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Forty-four years and $100 billion dollars since President Richard Nixon signed the National Cancer Act, we can look back at many basic science and clinical achievements in cancer care.

It’s been a period of evolution based on the results of large co-operative clinical research trials representing less than 2 percent of cancer patients in disease centric studies. Evidence-based management pathways rooted in pathology and staging have become the norm for the remainder of the 1.5 plus million new cancer cases diagnosed in 2014.

Today we are witnessing a revolution in the management of malignant disease. Precision medicine is the banner for the new science. Individualized molecular and genomic diagnosis and classification are now available to all patients regardless of geography. This is creating a new approach to clinical research and personalized therapeutics. Cancer care is now patient- and not disease-centric.

Patient-specific molecular information now drives a new paradigm of targeted therapeutics such as “basket clinical studies,” in which diverse cancer types are aggregated by a
common targetable driver mutation, and “umbrella studies,” in which a single type of cancer is treated according to specific mutations present.

THE ARTICLES IN THIS EDITION SHOWCASE SOME OF THESE DEVELOPMENTS:

Dr. Howard Silverboard reviews the opportunities unfolding in the lung cancer arena in “Genetic Lab Techniques Advance Lung Tumor Therapy.” The role of genomics in management and its inherent challenges are introduced. As an example of patient-driven advocacy, the efforts of the Bonnie J. Addario Lung Cancer Foundation is a model of the new paradigm for integration of diverse resources.

Dr. Benedict Benigno introduces the clinical challenges of ovarian cancer as a “silent killer,” drawing on his 40 years experience in “Ovarian Cancer in the Future Present Tense.” He reviews the collaborative and novel teamwork that exemplifies and leverages the gain in molecular insight and the potential value for the individual patient with ovarian cancer. He reviews the application of precision medicine to the management of ovarian cancer and expectations and plausible expectations for the future.

The hematological malignancies spearheaded the development and clinical application of personal molecular analysis for the individualized management of the acute and chronic leukemias; myeloma as well as stem cell manipulation in bone marrow transplants. Dr. Kent Holland reviews the dramatic application of these principles as tools in “New Targeted Treatments for Hematological Malignancies” that have revolutionized outcomes for patients treated in a leukemia center. He drives home the “bench to bedside” clinical science and knowledge-driven treatments available today.

The patient and his or her family are often the ones caught between the opportunities and costs of the rapidly changing cancer landscape. Navigating this complicated course reminds us of the oath we took to care and put the patient first. The management of melanoma integrating the targeted therapeutics with these clinical principles finds a narrative in “Hitting the Sweet Spot” by Dr. Jonathan Lee. He discusses the importance of, multidisciplinary teams and teamwork, the navigation through the complicated management pathways of melanoma care and how modern technology can deliver sophisticated care across geographical boundaries.

Future executable opportunities from cancer biological advances will be measured in months, not decades. Patient care will be focused once more on where it belongs – the patient. Clinical trials will offer more, closer to home.
Hitting the Sweet Spot

Developing a comprehensive multidisciplinary melanoma program for the 21st century can bridge the divide between one-on-one patient care and the practicality and efficiency of partnering with healthcare systems.

By Jonathan H. Lee, M.D.

In the past two decades, remarkable advances have been made in cancer diagnosis and treatments. Diagnostic modalities have become more sophisticated and sensitive; surgical interventions less invasive; radiation therapies more targetable; and systemic therapies more personalized. With development of cancer treatment pathways, the overall provision of cancer care has become more streamlined. Often unrecognized, however, is the impact of continuing evolution of cancer care delivery.

One of the most substantial improvements in quality of cancer care derived from the advent of Multidisciplinary Clinical Programs (MCPs). Often, these MCPs include a group of physicians from different disciplines (medical oncology, surgical oncology, radiation oncology, pathology, radiology, etc.) with similar clinical interests/expertise and institutional support staff. They get together on a regular basis to discuss and coordinate patient care in disease-specific tumor boards. These MCPs can significantly improve the quality of cancer care by improving coordination and decreasing lag time.

To improve upon this platform, we must first go back to the fundamentals of traditional cancer care. Physicians, whether individually or in the setting of MCPs, have traditionally provided three cancer-related services – diagnosis, treatment and surveillance. However, in partnership with hospital systems, we can deliver cancer education, prevention and screening. Furthermore, by working with bona-fide cancer institutes, we can have access to research – basic science, translational, clinical and population research.

To highlight the importance of research in cancer care, up until a few years ago, the NCCN Treatment Guideline listed “Clinical Trial” as the preferred therapy for patients with metastatic melanoma. Some of these clinical trials have resulted in the development of new first-line therapies. Then there is the concept of “disease treatment” vs. “patient care.” Beyond the traditional core medical services (diagnosis, treatment and surveillance), by leveraging resources of hospital systems and cancer institutes, we can now offer extended medical services such as palliative care, OT/PT/rehab, genetic counseling, behavioral health, cancer support groups, financial assistance, clinical trials and survivorship.

Our comprehensive multidisciplinary melanoma program was built on these principles. It includes all the elements listed above – from education to survivorship – to take care of the patient, rather than just treating a disease.

Delivering, rather than just providing, these robust MCP contents and resources to the patients requires someone to bridge the gap between the healthcare system and the patient – Oncology Nurse Navigation. While manifestations of oncology nurse navigation vary among different organizations, the concept remains the same – the patients have needs, and MCPs have resources.
One of the most substantial improvements in quality of cancer care derived from the advent of Multidisciplinary Clinical Programs

Traditionally, the majority of the burden to obtain these resources has fallen on the patient and their families. Therefore, the role of navigation is to assist in identification, coordination and delivery of needed resources to the patients. The dimensions of navigation include physical, emotion/psychological and intellectual. Thus, oncology nurse navigation improves cancer care coordination and delivery.

Another aspect of cancer care delivery hinges on geographic limitations. Traditionally, the patients and their families had to travel many hours to a regional referral center to receive specialized cancer care. By developing a geographic clinical network infrastructure and regional research hubs, by working closely with local physicians, and by utilizing teleconference and electronic communications platforms, we are able to coordinate and deliver a significant amount of quality cancer care, including clinical trials, near patients’ own homes.

Developing a comprehensive multidisciplinary melanoma program for the 21st century requires efforts that extend beyond what has so far been described. Cancer is a moving target, and cancer care is also an evolving process. Most obvious examples are clinical trials and molecularly based precision medicine. As part of the Georgia NCI Community Oncology Research Program (NCORP) organization, and by maintaining active relationships with the pharmaceutical industry, our melanoma program maintains ongoing access to promising NCI and industry clinical trials for our patients. These efforts also include trials designed to determine the impact of multi-gene panel molecular tumor profiling in patient management, as well as routine genetic mutational analysis for earlier stage melanoma patients. The development of a prospective melanoma clinical database to collect and store all these clinical and molecular data for future research also adds to the richness of the program.

Doctors used to make house calls – we do not do that anymore. But by establishing a multidisciplinary melanoma program that is comprised of dedicated healthcare providers and administrators, by utilizing rich resources of a large hospital system and a cancer institute, by working together with a network of affiliated and non-affiliated physicians, by adopting the latest advancements in research and technology, and by effectively utilizing a navigational platform, perhaps we can hit that sweet spot.
Ovarian cancer is an avaricious tumor, and its domain is nothing less than the entire abdominal cavity. It can extend from the deepest part of the pelvis up to the diaphragm and to the right and left of the colon and everything in between. It can appear after a few weeks of the mildest symptoms, and by then it has already declared open season on the body of a woman. It is fiendishly difficult to treat and unrelenting in its destructive ambition. It is a modern day scourge, casting a narrow and selective net, forever changing the lives of its victims.

The initial symptoms of ovarian cancer are vague and frequently present as gastrointestinal disorders. The ovary is the only organ in the body that has its functioning cells facing the interior of the abdomen, so long before a tumor actually forms, cells detach and implant on the undersurface of the diaphragm, the capsule of the liver, and most important, on the surface of the bowel.

Hundreds of nodules accumulate on the serosal surfaces of the large and small bowel, impeding the smooth flow of intestinal contents, and cause, along with the production of ascites, the cramping distention of the abdomen, which is the hallmark of ovarian cancer. The presentation is actually an intermittent, partial small bowel obstruction and represents a stage 3 cancer at the time of diagnosis. The finding of a stage 1 cancer is usually a serendipitous event – the surgeon is operating for some other reason, and a small nodule on an ovary is discovered.

Despite what you may have been told, there is no way to screen for ovarian cancer. CA-125 is a protein that has been around since 1981 and is merely a test for inflammation. It is by no means specific for this cancer. In fact, the CA-125 blood test is negative in 20 percent of patients with advanced ovarian cancer.

My lecture contains a slide with the heading, Is It Possible To Screen For Ovarian Cancer? The remainder of the slide contains the word no in 41 languages. Many laboratories are involved in the discovery of a diagnostic test for ovarian cancer that would approach 100 percent accuracy. Such a test would be one of modern oncology’s Holy Grails!

The Ovarian Cancer Institute was founded in 1999, and its work is centered in the McDonald Laboratory in the Department of Biology at The Georgia Institute of Technology. For the past 15 years, we have been investigating the genetic and molecular structure of ovarian cancer in the hope that a highly accurate diagnostic test might one day emerge.

Tissue and serum samples are immediately flash-frozen in my operating room at Northside Hospital and transported to the lab at Georgia Tech. They are stored in the minus 80 degree Celsius freezer, render-
ing them “eternal.” These specimens can be as accurately studied 100 years from now as they would be on the day they were collected. We now have one of the largest serum, tissue and data banks for ovarian cancer in the world.

This work is unfortunately expensive. Several years ago the Institute paid $250,000 for a laser capture dissection microscope. This device allows us to outline precisely the tissue we wish to analyze and then detach it from the specimen. The DNA from this tissue is extracted, thus allowing for precision analysis. The DNA is not contaminated by stroma or connective tissue but represents the epithelium of the ovarian cancer. The DNA is then transported to a microarray analyzer. This unit allows us to identify genes that are aberrantly expressed in ovarian cancer tissue.

Years ago, if researchers were interested in studying the genetic morphology of a cancer, they would have to proceed one gene at a time. Today, the microarray analyzer prints out the entire genetic composition of a cancer in quadruplicate on a microchip the size of a thumbnail.

The Ovarian Cancer Institute is very fortunate to be located at Georgia Tech, where there are so many departments working in areas related to ovarian cancer research, including bioengineering, bio-informatics and nanotechnology. There are many ways in which basic science research may eventually impact the way in which patients with cancer of the ovary are treated, but for now, the Ovarian Cancer Institute is focusing on three areas.

1 The Diagnostic Test

If only it were as simple as it is with cancer of the cervix. A pap smear is positive, a biopsy directed with the colposcope shows a CINIII lesion and a LEEP conization is done in the office under local anesthesia completing treatment and preserving the uterus.

The pap smear, unfortunately, is useless in the diagnosis of cancer of the ovary. A positive pap smear has led me to the diagnosis of this cancer only three times in my career. A diagnostic test for ovarian cancer must approach 100 percent accuracy, otherwise cancers will be missed or women will undergo unnecessary surgery.

Our initial attempts at the discovery of a diagnostic test at the Ovarian Cancer Institute involved the study of proteins. These are large and cumbersome structures that produced inaccurate results. We eventually started using mass spectrophotometric analysis of metabolites found in our serum samples. This instrument is amazingly accurate in separating out peaks in similar metabolites from the many samples studied.

We published our results several years ago and reported a nearly 100 percent accuracy. The only time that we found a positive result in a patient with a benign tumor was in someone whose mother and grandmother had died of ovarian cancer. The justifiable criticism of this paper concerned the fact that there were so few samples from stage 1 cancers. No one wants a diagnostic test that is positive only in advanced disease. We then purchased 90 serum samples from patients with stage 1 disease and found that our test picked up every one of them. The data analysis is complete, and we are about to publish our results. It should be noted that the test will be run on a single drop of serum and cost only a few dollars.

2 Targeted Gene Therapy

Very little has changed since Sidney Farber ushered in the modern age of chemotherapy in the mid-1940s. Newer drugs have been developed, dosage has changed as have routes of administration. One thing, however, has remained constant – the pineal gland gets as much of the drug as does the nucleus of the cancer cell.

This is most unfortunate since chemotherapy is a poison, and the dose and the interval between treatments is directly related to the body’s ability to withstand repetitive poisoning. It would be wonderful to be able to deliver the chemotherapy drug to the cancer cell and only to the cancer cell. This would allow the use of a dosage unthinkable today.

Modern genetic profiling identifies specific genes disrupted in a cancer. It is estimated that only 10 percent of mutated genes in a cancer are druggable at the protein level, which is the level at which drug therapy is currently focused.
Targeted gene function at the RNA level is preferred because all malfunctioning genes in a cancer can be targeted at the RNA level. The problem resides in the inability to deliver these RNA-inhibiting drugs directly to the cancer cell. It is important to remember that DNA is the same in every cell, but RNA codes for specific function. In collaboration with the nanotechnologists at Georgia Tech, we are developing a new class of nanoparticle delivery vehicles for this purpose. These technologies are being tested in animals and, if successful, will lead to phase 1 trials in humans.

Personalized medicine in oncology simply refers to treatment based on the structural idiosyncrasies of an individual’s cancer. Once this is nailed down, we should remember that the initial regimen might not be the proper treatment should the cancer return. This recommendation is based on the work of the Ovarian Cancer Institute published a few years ago. We used the microarray analyzer to compare the structure of the primary ovarian cancer with that of the recurrent cancer expecting them to be identical. To our surprise they were frequently quite disparate.

In collaboration with the College of Computer Science at Georgia Tech, we are developing computational algorithms that can accurately predict drug responsiveness in patients based on genomic/gene expression profiles. This approach uses learning algorithms, which are much more accurate than current methods employed by commercial firms such as Foundation Medicine etc.

This development is being coupled with genomic studies (DNA/RNA sequencing analyses) in both primary and recurrent ovarian cancers, all collected from the same cohort of patients. Further studies aim to validate these predictions in current patients by establishing primary cell lines from patient tumor samples. By submitting the patient sample to genomic profiling, we will be able to predict drug responsiveness and hopefully delete chance from the equation.

In reflecting over a 40-year career devoted to the care of women with ovarian cancer, I find myself consumed with the sheer barbarity of it all. A sharp knife opens the abdomen from the pubic symphysis to the xiphoid process to remove cancerous tumors from multiple areas. This is followed by six rounds of chemotherapy, a recurrence and then more surgery and chemotherapy, etc.

I would like to envision the next generation of oncologists sending a newly diagnosed patient to an interventional radiologist to have some cells sucked through a skinny needle passed into the tumor under CAT scan guidance. These cells would be easily grown in the cell culture laboratory – and then a geneticist would create the exact antidote to the nuclear protein in the cancer cell.

This material would then be injected into the patient at 10 in the morning, killing every cancer cell without harming a hair on her head and seeing to it that she is not late for her 2 p.m. tennis match. I would call this designer therapy – Giorgio Armani does cancer treatment. Maybe one day we will see this idea come to fruition.
Contemporary lung cancer therapy requires an understanding of the molecular composition and biologic activity of individual tumor cells. Advances in laboratory technique, characterization of biomarkers and the identification of genetic alterations have facilitated a transformation in the diagnosis and management of patients with lung cancer in 2015. Therefore, a lung tumor diagnosed today requires both accurate pathologic subtyping and genomic analysis to determine the optimal therapy.

Genomic testing of lung tumors has become a new standard of care now that genetic factors have been identified in the development of virtually all cancers. Lung adenocarcinomas harboring epidermal growth factor receptor (EGFR) mutations and anaplastic lymphoma kinase (ALK) rearrangements are among the best understood. Consequently, “small molecule” therapy targeting the respective oncogenic pathways related to these target molecules have been developed and continue to be investigated.

Erlotinib and crizotinib respectively, are examples of such medications that are classified as tyrosine kinase inhibitors (TKIs). By targeting these specific molecules, investigators aim to preferentially kill malignant cells while preserving normal tissues. From a patient’s perspective, the enhanced sensitivity toward tumor cells translates to fewer side effects and improved survival when compared to more traditional systemic chemotherapy.

However, despite the recent progress of targeted therapies, these medications are not curative, and disease relapse consistently occurs through acquired resistance. Another major barrier to the advancement of lung cancer therapy includes the high level of heterogeneity inherent to lung cancer genomics. Whereas a handful of identifiable markers are associated with a majority of breast cancers, our current understanding of lung cancer encompasses only about 20 percent of such tumors.

The variety of oncogenic alterations present in lung cancer appears to be far more numerous, and therefore much work remains. Many more new molecular targets will need to be identified, and ultimately clinical trials will need to be performed. Northside Hospital (NSH) seeks to become a leader in lung cancer related research through an array of public and private partnerships.

In association with the Addario Lung Cancer Medical Institute and its sister organization, The Bonnie J. Addario Lung Cancer Foundation (BJALCF), patients may participate in studies aimed to identify new molecular targets and advance our understanding of lung cancer genomics. In a collaborative manner, ALCMI aims to identify unique populations of lung cancer patients with unique molecular targets by collecting proteomic, genomic, molecular and clinical data across a multitude of institutions and oncology networks. The ultimate goal is development of more novel and targeted therapies to further impact the lives of lung cancer patients.

The Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST) is another important study open for patient enrollment at NSH. This study is sponsored by the National Cancer Institute (NCI) and similarly seeks to analyze tumor specimens and identify genetic targets. In addition, ALCHEMIST investigators will study the efficacy of genetic-based drugs among surgically resected patients with EGFR or ALK positive lung cancer in reducing recurrence among patients at earlier stages of disease.

Patients with squamous cell carcinoma (SCCA) of the lung demonstrate a genetically distinct morphology when compared to adenocarcinoma and its related mutations described above. Furthermore, delineation of molecular genotyping and the development of appropriate targeted therapy aimed at SCCA has lagged. Subsequently, the NCI, NSH and the cancer research cooperative group SWOG Cancer Research, among others, are collaborating to enroll patients in the Lung-MAP clinical trial.

The Lung-MAP clinical trial will test the efficacy of five investigational drugs. The study aims to build on the demonstrated progress against adenocarcinomas of the lung by matching treatment regimens against specific mutations found among patients with SCCA. Patients with SCCA who have failed first-line conventional therapies are eligible for enrollment.
NEW TARGETED TREATMENTS FOR Hematological Malignancies

By Kent Holland, M.D.

In the past two decades, translational research in molecular genetics and improved clinical laboratory techniques to detect the presence of minimal residual disease following a course of treatment have promoted the paradigm of personalized treatment algorithms and the increasing use of targeted therapies for patients with hematological malignancies. The shift from one-size-fits-all therapy to developing a customized treatment approach has the benefit of identifying early a patient’s prognosis and to guide the physician in selecting the optimal treatment pathway based in part upon the molecular genetic pathology.

Monitoring the impact of the therapy with measurement of minimal residual disease provides feedback upon the effectiveness of the therapy and whether additional interventional therapy is required. It is anticipated over the upcoming decade that these algorithms will become more complex with the further identification of relevant genetic mutations, their impact upon disease pathology and the benefit, as well as limitations, of combining novel targeted therapies.

Below are current examples of the practices in the management of patients with hematological malignancies. The concept of the detection of minimal residual disease, its association with relapse and the development of novel treatment approaches to eradicate the residual disease were pioneered in the fields of hematopoietic stem cell transplantation and acute leukemia therapy. These continue to be arenas where new models of therapy are being developed and subsequently expanded into the other areas of hematological malignancies.

Acute Myelogenous Leukemia

Acute Promyelocytic Leukemia (M3 AML)

Molecular genetic testing of leukemia supersedes histopathology in guiding treatment decisions and predicting prognosis in patients with acute myelogenous leukemia (AML). The FAB pathological subtypes of AML primarily have historical context, with genetic testing splitting patients into either non-M3 (M0-M2, M4-M7) or M3 (Acute Promyelocytic Leukemia (APL)) groups based upon the absence or presence of the fusion promyelocytic leukemia gene (PML) with part of the retinoic acid receptor alpha (RARA) gene, which results from the translocation of chromosome 15 and 17.

The PML-RARA gene fusion is found in nearly 98 percent of patients with acute promyelocytic leukemia. This identified sub-group, who otherwise present with standard risk features, are no longer treated like the non-M3 AML patients with conventional cytarabine and anthracycline induction chemotherapy, but rather with a combination of targeted therapy using all-transretinoic acid (ATRA) and intravenous Arsenic Trioxide.

ATRA targets the RARA moiety of PML-RARA gene, and Arsenic Trioxide attaches to the RBCC (Ring Finger, B boxes...
and coiled coil) domain of the PML moiety. This therapy is well tolerated and is associated with 97 percent even-free survival and a 99 percent long-term overall survival (See Figure 1).5

**Non-M3 Acute Myelogenous Leukemia with Normal Cytogenetics**

The majority of patients with de novo AML fall into the non-M3 histopathology group and are further subdivided into prognostic groups based upon cytogenetics and molecular testing (See Table 1). Recent advances in diagnostic molecular genetic testing have allowed us to further tease out patients who will likely do well following conventional chemotherapy versus those who are at high likelihood for relapsing or failing primary therapy.

As an example, patients that present with otherwise normal karyotyping of the leukemia cells will have molecular testing performed to identify those who will have a favorable prognosis following conventional chemotherapy versus those who are at high risk to relapse and have a poor prognosis for survival. FMS-like tyrosine kinase 3 (FLT3) is a cytokine receptor that is expressed on the surface of many hematopoietic progenitor cells. Signaling of FLT3 is a critical pathway for the normal maturation of hematopoietic progenitor cells and is one of the more common mutations found in AML.6, 7

Internal tandem duplications or mutations of the tyrosine kinase domain of FLT3 have been associated with a worse prognosis. Nucleophosmin is a protein encoded by the NPM1 gene that is associated with ribonucleoprotein structures that bind single-stranded and double-stranded nucleic acids.8

For AML patients who have normal cytogenetics and NPM1 gene expression and do not have mutated FLT3 Internal tandem duplications (NPM1 Pos and FLT3-ITD Neg), treatment with chemotherapy alone is associated with a favorable disease outcome (Figure 2).9 Conversely, patients whose AML expresses FLT3 (FLT3+ ITD) have an overall poor prognosis, even in the presence of NPM1 positivity, and are generally referred to undergo allogeneic bone marrow transplantation after entering into a remission with initial therapy.

CCAAT/enhancer-binding protein alpha is a protein that in humans is encoded by the CEBPA gene, which can cause growth arrest of cultured cells.10 Mutation of CEBPA has been associated with a favorable prognosis for patients who otherwise have normal cytogenetic testing, thereby obviating the need to refer for allogeneic bone marrow transplant therapy.9

**Targeted Therapy in AML**

Clinical trials are underway evaluating the benefit of targeted therapy for causative gene mutations in AML. Tyrosine kinase inhibitors for FLT3 mutations are in clinical trials for AML patients. A randomized trial compared sorafenib versus placebo in 276 patients with non-M3 AML who received standard induction and consolidation chemotherapy was recently presented.11 The 3-year event-free survival was observed to be superior for the sorafenib group (56 percent vs 38 percent, P = .017), however, there was not an observed overall survival advantage (63 percent vs 56 percent, P = .382). The trial’s limitation was that only 17 percent of subjects also had FLT3-ITD mutation.

We are currently conducting a randomized clinical trial with the kinase inhibitor Midostaurin in FLT3-ITD-positive AML patients who are to undergo consolidation with allogeneic hematopoietic stem cell transplantation. Midostaurin in phase II clinical trials has shown efficacy in patients with FLT3 mutations.12 The trial is designed to evaluate the benefit of maintenance adjuvant therapy with Midostaurin. The primary objective is to determine whether there will be an improved overall and event-free survival for these high-risk patients.

<table>
<thead>
<tr>
<th>FAVORABLE-RISK AML</th>
<th>Normal Cytogenetics with: NPM1 mutation or isolated CEBPA mutation in the absence of FLT3 (FLT3-, NPM1+)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Inv(16) or t(16;16) t(8;21) t(15;17) {PML-RARA}</td>
</tr>
<tr>
<td>INTERMEDIATE-RISK AML</td>
<td>Normal cytogenetics +8 t(9;11) Other non-defined</td>
</tr>
<tr>
<td></td>
<td>t(8;21), inv(16), t(16;16) With c-KIT mutation</td>
</tr>
<tr>
<td>POOR-RISK AML</td>
<td>Complex (≥ 3 abnormal) -5, 5q-, -7, 7q- 11q23-nont(9;11) t(6;9) t(9;22)</td>
</tr>
<tr>
<td></td>
<td>Normal Cytogenetics with FLT3-ITD mutation and in the absence of NPM1 mutation (FLT3+, NPM1-)</td>
</tr>
</tbody>
</table>

Table 1. Risk stratification table for Acute Myelogenous Leukemia based upon cytogenetics and molecular genetic mutation testing.

**Figure 2: Outcome of cytogenetically normal acute myeloid leukemia (CN-AML) according to IDH1 mutational status. (A) Relapse-free survival and (C) overall survival in CN-AML with mutated NPM1 without FLT3 internal tandem duplication (ITD); (B) relapse-free survival and (D) overall survival in CN-AML lacking the genotype of mutated NPM1 without FLT3-ITD. Schenk RF; et al. NEJM 2008, 358:1909-1918.**
Acute Lymphoblastic Leukemia (ALL)

Advances in the detection of minimal residual disease following treatment for leukemia has been able to identify those patients who may be in a complete remission but are still at high risk for early disease recurrence. The use of molecular real-time polymerase chain reaction genetic probes and advances in multi-color flow cytometry analysis have allowed the ability to detect one leukemic cell in greater than $10^5-10^6$ bone marrow/blood cells analyzed. For both AML and ALL patients, these diagnostic tools are being performed on bone marrow specimens obtained following curative intent therapy.

For patients with ALL, the presence of minimal residual disease following induction therapy is associated with poor prognosis. In an attempt to improve survival for this poor risk cohort, we are currently conducting a randomized clinical trial evaluating the benefit of the novel bi-specific T-cell engager antibody (BiTE) in being able to eradicate the residual acute leukemia following induction therapy and to determine whether this will result in improved overall survival and event-free survival.

BiTEs are two fused synthetic antibodies (See Figure 3), one of which attaches to and activates a cytotoxic T-cell and the other attaches to the targeted tumor cell. Blinatumomab, a recently FDA-approved biological agent, is a bispecific monoclonal antibody that engages the CD3 receptor on a T-cell that brings the host’s immune cell adjacent to pre-B ALL tumor cell by attaching to the CD19 leukemia cell receptor. This action fosters a robust immune response against the ALL tumor cells and results in rapid tumor lysis, resulting in achieving a complete remission in 80 percent of patients treated.

In the recent Phase II BLAST trial, Blinatumomab was administered to patients with ALL who had entered into a complete remission following induction chemotherapy but had persistent minimal residual disease detected ($>10^{-4}$). In 88 patients studied, 78 percent entered into a complete remission following the first cycle of Blinatumomab and 80 percent following the second cycle. Treatment interruptions due to treatment-related adverse events occurred in 28 percent of patients. Based upon these encouraging findings, a Phase III trial has been initiated to determine if the addition of Blinatumomab to standard of care therapy for ALL will result in improved event-free and overall survival. A summary of the trial is shown in Figure 4.

Multiple Myeloma

Incremental advances over the past two decades in the management of multiple myeloma have improved the quality of life and prolonged survival in patients with multiple myeloma. Recent efforts have focused on the role of adjuvant therapy following high-dose chemotherapy and autologous hematopoietic stem cell transplantation in an effort to improve progression-free and overall survival.

Our group was a co-participant in the randomized clinical trial comparing the value of administering the oral drug lenalidomide as long-term maintenance therapy following autologous hematopoietic stem cell transplantation. Lenalidomide is part of a class of drugs called Immunomodulatory drugs (IMiDs) that work against cancer cells in part by impacting the functioning of the immune system and bone marrow microenvironment. This pivotal placebo controlled randomized trial demonstrated improved progression-free survival and a lower incidence of death for those patients who received lenalidomide maintenance therapy (See Figure 5) and has been adopted as standard of care for patients following transplant therapy. As an observed adverse effect, there was a modestly higher risk for developing myelodysplastic syndrome in the lenalidomide treatment arm. As such, patients should have hematological monitoring long term.
For nearly 40 years, Atlanta Gastroenterology Associates has been a leader in bringing the latest medical advancements in gastroenterology and hepatology to patients in Atlanta, Georgia and the Southeast. Today, AGA is the only practice in the metro area to offer Fuse™ - Full Spectrum Endoscopy™. Available exclusively in AGA outpatient endoscopy centers, Fuse technology allows our physicians to see nearly two times more surface area during a colonoscopy, making it possible to detect hard to find cancers and remove pre-cancerous polyps.

Patients are eligible if they have recurrent myeloma and have not demonstrated disease resistance to Bortezomib therapy.

In a Phase II trial study, 15 of 20 patients with recurrent disease demonstrated a partial response when treated with Daratumumab combined with lenalidomide.21 We are currently conducting a pivotal randomized clinical trial comparing the combination of the Daratumumab antibody with Bortezomib and Dexamethason. Patient eligibility includes patients who
have progressed following an autologous hematopoietic stem cell transplant and have not demonstrated disease resistance to Bortezomib.

**Chronic Lymphocytic Leukemia**

A new class of oral agents that target the B-cell Receptor pathways of B-cell malignancies has added potent new therapy for patients with refractory or high-risk chronic lymphocytic leukemia (CLL), mantle cell lymphoma and follicular non-Hodgkin’s lymphoma. The first of these drugs to be FDA approved is the Bruton’s Tyrosine Kinase (BTK) inhibitor Ibrutinib.22, 23, 24

Investigation into the genetic mutation of inherited X-linked Agammaglobulinemia showed that critical mutations of BTK prevent the maturation of pre-B cells into B-lymphocytes. Ibrutinib was developed to block the critical BTK pathway, thereby mimicking this naturally occurring mutation. (see Figure 8)

Ibrutinib is an orally available BTK inhibitor that induces apoptosis and inhibits cellular migration and adhesion of malignant B-cells. The agent irreversibly binds to the Cys-418 portion of BTK and has no observed cytotoxic effect on T-cells. In clinical trials with mantle cell lymphoma Ibrutinib produced unprecedented rapid regression of lymph node masses in patients with relapsed and refractory disease.25 In comparison to conventional chemotherapeutic agents, the drug was reasonably well tolerated.

In chronic lymphocytic leukemia (CLL), Ibrutinib inhibits anti-IgM and prosurvival signals in CLL cells, including the Akt, extracellular signal-regulated kinase (ERK), and nuclear

**Reference**

12. Fischer T, et al. Phase IIb trial of oral midostaurin (PKC412), the FMS-like tyrosine kinase 3 receptor (FLT3) and multi-targeted kinase inhibitor, in patients with acute
factor kappa light-chain enhancer of activated B cells (NF-κB) pathways. BTK inhibition blocks the chemokine-mediated homing and adhesion of B cells. The induced cytotoxicity in CLL cells is independent of mutational IgVH status or cytogenetic abnormalities, including the poor-risk patients who have deletion of chromosome 17p (TP53).

In the clinical trial evaluating the efficacy of Ibrutinib in patients with recurrent CLL published by Byrd et al, 71 percent of patients with refractory CLL responded (See Figure 9). The dramatic responses were seen across the spectrum of patients. Ibrutinib was associated with a high frequency of durable remissions in patients with relapsed or refractory CLL and small lymphocytic lymphoma, including patients with high-risk genetic lesions.

Based upon these extraordinary responses, trials have been initiated in patients with treatment-naïve disease. The PI3Kδ inhibitor Idelalisib acts upstream to the BTK pathway and has shown similar efficacy and side effects in patients with CLL and lymphoma and was recently approved by the FDA. We are currently conducting clinical trials evaluating the benefit of combining PI3Kδ inhibitors and Ibrutinib in patients with B-cell lymphoproliferative diseases.
As cancer care becomes increasingly more sophisticated, so does the field of radiation oncology. Mark McLaughlin, M.D., medical director of radiation oncology for WellStar Health System, says that one of the most exciting developments in the field is the use of TomoTherapy, a versatile radiation therapy system available for the treatment of a wide variety of cancers.

"TomoTherapy operates from the principle of delivering the maximum dose of radiation to tumor tissue while at the same time protecting surrounding healthy tissue," he says. "Its image guidance allows us to adjust, in real time, for any movement the patient may have during treatment and still deliver a precise dose of radiation."

**Customized treatments, improved patient outcomes**

The TomoTherapy® System, which is capable of treating a broad range of tumors, from the most common to the most complex, combines daily 3-D imaging with intensity modulated radiation therapy (IG-IMRT), giving clinicians greater ability to customize treatment for each patient and minimize radiation exposure.

Unlike conventional systems, which allow radiation to be delivered from only a few directions, the TomoTherapy System rotates in 360 degrees, meaning that treatments can be delivered continuously to the tumor from every angle. More beam directions give physicians more control in how they plan treatments — and more assurance that the dose will be confined to the tumor, reducing the risk of short- and long-term side effects.

McLaughlin says that the ability to track changes in the size or location of a tumor is very beneficial for cancer patients.

"The conformality and tracking capability allow us to target an intense amount of radiation exactly to the tumor site, while reducing the negative impact on surrounding healthy tissue," he says. "This combination can lead to improved outcomes for patients."

**Technologies add new layers to multidisciplinary care**

The WellStar Kennestone Hospital Cancer Center soon will become one of only two facilities in Georgia to offer the TomoTherapy System. According to Joel Helmke, vice president of oncology services, the addition of TomoTherapy is a complement to WellStar's multidisciplinary system of cancer care and indicates the health system's strong commitment to providing the most progressive care possible at any given time.
“It’s very exciting to be building on our rich history of technological innovation in cancer care, which dates back to the arrival of the CyberKnife® System in the early 2000s,” he says. “We are positioning ourselves to provide innovative treatments and world-class care to our patients today and in the future.”

CyberKnife is a radiosurgery system designed to treat cancer anywhere in the body, with sub-millimeter accuracy and image guidance technology. It is used for brain and spine tumors, lung cancer, pancreatic cancer, liver tumors, prostate cancer and additional cancers that in the past had no available treatment, including surgery or conventional radiation therapy.

Together, CyberKnife and TomoTherapy offer an expanded range of treatment options for a variety of cancers with fewer side effects than previous radiation delivery methods that are less precise. Already one of the top 10 busiest sites in the country for CyberKnife surgeries, WellStar expects to attract a similar high volume of patients who desire radiation delivery via TomoTherapy technology. Additionally, physicians from all over the U.S. visit WellStar to learn CyberKnife techniques, and the health system anticipates that it will also become a destination for physicians to learn how to use TomoTherapy for their cancer patients.

Joshua H. Levine, president and CEO of Accuray, says that the company’s partnership with WellStar on the use of these technologies has contributed to developments in cancer treatment.

“The long-term relationship we’ve had with the WellStar Health System team has enabled us to work with a true partner to significantly and positively impact the way cancer is managed. We have similar goals, with each of us striving to provide patients with the most technologically advanced options to treat their cancer,” he says. “More than eight years ago, WellStar was the first medical center in Georgia to begin using the CyberKnife System. They are again breaking new ground with the installation of the TomoHDA™ System, which will enable WellStar clinicians to easily and efficiently treat a broad range of cancer cases, from those that are highly complex to those that are more routine.”

McLaughlin says that WellStar physicians will first focus on the disease sites that would most benefit from TomoTherapy treatment.

“This will give us a better way to deliver radiation to head-and-neck cancer patients, who often experience problems with nonfunctioning salivary glands after treatment. TomoTherapy’s precise delivery will help us reduce or even eliminate that issue,” he says, adding that lung, breast and prostate cancer patients will also benefit from TomoTherapy. “The accuracy and ability to spare healthy surrounding tissues will give these patients an improved quality of life.”

WellStar currently is in the process of training staff and preparing the room that will house the TomoTherapy System. Patients will have access to this therapy modality by mid-April 2015.

For referrals, contact Madge Reynolds at 770-793-7550.

The TomoTherapy Process

The TomoTherapy® platform introduces a new, integrated way to deliver radiation treatments for cancer. The process makes it easier on clinicians and patients alike.

Planning. Before beginning a TomoTherapy treatment, the doctor uses 3-D images from a combination of scanning technologies (such as CT and MRI) and special software to establish the precise contours for each treatment volume (tumor) and any regions at risk (sensitive organs or structures). The doctor then decides how much radiation the tumor should receive, as well as acceptable levels for surrounding structures.

Patient positioning. As both a treatment delivery machine and a CT scanner, the TomoTherapy system allows doctors to take a CT scan just before each treatment. With the scan, they can verify the position of the tumor and, if necessary, adjust the patient’s position to make sure radiation is directed right where it should be.

Precise treatment delivery. The TomoTherapy treatment system delivers radiation therapy with a spiral delivery pattern (TomoHelical™) or discrete-angle approach (TomoDirect™). Photon radiation is produced by a linear accelerator (or linac for short), which travels around the patient and moves in unison with a device called a multi-leaf collimator, or MLC, that shapes the beam. Meanwhile, the couch is also moving — guiding the patient slowly through the center of the ring.

Custom imaging by the day. The full TomoTherapy treatment typically takes 10 to 20 minutes from when the patient enters the treatment room until they leave. This includes daily CT scanning and treatment (“beam-on time”) as well as patient set-up, positioning and image registration to ensure accuracy. The system’s CTrue™ imaging allows clinicians to see what they plan to treat immediately prior to beginning each treatment fraction. This is important because anatomy can change from day to day.
Pulmonology, an internal medicine subspecialty, is concerned with diseases of the lungs and bronchial tubes and often involves evaluation of the upper respiratory tract (nose, pharynx and throat) as well as the heart. Interventional pulmonology is a relatively new field in pulmonary medicine that uses endoscopy and other tools to diagnose and treat conditions in the lungs and chest.

Flexible bronchoscopy useful in diagnostics, therapeutic applications

“Fiber optic bronchoscopy did its part to change the world in late ’60s and early ’70s,” says William R. Kenny, M.D., of Piedmont Physicians Pulmonary of Atlanta. “The technology kept evolving, resulting in flexible bronchoscopes with ultrasound probes that can transmit data in real-time today. Now, we are able to see through the wall of the trachea or bronchus, which is especially helpful to examine and needle biopsy lymph nodes or masses that are suspicious for cancer or infection.”

This technique, called endobronchial ultrasound (EBUS), uses ultrasound along with bronchoscopy to visualize the airway wall and structures adjacent to it. It offers physicians a means of making more accurate diagnoses as well as performing therapeutic procedures in patients with certain lung diseases and conditions. According to Dr. Kenny, having this improved visualization can lead to a more accurate diagnosis and help determine the best course of treatment. It can also assist in more accurate staging of cancers.

“The electromagnetic navigation (ENB) procedure makes it possible to perform diagnostics on nodules in the lungs that were previously not accessible,” says Dr. Kenny. “The superDimension™ navigation system creates a 3-D CT scan of the nodule, plotting its exact location in the lung. Then, the system guides a steerable catheter that can biopsy a tumor distally in the lung. This is a big improvement over the use of interventional radiology, with less risk of pneumothorax.”

Dr. Kenny adds that flexible bronchoscopy is helpful in performing therapeutic applications via various instruments that can be passed through the bronchoscope.

“Most of the scopes have channels that can accommodate brushes and biopsy forceps, which obtain cytology and histology specimens,” he says. “We can also use scopes for procedures such as balloon dilation of a constricted bronchus, cauterization of a mass or loop cautery to remove a polyp, obtaining uncontaminated fluid samples, or removing a foreign body that the patient accidentally aspirated.”

The advancing technology continues to provide pulmonologists with enhanced capabilities.

“The scopes are getting better all the time,” Dr. Kenny says. “For example, today we have digitized images. Everything I’m looking at on the screen is a digital image that can be copied, printed or magnified. That’s an advantage.”

Interventional pulmonology plays important role in multidisciplinary approach

Interventional pulmonology (IP) is a discipline that involves the use of less invasive endoscopic procedures in the diagnosis and potential therapy of patients with malignant and non-malignant diseases involving the lung and the chest cavity.
According to Rabih Bechara, M.D., FCCP, Chief of Interventional Pulmonology, Pulmonary & Critical Care Medicine at Cancer Treatment Centers of America, because of its numerous applications, IP plays an important role in a multidisciplinary approach to treating patients with lung diseases.

“Patients have better outcomes when a team of physicians cares for them; importantly, each member of that team brings his or her special set of skills to the table,” says Dr. Bechara, who is also Professor of Medicine at Georgia Regents University School of Medicine. “For example, a patient with cancer may be receiving treatment from a radiation oncologist. Another team member, the interventional pulmonologist, can assist the radiation oncologist by placing markers in the patient’s tumor to help guide the delivery of radiation in a more accurate and safe manner.”

Interventional pulmonologists perform therapeutic procedures in patients with malignant or benign airway obstruction. In addition, they perform advanced endoscopic procedures that enable thoracic surgeons to localize small lung nodules prior to surgery. The latter results in less tissue loss during resection. Additionally, IP has taken on an increasingly important role in the staging of lung cancer, a crucial step in the management of patients with lung malignancies.

“Earlier diagnosis is always best, but appropriate staging is equally important in directing what type of therapy is needed,” says Dr. Bechara. “In the past, we relied on more traditional invasive surgical procedures to stage patients with nodes in the chest area. But today, endoscopic ultrasonography provides high specificity and sensitivity, is much less invasive and is very reliable in the staging process.”

Endoscopy can also prove helpful for cancer patients who have become resistant to their current treatment.

“We know that cancer cells sometimes mutate, therefore becoming resistant to treatment. So if a patient isn’t responding to therapy, something may have changed within their cancer cells,” Dr. Bechara says. “The latest endoscopic techniques allow the interventional pulmonologist to re-biopsy these patients in order to acquire new tissue, which can be examined to see if the cancer cells have mutated. Then, the multidisciplinary team can create a new treatment plan, tailored to the patient, based on the specific characteristics of his or her cancer cells.”

In its 2015 State of Tobacco Control report, the American Lung Association gave the state of Georgia poor grades for its efforts toward curbing tobacco use. States were evaluated in four categories: Tobacco Prevention Control and Spending, Smokefree Air, Tobacco Taxes and Access to Cessation Services.

Georgia received a grade of C in the Smokefree Air (state smoking restrictions) category and failed in the remaining three categories. Not surprisingly, it received a grade of F in the Tobacco Taxes category, due to having the fourth lowest cigarette tax in the country at 37 cents per pack.

On a positive note, the Lung Association did give Georgia a “thumbs up for expanding coverage of cessation medications and individual counseling to the entire Medicaid population. Previously this coverage was only available for pregnant women.”

Substantial improvement in these grades could be achieved if Georgia’s elected officials will take the following three actions recommended by the American Lung Association:

1. Substantially increase the price of tobacco products, including electronic smoking devices;
2. Increase the number of local comprehensive smokefree air laws; and
3. Increase tobacco control program funding.
The Southeast Permanente Medical Group (TSPMG) is part of Kaiser Permanente’s integrated health care delivery system. Our physicians are connected through one of the largest electronic medical record systems in the U.S., helping us lead the way in improving clinical practice and overall health care quality.

As the Southeast’s largest mutual professional liability insurer, MAG Mutual empowers physicians to focus on delivering quality care by leading the way in proactive patient safety resources, unrivaled claims defense and expert risk management services.

The Doctors Company is fiercely committed to defending, protecting, and rewarding the practice of good medicine. We are the nation’s largest medical malpractice insurer, with 73,000 members, $4 billion in assets, and over $1 billion in surplus.

VITAS Innovative Hospice Care® is the nation’s leading provider of end-of-life care. VITAS serves patients and families in the 24 county Atlanta Metropolitan area, providing care for terminally ill patients, in their homes, inpatient hospice units as well as in hospitals, nursing homes, assisted living communities, and residential care facilities.

Join the MAA today!
For membership information, contact David Waldrep, Executive Director at 404-881-1020.

The Medical Association of Atlanta (MAA) is a non-profit association dedicated to the advancement of organized medicine in Atlanta.
In February, the Medical Association of Atlanta hosted its annual Legislative Dinner in Buckhead. Thirteen State Senators and Representative attended the dinner and discussed issues pertinent to Atlanta’s healthcare community. Donald Palmisano and Marcus Downs from the Medical Association of Georgia were also present to provide their perspectives on the current legislative session.

Tumors have nowhere to hide

Patients now have somewhere to turn

The future of cancer treatment is here. And it’s only available at WellStar. WellStar is the only health system in metro Atlanta to offer TomoTherapy® and CyberKnife® for the treatment of both cancerous and non-cancerous tumors.

TomoTherapy

Unlike conventional systems, which allow radiation to be delivered from only a few directions, TomoTherapy rotates in 360 degrees, meaning that treatments can be delivered continuously to the tumor from every angle. More beam directions give physicians more control in how they plan treatments – and more assurance that the dose will be confined to the tumor.

CyberKnife Robotic Radiosurgery System

The CyberKnife Robotic Radiosurgery System involves no cutting, and for many, can offer a non-invasive alternative to surgery for the treatment of tumors. The system is composed of a radiation delivery device, which is mounted on a flexible robotic arm which enables CyberKnife to deliver radiation to tumors anywhere in the body. Its exceptional tracking ability eliminates the need for patients to have stabilizing head frames or limited breathing during treatment.

State Legislators in Attendance

Senator Renee Untermann
Senator Judson Hill
Senator Nan Orrock
Senator Vincent Fort
Senator Gail Davenport
Senator Donzella James
Representative Roger Bruce
Representative Sharon Cooper
Representative Demetrius Douglas
Representative Pat Gardner
Representative Buddy Harden
Representative Lee Hawkins
Representative Beth Beskin
This Month’s Featured Board Members

Barry Silverman, MD

Dr. Barry Silverman is a cardiologist who has been practicing at Northside Cardiology in Atlanta for 42 years. He went to medical school at Ohio State University, trained in internal medicine at Vanderbilt University Hospital, and did a fellowship in cardiology at Johns Hopkins Hospital.

He came to Atlanta to join the Emory University Cardiology division and start the cardiology department at Northside Hospital. He has been involved in organized medicine since his arrival in Atlanta in 1973. He organized the internal medicine education program at Northside and supervised the program for 25 years. He was the chairman of the Georgia College of Physicians state education meeting and the Georgia chapter of the American College of Cardiology state education meeting.

Dr. Silverman has served as an editor for Atlanta Medicine for 15 years. In addition to his clinical practice, he volunteers at Grady Memorial Hospital.

Matthews Gwynn, MD

Dr. Matthews Gwynn has been a partner with Atlanta Neurology for 24 years and led the development of the Stroke Center at Northside Hospital and serves as its medical director. His areas of expertise include use of botulinum toxin for neurological disease, telemedicine, stroke, and movement disorders.

Dr. Gwynn is a graduate of the University of Virginia School Of Medicine, completed his internal medicine residency at the University of Alabama-Birmingham and neurology fellowship at the University of Virginia, and is board certified in both internal medicine and neurology.

He is past-chairman of the department of internal medicine at Northside Hospital and chief of the neurology sections at both Northside Hospital and Emory St. Joseph’s Hospital.

Dr. Gwynn served as president and chairman-of-the-board of the Medical Association of Atlanta and treasurer of the Medical Association of Georgia, is the CEO and founder of AcuteCare Telemedicine, and is an owner of Neurotrials Research.

W. Hayes Wilson, MD

Dr. Wilson is the President of Piedmont Rheumatology Consultants. He is chief of the Division of Rheumatology at Piedmont Hospital, chairperson of the Medical and Scientific Committee of the Arthritis Foundation, and serves on the Board of Directors of the Arthritis Foundation National, medical advisory board for the Lupus Foundation of America, Georgia Chapter. Dr. Wilson is also a Fellow of the American College of Rheumatology and serves as Vice Chairman of the board of directors for the BreakThru House Ministry.
Bone marrow transplants that result in world travel.

Northside Hospital Cancer Institute’s survival rates are among the highest in the country for bone marrow transplants. That’s for both related and unrelated donors. It’s one reason why so many people from across the country trust Northside with their cancer care. Northside has seen thousands of cancer survivors walk out their doors. And then, go just about anywhere. For help finding a cancer specialist, call 404-531-4444.

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