgens to the androgen receptor gene results in its activation and ability to activate the transcription of other genes. The AR gene contains a polymorphic CAG trinucleotide repeat in the first exon. Shorter repeats are associated with increased transcriptional activity of the AR gene. As prostate cancer depends on androgens, it has been suggested that shorter repeats would be associated with increased risk for prostate cancer. Studies have shown that CAG repeats are, on average, shorter in African-American individuals than in Caucasians perhaps corresponding to the increased incidence of the disease in the African-American population. Another study demonstrated a 3% increase in the risk of prostate cancer with each single decrease in the number of CAG repeats.
With increasing popular press addressing the role of genetics in cancer, the population is becoming more and more interested in personal cancer risk assessment. High-risk clinics designed to assess risks for prostate cancer and provide comprehensive medical management have already been developed. The identification of hereditary prostate cancer families allows for the education of the consultant and other family members regarding their risks and surveillance strategies.

Current recommendations for men from high-risk prostate cancer families include digital rectal exam and prostate specific antigen annually beginning at age 40. Although prostate cancer susceptibility genes have not yet been cloned, two studies have addressed the interest in genetic testing for prostate cancer. Both studies suggested a strong interest and high uptake of genetic testing for hereditary prostate cancer.

In summary, the genetics of hereditary prostate cancer appear to be complex. There are likely to be several patterns of inheritance and multiple genes implicated in the syndrome. With the completion of the Human Genome Project, prostate cancer susceptibility genes will likely be cloned in the near future and clinical genetic testing for hereditary prostate cancer will inevitably be developed. This will allow for improved identification and risk assessment of high-risk individuals and families. Once identified, these individuals can be counseled regarding increased surveillance in hopes of reducing mortality from this disease.

15. Berry R et al. Linkage analyses at the chromosome 1 locus 1q24-25 (HPC1), 1q42.2-43, (PCAP), and 1p35 (CAPB) in families with hereditary prostate cancer. AJHG 2000;66:539-46.
17. Gibbs M et al. Analysis of chromosome 1q42.2-43 in 152 families with high risk of prostate cancer. AJHG 1999;64:1087-95.
21. Sinclair CS et al. BRCA1 and BRCA2 have a limited role in familial prostate cancer. Cancer Res 2000;60:1371-5.

RISK FACTORS
St. Luke’s Medical Center - 1998

Key risk factors for prostate cancer are age, race and family history. Current information from the National Cancer Institute indicates that 75% of prostate cancers are diagnosed in men ages 65 and older and that African-American men have the highest incidence of prostate cancer world-wide. In addition, risk increases for men who have a father or brothers diagnosed with this disease. If a man has three relatives with prostate cancer, the risk is more than ten times greater. Factors such as hormones, diet, environmental exposures and other lifestyle changes are increasingly being studied as to how they may relate to prostate cancer. As shown in the accompanying chart, in 1998 at St. Luke’s Medical Center, 66% of the patients diagnosed with prostate cancer were age 65 or older, 9% had first degree relatives diagnosed with this disease, and 5% of the patients were of African-American descent.
The Visiting Nurse Association of Wisconsin Hospice provides a specialized, family centered oncology program for end-of-life care. Although most hospice care is provided in patients' homes, the VNA also cares for patients in assisted living centers, nursing homes and hospitals. Recently, the Milwaukee Hospice Residence became part of the VNA. It's a seven-bed residential facility for people who desire a home-like atmosphere, but can no longer remain in their own home. VNA Hospice is one of only a few hospices in Wisconsin that also offers a pediatric program.

The VNA Hospice team works in collaboration with the patient's own physician to focus on pain management, symptom control, comfort and care. The team is comprised of the Hospice medical director, nursing, social services, spiritual counselors, rehabilitation therapy, IV and respiratory therapy, home health aides and volunteers. During the past year, the number of oncology-certified VNA nurses has increased by 150%.

The VNA is always seeking ways to expand and support the continuum of care offered to patients and staff of the Vince Lombardi Cancer Clinics. Of the more than 80 hospice patients we visit each month, 88% have been diagnosed with cancer. For those patients who come to the Vince Lombardi Cancer Clinics from outside the Milwaukee area, the VNA is able to continue their care when they return home anywhere in Eastern Wisconsin. Hospice services have recently been extended to the far north with the licensure of our Sturgeon Bay branch.
As the goals of treatment turn from cure to comfort, the patient's physician will determine when it is appropriate to transition to hospice care. Since Medicare coverage for hospice care often exceeds that for home health care it is in the patient's best interest to be referred to hospice early on, rather than in the final days or weeks of life. Hospice is covered through Medicare, Medicaid, private health insurance, and private resources. Social work staff assists in accessing and utilizing all available reimbursement. Contributions to the Visiting Nurse Association Fund assist patients who do not have the resources to pay for hospice services.

Grief counseling and support groups assist the family during and after the loss of a loved one. These services continue for a full year.

The Visiting Nurse Association of Wisconsin oncology program is designed to center around the patient and their family. The specially trained Hospice team provides physical, emotional and spiritual care, helping the patient to live out their life with meaning and dignity.

For more information about the VNA's oncology program, hospice care and pain management, contact Mary Runge at 414-438-8000.
Pre-clinical Research Study to Evaluate the Potential for PSMA-Specific T cells as Therapy for Patients with Prostate Cancer

*Nina K. Garlic, PhD*
*Ann V. LeFever, PhD*

This is a research study being conducted by Nina K. Garlic, Ph.D. and Ann V. LeFever, Ph.D. of the Immunotherapy Program at St. Luke's Medical Center.

**Purpose**

Prostate-specific membrane antigen (PSMA) is a protein that is present at high levels on the surface of prostate cancer cells. We have obtained purified PSMA from Northwest Biotherapeutics, Inc. (Seattle, WA). It will be used to optimize a method of generating prostate-specific killer immune cells in the laboratory. The information obtained from this research will help us to develop new therapies for patients with prostate cancer.

**Background Information**

T cells: T cells are a type of immune cell that are present in blood and are necessary to fight cancer (See Figure 1).

In patients with cancer, T cells are not present in sufficient numbers to kill the tumor, or the T cells that are present are dysfunctional. Therefore, the tumor grows (See Figure 2).

**Dendritic cells (DCs):** In recent studies, dendritic cells (DCs) (See Figure 3) have been used as an efficient approach to stimulate tumor-specific T cells in the laboratory. DCs are present in blood and have the capacity to uptake tumor protein and process it. These tumor protein-loaded DCs can efficiently stimulate T cells to kill tumors.
PSMA: The tumor protein to be used in this study is PSMA. PSMA is over-expressed by a large proportion of prostate cancers1 and is very highly expressed in higher-grade prostate cancer, in metastatic disease1 and in hormone-refractory prostate cancer.13 Clinical responses have been observed in patients with advanced prostate cancer after vaccination with PSMA-loaded DCs.4,6

Methods
The ability to generate prostate-specific T cells in the laboratory, from the blood of healthy individuals as well as patients with prostate cancer has been demonstrated.7-9 In our study, T cells from the blood of patients with prostate cancer will be stimulated in the laboratory with their own DCs loaded with PSMA. A method of non-specific T cell expansion will be optimized to expand the T cells to numbers that will be required for therapy. The specificity and activity of the responding T cells will be monitored using assays that measure the ability of the T cells to kill prostate cancer cells. The data from this study will provide the basis for clinical trials to test the efficacy of tumor-specific T cell therapy for patients with cancer.

Potential Clinical Trials
1. Phase I trial to test the safety and toxicity of PSMA-specific T cell therapy in a dose escalation trial in patients with advanced, refractory disease.
2. Phase I/II trial to test the safety and efficacy of PSMA-specific T cell therapy as adjuvant therapy after surgery or radiation therapy.
3. Phase I/II trial to test the safety and efficacy of PSMA-specific T cell therapy in combination with other immunotherapy including vaccination with tumor antigen-loaded DCs.

Reference List
Eastern Cooperative Oncology Group (ECOG) Studies

Nancy Briggs, RN, MSN, OCN, Research Coordinator
Gary Shapiro, MD, Principal Investigator

The Medical Oncology Clinic at Sinai Samaritan Medical Center is an affiliate of the University of Wisconsin’s Comprehensive Cancer Center (UWCCC) and the Eastern Cooperative Oncology Group (ECOG). In addition, the clinic is a charter member of the Wisconsin Oncology Network (WON), a newly developed statewide network of UWCCC affiliated hospitals and clinics. Through this network, Wisconsin’s cancer patients have greater access to innovative investigational cancer treatments. These include agents that have just come out of the laboratory and are being evaluated in humans for the first time.

Active ECOG studies include evaluation of Taxol and oral Estramustine given weekly for patients with metastatic hormone-refractory prostate cancer. Patients eligible for this study have had prior hormonal therapy with evidence of treatment failure. In addition, an intergroup study is evaluating continuous versus intermittent combined androgen deprivation in newly diagnosed metastatic prostate cancer patients. Both of these studies are assessing quality of life concerns for patients undergoing treatment.

In nursing research, Sinai Samaritan Medical Center, in collaboration with the University of Wisconsin-Madison School of Nursing, is conducting a randomized study addressing medication side effects, quality of life and barriers to pain control in outpatients with metastatic prostate cancer and other advanced diseases.

This study offers 1:1 nurse-patient interaction as an innovative approach to cancer pain education. For more information about these studies, contact Nancy Briggs, research coordinator at 414-219-6591.
Radiation Therapy Oncology Group

Monique Swiecichowski, RN, BSN, Research Coordinator
Mitchell Pincus, MD, Principal Investigator

St. Luke’s Medical Center (SLMC) has been an affiliate member of the Radiation Therapy Oncology Group (RTOG) since 1993. In 1998, West Allis Memorial Hospital (WAMH) began offering RTOG protocols to their radiation patients as a ‘joint center’ with SLMC. RTOG is a multi-center organization that includes 27 full member institutions and more than 180 affiliate institutions in the United States and Canada. Founded in 1968, it was organized as a national clinical cooperative group for the purpose of conducting radiation therapy research and cooperative clinical investigations.

Seven new studies opened this year. New clinical trials dedicated to increasing the survival of patients with malignant diseases were made available to patients being treated for cancer of the anal canal, recurrent head and neck cancer, advanced head and neck cancer, anemic head and neck cancer patients, and prostate cancer patients. Clinical trials are currently available for the treatment of prostate cancer for locally confined, intermediate-risk, and high-risk disease, as well as for patients with PSA elevations status post prostatectomy.

Two studies are also available that contribute to improving the quality of life of cancer patients. RTOG 98-09 is intended for patients with GI symptoms following the completion of radiotherapy to the pelvis used in, among others, the treatment of prostate cancer. This study will evaluate the drug’s effectiveness against bowel injury, evidenced by proctitis, diarrhea and/or melena, caused by radiation and identify side effects of the drug. This double-blinded study randomizes patients to one of two doses of Elmiron or placebo and does not exclude the concurrent use of medications used for symptom management. RTOG 97-14 compares a single fraction (8 Gy) to 10 fractions (30 Gy total) for palliative treatment of prostate cancer patients with painful bone metastases. Frequency and duration of pain relief, quality of life, cost-effectiveness, and incidence of secondary pathologic fractures will be compared.

The nature of cooperative groups is to evaluate and re-evaluate current standards of care. RTOG has completed a study investigating the use of radioactive seed implants for the treatment of prostate cancer. The study was designed, in part, to establish quality assurance standards for future protocols. Once the data is evaluated, it is anticipated that clinical trials will be developed using this method of treatment. We expect to make these trials available to our patients as well. For more information about these studies, please contact Monique Swiecichowski at 414-649-5990.
Cancer Conferences

Metro Region
CANCER CONFERENCES IN THE

Educational Tumor Boards and Second Opinion Programs for Oncology

Tumor Boards and Second Opinion Programs are offered through weekly and/or monthly cancer case conferences. These conferences provide an educational and consultative forum for health care providers to discuss newly diagnosed cancer cases.

The consultative forum, allows physicians to bring forth a variety of cancer cases that are different and unique each week. An overview of the diagnostic findings is followed by a professional and consultative dialog among multispecialists. The outcome consists of recommendations that lead the way for “best” practice patterns of treatment. It is important to note that patient names are always withheld to protect a patient’s confidentiality and privacy.

The serial conferences listed below are open to all health care providers of Aurora Health Care. Please note new time and room locations of conferences in 2001.

TUMOR BOARD

- Weekly luncheon Tumor Boards are held each Friday from 12:00 noon to 1:00 pm
  - St. Luke’s Medical Center HS3 and/or the Stiemke Auditorium
  - Sinai Samaritan Medical Center Rapkin Auditorium
  - West Allis Memorial Hospital Conference Room A/B

- Monthly luncheon Tumor Boards are held the third Friday of each month from 12:00 noon to 1:00 pm
  - Hartford Memorial Hospital Board Room

BREAST CONFERENCE

- Weekly breakfast meetings are held each Wednesday from 7:30 am to 9:00 am
  - St. Luke’s Medical Center HS3

- Monthly luncheon meetings are held from 12:00 noon to 1:00 pm
  - Sinai Samaritan Medical Center 4th Friday of each month Rapkin Auditorium
  - West Allis Memorial Hospital 1st Friday of each month in Conference Room A/B

GI CONFERENCE

- Weekly breakfast meetings are held each Thursday from 7:00 am to 8:00 am
  - St. Luke’s Medical Center HS3

Each of the above conferences offer Continuing Medical Education (CME) credit.

The format suggested for the above serial conferences include a prospective case presentation which consists of a narrative medical overview, surgical findings, projection of radiology films and pathological specimens, and consultative discussion from the multidisciplinary team including medical and radiation oncologists. All types of cancers and disease sites are presented over the course of the year. Videoconferencing to broadcast an outside speaker is available. Please call 414-649-7290 if you would like to present a case.
Regional Activities

in Aurora's Metro Region
Our community outreach efforts focus on educating people in Eastern Wisconsin about the facts that increase the risk of developing cancer, identifying ways to reduce their risk, and emphasizing the importance of early detection. One method of reaching that goal is via our Vince Lombardi Cancer Hotline. The hotline is a toll free service to respond to phone inquiries about cancer from consumers, patients, physicians and other health professionals. Hotline staff put callers in touch with accurate answers to a variety of cancer questions. Written information is often mailed to the caller or they are referred to one of the Vince Lombardi Resource Libraries located in our eight Vince Lombardi Cancer Clinics. The libraries offer computer access along with an extensive array of the latest videos, books and pamphlets that can be checked out.

Another method of outreach is that we continue to let our communities indicate the outreach activities that best meet their needs. These activities have included our cancer experts presenting information at local churches and businesses as well as partnering on “getting the message out” at larger events with local/regional and/or national patient advocacy groups. The American Cancer Society Relay for Life in Washington County, and the Susan G. Komen Breast Cancer Foundation-Race for the Cure in Milwaukee County were two large events that rallied our patients and staff around a very significant message – that of life!

Cancer Services also hosted Aurora’s First Annual Men’s Health Event on September 26, 2000 at the Italian Community Center. The event was co-sponsored by the “Buddies Against Prostate Cancer” also known as Bob Reitman, Gary Grunau and Ken Sanders. The focal topic of the conference was prostate cancer with keynote speaker and prostate cancer survivor Senator Bob Dole. Approximately 500 people attended this event to hear Senator Dole as well as to have the unique opportunity to interact with physicians and other health professionals on a variety of topics such as: Heart Care, Glaucoma, Mental Health, Sleep Disorders and Cancer.
Vince Lombardi Cancer Counseling Services

Under the medical direction of Jeffrey Knajdl, MD, and with nursing coordination and clinical services provided by Barbara Clinkenbeard, RN, MS, NP, the Cancer Counseling Center continues its mission to identify and treat psychosocial distress in cancer patients. This is born out of the recognition that nearly 50% of cancer patients will experience a high enough level of distress to meet the criteria for a psychiatric disorder at some point during their diagnostic, treatment, or post-treatment phase. By decreasing levels of distress, patients may experience a host of benefits including a higher quality of life, better nausea and pain control, relief from depression and anxiety, improved relationships, and even prolongation of one’s life.

This psycho-oncology program has been carefully designed under the working models of other programs in the nation. It is the only program like it in the state of Wisconsin. The National Comprehensive Cancer Network (NCCN) has published a set of guidelines by which psychosocial distress in cancer patients should be managed. The Cancer Counseling Center embraces the approach, which includes integration of decision trees for the delivery of psychiatric, psychological, social, and spiritual services. The NCCN also endorses the use of a psychosocial screening tool called a “distress thermometer.” It will ultimately be used in the Vince Lombardi Cancer Clinics to screen all patients at the time of entry into the clinic system and is designed to facilitate further exploration into the nature of patients’ distress whether it is a physical, spiritual, family, emotional, or other type of problem.
Treatment modalities for patients and their families may include: 1) counseling or psychotherapy in an individual family or group setting, 2) psychotropic medication management, 3) providing access to educational support groups, nutritional counseling, spiritual care, and other complementary services, or 4) providing a combination of these three types of intervention, which is what often occurs.

Additions for the year 2000-2001 to the psycho-oncology program include art therapy, pet therapy, a breast cancer psychotherapy group, an on-site psychologist for delivery of additional services, and a therapist whose role would be to offer the complementary treatment modalities of massage, movement therapy, expressive therapy, and guided meditation.
support groups

For people whose lives have been touched by cancer.

To provide education, a sharing of experiences, and inspiration.

A Time to Grieve
Third Thursday of each month from 1:30 p.m. to 3:00 p.m. at Aurora Health Center in the Slinger Community Room.

The ABMT Support Group
For people who have undergone an autologous bone marrow transplant. Held at St. Luke's Medical Center. Call the Vince Lombardi Hotline for meeting dates and times.

Breast Friends - The Breast Cancer Support Group
For women who have been diagnosed with breast cancer, their families and friends. Meets the last Tuesday of each month from 6:00 p.m., to 8:00 p.m. at St. Luke's Medical Center in the Cancer Counseling Center.

Care for the Caregiver Support Group
For individuals who care for an aging or disabled individual. Every other Thursday from 10:00 a.m. to 11:30 a.m. at West Allis Memorial Hospital.

Every Day Counts
First Wednesday and third Tuesday of each month from 1:00 p.m. to 2:00 p.m. at Aurora Health Center in the Slinger Community Room.

Experiencing Grief
Recently Widowed
For people who have lost a loved one and are going through the grieving process. Meets Tuesdays for eight weeks from 1:00 p.m. to 3:00 p.m. or 7:00 p.m. to 9:00 p.m. at St. Luke's Medical Center. To register call 414-328-6280.

Kids' Connection
To help children ages 5 through 18 cope when a parent or loved one has cancer. This group is offered periodically and meets for 4 weekly sessions from 6:00 p.m. to 7:30 p.m. at St Luke's Medical Center in the Immunotherapy Conference Room. Registration by custodial parent or guardian is required.

Living Through Loss Support Group
Designed to help people move through the grieving process. First and third Tuesday of each month from 10:00 a.m. to 11:30 a.m. or 6:00 p.m. to 7:00 p.m. at West Allis Memorial Hospital.
Look Good... Feel Better
For people who are undergoing cancer treatment. This program presents techniques to help people gain control and even triumph over the cosmetic side effects of treatment. Offered six Mondays per year from 1:00 p.m. to 4:00 p.m. Call the hotline for dates and pre-registration.

Make Today Count
For people with cancer or other life-threatening illnesses and their families. This group is a cooperative effort of St. Luke’s Medical Center and the American Cancer Society. Meets the fourth Thursday of each month January through October and the third Thursday of November and December (to accommodate the holidays) from 7:00 p.m. to 8:30 p.m. at St. Luke’s South Shore, 5900 South Lake Drive, Cudahy.

Ovarian Cancer Awareness Group
For women who are at risk for or have been diagnosed with ovarian cancer. First Tuesday of each month from 6:30 p.m. to 8:00 p.m. at St. Luke’s Medical Center.

Positive People
Mutual support, socializing, advocacy, and education for persons with cancer, their families and friends is provided. It also offers an opportunity to share problems and concerns encountered while coping with this disease. For more information call (414) 328-7405.

Rebound – Living with Breast Cancer
Rebound is a highly personalized and intimate support group for women who have recently been diagnosed with breast cancer. The rebound program works with breast cancer patients to address the physical and emotional adjustments they face during breast cancer treatment. Rebound meetings combine education on health-related topics, along with group sharing of feelings and experiences related to breast cancer. All information is strictly confidential. Meets Wednesdays from 4:40 p.m. – 6:30 p.m. at Sinai Samaritan Medical Center’s Behavioral Health Clinic.

Refocusing On Hope - A Support Group
For People With A Primary Brain Tumor
For people who have been diagnosed with primary brain tumors, their families and friends. For information on the meeting location, dates, and time, please call the Vince Lombardi Cancer Hotline.

Us Too! - The Prostate Cancer Support Group
For men who have experienced prostate cancer and their families and friends. Meets the first Wednesday of each month from 7:00 p.m. to 8:30 p.m. at St. Luke’s New Berlin Health Care Center, 14555 West National Avenue, New Berlin, in the Community Events Room.

Women Supporting Women
Breast Cancer Survivor Group
For women of color who have experienced breast cancer. Women of color who are supportive of each other. Meets the third Saturday of every month from 11:00 a.m. to 1:00 p.m. at House of Peace, 17th and Walnut.

Your Caring Connection
For patients experiencing cancer, their families and friends. Meets the second Monday of each month from 6:30 p.m. to 8:00 p.m. at St. Luke’s Medical Center in the Cancer Counseling Center. For more information, please call the Vince Lombardi Cancer Hotline.

*For more information, please call the Vince Lombardi Cancer Hotline at 1-800-252-2990 or 414-649-7200.
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1999 Primary Site Table For Metro Region Cancer Programs
### 1999 Primary Site Table For Metro Region Cancer Programs

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This report INCLUDES CA in-situ cervix cases, squamous and basal cell skin cases, and intraepithelial A=Analytical, NA=Non-Analytical
INCIDENCE OF NEW CANCER CASES
1995 – 1999

3,001 new cancer cases were seen in the Metro Region in 1999. The number of new cancer cases has increased at all the facilities from the previous year of 1998. Site numbers include St. Luke's Medical Center 2,043 (includes St. Luke's South Shore) with 86% classified as analytic (diagnosed and or treated within the first course of treatment), Sinai Samaritan Medical Center, 342 with 90% analytic, West Allis Memorial 513 with 91% analytic and Hartford Memorial with 78% analytic.

NEW CASES BREAKDOWN
Analytical vs. Non-Analytical (First Course vs. Subsequent Rx)

The analytical percentages at each facility are as follows: St. Luke’s Medical Center 86% classified as analytic (diagnosed and or treated within the first course of treatment), Sinai Samaritan Medical Center, 90% analytic, West Allis Memorial 91% analytic and Hartford Memorial with 78% analytic.
Metro Region's Top Ten Sites

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<th>Site</th>
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<th>WAMH</th>
<th>SSMC</th>
<th>HMH</th>
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<td>103</td>
<td>25</td>
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<td>7</td>
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BENCHMARK COMPARISONS TOP 5 SITES

When comparing the top five sites in order of decreasing frequency in the Metro region to the incidence of cancer cases reported by the state and the National Cancer Data Base (NCDB), it is noted that the Metro region sees a higher percentage of breast cancer cases (19%), fewer prostate cases (9%) and a relatively equal number of lung (14%), colorectal (12%), and bladder cases (5%).

RACE BY HOSPITAL

Review of all (3,001) new cases in 1999 shows the population served at St. Luke's Medical Center, West Allis Memorial Hospital and Hartford Memorial Hospital is predominantly white with 97%, 99% and 100% respectively. By contrast the central city location of Sinai Samaritan Medical Center serves a more diverse population with the majority being of African American (53%) descent.
MALE VS. FEMALES

More women than men were seen at all Metro region sites in 1999. In total, 1,638 or 55% were women with 1,363 or 45% being male. According to the State of Wisconsin's Cancer Incidence and Mortality Report for 1998, cancer rates were higher for men than women for all primary sites groups. The annual cancer incidence rate was 432 per 100,000 population for males and 339 per 100,000 population for females. Of the total number of cases the incidence was split 50/50.

AGE AT DIAGNOSIS WITHIN METRO

When comparing age differences among the Metro Region Hospitals we find younger patients being diagnosed at Sinai Samaritan Medical Center with a mean age of 65. At St. Luke's Medical Center and West Allis Memorial the mean age is 75 with St. Luke's Medical Center showing a larger portion of the patients being diagnosed younger than the mean, whereas at West Allis Memorial Hospital, the patients are being diagnosed at ages slightly higher than the mean. Of the key findings of the Wisconsin Cancer Incidence and Mortality report is that 60% of the newly diagnosed cases in 1998 were age 65 and older.
<table>
<thead>
<tr>
<th>Cancer Committee Members</th>
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</thead>
</table>

- Patty Abella, RN, MSN  
  Medical Oncology
- Betty Amuzu, MD  
  OB/GYN
- Saleen Bahktiar, MD  
  General Surgery
- Linda Barrows, MD  
  Physical Medicine & Rehab
- Kenneth Bastin, MD  
  Radiation Oncology
- Diane Beier, CICSW  
  Social Services
- Nancy Briggs, RN, OCN  
  Research
- James Bruckman, MD  
  Radiation Oncology
- Jerome Buboltz, MD  
  Internal Medicine
- Laura Burke, PhD  
  Nursing Research
- Jeffrey Butler, MD  
  Urology
- Jacque Coons, RRT  
  Quality Management
- Maria DeNario, MSN  
  Social Services
- Jeffrey Derus, MD  
  Chairman, Urology
- Ajit Divgi, MD  
  Medical Oncology
- William Donegan, MD  
  Chairman, Surgery
- A. Craig Evans, MD  
  Gynecologic Oncology
- Donald Feinsilver, MD  
  Psychiatry
- Cindy Ganzel, RN  
  RHIT Cancer Registry
- Daniel Geenen, MD  
  Gastroenterology
- Mark Gennis, MD  
  Internal Medicine
- Perry Gould, MD  
  Radiation Oncology
- Vicki George, RN, PhD  
  Administration
- Ronak Grossman, MD  
  Radiology
- Uday Gupte, MD  
  Gastroenterology
- Barb Haag-Heitman, RN  
  Women's Health
- Sheri Hackbarth, RHIA  
  Cancer Registry
- Robert Hall, MD  
  Pathology
- John P. Hanson, MD  
  Medical Oncology
- Ronald Hart, MD  
  Medical Oncology
- Oza Holmes, RN, OCN  
  Breast Health Center
- Margery Howard, MD  
  Medical Oncology
- Rakesh Jagetia, MD  
  Chairman, Radiation Oncology
- Julie Jensen, RN, MSN  
  NP Nursing
- Pat Kadlec, RN  
  Outpatient Nursing
- Mary Kannenberg, RHIA  
  Quality Management/CIS
- John Kelly, MD  
  Otolaryngology
- Richard Kellar  
  Administration
- Thomas Kinney, MD  
  Plastic Surgery
- Jeffrey Knajdl, MD  
  Psychiatry
- Daniel Kopesky, MD  
  OE/OCN
- William Laffey, MBA  
  Regional Director Cancer Services
- Margaret Lange, RN  
  Outpatient Oncology
- Ann Lefever, PhD  
  Immunotherapy
- Patricia Leithen, MD  
  Family Practice
- David Lewis, MD  
  General Surgery
- Janet Lotegualaki, RN, OCN  
  CNS
- Pamela Lyon, RN, OCN  
  Breast Care Coordinator

- Pamela Maier, RN  
  Inpatient Nursing
- Rev. Marcia Marino  
  Pastoral Care
- Linda Martin, BSW  
  Social Services
- Jennifer Martone, RN, MSN  
  Inpatient CNS
- Mary Mavraganis, MS  
  Social Services
- Angela Mengelt, MS  
  Genetic Counselor
- Donna Metoff, RN, MSN  
  Inpatient Nursing
- Wendy Mikkelsen, MD  
  Breast Surgery
- Tracy Miller  
  Cancer Registry
- Mahmood Mirhoseini, MD  
  Cardiothoracic Surgery
- David Munoz, MD  
  Family Practice
- Sharon Neidinger, RN  
  VLOCC
- Michael Nordstrom, MD  
  Otolaryngology
- William Pao, MD  
  Radiation Oncology
- Wendy Paulson  
  SLSS Oncology
- Jorge Pellegrini, MD  
  Pathology
- J. Pickeral, MD  
  Pathology
- Mitchell Pincus, MD  
  Radiation Oncology
- Becky Pogacar, RN, MSN  
  Nursing
- Kim Reed, RN  
  Inpatient Nursing
- Diane Reif, RN  
  Patient Care Manager
- Lisa Robinson, RHIA, CTR  
  Clinical Data Registries
- Terence Roth, MD  
  Surgery
- Mary Runge, RN, MBA  
  VNA Hospice Services
- Lori Sadowski, RN  
  Inpatient Nursing
- Suzanne Schmidt, RN  
  Breast Coordinator
- Jane Seymour, RHIT, CTR  
  Cancer Registrar
- Gary Shapiro, MD  
  Medical Oncology
- Monique Swiecichowski, RN  
  Research
- Robert Taylor, MD  
  Medical Oncology
- Donna Thesfeld, RN  
  Quality Management
- Elaine Thomas, MD  
  Pediatrics
- Mary Tiller, MD  
  Pain Management
- Sue Toth, RN  
  Breast Care Coordinator
- Allen Torkelson, MD  
  Medical Oncology
- Jonathan Treisman, MD  
  Medical Oncology
- Carol Tutino, RN, CCRC  
  Research
- Kerry Twite, RN, OCN-CNS  
  VLCC
- Shelly Underhill, MD  
  Pathology
- Vicki Volp, RN, MSN  
  Quality Management
- Marija Weidman, RN, MSN  
  Business & Market Dev.
- Mark Wenzel, MD  
  Radiology
- Phil Whitton, RTRT  
  Manager Radiation Oncology
- Len Wilk, FACHE  
  Administration
- Walter Wong, MD  
  Radiation Oncology
- J/Anna Yeh, PharmD  
  Pharmacy
- Sol Yoder, PharmD  
  Oncology Pharmacy
- George Yu, MD  
  Pathology

- Member  
  C Chairperson  
  L Liaison