INAUGURAL EDITION

Journal of Indy Hematology Review 2022

19th Annual Indy Hematology Review™

Saturday, September 10, 2022 | The Westin Indianapolis

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Disclosures, Bios, Presentation Slides

Disclosure information, biographies, and faculty slides (as permitted by each faculty member) will be available at www.indyhematologyreview.com

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CHAIRMAN'S LETTER

What is your SCORE?
Exciting and emerging clinical data presented at the major medical congresses over the past year would further enhance outcomes for our patients, BUT in spite of this remains the question: is this data applicable to all persons?

Disparities in cancer treatment, a major contributor to worsening outcomes in cancer mortality for racial minorities, can be related to the underrepresentation of these minorities in clinical trials. Race reporting is frequently omitted in clinical trials resulting in regulatory approval, but worse in studies outside regulatory purview. In the decade ending in 2018, only 7.8% of 230 trials (recruiting 112,293 patients) documented the four major races in the US, with 25.2% of these clinical trials reporting racial subgroups. These studies largely underrepresented Blacks, Hispanics, and Native Americans in their proportion of U.S. cancer incidence. This gap in representation is worse for specific tumor types, particularly in prevalence-adjusted participation for cancers that are more common in African Americans.

The modern Hippocratic oath begins with "I", and similarly, diversity can only be achieved when each individual team member and corporation embraces DEIA efforts. An individual's diversity plan is central to this altruistic and self-preserving desire. Achieving diversity in medical research is beneficial for minority and majority persons for both individual economic and scientific reasons. The individual diversity plan should include the following.

1. To understand and address unconscious bias and develop strategies to overcome these issues in the immediate environment, community, and practice.
2. Implement a cultural competency plan with cultural humility and remove communication barriers. Cultural competency is defined as healthcare providers' ability to function effectively in the context of cultural differences.
3. Self-education on the historical, structural, and systemic effects of racism, redlining, and economic factors precluding or preventing enrollment in clinical trials with their applicability to one's community.
4. Develop a diverse workforce and research teams and enhance organizational DEIA plans.

Creating an individual diversity plan and critically evaluating medical data for diversity ensures that the data used for decision-making is applicable to the patient in the "room with you". Communicating data applicability or lack thereof is paramount to honest patient care and a transparent provider-patient relationship.

On February 11, 1861, a stone's throw from here, Abraham Lincoln, on his way to Washington to assume the Presidency stated: *"I appeal to you to constantly bear in mind that not with politicians, not with Presidents, not with office-seekers but with you is the question: Shall the Union and shall the liberties of this country be preserved to the latest generations?"*

With YOU lies the power. Your SCORE as an "INDIVIDUAL PROVIDER, EXECUTIVE, SALESPERSON, etc." can be the difference in improving clinically meaningful outcomes for all people with cancer.

Welcome to our 19th Annual Indy Hematology Review, thank you for your support and **please join us on March 18, 2023, to celebrate our 2 decades of education and our 20th Annual Review.**

Ruemu Ejedafeta Birhiray, MD
Chairman

SYMPOSIUM AGENDA

SATURDAY, SEPTEMBER 10, 2022

All sessions are in Grand Ballroom 4-5 (2nd Floor) unless otherwise noted

6:30 a.m. – 2:00 p.m.	**Registration** Grand Ballroom Foyer
7:00 a.m. – 7:45 p.m.	**Breakfast Product Theaters** Capitol Ballroom 1, Cameral, Council (1st Floor) and House (2nd Floor)
7:00 a.m. – 4:05 p.m.	**Exhibitor Displays** Grand Ballroom 1-3
8:00 a.m. – 8:30 a.m.	**State of the Art: 2022: Emerging Therapies in Hematologic Malignancies** Ruemu Birhiray, MD, Chairman
8:30 a.m. – 9:00 a.m.	**Treating Multiple Myeloma: The Cure is Within Reach; Goals of Current Therapy** Kenneth Anderson, MD
9:00 a.m. – 9:30 a.m.	**A Journey of Hope: An Update of the Treatment of Waldenström's Macroglobulinemia and Lymphoplasmacytic Lymphoma in 2022** | Steven Treon, MD, MA, PhD, FACP, FRCP
9:30 a.m. – 10:00 a.m.	**Amyloidosis: Diagnosis, Risk Stratification and Treatment** Morie Gertz, MD, MACP
10:10 a.m. – 10:40 a.m.	**Targeting and Treating: Indolent and Mantle Cell and Hodgkin Lymphoma in 2022** Nancy Bartlett, MD
10:40 a.m. – 11:10 a.m.	**What We Recommend in 2022 for the Treatment of Aggressive B and T Cell Lymphoma: An Indy Hematology Review Perspective** | John Leonard, MD
11:10 a.m. – 11:40 a.m.	**Acute Lymphoblastic Leukemia: Biologic and Targeted Therapy** Hagop Kantarjian, MD
11:50 a.m. – 12:20 p.m.	**Chronic Myeloid Leukemia: A New Drug and New Goals** | Richard Larson, MD
12:20 p.m. – 12:50 p.m.	**Classical Hematology: Disorders of Thrombosis, Bleeding and Cytopenias** Craig Kessler, MD
1:00 p.m. – 1:45 p.m.	**Luncheon Product Theaters** Capitol 3, Cameral, Council, (1st Floor) House (2nd Floor)
2:00 p.m. – 2:45 p.m.	**T. Howard Lee Keynote Lecture: Targeted and Cellular Therapy for Diffuse Large Cell Lymphoma: The End of a Journey?** | Sonali Smith, MD, FASCO
2:45 p.m. – 2:50 p.m.	**Challenging Cases Presentation** | Michael Wiemann, MD, FACP
2:50 p.m. – 3:20 p.m.	**Annual Steven Coutre Chronic Lymphocytic Leukemia Memorial Lecture: What Would Steve Do? Treatment of CLL in 2022** | Adrian Wiestner, MD, PhD
3:20 p.m. – 3:35 p.m.	**Minimal Residual Disease (MRD) Panel: Leukemia, Myeloma and Lymphoma** Rami Komrokji, MD, Sonali Smith, MD, FASCO, Saad Usmani, MD, MBA, FACP, Adrian Wiestner, MD, PhD
4:05 p.m. – 4:35 p.m.	**Emerging and Current Therapies for Myeloproliferative Neoplasms** Ruben Mesa, MD, FACP

SYMPOSIUM AGENDA

SATURDAY, SEPTEMBER 10, 2022

All sessions are in Grand Ballroom 4-5 (2nd Floor) unless otherwise noted

4:35 p.m. – 5:05 p.m.	**Myeloproliferative Neoplasms: Prognostication and Therapeutic Implications** Ayalew Tefferi, MD
5:05 p.m. – 5:35 p.m.	**Current Approaches to the Treatment of Acute Myeloid Leukemia and Acute Promyelocytic Leukemia** | Martin Tallman, MD
5:35 p.m. – 6:05 p.m.	**Myelodysplastic Syndrome: Teaching an Old Dog New Tricks with Emerging and Targeted Therapies** | Richard Stone, MD
6:05 p.m. – 6:35 p.m.	**The Holy Grail of Hematopoietic Stem Cell Transplantation: Achieving the Cure for Hematologic Malignancies in 2022** | Richard Childs, MD
6:35 p.m. – 6:45 p.m.	**Q & A | Wrap Up and Adjourn** | Ruemu Birhiray, MD, Chairman
6:45 p.m. – 7:00 p.m.	**Hematologic Malignancies Town Hall Reception**
7:00 p.m. – 8:30 p.m.	**Hematologic Malignancies Town Hall** | Ruemu Birhiray, MD – Moderator, Michael Wiemann, MD, FACP, Morie Gertz, MD, MACP, John Leonard, MD, Charles Schiffer, MD, Nancy Bartlett, MD, Ruben Mesa, MD, FACP, Rami Komrokji, MD, Saad Usmani, MD, MBA, FACP, Adrian Wiestner, MD, PhD

NURSING/ALLIED PROVIDERS AGENDA

SATURDAY, SEPTEMBER 10, 2022

All sessions are scheduled in Capitol Ballroom 2 (1st Floor) unless otherwise noted
Moderators: Donna M. Birhiray, OTR, MBA \| Thalia Hammond

8:00 a.m. – 8:30 a.m.	**State of the Art: 2022: Emerging Therapies in Hematologic Malignancies** Ruemu Birhiray, MD Grand Ballroom 4-5
8:30 a.m. – 9:00 a.m.	**Aggressive Lymphomas** | John Leonard, MD
9:00 a.m. – 9:30 a.m.	**Management of Long-Term Survivors of Hematologic Malignancies** Sandra Garofalo, MS, APRN, AOCNP
9:30 a.m. – 10:00 a.m.	**Benign Hematology and Coagulopathy** | Craig Kessler, MD
10:10 a.m. – 10:40 a.m.	**Acute Leukemia** | Rami Komrokji, MD
10:40 a.m. – 11:10 a.m.	**Chronic Leukemias** | Richard Larson, MD
11:20 a.m. – 11:45 a.m.	**Myeloproliferative Neoplasms** | Ayalew Tefferi, MD
11:45 a.m. – 12:10 p.m.	**Indolent Lymphomas and Hodgkin's Lymphoma** | Nancy Bartlett, MD
12:10 p.m. – 12:35 p.m.	**Recognizing Toxicities of Oral Oncolytics in the Management of Hematologic Malignancies** | David Reeves, PharmD, BCOP
12:35 p.m. – 12:55 p.m.	**Multiple Myeloma and Waldenström's** | Saad Usmani, MD, MBA, FACP

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REMEMBERING ONE OF THE GREATS: DR. STEVEN COUTRE

Written by Nicola Donelan

On November 9, 2021, our community lost a giant and a dear friend. Steven Coutre, MD, professor of hematology at the Stanford School of Medicine, following a prolonged illness and hospitalization. He was 62. Dr. Coutre was the director of Stanford Health Care's hematology clinic and an international leader in research, development, and deployment of ground-breaking treatments for patients with blood disorders, including chronic lymphocytic leukemia (CLL), a disease which he also suffered from himself.

PERSONAL HISTORY

Dr. Coutre was born on May 27, 1959, in Evanston, Illinois, the second oldest of six siblings. He displayed academic promise early on, graduating from Maine North High School in Des Plaines, Illinois, as valedictorian, then attending an accelerated science program in biochemistry at Northwestern University.

He graduated from Stanford School of Medicine in 1986, completed his residency and internship at Yale University and his fellowship in Hematology and Oncology at Stanford University. He was appointed an acting assistant professor of medicine at Stanford in 1995 and became a full professor in 2013.

Dr. Coutre met his wife Kathy at Yale New Haven Hospital. They married in Connecticut in 1991 and after moving to Palo Alto, California, started a family there with the arrival of twins Brooke and Evan in 1992.

OUTSIDE OF WORK

Steve was energetic and efficient, qualities that applied to his research, patient care and equally to his many interests outside of work. He was fully engaged in everything he did and always valued and prioritized his time with family.

He had a love for traveling, particularly Hawaii and Italy, and hiking, exploring national parks with friends. At home, Steve could often be found caring and tending a yard full of diverse plants as well as his hives. As an amateur beekeeper, he would harvest honey to share with friends and local restaurants.

RESEARCH AND CLINICAL CONTRIBUTIONS

Dr. Coutre was a hematologist, leukemia specialist, and professor at Stanford Health Care in Palo Alto, California, as well as a former member of the American Society of Hematology Committee on Practice. As director of Stanford Health Care's hematology clinic, he was integral to the development of new therapies for blood disorders such as multiple myeloma (MM) and CLL.

Integral to this was the widely recognized research program Dr. Coutre established under the Division of Hematology at Stanford Medicine, with the aim to understand, and develop treatments for, hematological disorders and malignancies.

At the same time, he was a compassionate physician, said to be beloved by his many patients, who suffered from a number of different of blood disorders. These ranged from malignancies to non-malignant conditions, such as anemia and blood-clotting disorders.

He treated patients at the Stanford Cancer Institute and ran clinical trials at the Hematologic Malignancies Program that aimed to uncover new drugs and treatments that could help patients, including a recent phase-3 clinical trial funded by the National Cancer Institute that was testing a new anti-cancer drug in older patients with CLL.

Along with Tait Shanafelt, MD, professor of hematology and the chief wellness officer at Stanford Medicine, he helped run another large, multi-center phase-3 clinical trial. The results, published in The New England Journal of Medicine in 2019, showed that a combination of two drugs can keep CLL patients disease-free and alive longer.

RECENT MEMORIES

It seems only yesterday, though in reality it is almost a year, since Dr. Coutre participated in the 18th Annual symposium, talking about the remarkable progress made in CLL treatment during the last decade, progress he was at the heart of.

"Someone else presented one of his talks, but Dr. Coutre pre-recorded his patient talk and joined us live, virtually, from his hospital bed for the hematological malignancies town hall," said Dr. Ruemu Ejedafeta Birhiray, MD, President/CEO, Indy Hematology Education, Inc., and organizer of the Indy Hematology Review symposium.

"It's a very important part of the meeting, where we present cases, and Dr. Coutre was with us asking questions and giving us his views in real time. Who, ill in a hospital bed, volunteers to do all of this? It shows his selflessness, his willingness to put the patients and hematology community first," added Dr. Birhiray.

Throughout the ongoing COVID-19 pandemic, which would contribute to complications in his own health, Dr. Coutre provided guidance to physicians and CLL patients alike about the potential impact COVID-19 could have on their health and treatment.

"Steve was pragmatic, with a keen sense for what actually works, what can really translate from research to the clinic and provide benefit," said Adrian Wiestner, MD, PhD, Senior Investigator with tenure and chief of the Laboratory of Lymphoid Malignancies, Hematology Branch, NHLBI, NIH (Bethesda, MD).

"He was very involved in developing targeted therapies for patients with CLL, which is probably his contribution with the most impact in research and for patients. However, I know that his mentorship has also had a big impact on many people. He was really great at moving things forward for his patients, in clinical research and in people's careers," said Dr. Wiestner.

THE FUTURE

The Coutre family has established *"The Dr. Steven E. Coutre Research and Education Fund"* at Stanford Medicine to further Steve's passion and legacy in research and standards of care for hematologic malignancies, including Chronic Lymphocytic Leukemia, and to support the continued education of the next generation of Hematology fellows.

Dr. Birhiray added *"We decided to honor Dr. Coutre's legacy by naming our CLL lectures after him. Dr. Adrian Wiestner from the National Institutes of Health is the ideal person to present the first one, speaking from one of the nations, if not the world's, top institutions on CLL research."*

On Saturday, September 10th, 2022 Dr. Wiestner, will give the inaugural Annual Steven Coutre Chronic Lymphocytic Leukemia Memorial Lecture: *"What Would Steve Do? Treatment of CLL in 2022."*

We, the hematology community, look forward to each future Steven Coutre Chronic Lymphocytic Leukemia Memorial Lecture as we continue to honor his memory.

2022 FACULTY AND ABSTRACTS

Ruemu E. Birhiray, MD
Partner, Hematology Oncology of Indiana, a Division of American Oncology Network and President and CEO, Indy Hematology Education Inc. Clinical Professor, Marian University College of Osteopathic Medicine (Indianapolis, IN)

Dr. Birhiray is an attending physician in medical oncology, hematology, and hematopoietic stem cell transplantation at Hematology-Oncology of Indiana, and at St. Vincent Hospital in Indianapolis, IN. After completing his internal medicine residency at Columbus Hospital in Chicago where he also served as Chief Medical Resident in 1994, he was a postgraduate fellow in bone marrow transplant at Johns Hopkins University in Baltimore and in medical oncology at the National Cancer Institute, National Institutes of Health in Bethesda, Maryland.

INDY HEMATOLOGY REVIEW 2022: Abstract
Data presented in the past year has led to significant advances in the treatment of hematologic malignancies and disorders with potential meaningful impact on patient outcomes.
The proceedings of the Annual Indy Hematology Review below are meant to highlight these results. My opinion on these data and their potential impact are as follows:

PRACTICE Changing
Teclistimab in R/R Myeloma
Ibrutinib + BR as initial therapy in Mantle Cell Lymphoma
Brentuximab + AVD in Stage III/IV Hodgkin's Lymphoma
FIXED DURATION THERAPY IN CLL: Ibrutinib and Venetoclax
CART-T Therapy as SECOND-LINE THERAPY in Transplant Eligible-Relapsed DLBCL
Practice Confirming
Autologous Stem Cell Transplantation in Myeloma
Potentially Practice Changing:
Polatuximab Vedotin + CHP in High Risk DLBCL
Quizartinib + Standard Chemo in mutant FLT-3-ITD AML
Ivosidenib + Aza in Elderly (≥75yrs) IDH1-mutant Newly Diagnosed AML
Non-covalaent BTKi in R/R CLL: Pirtobrutinib and MK-1026
Mosunetuzumab in DLCBL
TKI discontinuation for CML in MR4 with close monitoring
Stay Tuned
Margrolizumab in TP-53 mutant AML
Bispecific antibodies in R/R lymphoma and RRMM
Parsaclisib in Relapsed Mantle Cell Lymphoma
CPX-351 and Venetoclax in MDS
Pyruvate Kinase Activators in SCD
CAR-T Cellular Therapy: Primary CNS Lymphoma

Kenneth Anderson, MD
Kraft Family Professor of Medicine, Harvard Medical School, Program Director of the Lebow Institute for Myeloma Therapeutics and Jerome Lipper Multiple Myeloma Center, Dana-Farber Cancer Institute (Boston, MA)

Over the last four decades, he has developed laboratory and animal models of myeloma in its microenvironment which have allowed for both identification of novel targets and validation of novel targeted therapies. He has then rapidly translated these studies to clinical trials culminating in FDA approval of novel targeted therapies, which have markedly improved patient outcome.

Current therapies: There are 15 classes of novel agents and 30 FDA approved treatment regimens for multiple myeloma (MM). Intervention in high risk smoldering MM with lenalidomide (R) or immune protocols is directed to delay progression to active disease. Combination novel agent therapies achieve minimal residual disease negative (MRD-) responses associated with prolonged progression free (PFS) and overall survival (OS). Daratumumab, R, bortezomib, dexamethasone (D-RVd) before and after autologous stem cell transplant (ASCT) followed by DaraR maintenance achieves MRD- responses in the majority of patients; and DaraRD prolongs both PFS and OS in newly diagnosed transplant-ineligible patients. Carfilzomib (K)RD and DaraKRD in the ASCT paradigm achieves MRD- responses even in high-risk disease. Relapsed MM treatment is informed by frailty status, comorbidities, risk assessment, treatment history, and therapeutic goals. Approved triplet therapies incorporating pomalidomide (P) and/or K include DaraPd, isatuximabPd, KPd, elotuzumabPd, DaraKd, and isatuximab Kd. For triple class refractory MM, belantomab mafodotin and CAR T cells are FDA approved; the latter achieve MRD-responses in heavily pretreated MM and are under evaluation in the disease course. Bispecific T cell engagers (BiTEs) are achieving high rates and extent of response in relapsed refractory MM. **Future therapies:** Novel CART and BiTE targets and constructs may improve outcome and availability of these therapies. In the future, Dara RVD will achieve high rates of response in newly diagnosed MM; then ASCT will be compared with CAR T cells and/or BiTEs to both achieve durable MRD-responses and restore memory anti-MM immunity, allowing patients to be disease free and off all therapy.

Nancy Bartlett, MD
Dr. Bartlett is Professor of Medicine in the Department of Medicine at Washington University and holds the Koman Chair in Medical Oncology (St. Louis, MO)

Her clinical research has focused on developing clinical trials to evaluate new therapies for both Hodgkin and non-Hodgkin lymphoma. She currently serves as Vice Chair of the Alliance Lymphoma Committee and is a member of the NCI Lymphoma Steering Committee and the Lymphoma Research Foundation scientific advisory board.

Abstract unavailable at the time of publication

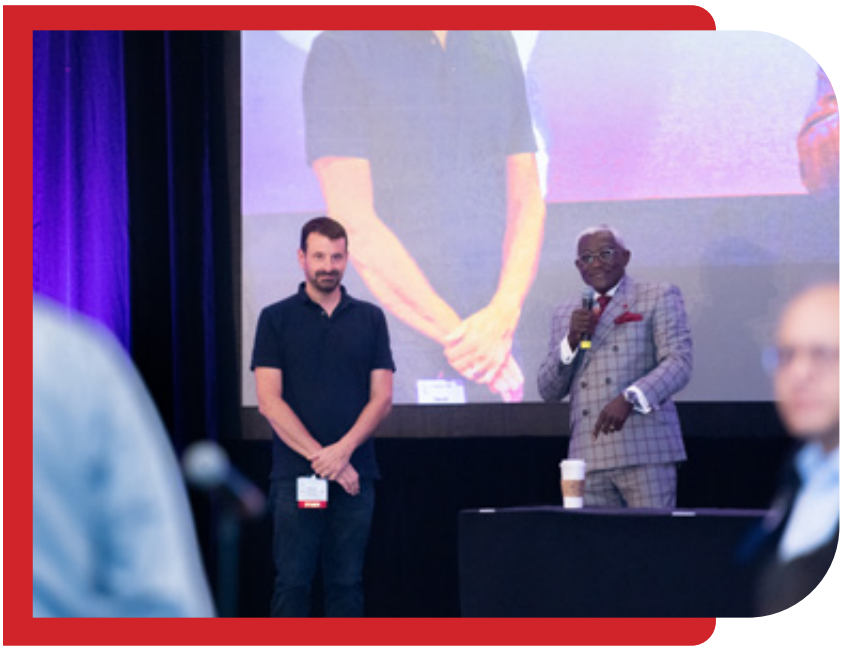
Richard Childs, MD
Clinical Director, National Heart, Lung, and Blood Institute (NHLBI) at the National Institutes of Health (NIH), (Bethesda, MD)

Dr. Childs oversees one of the NIH's

2022 FACULTY AND ABSTRACTS CONTINUED

largest clinical and translational science programs, directing an office with more than 160 staff members who have oversight of approximately 350 clinical researchers conducting over 250 investigator-initiated clinical trials.

Allogeneic transplant approaches to hematological malignancies: The results of Allogeneic Hematopoietic Stem Cell Transplantation (ASCT) have improved greatly over the past 2 decades. Allogeneic transplant approaches have improved transplant outcome including the use of reduced intensity conditioning, better antiviral therapies, better agents to prevent and treat graft-vs-host disease that have played a role in reducing the risk of mortality associated with the procedure. The increasing size of the unrelated donor registry, and the ability to safely transplant patients lacking an HLA matched donor with allografts from haplo-identical donors and unrelated cord-blood has led to an increase in the annual numbers of ASCT performed for a variety of different malignant and non-malignant hematological disorders. A review of the results of clinical trials evaluating transplant outcomes in patients receiving related, unrelated, and mismatched allografts including haplo-identical transplants versus cord blood transplants will be discussed. In summary, the following topics will be discussed: Update on allogeneic transplantation for malignant and nonmalignant diseases: description of the state of the art of transplantation in 2022; data on choosing the optimal stem cell donor; characterize new tools to prevent and treat CMV; and characterization of new treatments to prevent and manage acute and chronic GVHD.



Sandra G. Garofalo MS, APRN, AOCNP
Nurse practitioner, Hematology Oncology of Indiana, a Division of American Oncology Network, (Indianapolis IN)

Sandra G. Garofalo has over 17 years of experience in the field of oncology. She completed her Bachelor of Science in nursing as well as her Master of Science at The Ohio State University. She started her nursing career in hematopoietic stem cell transplant at The Medical University of South Carolina. Since that time, she has had extensive experience in hematological and solid tumor malignancies as well as benign hematology at The James Cancer Center at The Ohio State University. She currently works as a nurse practitioner at Hematology Oncology of Indiana and St. Vincent's Hospital in Indianapolis.

Survivorship begins at diagnosis: Hematological disorders are diagnosed in great frequency in the US. Over 1.5 million people are estimated to be in treatment or remission for hematological disorders. There is an increased population of survivors over time, especially since the year 2000. **Recognized standard for clinical direction and policy in cancer care:** NCCN standards of survivorship care include screening, monitoring for long-term effects, health maintenance and management, coordination of care as well as support and education and survivorship. Frequent follow-up with clinical assessment, labs and imaging as recommended. Monitoring and management of long-term physical as well as psychological effects of hematological malignancies as well as chemotherapy as part of survivorship care. First year survivorship is an opportune time to make changes that will affect disease prevention and wellness habits. Psychosocial issues are an important issue that impacts patients and should continue to be assessed throughout survivorship. Continuing education, emotional and social support are essential aspects in continuing care of patients who are in remission and on maintenance therapy of hematological malignancies. Case studies will be presented, examined, and discussed to further illustrate appropriate survivorship care.

Morie Gertz, MD, MACP
Roland Seidler Jr. Professor, Art of Medicine, Chair Emeritus, Department of Internal Medicine, Mayo Clinic (Rochester, MN)

Dr. Gertz is a Master of the American College of Physicians. His undergraduate degree was awarded with highest distinction from Northwestern University graduating Phi Beta Kappa.

Light chain amyloidosis: The greatest challenge facing patients with amyloidosis is early diagnosis. Often patients with Monoclonal gammopathy of undetermined significance (MGUS) or smoldering multiple myeloma are monitored for the development of CRAB (calcium problems, renal problems, anemia, and bone problems) or progressive

rise in the level of the involved light chain. The development of light chain amyloidosis is part of the natural history of MGUS. Any patient with a monoclonal gammopathy that has edema, dyspnea, unexplained weight loss or peripheral neuropathy should be screened for amyloidosis. Patients diagnosed before the development of significant cardiomyopathy have a significant survival advantage over those patients that are diagnosed at the onset of cardiac failure. Hematologic response criteria and organ response criteria in assess the benefits of therapeutic intervention. The goal of therapy is not simply a hematologic response as it is in myeloma but also improved organ function related to amyloid deposition.

Therapies: Bortezomib has been the Backbone of the therapy for amyloidosis for over 10 years and is required in all newly diagnosed patients. The current standard of care for newly diagnosed patients combines daratumumab bortezomib cyclophosphamide and dexamethasone for 6 cycles given every 4 weeks followed by daratumumab maintenance therapy to a total of 24 cycles. This regimen results in a hematologic complete response rate of 59% at a median follow-up of 20 months. The cardiac response rate of 12 months is 57% and the renal response rate at 12 months is 57%. For patients failing to achieve a complete response strong consideration should be given to consolidation therapy with autologous peripheral blood stem cell transplantation.

Hagop M. Kantarjian, MD

Professor and Chair, Department of Leukemia, Samsung Distinguished Leukemia Chair in Cancer Medicine the University of Texas MD Anderson Cancer Center (Houston, TX)

Dr Kantarjian's research focuses on translational-clinical developmental therapeutics in leukemia. Over the past 4 decades, he has made several contributions that improved patient prognosis and survival across the leukemia entities and MDS/MPN. These include the development of several of the BCR::ABL1 tyrosine kinase inhibitors in CML; multiple chemotherapy regimens and targeted therapies in AML; the HyperCVAD regimens and its derivatives in Ph+ and preB ALL including ponatinib-blinatumomab, and blinatumomab and Inotuzumab regimens; and decitabine in MDS and ruxolitinib in MF.

Progress in ALL therapy: The rapid progress in research and therapy of acute lymphoblastic leukemia (ALL) questions the value of the traditional research methodologies. There are now multiple exciting and highly effective research modalities targeting CD19, CD20, CD22 and others. These include, antibody drug conjugates (ADCs), bispecific T-cell engagers (BiTEs), and chimeric antigen receptor (CAR)-T cellular. The cure rates in children with ALL are 80-90 % with regimens delivered over 2.5 to 3 years, and that combine about 15 chemotherapy drugs in intensive treatments that include induction, intensifications, maintenance and central nervous system (CNS) prophylaxis. The same regimens applied in adult and older ALL result in 5-year survival rates of 20-60+% depending on age: 60- 70% in adolescent and young adults, 50- 60% in patients 40-60 years old, and (until recently) 20- 25% in patients 60 years and older.

Philadelphia chromosome (Ph)-positive acute lymphoblastic leukemia: Before 2000, patients with Ph-positive ALL were treated with intensive chemotherapy followed by allogeneic stem cell transplant (SCT) when possible. This resulted in 5-year survival rates of 10% to 30%. Since 2000, combinations of TKIs (imatinib in 2000; dasatinib in 2006; ponatinib in 2012) with Hyper-CVAD improved the survival and reduced the need for allogeneic SCT. At MD Anderson, using combination therapy of ponatinib with blinatumomab, both starting in induction. Ph-positive ALL patients had much better prognoses (CR-CRi rate was 97%, the CMR rate 79%, and the 3-year survival rate 95%).

Pre-b acute lymphoblastic leukemia: With the Hyper-CVAD regimen and similar modern anti-ALL regimens that include rituximab, the CR rates are 90+%, but cure rates remained at about 50-60%. The "great therapeutic escape" in ALL happened around 2010 with the discovery of the powerful anti-ALL effects of CD19 and CD22 targeted therapies. Among 63 adults with pre-B ALL treated so far, the CR rate was 100%, MRD negativity rate 95%, and estimated 3-year survival rate 84%. The treatment of older ALL (age 60+ years) is challenging, current therapies for this age group are also discussed.

Craig Kessler, MD

Professor of Medicine and Pathology and attending physician in the Division of Hematology-Oncology at Georgetown University Medical Center (Washington, DC)

He also serves as the Director of the Division of Coagulation in the Department of Laboratory Medicine and is the Director of the Therapeutic and Cellular Apheresis Unit. With a distinguished career beginning in 1973, Dr Kessler earned his medical degree from Tulane University School of Medicine in New Orleans, Louisiana. He remained in New Orleans to complete his medical internship and residency before moving to Baltimore, Maryland, in 1976 to assume a Fellowship in Special Hematology at Johns Hopkins Hospital.

Abstract unavailable at the time of publication

Rami S. Komrokji, MD

Dr. Komrokji is the Vice Chair of the Malignant Hematology Department and the head of the Leukemia and MDS Section at the Moffitt Cancer Center (Tampa, FL)

He is a senior Member of the Malignant Hematology and Experimental Therapeutics Program at the Moffitt Cancer Center, and Professor in Medicine & Oncologic Sciences at the College of Medicine, at the University of South Florida in Tampa, Florida. Dr Komrokji is world renowned expert in myeloid neoplasms where he led several clinical trials and lectured worldwide.

2022 FACULTY AND ABSTRACTS CONTINUED

His work paved the FDA approval for luspatercept in myelodysplastic syndromes and pending approval for Pacritinib in myelofibrosis.

Abstract unavailable at the time of publication

Richard Larson, MD
Professor of Medicine in Hematology/Oncology, Director of Hematologic Malignancies Clinical Research Program, the University of Chicago Comprehensive Cancer Center (Chicago, IL)

Dr. Richard Larson is Professor of Medicine in the Section of Hematology/Oncology and Director of the Hematologic Malignancies Clinical Research Program at the University of Chicago. He received his medical degree from the Stanford University School of Medicine in 1977, and completed his postdoctoral training in Internal Medicine, Hematology, and Medical Oncology at the University of Chicago. He has been a member of the faculty in the Section of Hematology/Oncology and the Comprehensive Cancer Center, University of Chicago since 1983.

Therapies for Chronic Myeloid Leukemia (CML): With the availability of potent oral BCR-ABL1 tyrosine kinase inhibitors (TKI), the survival of newly diagnosed patients with CML in chronic phase now approaches that of the general population. Risk assessment is still an important component of selecting between initial treatment options. Both the Sokal and ELTS scores identify patients at low, intermediate, and high risk of disease progression as well as achievement of a deep molecular remission (DMR, transcript level <MR4.5 on the International Scale.) Risk score calculators are available at: www.leukemianet.org and through UpToDate and other clinical decision tools online. Risk scores at diagnosis correlate with the ability to achieve Treatment-free Remission (TFR) after several years of TKI therapy. Patients who have the best long-term outcomes are those who achieve the optimal milestones at 3, 6, and 12 months proposed by the European LeukemiaNet Recommendations on CML.

Treatment of chronic phase CML with asciminib: In 2021, a new oral agent was approved by the FDA for third-line treatment of chronic phase CML, asciminib, which binds to the myristoyl site of the enzyme. The approval was based largely on the results from the phase 3 ASCEMBL study, comparing asciminib (ASC) at 40 mg BID to bosutinib (BOS) at 500 mg daily after >2 prior TKIs. The primary endpoint, major molecular remission (MMR) at week 24, was observed in 26% of ASC patients and 13% of BOS patients, a difference of 12% (2-sided P=0.029). A key secondary endpoint, MMR at 96 weeks, was observed in 38% of ASC patients and 16% of BOS patients, a difference of 22% (2-sided P=0.001). Treatment-free remission (TFR) involves prospective discontinuation of TKI therapy with more frequent molecular monitoring. The goal is to maintain DMR without treatment, thereby eliminating chronic side-effects (fatigue, rash, GI symptoms), reducing complications of treatment (vascular toxicity), and reducing costs. The best results are achieved after >5 years of total therapy and >2 years in DMR.

John Leonard, MD
John P. Leonard, MD, is the Richard T. Silver Distinguished Professor of Hematology and Medical Oncology and Senior Associate Dean for Innovation and Initiatives at Weill Cornell Medicine. (New York, NY)

Dr. Leonard is Executive Vice Chairman of the Weill Department of Medicine at Weill Cornell Medicine and New York-Presbyterian Hospital, where he also serves as Attending Physician. Dr. Leonard's primary research interest is in the development of novel therapeutic strategies for the treatment of lymphoma and related hematologic malignancies, and he has lectured at major international meetings on these topics.

Abstract unavailable at the time of publication

Ruben Mesa, MD, FACP
Executive Director of the Mays Cancer Center, at UT Health San Antonio MD Anderson Cancer Center. (San Antonio, TX)

Having joined UT Health in 2017, Dr. Mesa began as Director of the cancer center. After earning degrees in nuclear engineering and physiology, with minors in radiation biophysics and bioengineering, from the University of Illinois at Urbana-Champaign, Dr. Mesa received his

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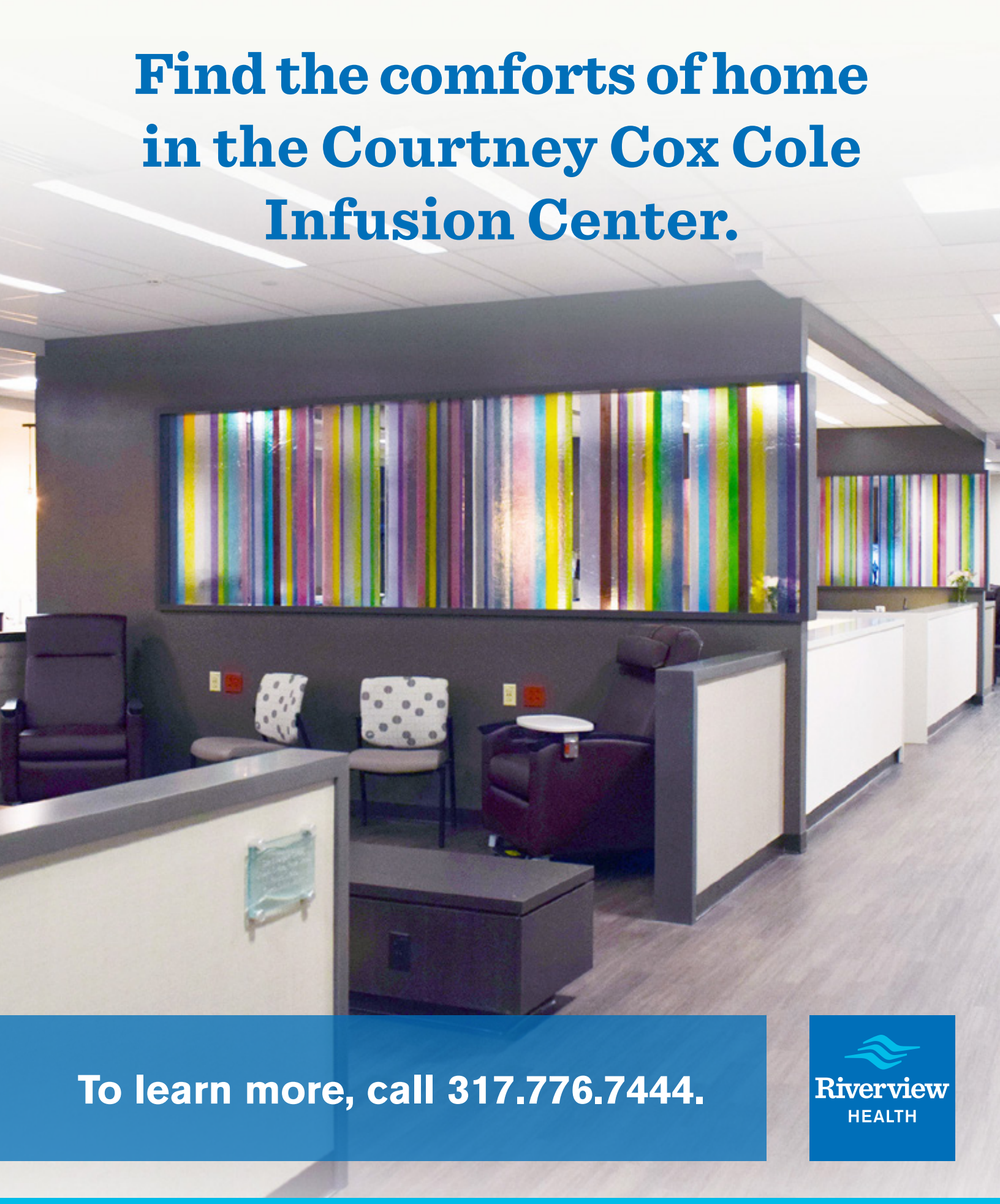

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medical degree from the Mayo Graduate School at the Mayo Clinic College of Medicine in Rochester, Minnesota.

Therapies for essential thrombocythemia (ET): Management of essential thrombocythemia (ET) historically has consisted of aspirin, hydroxyurea, anagrelide, new options under consideration include the LSD1 inhibitor IMG7289 (bomedemstat) and ROPEG INFa2b (Besremi) is proceeding in a randomized phase III trial (anagrelide) as comparator arm (NCT04285086) in ET patients who failed hydroxyurea and have leukocytosis. Polycythemia vera (PV) therapy has now the addition of the recently approved in USA (and already approved in EU) ROPEG INFa2b (Besremi) with new approaches with the utilization of hepcidin "mimetics" such as PTG-300 are interesting. Myelofibrosis has a significant pipeline of new therapies in development with longstanding data continuing to support the safety and efficacy of JAK inhibition. Ruxolitinib, approved since 2012 (with benefits in MF associated splenomegaly, symptoms, and likely survival), and fedratinib, approved since 2019 (associated improvements in splenomegaly and symptoms) Pacritinib, JAK2 and IRAK1 inhibitor now approved for MF with thrombocytopenia and, momelotinib, JAK2 and ACVR1 inhibitor, presented data further showing activity to improve splenomegaly, symptoms, and anemia (including transfusion dependence) in MF patients. Great excitement exists for the numerous new mechanisms of action being tested in MF in the front-line setting (alone or combined with JAK inhibition) including BET inhibition (pelabresib), BCL-XL inhibition (navitoclax), MDM2 inhibition (navtemadlin), or PI3 Kinase inhibition (parsaclisib). telomerase inhibition (imetelstat), anemia targeting TGF-beta ligand trap (luspatercept), cd123 (tagraxofusp). The outcoming of these trials will be important to assess in which patients is a combination approach active.

David Reeves, PharmD, BCOP
Associate Professor of Pharmacy Practice, College of Pharmacy and Health Sciences, Butler University, Clinical Pharmacy Specialist in Hematology/Oncology, Franciscan Physician Network Oncology/ Hematology Specialist (Indianapolis, IN)

David is an associate professor of pharmacy practice for the College of Pharmacy and Health Sciences at Butler University and clinical pharmacy specialist in hematology/ oncology at Franciscan Physician Network Oncology/Hematology Specialists in Indianapolis, IN.

Adverse effects of oral oncolytic therapies: The number of oral oncolytic therapies for hematologic malignancies and their use continues to expand, benefiting many patients. However, these medications are not without adverse effects. New data demonstrates the tolerability of newer agents decitabine/cedazuridine and azacitidine, particularly when compared to their parenteral counterparts. Likewise, the toxicity of recently approved asciminib appears comparable to other BCR- ABL 1 kinase inhibitors.

Safety data published in 2021/2022 of medications currently in use are helping clinicians further understand the toxic effects of oral oncolytics. Venetoclax use continues to expand, particularly in elderly and as combination therapy. Recent data continues to demonstrate a manageable safety profile, even in patients at highest risk for toxicity, such as octogenarians. Studies of BTK inhibitors suggest that atrial fibrillation risk is highest with ibrutinib and results in increased healthcare utilization. Appropriate management of BTK inhibitor cardiovascular effects is necessary to minimize discontinuation. Newer toxicities have also been described, including hemorrhagic dermatologic effects of BTK inhibitors. **Safety of BCR-ABL 1 kinase inhibitors:** Imatinib or nilotinib may be viable subsequent treatment options in those developing dasatinib induced pleural effusion and that cardiovascular effects observed with real-world use of these agents is similar to phase 3 trials. An area of increasing interest is the atherosclerotic effects of BCR-ABL 1 kinase inhibitors, of which, imatinib may have less potential for atherosclerosis. As data evolves, we continue to refine our understanding of oral oncolytic tolerability and increase our ability to maximize therapy by proactively recognizing and managing adverse effects.

Charles Schiffer, MD
Emeritus Professor of Oncology and previously the Joseph Dresner Chair for Hematologic Malignancies and Director of the Leukemia/Lymphoma Multidisciplinary Program at Wayne State University School of Medicine and the Karmanos Cancer Institute. (Detroit, MI)

Dr. Schiffer has authored and co-authored more than 350 articles and 80 book chapters on topics concerning the treatment of leukemia in adults, platelet transfusion, and granulocyte transfusion therapy, among others.

Abstract unavailable at the time of publication

Dr. Sonali Smith, MD, FASCO
Dr. Sonali M. Smith is the Elwood V. Jensen Professor of Medicine, Section Chief of Hematology/Oncology, Co-Leader of the Cancer Service Line, and Co-Director of the Lymphoma Program at the University of Chicago in the Department of Medicine. (Chicago, IL)

She is a clinical investigator in lymphoma and a clinical expert in Hodgkin and non-Hodgkin lymphomas. As faculty member at the University of Chicago since 2001, she has over 200 publications in peer-reviewed journals and has written over 25 review articles on lymphoid malignancies. She is particularly interested in targeted agents and pathway inhibitors and has first and senior author publications through cooperative group trials and investigator-initiated trials. She has had many active leadership roles including Vice-Chair

of the SWOG Lymphoma Committee, Chair of the Lymphoma Research Foundation Scientific Advisory Board, immediate past Chair of the ASCO Communications Committee, and now Chair of the ASCO Annual Meeting Scientific Committee in 2021-2022. She has won numerous teaching awards and considers mentorship a key aspect of her career.

Abstract unavailable at the time of publication

Richard Stone, MD
Chief of Staff and Director of Translational Research, Adult Leukemia Program, Professor of Medicine, Harvard Medical School, Dana-Farber Cancer Institute (Boston, MA)

Richard Stone, MD, is the Chief of Staff at Dana-Farber Cancer Institute (DFCI). He is also Director of Translational Research for the Leukemia Division of Medical Oncology at DFCI, and Professor of Medicine at Harvard Medical School. He is nationally recognized for his translational and clinical research concerning blood and bone marrow malignancies including acute leukemia, myeloproliferative disorders, and myelodysplastic syndrome.

Advances in diagnosis and prognostics of myelodysplastic syndrome (MDS): The international consensus conference looked at data noting that the clinical behavior MDS is not closely correlated to the marrow blast count, designated a new category for patients with 10 to 19% marrow myeloblasts, namely MDS/AML. Further, a sophisticated prognostic scoring system for MDS patients that considers the presence or absence of 17 genes commonly mutated in these disorders along with clinical features including karyotype, blast count, hemoglobin, and platelet count. Patient details can be input at https://mds-risk-model.com to yield a prognostic score which falls into one of six categories. Not only is the IPSS-M more accurate than the IPSS-R, it also can be applied to those with secondary or treatment related MDS. Therapy for lower risk MDS, especially those with SF3B1 mutations, now includes luspatercept; recent data suggests activity in lower risk patients. In uncontrolled data the addition of venetoclax to azacitidine in higher risk MDS patients leads to impressive response rates. An ongoing phase three trial comparing azacitidine therapy with venetoclax or placebo with a primary endpoint of overall survival may help establish a new standard of care in MDS. Although the phase three trial testing the addition of the TP53 refolding agent APR246 to azactidine was negative, magrolimab, which binds to a 'don't eat me' signal on MDS cells could be particularly useful for those within the adverse category of TP53 mutant disease.

Martin Tallman, MD
Most recently, Professor of Medicine at Weill Cornell Medical College in New York, USA, and former Chief of Leukemia Service at Memorial Sloan Kettering Cancer Center. Dr. Tallman completed his fellowship in hematology/oncology at the University of Washington and the Fred Hutchinson Cancer Research Center in Seattle, Washington, USA. (New York, NY)
His research interests include clinical investigation in acute myeloid leukemia, acute lymphocytic leukemia, acute promyelocytic leukemia, and hairy cell leukemia.

Recent progress in acute myeloid leukemia (AML): Includes insights in genetic pathogenesis, intensified induction and less intensive consolidation, recognition of inherited familial predisposition syndromes, development of targeted therapies, expanded availability and advances in hematopoietic cell transplantation, shift in approach to older adults and incorporation of minimal (measurable) residual disease into clinical decisions. Patients (pts) with recurrent genetic abnormalities now are classified as AML if >/=10% blasts in bone marrow or blood including NPM1 and bZIP CEBPα. FLT3 allelic ratio is eliminated and pts with FLT3-ITD mutations now are classified as intermediate-risk. The combination of Venetoclax (Ven) and hypomethylating agents (HMA) is an exceptionally important advance. It provides effective tolerable treatment for older adults and those unsuitable for intensive chemotherapy (IC). HMA/Ven serves as a backbone for additional combinations (triplets) including FLT3 inhibitors and other novel agents. Among most anticipated are Magrolimab (anti-CD47 antibody) and SNDX-5613 (menin inhibitor) which appears promising in pts with MLL gene rearrangements and those with NPM1 mutations.
Acute promyelocytic leukemia: This disease is highly curable with all-trans retinoic acid (ATRA) (administered

at first suspicion of disease) and arsenic trioxide (ATO). 75% of patients present with low-risk disease among whom ATRA and ATO without chemotherapy or maintenance cures approximately 98% if patients survive induction since no primary resistance exists. Those with high-risk disease require addition of chemotherapy usually anthracycline or gemtuzumab ozogamicin and some protocols maintenance. Oral ATO is forthcoming. The changing AML landscape moves away from IC towards often oral targeted therapies which places increased burden on outpatient care.

Ayalew Tefferi, MD
Barbara Woodward Lips II Professor of Medicine at the Mayo Clinic (Rochester, MN)

Dr. Tefferi's research interest is primarily focused on myeloid neoplasms including acute myeloid leukemia and chronic myeloid neoplasms. His web of science core collection publications, as of 6/3/2021, number over 1500 with an H-index of 120. He has participated in hundreds of invited lectureships including service as core faculty for GW, MDACC and Harvard annual board review courses.

Myeloproliferative neoplasms (MPNs): Polycythemia vera (PV), essential thrombocythemia (ET) and primary myelofibrosis (PMF) constitute the three classical myeloproliferative neoplasms (MPN) and are morphologically and molecularly inter-related. These MPNs are characterized by JAK-STAT activating JAK2, CALR or MPL mutations that give rise to stem cell-derived clonal myeloproliferation, which is prone to leukemic and, in case of PV and ET, fibrotic transformation. In PMF, abnormal megakaryocyte proliferation is accompanied by bone marrow fibrosis while the clinical phenotype is pathogenetically linked to ineffective hematopoiesis and aberrant cytokine expression. In PV and ET, the main determinant of survival is age, with additional prognostic contribution from leukocyte count, karyotype, and certain high-risk mutations. In PMF, type 1-like CALR mutation has been associated with favorable prognosis while ASXL1, SRSF2, U2AF1-Q157, EZH2, CBL and K/NRAS mutations and specific cytogenetic abnormalities have been shown to be prognostically detrimental. Such information has enabled development of exclusively genetic (GIPSS) and clinically integrated (MIPSSv2) prognostic models for PMF, as well as for ET and PV (MIPSS-PV/ET). Such prognostic models facilitate individualized treatment decisions. Management in both ET and PV often includes daily aspirin therapy and, in case of PV, phlebotomy; cytoreductive therapy is reserved for use in high-risk patients. Allogeneic stem cell transplantation remains the only treatment modality in MF with the potential to prolong survival, whereas drug therapy, including JAK2 inhibitors, is directed mostly at the inflammatory component of the disease and is therefore palliative in nature. Similarly, disease-modifying activity remains elusive for currently available investigational drugs while their additional value in symptom management awaits controlled confirmation.

Steven P. Treon, MD, MA, PHD, FRCP, FACP
Steve Treon is the Director of the Bing Center for Waldenstrom's Macroglobulinemia (WM) at the Dana Farber Cancer Institute (DFCI), a Professor of Medicine at Harvard Medical School, and Chair of the WM Clinical Trials Group (Boston, MA) His laboratory first identified highly recurring activating mutations in MYD88 and CXCR4 using whole genome sequencing. Professor Treon's laboratory also identified that Bruton's tyrosine kinase (BTK) was a downstream target of mutated MYD88, and enabled a clinical trial with the BTK inhibitor ibrutinib that resulted in the first-ever approval of a drug by the U.S. FDA and the European Medicines Agency for WM. Professor Treon also made major contributions to the investigation and advancement of many novel agents used to treat WM including monoclonal antibodies, nucleoside analogues, bendamustine, proteasome inhibitors, and BTK inhibitors.

Disease etiology: Waldenstrom's macroglobulinemia (WM) is an indolent B cell lymphoma that is classified as an IgM producing lymphoplasmacytic lymphoma under WHO classification system. Morbidity related to WM includes tumor infiltration of the bone marrow and extramedullary sites, as well as paraprotein production that can cause symptomatic hyperviscosity, demyelinating neuropathy, cryoglobulinemia, or cold agglutinemia. Approximately 95-97% of WM patients harbor activating mutations in MYD88, most typically L265P variant, whilst up to 40% can carry somatic mutations in CXCR4 that include both nonsense and frameshift variants1. MYD88 mutations trigger downstream NFKB pro-survival signaling mediated by BTK, whilst CXCR4 mutations trigger AKT and ERK that impact drug sensitivity particularly to BTK-inhibitors.

BTK-inhibitors: The above findings have triggered development of BTK-inhibitors including both covalent and non-covalent agents. Ibrutinib alone and in combination with rituximab is highly active, producing responses in over 90% of patients, and long-term disease control though underlying MYD88 and CXCR4 mutation status can impact time to major response, response depth, and/or progression-free survival. Zanubrutinib has shown overall responses in 90% of WM patients, and in a randomized study (ASPEN trial) exhibited deeper responses (VGPR or better) in comparison to ibrutinib. Less patients on zanubrutinib had atrial fibrillation on ASPEN study; conversely fewer patients on ibrutinib experienced Grade 3 or higher neutropenia highlighting important differences between BTK-inhibitors. Genomic differences were also apparent in the ASPEN study. CXCR4 mutated patients exhibited fewer VGPR or better responses on both arms. However, patients with CXCR4 mutations exhibited better progression-free survival on

zanubrutinib, while significant activity was observed for MYD88 wild-type patients who received zanubrutinib in a dedicated single arm cohort on ASPEN. Acalabrutinib is also active in WM, with 90% overall response activity in both treatment naïve and previously treated WM patients. Atrial fibrillation was seen in 12% of previously treated WM patients, similar to the incidence observed with single agent ibrutinib. Compliance, necessity for deep IGM reduction, morbidity, presence, or predisposition to adverse events including atrial fibrillation and cytopenias, as well as underlying genomic findings are key considerations to the choice of a BTK-inhibitor for WM therapy. Dose reduction, and switchover to an alternate covalent BTK-inhibitor represent approaches for managing intolerance. **Novel therapeutics:** Novel non-covalent BTK-inhibitors, and venetoclax represent novel therapeutics for acquired resistance to covalent BTK-inhibitors. Targeting CXCR4 in CXCR4 mutated WM patients is under evaluation with encouraging findings.

Saad Z. Usmani, MD MBA FACP
Chief of Myeloma Service Member, Memorial Sloan Kettering Cancer Center, Attending Physician, Myeloma, Cellular Therapy and Adult BMT Services (New York, NY)

Dr. Saad Zafar Usmani received his medical education at Allama Iqbal Medical College in Lahore, Pakistan. He completed a residency in internal medicine at Sinai-Grace Hospital/Wayne State University in Detroit, Michigan and a fellowship in hematology and oncology at the University of Connecticut Health Center in Farmington, Connecticut. He then joined the Myeloma Institute for Research & Therapy, University of Arkansas for Medical Sciences in Little Rock, AR in 2010 as the Director of Developmental Therapeutics and Assistant Professor of Medicine. He was recruited to the Levine Cancer Institute/Atrium Health in 2013 as the inaugural Division Chief of Plasma Cell Disorders and Director of Clinical Research for Hematologic Malignancies where he built an internationally renowned myeloma program. He now serves as the Chief of Myeloma Service at MSKCC.

Abstract unavailable at the time of publication

Michael Wiemann, MD, FACP
Vice President, Indy Hematology Education, Inc., President of Providence Hospital, Executive Vice President West Region, St. John Providence Health System (Warren, MI)

Dr. Wiemann is the President of the Ascension Medical Group, Michigan, and Clinical Professor of Medicine at Michigan State University College of Human Medicine. Dr. Wiemann is a medical oncologist and Co-Founder of the Indy Hematology Review. While in Indianapolis, he held several leadership positions at St. Vincent Hospital and Health Center, including Medical Director of Oncology, Chief Medical Officer, and Interim President.

Abstract unavailable at the time of publication

Adrian Wiestner, MD, PhD
Dr. Adrian Wiestner earned his M.D. from the University of Basel Medical School in Switzerland in 1992, and he received his Ph.D. in genetics in 1998. He joined the NHLBI Hematology Fellowship Program in 2000. In 2013, Dr. Wiestner was promoted to Senior Investigator with tenure and chief of the Laboratory of Lymphoid Malignancies, Hematology Branch, NHLBI, NIH. Dr. Wiestner combines clinical and laboratory investigation in B-cell malignancies, in particular Chronic Lymphocytic Leukemia, focusing on identifying pathogenic mechanisms and testing targeted therapies in clinical trials. Dr. Wiestner has authored over a hundred publications and serves as editor-in-chief of Seminars in Hematology.

Therapies for Chronic lymphocytic leukemia (CLL): Treatment options for patients with CLL have rapidly evolved over the last 10 years. Multiple randomized studies demonstrated improved progression-free and, in some cases, overall survival for targeted agents over chemoimmunotherapy. Bruton tyrosine kinase (BTK) inhibitors, including ibrutinib and acalabrutinib, and the BCL2 targeting drug venetoclax are FDA approved for all lines of therapy. Ibrutinib and acalabrutinib bind covalently to a cysteine residue in BTK achieving long lasting inhibition of the kinase. Initial studies used continuous oral therapy untill disease progression or toxicity. Adverse events are a leading cause of treatment discontinuation and tolerability is a key factor in treatment decisions. Resistance to covalent BTK inhibitors can develop after years on therapy and has been linked to mutations in BTK. Non-covalent inhibitors, such as pirtobrutinib, can overcome resistance to covalent inhibitors. Venetoclax in combination with an anti-CD20 antibody, either rituximab investigated in relapsed/refractory patients, or obinutuzumab in front-line, offers effective time-limited treatment. With venetoclax, undetecatable minimal residual disease has become a key endpoint, is achieved in the majority of patients and predicts for long PFS after cessation of therapy. Multiple combination regimens of doublets or triplets, combining venetoclax with anti-CD20 and/or a BTK inhibitor are ongoing. The Covid pandemic has highlighted the challenges of achieving a response to vaccines in the setting of an immunosuppresive disease and treatments that can interfere with humoral immune responses.

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Pushing the Needle to Force a Change in the Current Disparities in Health Care: An Interview with Ruemu Birhiray, MD

Written by Nicola Donelan

Many years ago, Dr. Ruemu Birhiray moved from Nigeria, where he went to medical school, to the United States of America to do his residency and fellowship. He was fortunate to receive the highest standard of education and completed fellowships at John Hopkins University and The National Cancer Institute in Bethesda, Maryland. He has been working in the hematology oncology field for more than three decades. Ruemu feels a deep appreciation for what he has personally gained but is at the point in his life where he has the desire to give something back to the society.

"I was blessed by this country in the sense that I got the best possible training, and I've been practicing in the community, and so I'm beginning to get to a point in my career where you begin to look back and say to yourself, I have personally gained, but now what am I going to leave behind?" says Ruemu.

Ruemu's journey has brought him to this place where he feels that he can use his training and experience to ensure that the next time someone like him is seeing an oncologist for cancer treatment that maybe there will be data that is applicable to people of color, to minorities.

TACKLING DISPARITIES IN HEALTHCARE

Major stakeholders such as the government, the FDA, the NIH, community leaders, medical school leadership and practicing oncologists all need to be engaged in order to facilitate equity, diversity, and inclusion (EDI) and address barriers to cancer clinical trial recruitment and participation. Ruemu explains an initiative called **D.R.I.V.E.** that they have developed at the Indy Hematology Education Inc. in order to make the idea of change, that so many have been discussing for years, become a reality.

The 5-Step **D.R.I.V.E.** action plan aims to ensure HealthCare Justice by 2030 with clinical trial EDI being the goal. What exactly does D.R.I.V.E. stand for?

D stands for Diversity. All clinical trials must include a Diversity Officer who is tasked just like a DSMB in safety to ensure a diversity plan is established, maintained, and modified during the course of each study to meet its accrual goals of inclusion and diversity. Ruemu explained that a Diversity Officer ought to be trained and have specific qualifications to enable them to monitor clinical studies for diversity in real time. So as a study goes on if the Diversity Officer sees you're not meeting your goals they can react in time.

R stands for Ranking. Create a Ranking System for measuring the relative diversity of enrolled subjects in a clinical trial that are published with each trial. Studies are ranked from 0 to 5, with 5 being the maximum diversity and 0 being the least diverse. Ruemu believes that if this ranking system was implemented and enforced it would have a huge impact on EDI for clinical trials.

I stands for Individual. Create an Individual/Personal diversity plan to ensure your minority patients are enrolled or participating in clinical research. Each one of us should have an individual plan on how to increase diversity.

V stands for Verification. Verify and ensure that podium presentations at major conferences are preferentially given to clinical trials meeting diversity goals. Just imagine a world where only studies with a high diversity ranking would be accepted in major journals, or for presentation in major congresses and conferences. This would rapidly lead to investigators being forced to innovate and find ways to increase diversity or get left behind in the dust.

E stands for Elevate. Elevate, train, and recruit minority investigators to participate in all clinical trials. Ruemu brought up a very good point from

a recent conversation he had with a colleague who complained of not being able to recruit minority patients to his clinical trial. Ruemu then asked him a pertinent question. ***"How many people do you have on your study staff that look like the new patients that you're trying to enroll?"*** The answer to this question was nobody, not even the coordinator.

The COVID-19 pandemic glaringly highlighted the issues of distrust and the damaging controversy of spreading misinformation among minorities and the general population when it comes to clinical studies. Ruemu brought up the infamous Tuskegee Syphilis Study that enrolled hundreds of African Americans until 1972. This recent history is fresh in the minds of many minorities and leads to distrust and hesitancy when it comes to anything health related. If minority investigators and staff become more commonplace in clinical studies, perhaps building back this trust can be possible.

THE BLACK PAPER SUMMIT

The Black Paper Summit will be held on September 9, 2022 with the goal of creating a consensus position paper "the Black Paper" of major stakeholders on immediately actionable practical strategies for promoting EDI in clinical research. It is a first of its kind, with a goal of creating a consensus of immediate action items without having to wait for legislation to be passed. According to Ruemu, it is not meant to represent the black race, but rather to represent the opposite of the white paper.

"I see a lot of white papers on EDI which are position papers on saying, we stand with the black community, we believe that diversity should be achieved, here are some of the problems why it is difficult to have diversity in research. But I find it frustrating, because I can read all of those reasons and read about all the barriers but that's not going to solve the problem. So that's why I came up with my approach, which is at least a solution-based approach. So, let's apply those solutions now, let's not wait until tomorrow," says Ruemu.

Ruemu is hoping that the D.R.I.V.E. initiative will become globally accepted, and says, ***"I think it will move the needle very quickly, it will force the industry to change. It will be the disruptive, but it will be beneficial to all of us".***

T. HOWARD LEE AWARD RECIPIENTS

T. Howard Lee, MD, founder and President Emeritus, Hematology Oncology of Indiana, PC (Indianapolis, IN)
The following respected individuals have been presenters and recipients at the T. Howard Lee Keynote Lecture:

2003: Professor Bertrand Coiffier, MD
Bertrand Coiffier is Professor of Hematology at the Department of Hematology, Hospices Civils de Lyon and the University Claude Bernard, Lyon, France, Chairman, GELA

2004: Kanti Rai, MD
Past President of American Society of Hematology, ASH, Chief, Division of Hematology/Oncology, Long Island Jewish Medical Center, Professor of Medicine, Albert Einstein College of Medicine

2005: Claire Dearden, MBBS
Dr Claire Dearden is Consultant Hematologist and Head of the Chronic Lymphocytic Leukemia (CLL) Unit at The Royal Marsden and The Institute of Cancer Research, and Medical Director of the South West London Cancer Network.

2006: Sandra Horning, MD
Professor of Oncology, Sanford University, Past President of The American Society of Oncology, ASCO

2007: Lewis R. Silverman, MD
Director, Myelodysplastic Syndrome and Myeloproliferative Disease Program, Mount Sinai School of Medicine, New York, NY

2008: Neal Young, MD
Chief of the Hematology Branch of the National Heart, Lung and Blood Institute, National Institute of Health, Bethesda, MD

2009: Professor Michael Pfreundschuh, MD
Professor and Director of Medical Oncology, Department of Internal Medicine, Saarland University, and Chairman, German Lymphoma Group

2010: James Armitage, MD
Past President of ASCO, Joe Shapiro Professor of Medicine, and Past Dean, University of Nebraska Medical School, Omaha, NE

2011: Michael Keating, MBBS
Professor of Medicine and Internist, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX

2012: Kenneth Anderson, MD
Kraft Family Professor of Medicine, Department of Medicine, Harvard Medical School, Medical Director, Kraft Family Blood Center, Dana-Farber Cancer Institute, Boston, MA

2013: Susan O'Brien, MD
Ashbel Smith Professor and Chief of the Section of Acute Lymphocytic Leukemia, Department of Leukemia at the University of Texas MD Anderson Cancer Center

2014: Ross Levine, MD
Associate Attending Physician at Memorial Sloan-Kettering Cancer Center, Associate Professor of Medicine at Weill Cornell Medical College, New York, NY

2015: Stephen Ansell, MD, PhD
Professor of Medicine, Mayo Clinic Department of Hematology at the Mayo Clinic, MN

2016: David Porter, MD
Abramson Cancer Center, University of Pennsylvania Health System, Jodi Fisher Horowitz Professor of Leukemia Care Excellence Director, Blood and Marrow Transplantation, Philadelphia, PA

2017: Bruce Cheson, MD
Deputy Chief, Division of Hematology/Oncology in the Department of Medicine, Head of Hematology and Professor of Medicine, Lombardi Comprehensive Cancer Center, Georgetown University Hospital, Washington, DC

2018: Thomas Kipps, MD, PhD
Deputy Director of Research, Moores UCSD Cancer Center; Professor of Medicine UC San Diego, School of Medicine, San Diego, CA

2019: Pier Luigi Zinzani, MD, PhD
Professor of Hematology, Head of Lymphoma Group, Institute of Hematology, “L. e A. Seràgnoli”, University of Bologna, Bologna, Italy

2020: Edward Stadtmauer, MD
Professor of Medicine and Section Chief of the Hematologic Malignancies in the Division of Hematology-Oncology at the Hospital of the University of Pennsylvania, Philadelphia, PA

2021: Ranjana Advani, MD
Saul A. Rosenberg Professor of Lymphoma at Stanford University School of Medicine and Physician Leader of the Lymphoma Clinical Care Program, Stanford, CA

2022: Sonali Smith, MD, FASCO
Elwood V. Jensen Professor of Medicine, Section Chief of Hematology/Oncology, Co-Leader of the Cancer Service Line, and Co-Director of the Lymphoma Program at the University of Chicago in the Department of Medicine

2022 T. HOWARD LEE PRESENTER: SONALI SMITH, MD, FASCO

Discussing Equity for Women in Healthcare Leadership: An Interview with Sonali Smith, MD, FASCO

Written by Nicola Donelan

Dr. Smith's career path became defined early on during medical school, when she met patients who were not dying from cancer but living with it. Being around their fortitude, seeing people dealing with something life-threatening, but thriving despite it, was so inspirational to her. She also recognized she had an innate interest in everything oncology related and an attraction to the humanistic aspect of managing the care of cancer patients.

"When people have cancer, their family is really drawn to their journey," said Smith. "The combination of having the engaged patient and family along with just fascinating biology, and the ability to have a holistic care model, really drew me to the field of hematology oncology," she explained.

After studying at the Northwestern University Feinberg School of Medicine, she went on to a hematology/oncology fellowship at The University of Chicago Department of Medicine in 1998. She became a faculty member in 2001 and has served as the Director of the Lymphoma Program from 2011 to 2020. In 2017, she was promoted to professor and honored as the Elwood V. Jensen Professor of Medicine and appointed Chief of the Section of Hematology/Oncology in 2020.

MENTORSHIP

Growing up, Dr. Smith was always interested in biology, but also thought she would become a teacher. Along the way, she felt very lucky to have had the mentors that created a village of supporters rather than just single 'parental-figure' types. People who she could bounce ideas off, help open doors, encourage her when the time is right to apply for jobs or grants.

"Mentoring today is more about creating a village of supporters and having people who believe in you even when you don't believe in yourself," said Smith when asked about the importance of mentorship.

From that village, she picked out very early mentors in Drs. Richard Larson, Everett Vokes, and Koen Van Besien. Dr. Julie Vose, a former ASCO president, introduced her to the field and gave her early opportunities that became fruitful. Over the years Drs. Funmi Olapode, M. Eileen Dolan, and Wendy Stock became mentors.

At the University of Chicago Dr. Larson introduced her to the Cancer and Leukemia Group B (CALGB), a cancer research cooperative group, where she met Drs Nancy Bartlett, Bruce Cheson and John Leonard. She called them all creative people, very smart, very hard-working who got her really interested in how to think about lymphomas. Dr. Leonard is also among her more recent peer mentors, along with Dr. Andrew Evens and Dr. Jonathan Freidberg.

THE ELUSIVE WORK-LIFE-BALANCE

"Life is always imbalanced," said Smith. Some days are all about her children, some all about her work. As such, she thinks it does even out over time if you take a longer-term view, but to think of each day as a balancing act creates more stress.

"Most days, it's imbalanced. But if you look at it over the course of weeks or months, it does eventually, even out. You know, and I think that's where the balance is," said Smith.

In striving to be present for her four children and her work she emphasized the importance of quality over quantity. For instance, dinners are

important to her family, it is a place they sit down together and talk about the day. And to emphasize the quality family time, phones or other electronics are not allowed at the dinner table. Child-raising responsibilities were shared with her husband, surgical oncologist Dr. Norm Smith, who she described as a strong partner. While it was difficult for them both, he was very supportive, meaning she could take work trips or work late when necessary. He would pick up the pieces if she couldn't, and she did the same for him. To this day Dr. Smith has not missed any of her four children's school assemblies.

EQUITY IN MEDICINE

Dr. Smith believes it is right to highlight that women do drop out of academics and sometimes a lot of that is to do with the being the main pressure of having a family or caregiver for parents. They may or may not come back, but historically there are many more demands on women than men in these areas, and that is an important reality that cannot be discounted. Smith realized she couldn't do everything at once, so she changed her mind set and decided to define her success by the long-term course of her career.

The other piece of the puzzle is that she doesn't think women are traditionally taught the hard skills of what it takes to succeed, project management or team leadership for instance. There also aren't as many women in leadership positions that can be role models for younger women. Dr. Smith believes we need more women in these positions and is confident that more women will become leaders. Flexibility could be key to that, which is something her job at The University of Chicago had early in her career. If flexibility and key skill training can be provided, she thinks we'll see more women in positions of leadership.

Dr. Smith also stressed it is important for women to recognize they are not alone, that they are part of a much broader community. For her, that's all the Women Leaders in Oncology/ Women Who Conquer Cancer (WLO/ WWCC), Women in Lymphoma (WiL) and other various organizations do a great job to enable women in the field to create a network with each other. They include ASCO and the American Society of Hematology (ASH). All have initiatives to help address and improve gender equality. Dr. Smith was part of organizing the inaugural ASCO Women's Networking Center. She said the response to it has been amazing, women have opportunities to learn, and she believes it is a model for bigger organizations and society in general. Such initiatives help put the issues women face front and center, providing safe spaces for women to discuss their challenges. It is a vital part of helping provide women with the soft and hard skills required for leadership, she explained. In a recent presentation for WLO/WWCC following the annual ASCO meeting, Dr. Smith highlighted a number of female lymphoma investigators and leaders in oncology and lymphoma, showcasing that women leadership is rising.

LEADERSHIP IN PRACTICE

In 2020 Dr. Smith was selected as Section Chief for Hematology/ Oncology at The University of Chicago Department of Medicine. Now she's managing the budget and infrastructure for a new program, looking at faculty evaluation and recruitment, on top of her other day to day responsibilities as a physician. While she's grateful and excited for this opportunity, she stressed that it is important to prepare for opportunities that you don't expect. It highlighted to her that you need to plan ahead for leadership roles and develop the skills you will need in them.

Medicine doesn't train you for this aspect of the job, like perhaps an MBA would. That has been a challenge, and Dr. Smith thinks that doctors in these positions could learn a lot from the business world. She also recognizes the knowledge base she can build and share with other women so that when they have more information when up for similar leadership positions in medicine.

Being a leader at this time is significant in part because it of the treatments becoming available for lymphomas. Dr. Smith noted that there's been more drugs approved in the last few years than the previous decade, but perhaps the most promising new treatment is immunotherapy including CAR T-cell therapy, bi-specific antibodies, and new antibody-drug conjugates.

"I think, are really changing how we manage patients, and we have many more survivors than we ever have" said Smith as she explained what an incredible time it is to be in the hematology oncology field.

WORDS OF WISDOM

In closing our interview, Dr. Smith had a few words of advice for colleagues at earlier stages in their careers. She said it is often hard for young female doctors to recognize opportunities so it's important to realize when they arise and when doors are being opened for you. Sometimes that comes down to taking a chance. Networking really helps you to realize you are not alone, that there are people out there who can and want to help you succeed. So be open to them, she said.

"Don't second guess yourself or think you're not qualified, don't downplay yourself or your knowledge," said Smith.

"Pursue a career that brings you joy and pay attention to self-care because it is very easy but harmful to put yourself last," warns Smith.

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An Interview with Nurse Practicioner Sandra Garofalo, MS, APRN, AOCNP

Written by Nicola Donelan

Sandra G. Garofalo, MS, APRN, AOCNP is a nurse practitioner specializing in hematology/oncology in the American Oncology Network at Ascension St. Vincent Indianapolis Hospital. She has over 17 years of experience working in oncology. In a recent interview, we caught up with Sandra who told us about her personal journey towards becoming a nurse, how her career evolved to specialize in hematology/oncology and what she is looking forward to most at Indy Hematology Review meeting this year.

Sandra studied at The Ohio State University, where she obtained both a Bachelor of Science in Nursing and a Master of Science degree. She worked as a registered staff nurse at the Ohio State University, before moving to the Medical University of South Carolina. She later returned to the Ohio State University in 2013 as a staff registered nurse while working on her master's program. She was able to gain extensive experience in hematological and solid tumor malignancies as well as benign hematology, before moving to her current position as a nurse practitioner in 2019 at Hematology Oncology of Indiana and St. Vincent's Hospital in Indianapolis.

AN UNEXPECTED JOURNEY

Sandra grew up in Cleveland, Ohio. Her parents emigrated from a very impoverished post-war Italy to the US, where they worked very hard to be successful and she naturally adopted their worth ethic. Originally intending to graduate from undergraduate studies as a teacher, right before Sandra finished her degree, she had an experience that would change the course of her career. She became the mother of premature twins and being in the Neonatal Intensive Care Unit (NICU) and seeing the nurses at work inspired her to become one. While her intention had been to graduate and work in nursing with infants, there were no positions available at that time. Remembering the kindness of the nurses during her rotation at the James Cancer Hospital, she decided to do her first year there and fell in love with it. She hasn't left oncology since and describes it as a calling, something she never expected, but naturally became the right career for her.

There have been a number of people who have supported Sandra along the way, and without wanting to pick one person out she cited the nursing staff in her first long-term job at the bone marrow transplant unit of the Medical University of South Carolina. Two oncologists Sandra mentioned as mentors were Dr. Robert Stewart and the late Dr. Deborah Frei-Lahr. She was inspired by the way they connected to their patients and fought for them. Being on that unit was a new experience for her, but she took a lot from how personal their staff and doctors' interactions were with their patients; how they knew their lives, their families and were all on a journey with them. Sandra's practice was also truly inspired by Dr. Birhiray, whom she admires for his depth of knowledge and endless dedication and sheer love for his patients. His example is a constant reminder that oncology is more than science and statistics, but we that are in the business of hope and humanity, she emphasized.

CHALLENGING AND REWARDING

In Sandra's experience, she found that hematology is one of those fields, even within oncology, that people shy away from, and that perhaps it can be intimidating to nurses who have worked in other areas. She attributes that to hematology being a disease that can affect such a broad area of the body. In other areas of medicine, you might be treating people for something quite specific, i.e., dealing with the heart in cardiology, or the gut in gastrointestinal surgery. From the conversations she's had with nurses in other specialities, hematology feels nebulous, vague, and hard to pinpoint, because the cancer can be everywhere in the body. Sandra also acknowledged it can be difficult. Patients come in where they've been living a normal life up until that point. They get a blood draw and suddenly they are being given a serious diagnosis. It's a massive shock. However, she explained, if you learn as much as you can and really get to know your patients, hematology is a really rewarding speciality to work in. She also noted that this career is not easy and that they'll constantly be learning, but the key is to embrace the uniqueness of the experience.

When asked what the main challenges are she faces at work, Sandra says with certainty that time is the biggest challenge. There is never enough time to see all their patients. It's not like primary care where you can schedule an appointment three or six weeks out, chemotherapy and other treatments can't wait. Some patient visits also just take more

time, explained Sandra, and this is unavoidable even when the waiting room is full. This might be when a patient has a new diagnosis, new treatment plan or perhaps it is time to start talking about end-of-life care. Those are not things that can be rushed. Communication is key in those situations, said Sandra, both with the patient and with the unit staff.

DRIVING HOPE

Sandra was keen to highlight that there have been amazing advances during the time she's been in oncology. For instance, the side effects for bone marrow transplant are less serious than they used to be, and there are also more treatments available for lymphomas. She said diagnosis had been a death sentence previously, but that has changed for many patients with the advent of immunotherapy, which has been such a game changer for so many.

At this year's Indy Hematology Review meeting Sandra is really looking forward to hearing more about Dr. Birhiray's new initiative, D.R.I.V.E. It was born out of the COVID-19 pandemic but will address longstanding historical issues with enrolment for clinical trials. Most current clinical trials rarely enroll minorities of color, including African Americans, Native Americans, and Hispanic Americans. That means there's a data discrepancy, even in diseases that disproportionately affect certain populations of people. For example, multiple myeloma occurs in 20% of African Americans. It's not just in oncology, this is the case across the board for vaccine development, cardiovascular, hypertension or diabetes. The D.R.I.V.E. initiative has a 5-Step action plan to ensure HealthCare Justice by 2030 with clinical trial equity and diversity and inclusion being reached so that treatments can be developed properly for diverse populations.

A favorite part of the symposium for Sandra is the evening panel with experts. She explains how experts in the field sit together on stage and talk about real-life case studies that can be very difficult or complicated. The discussions are about their thinking and the process they went through with their patients. They discuss questions such as: What did they not look at? What do they need to investigate? Is there a study that could support them? It is a brainstorming session that helps determine what is best for patients. She said it provides something that she thinks all physicians desire, especially when the pace of life and the clinic is so fast that there's often not time to discuss a complicated case with colleagues, to harness their knowledge and expertise. If it was possible for the organizers to have a second, similar panel, or make the existing one longer, Sandra thinks that would provide enormous value for the participants. Perhaps this is something to look forward to for future Indy Hematology Review meetings.

FDA Hematology, Oncology/Hematologic Malignancies Approvals from January 1, 2021

Betibeglogene autotemcel for the treatment of adult and pediatric patients with beta-thalassemia

On August 18, 2022, the Food and Drug Administration approved Zynteglo (betibeglogene autotemcel), the first cell-based gene therapy for the treatment of adult and pediatric patients with beta-thalassemia who require regular red blood cell transfusions.

Lisocabtagene maraleucel for second-line treatment of large B-cell lymphoma

On June 24, 2022, the Food and Drug Administration approved lisocabtagene maraleucel (Breyanzi, Juno Therapeutics, Inc.) for adult patients with large B-cell lymphoma (LBCL) who have refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age. It is not indicated for the treatment of patients with primary central nervous system lymphoma.

Tisagenlecleucel for relapsed or refractory follicular lymphoma

On May 27, 2022, the Food and Drug Administration granted accelerated approval to tisagenlecleucel (Kymriah, Novartis Pharmaceuticals Corporation) for adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

Ivosidenib in combination with azacitidine for newly diagnosed acute myeloid leukemia

On May 25, 2022, the Food and Drug Administration approved ivosidenib (Tibsovo, Servier Pharmaceuticals LLC) in combination with azacitidine for newly diagnosed acute myeloid leukemia (AML) with a susceptible IDH1 mutation, as detected by an FDA-approved test in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

Azacitidine for newly diagnosed juvenile myelomonocytic leukemia

On May 20, 2022, the Food and Drug Administration approved azacitidine (Vidaza, Celgene Corp.) for pediatric patients with newly diagnosed juvenile myelomonocytic leukemia (JMML).

Axicabtagene ciloleucel for second-line treatment of large B-cell lymphoma

On April 1, 2022, the Food and Drug Administration approved axicabtagene ciloleucel (Yescarta, Kite Pharma, Inc.) for adult patients with large B-cell lymphoma (LBCL) that is refractory to first line chemoimmunotherapy or relapses within 12 months of first line chemoimmunotherapy. It is not indicated for the treatment of patients with primary central nervous system lymphoma.

Ciltacabtagene autoleucel for relapsed or refractory multiple myeloma

On February 28, 2022, the Food and Drug Administration approved ciltacabtagene autoleucel (CARVYKTI, Janssen Biotech, Inc.) for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-CD38 monoclonal antibody.

Pacritinib for intermediate or high-risk primary or secondary myelofibrosis

On February 28, 2022, the Food and Drug Administration approved pacritinib (Vonjo) to treat intermediate or high-risk primary or secondary myelofibrosis in adults with low platelets

Mitapivat for hemolytic anemia in pyruvate kinase deficiency

On February 17, 2022, the Food and Drug Administration approved Mitapivat (Pyrukynd) to treat hemolytic anemia in pyruvate kinase deficiency

Abatacept for prophylaxis of acute graft versus host disease

On December 15, 2021, the Food and Drug Administration approved abatacept (Orencia, Bristol-Myers Squibb Company) for the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor (CNI) and methotrexate (MTX), in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell from a matched or 1 allele mismatched unrelated donor.

Rituximab plus chemotherapy for pediatric cancer indications

On December 2, 2021, the Food and Drug Administration approved rituximab (Rituxan, Genentech, Inc.) in combination with chemotherapy for pediatric patients (≥6 months to <18 years) with previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL).

Darzalex Faspro, Kyprolis, and Dexamethasone for Multiple Myeloma

On November 30, 2021, the Food and Drug Administration approved daratumumab + hyaluronidase-fihj (Darzalex Faspro, Janssen Biotech, Inc.) and carfilzomib (Kyprolis, Amgen, Inc.) plus dexamethasone for adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy.

Besremi (ropeginterferon alfa-2b-njft)

On November 12, 2021, the Food and Drug Administration approved Besremi (ropeginterferon alfa-2b-njft) injection to treat adults with polycythemia vera.

Asciminib for Philadelphia chromosome-positive chronic myeloid leukemia

On October 29, 2021, the Food and Drug Administration granted accelerated approval to asciminib (Scemblix, Novartis AG) for patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs), and approved asciminib for adult patients with Ph+ CML in CP with the T315I mutation.

Brexucabtagene autoleucel for relapsed or refractory B-cell precursor acute lymphoblastic leukemia

On October 1, 2021, the Food and Drug Administration approved brexucabtagene autoleucel (Tecartus, Kite Pharma, Inc.) for adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

Ruxolitinib for chronic graft-versus-host disease

On September 22, 2021, the Food and Drug Administration approved ruxolitinib (Jakafi, Incyte Corp.) for chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

Zanubrutinib for marginal zone lymphoma

On September 14, 2021, the Food and Drug Administration granted accelerated approval to zanubrutinib (Brukinsa, BeiGene) for adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.

Zanubrutinib for Waldenström's macroglobulinemia

On September 1, 2021, the Food and Drug Administration approved zanubrutinib (Brukinsa, BeiGene) for adult patients with Waldenström's macroglobulinemia (WM).

Belumosudil for chronic graft-versus-host disease

On July 16, 2021, the Food and Drug Administration approved belumosudil (Rezurock, Kadmon Pharmaceuticals, LLC), a kinase inhibitor, for adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy.

Asparaginase erwinia chrysanthemi (recombinant) for leukemia and lymphoma

On July 1, 2021, the Food and Drug Administration approved asparaginase erwinia chrysanthemi (recombinant)-rywn) (Rylaze, Jazz Pharmaceuticals, Inc.) as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adult and pediatric patients 1 month or older who have developed hypersensitivity to E. coli-derived asparaginase.

Avapritinib for advanced systemic mastocytosis

On June 16, 2021, the Food and Drug Administration approved avapritinib (Ayvakit™, Blueprint Medicines Corp.) for adult patients with advanced systemic mastocytosis (AdvSM), including patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL).

Pegcetacoplan for treat paroxysmal nocturnal hemoglobinuria

On May 14, 2021, the Food and Drug Administration granted approval of pegcetacoplan (EMPAVELI) a complement inhibitor indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

Loncastuximab tesirine-lpyl for large B-cell lymphoma

On April 23, 2021, the Food and Drug Administration granted accelerated approval to loncastuximab tesirine-lpyl (Zynlonta, ADC Therapeutics SA), a CD19-directed antibody and alkylating agent conjugate, for adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma.

Isatuximab-irfc for multiple myeloma

On March 31, 2021, the Food and Drug Administration approved isatuximab-irfc (Sarclisa, Sanofi-Aventis U.S. LLC) in combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy.

Idecabtagene vicleucel for multiple myeloma

On March 26, 2021, the Food and Drug Administration approved idecabtagene vicleucel (Abecma, Bristol Myers Squibb) for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. This is the first FDA-approved cell-based gene therapy for multiple myeloma.

Axicabtagene ciloleucel for relapsed or refractory follicular lymphoma

On March 5, 2021, the Food and Drug Administration granted accelerated approval to axicabtagene ciloleucel (Yescarta, Kite Pharma, Inc.) for adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

Lisocabtagene maraleucel for relapsed or refractory large B-cell lymphoma

On February 5, 2021, the Food and Drug Administration approved lisocabtagene maraleucel (Breyanzi, Juno Therapeutics, Inc.) for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

Darzalex Faspro for newly diagnosed light chain amyloidosis

On January 5, 2021, the Food and Drug Administration granted accelerated approval to daratumumab plus hyaluronidase (Darzalex Faspro, Janssen Biotech Inc.) in combination with bortezomib, cyclophosphamide and dexamethasone for newly diagnosed light chain (AL) amyloidosis.

Crizotinib for children and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma

On January14, 2021, the Food and Drug Administration approved crizotinib (Xalkori, Pfizer Inc.) for pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive. The safety and efficacy of crizotinib have not been established in older adults with relapsed or refractory, systemic ALK-positive ALCL.

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Hematology Oncology from an Ethiopian Perspective: An Interview with Tirumebet Mezgebu Minayehu, MD

Written by Nicola Donelan

Dr. Tirumebet Mezgebu Minayehu is a clinical hematologist and unit head at the Department of Internal medicine, Division of hematology at Saint Paul's Hospital Millennium Medical College in Addis Ababa, Ethiopia. She is one of only seven hematologists who treat adult patients with hematologic diseases in her country. The division of hematology at St. Paul hospital is one of the two teaching hospitals in Addis Ababa with a population of close to 5 million. Dr. Minayehu is the recipient of a scholarship that will enable her to attend the 19th annual Indy hematology review on September 10, 2022 in Indianapolis, USA. In a recent interview, we were able to learn a great deal about her training to become a hematologist, the challenges in diagnosis and treatment of hematological malignancies in Ethiopia, and her plans for using the information learned at the Indy hematology review for the betterment of her society and country.

In 2018, Dr. Minayehu completed her internal medicine training at Saint Paul's Hospital Millennium Medical College (SPHMMC), after which she received specialty hematology training at the Christian Medical College in Vellore, India. She was awarded third best internal medicine resident in 2018. There were three mentors that influenced her decision to become a hematologist and follow this career path: Dr. Afework Hagos, Internist, Clinical Hematologist, SPHMMC, Addis Ababa, Ethiopia; Dr.Kebede H.Begna, Internist, Hemato- Oncologist, Mayo Clinic, Minnesota, USA (remotely mentoring to conduct clinical research); and Dr.Vikram Mathews, Professor of Clinical Hematology, Christian Medical College, Vellore, India.

Caring for patients in Ethiopia comes with its own unique challenges. There is a striking lack of important diagnostic modalities, and due to limited resources, most diagnoses for hematological malignancies rely on morphological evaluations explained Tirumebet. Blood samples need to be sent to other countries that have better diagnostic capabilities and the results usually take about two weeks to come back. Often patients are unable to complete their treatments because of financial issues. Treatment regimens for hematological malignancies are quite expensive and require strong financial support which many patients do not have.

While resources are limited, there has been a marked improvement in the availability of first line treatment in the last three to four years in Ethiopia. According to Tirumebet, the National Minister of Health has been focused on expanding access to treatment in several different cities, and the Saint Paul Millennium Hospital is in the final stages of building infrastructure to support stem cell transplantation and radiotherapy. This is a hospital that see 450 patients per month for hematology, and 830 patients monthly for oncology, these numbers include patients who are on chemotherapy. And these numbers have significantly increased year after year as the public is more aware of hematological and other malignancies together with the availability of treatment options for these diseases.

The opportunity to attend the 19th Indy Hematology Review is very meaningful to Dr. Minayehu who explains several goals that she hopes to achieve during and after the meeting. Firstly, it allows for exposure to tell her story and describe the limitations that exist in Ethiopia. Secondly, the meeting is an opportunity to forge new and meaningful connections that could lead to future collaborations. Lastly, and most importantly explains Tirumebet, is the wealth of knowledge she hopes to gain and that she plans to disseminate upon her return in order to improve the level of clinical care offered in Ethiopia.

Dr. Minayehu is responsible for the preparation of guidelines, curriculums, and policies at a national level specifically for hematology oncology. In addition to seeing patients, Dr. Minayehu is involved in several ongoing research studies and collaborations. Currently she has two ongoing projects in conjunction with Dr.Kebede H.Begna from the Mayo Clinic looking at gastrointestinal lymphomas and patterns of lymphoproliferative disorder in Ethiopia. Her experience at the 19th Indy Hematology Review will definitely enrich the knowledge base for hematology oncology in her home country and perhaps spark some new research collaborations with other institutes.

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(a) Raise awareness and provide education regarding hematology and oncology diseases and disorders
(b) To encourage youth to pursue careers in hematology and oncology, and
(c) To connect individuals suffering from or affected by hematology and oncology diseases and disorders to organizations, programs, and service providers.

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EMERGING THERAPIES

Emerging Therapies in Hematologic Malignancies and Hematologic Disorders Clinical Significance of Current Data: "My Thoughts" 2022

- Practice changing
- Teclistimab in R/R Myeloma
- Ibrutinib +BR as initial therapy in Mantle Cell Lymphoma
- Brentuximab + AVD in Stage III/IV Hodgkin's Lymphoma
- FIXED DURATION THERAPY IN CLL: Ibrutinib and Venetoclax
- CART-T Therapy as SECOND-LINE THERAPY in TE-Relapsed DLBCL
- Practice Confirming
- Autologous Stem Cell Transplantation in Myeloma
- Potentially Practice changing:
- Polatuximab Vedotin + CHP in High Risk DLBCL
- Quizartinib + Standard Chemo in mFLT-3-ITD AML
- Ivosidenib + Aza in Elderly (≥75yrs) IDH1-mutant NDAML
- Non-covalaent BTKi in R/R CLL: Pirtobrutinib and MK-1026
- Mosunetuzumab in DLCBL
- Stay tuned
- Margrolizumab in TP53 mutant AML
- Bispecific antibodies in R/R lymphoma and RRMM
- Parsaclisib in Relapsed Mantle Cell Lymphoma
- CPX-351 and Venetoclax in MDS

Ruemu E. Birhiray, MD
Chair, Indy Hematology Review

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An Interview with Adrian Wiestner, MD, PhD: The Inaugural Speaker at the Annual Steven Coutre Chronic Lymphocytic Leukemia Memorial Lecture: "What Would Steve Do? Treatment of CLL in 2022."

Written by Nicola Donelan

In a recent interview with Dr. Wiestner we discovered exciting recent developments in translational research as well as how his background and experiences led to his passion for this field within hematology.

Dr. Wiestner graduated with an M.D. from the University of Basel, Switzerland, in 1992 and a Ph.D. in 1997. Following this, he went on to do his residency in the Department of Internal Medicine, at the same university, completing it in 2000, and joined the National Heart, Lung, and Blood Institute as a hematology fellow the same year. He became a clinical fellow at the National Cancer Institute (NCI) in 2003 and returned to the NHLBI in 2004, where he leads a research program aiming to improve the treatment of patients with lymphoid malignancies, such as chronic lymphocytic leukemia (CLL).

PAVING THE WAY TO BETTER THERAPIES FOR CLL

As a physician and scientist, being able to investigate what is going on with a disease when starting to treat a patient is fascinating because it allows researchers to look at what is happening directly, explained Dr. Wiestner. How the leukemia cells grow, what happens to them when treatment begins, how it affects those cells, puts them under stress in order to kill them, but also how they adapt and become resistant to treatment. There are several exciting areas of translational research in CLL at the moment, moving away from simply using chemotherapy. Getting to the heart of understanding what makes the cancer cells tick and identifying the critical cell survival and growth signaling pathways has been paving the way towards truly targeted therapy. Other areas of research that he believes are coming to the forefront for hematology oncology treatments include combination drug therapy, CAR T cell therapy and bi-specific antibodies. There are many clinical investigations going on to find optimal combinations that can overcome treatment resistance, provide long-lasting disease control or potentially cure the disease. One such drug class in late stage clinical development is the 'so-called' non-covalent Bruton tyrosine kinase (BTK) inhibitors, which can help restore targeting of this pathway in cells that have become resistant to covalent BTK inhibitors such as ibrutinib. There's also a newer class of small molecules entering clinical trials that lead to the entire degradation of BTK. Dr. Wiestner called this a really an exciting development, because it means that rather than just inhibiting the kinase, the whole molecule can instead be degraded, an advance which is on the leading edge of overcoming tumor resistance to treatment.

CAR T cells immunotherapy utilizes the patient's own T cells and the drawback though, as Dr. Wiestner explained, is that it is individualized therapy and takes a huge effort to generate this treatment. However, Dr. Wiestner was encouraged by another potential immunotherapy treatment that utilizes bi-specific antibodies. These antibodies recognize two different antigens or epitopes so that they can recruit T cells to kill the CLL tumor cells. The big advantage, Dr. Wiestner explained, is that as monoclonal antibodies they can be generated using standard techniques to be used as an "off-the-shelf" treatment that can be given to patients without individual generation or customization.

It was clear during our conversation that Dr. Wiestner is very positive about the future of translational research. He is motivated because of such positive developments, using basic science to ask and answer questions that leads to insights that will be beneficial for the patient. That's why he feels the last ten years of advancements have been so rewarding.

A REWARDING CAREER REQUIRES PASSION

When he reflected on his own training it seemed that all roads eventually led towards this career path in hematology oncology. The key to choosing a rewarding career path was to find an area he was interested in and passionate about. Something he would advise any young scientist or clinician to do because that is how you can sustain it over a career of 40 or 50 years. Hematology fulfils that in a number of aspects for Dr. Wiestner, but he also acknowledged that finding good mentors along the way was important. They influenced him to be open to unexpected discoveries. He made a special mention of his first mentor Dr. Radek Skoda from the University of Basel, Switzerland who taught him how to combine clinical work and interest with research in a laboratory setting.

Dr. Wiestner's PhD research in Dr. Skoda's laboratory was in genetics, working on a rare blood disease where the bone marrow makes too many platelets, called thrombocythemia. During his Ph.D. they identified a gene that was mutated and worked out how that mutated gene causes the disease. It was his "Wow!" moment, and from then on, he wanted to work in hematology. It just naturally became the right fit for him. Dr. Wiestner was also so convinced that he wanted to combine research and clinical medicine that he looked for specific positions that would allow him to do this and found a fellowship in hematology in the US.

As a scientist and physician, it comes down to being present for what happens during an individual interaction in a room with one person when discussing their health. He described how you get into such a trusting relationship with your patients, that can last for a long time and have an important part to play in helping them deal with or recover from a disease.

To Dr. Wiestner, being a physician is an incredibly privileged position, one that he loves.

We look forward to having Dr. Wiestner present the inaugural Annual Steven Coutre Chronic Lymphocytic Leukemia Memorial Lecture: "What Would Steve Do? Treatment of CLL in 2022."

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CONTINUING EDUCATION INFORMATION

PHYSICIANS

Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 8.75 Medical Knowledge MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

Learning Objectives (ACCME, ANCC, ACPE)

1. Review new emerging Hematology therapies for Multiple Myeloma, Waldenström's Macroglobulin, Lymphoplasmacytic Lymphoma, Polycythemia Vera, and Myelofibrosis.
2. Determine which targeted therapies will be appropriate for patients diagnosed with Indolent & Mantel Cell, Hodgkin's Lymphoma and Myelodysplastic syndrome.
3. Evaluate which biological therapies (beyond CHOPing) that are effective in treating patients with Acute Lymphoblastic Leukemia and other Lymphomas.
4. Discuss current treatment options for patients with Acute Myeloid Leukemia and Acute Promyelocytic Leukemia.
5. Implement best practices for the identification and treatment of patients who are candidates for Hematopoietic Stem Cell transplantation.
6. Review updated best practices for identifying, diagnosing, and treating patients with Chronic Myeloid Leukemia, Essential Thrombosis, Eosinophilia Mastocytosis
7. Discuss challenging hematologic malignancy cases and assess potential solutions for optimal patient care.

Physician Accreditation Statement

This live activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of Purdue University College of Pharmacy and Indy Hematology Education, Inc. Purdue University is accredited by the ACCME to provide continuing medical education for physicians.

Credit Designation Statement

Purdue University College of Pharmacy designates this live activity for a maximum of 8.75 AMA PRA Category 1 Credit(s)™. Symposium - 8:00 am – 6:45 pm. Purdue University College of Pharmacy designates this live activity for a maximum of 1.50 AMA PRA Category 1 Credit(s)™ (Town Hall Interactive Meeting – 7:00 pm - 8:30 pm). Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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Disclosures will be provided prior to conference.

All relevant conflicts of interest have been mitigated prior to the start of the activity.

None of the planners, reviewers, Indy Hematology staff, and Purdue University College of Pharmacy staff have relevant financial relationship(s) with ineligible companies to disclose unless listed below.

NURSES

In order to receive CE, you must attend the entire Symposium from 8:00 am – 6:45 pm. Successful completion of this CME activity requires participants to complete a post-Evaluation.

Nurses Accreditation Statement

Purdue University Continuing Nursing Education is accredited as a provider of nursing continuing professional development by the American Nurses Credentialing Center's Commission on Accreditation.

This program is approved for 8.75 contact hours (Symposium: 8:00 am – 6:45 pm).
This program is approved for 1.5 contact hours (Town Hall Interactive Meeting: 7:00 pm - 8:30 pm).

PHARMACISTS

In order to receive CE, you must attend the entire Symposium from 8:00 am – 6:45 pm. Successful completion of this CME activity requires participants to complete a post-Evaluation.

Pharmacists Accreditation Statement

Purdue University College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This is a knowledge based, continuing education activity of Purdue University, an equal access/ equal opportunity institution.

Symposium: 8:00 am - 6:45 pm.

Universal Activity Number (UAN): 0018-9999-22-013-L01-P

8.75 contact hours (0.875 CEU's).

Town Hall Interactive Meeting: 7 - 8:30 pm.
Universal Activity Number (UAN): 0018-9999-22-014-L01-P

1.5 contact hours (0.15 CEU's).

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