From the Guest Editor’s Desk

A Tribute to Professor Terence “Terry” John Hamblin

The following statement appeared as a guest editorial prepared by Drs. John M. Bennett, David Bowen and Daniel Catovsky, long time professional associates of Professor Hamblin in Leukemia Research.¹

With great sorrow we report the death of Professor Terry Hamblin on Sunday, 8 January 2012 from complications of a metastatic bowel carcinoma.


He was instrumental in the establishment of the first three International Symposia on MDS and served on the MDS-F Board of Directors and as its treasurer for a quarter of a century. His achievements in the field of MDS improved greatly how patients were managed. His group in Bournemouth developed the first scoring system for prognosis and published many of the early seminal clinical papers defining this disorder.

He served with great distinction as co-Editor-in-Chief of Leukemia Research for 26 years.

Professor Hamblin was awarded the Binet-Rai medal for outstanding research in Chronic Lymphocytic Leukemia (CLL) in 2002 and stated “This has been my most successful area of research.” His seminal work on the prognostic value of the IgH gene mutation status has become a cornerstone in the risk stratification of CLL patients. This important research discovery characterized two subtypes of chronic lymphocytic leukaemia those with or without somatic mutation of the immunoglobulin heavy chain variable region genes. The survival of patients with IgH mutation averages 25 years, if no mutations closer to 8 years.

In addition his contributions in the fields of apheresis, stem cell transplantation, myeloma, antibody therapy, cytokine therapy and DNA vaccines are well known. Professor Hamblin’s articles numbered over 200 peer-reviewed publications. In retirement he embraced the social network, writing an eloquent and informed ‘blog’, which embraced his varied interests in life including medicine, sports and religion.

For those who knew Terry, he will be remembered as a gregarious and spirited Englishman, ready to step in with an anecdote, a yarn or a joyful dance at social gatherings. He leaves his wife, Diane—married for 45 years—and 4 children, Karen, Richard, Angela and David, and grandchildren.

Meeting Highlights and Announcements

THE AMERICAN SOCIETY OF HEMATOLOGY 53RD ANNUAL MEETING & EXPOSITION

On behalf of the MDS Foundation and our Board of Directors, thank you for joining us for our recent Satellite Symposium:

Next Generation Approaches for Evaluation and Treatment of MDS

Manchester Grand Hyatt
San Diego, California
December 9, 2011

The MDS Foundation held its 13th consecutive satellite symposium on Friday preceding the American Society of Hematology’s annual meeting. This symposium entitled “Next Generation Approaches for Evaluation and Treatment of MDS,” was chaired by Dr. Stephen D. Nimer of Memorial Sloan-Kettering Cancer Center in New York City and Chairman of the MDS Foundation and its Board of Directors. The room was filled to capacity with an audience of approximately 700 hematologists from around the world.
The MDS Foundation is blessed with a strong and supportive circle of members and friends...

Download our ASH Presentations online at www.mds-foundation.org

- Introduction Presentation: Next Generation Approaches for Evaluation and Treatment of MDS
- Revised International Prognostic Scoring System (IPSS-R): Developed by the International Working Group for Prognosis in MDS (IWG-PM)
- Molecular Characterization of MDS & Predisposition
- Impaired ribosome function and the molecular biology of the 5q- syndrome
- Combinational therapy and newer agents in MDS
- Advances in HSC Transplantation for Myelodysplasia: Cord Blood Transplantation & RIC
The 12th International Symposium on
MYELODYSPLEASTIC SYNDROMES

Advancing Research & Patient Care: Join over 1,600 International Leukemia, Hematology, and Oncology professionals

Symposium Chairmen:
Arnold Ganser, M.D., Ph.D. Hannover Medical School, Germany
Wolf-Karsten Hofmann, M.D., Ph.D. University Hospital Mannheim, Germany

MDS 2013 will be held in central Berlin surrounded by the world famous cultural and historical sites the city has to offer

VISIT KENES.COM/MDS TO LEARN MORE.
The MDS 2013 program includes a Trainees program, Nursing program, Patient Forum, Debates, Case-based discussions, Topical workshops, Oral and Poster presentations on the following topics:

- Morphology in MDS
- PathogenenOMEs in MDS – new players and well known gamblers
- Diagnosis in 2013
- Challenging diagnostic cases – does molecular genetics lead the way?
- Bone marrow failure syndromes including childhood MDS
- Pathogenesis
- Treatment of low risk MDS patients – the standard, the new
- Treatment of high risk MDS patients
- Prognostication and QoL
- Future perspectives and new drug development
On behalf of The Myelodysplastic Syndromes Foundation and our Board of Directors, we invite you to join us for our Satellite Symposium:

**The Myelodysplastic Syndromes: Challenges and Strategies for Effective Outpatient Management**

May 3, 2012 • New Orleans, Louisiana

Hilton New Orleans Riverside

Lunch will be served. The first 350 people will be accommodated.

**LEARNING OBJECTIVES**

Upon completion of this program, participants should be better able to:

- Correlate diagnostic findings and patient-specific factors as they relate to risk stratification, treatment selection, and prognosis in MDS.
- Operationalize strategies to identify treatment triggers, facilitate treatment initiation, proactively identify and manage treatment-related adverse events.
- Identify best practice models for outpatient management of the older adult with MDS including supportive care strategies.
- Discuss the patient and family perspective relative to living with MDS and developing systems for active participation and support.

**AGENDA**

12:00–12:05 pm
Welcome and Introduction
Sandra E. Kurtin, RN, MS, AOCN, ANP-C

12:05–12:45 pm
Scientific Update: Recent Advances in Strategies for the Treatment of MDS — From Prognosis to Treatment Selection
Jean Ridgeway, MSN, APN, NP-C, AOCN

12:45–1:00 pm
Setting Expectations for the Initial Treatment of MDS: Practical Tools for Effective Management
Sandra E. Kurtin, RN, MS, AOCN, ANP-C

1:00–1:15 pm
Patient and Family Support Throughout the Continuum of Care
Jayshree Shah, APN-C, MSN, RN, BSN, BS

1:15–1:30 pm
Navigating the Web for MDS: Web-based Resources for Patients and Nurses
Sara M. Tinsley, ARNP, AOCN

**FACULTY**

Sandra E. Kurtin, RN, MS, AOCN, ANP-C
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Tucson, Arizona, USA

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John Theurer Cancer Center
Hackensack University Medical Center
Hackensack, New Jersey, USA

Sara M. Tinsley, ARNP, AOCN
Malignant Hematology Nurse Practitioner
H. Lee Moffitt Cancer Center
Tampa, Florida, USA
“helping you give hope...”

The MDS Foundation is a multi-disciplinary, international organization devoted to support, research, treatment, and education for patients, caregivers, physicians, and other health care providers. The organization is based upon the premise that international cooperation will accelerate the process leading to the control and cure of these diseases.

Please join us as a member of the Foundation.

JOIN US AS AN MDS CENTER OF EXCELLENCE

Apply for The Centers of Excellence Program:

Would you like your treatment center to become part of the Foundation’s research network and referral system for MDS patients?

Please call us for more information and an application.

MDS FOUNDATION PUBLICATIONS

The MDS Foundation provides the following information to physicians and patients, free of charge:

- The MDS News
- The MDS Messenger (Free E-News)
- Patient Diary
- What Does My Bone Marrow Do?
- Understanding Myelodysplastic Syndromes: A Patient Handbook*
- Anemia, Blood Transfusions, Iron Overload, & Myelodysplastic Syndromes: A Handbook for Adult MDS Patients*

* Select MDS Patient Handbooks are available in English and the following languages:

- Arabic
- Hebrew
- Romanian
- Czech
- Hungarian
- Russian
- Italian
- Spanish
- Japanese
- German
- Polish
- Turkish
- Greek
- Portuguese

FOUNDA TION INITIATIVES FOR 2012 AND BEYOND...

- WORLDWIDE PATIENT QUALITY-OF-LIFE FORUMS
- WORLDWIDE PATIENT SUPPORT GROUPS
- INTERNATIONAL NURSE LEADERSHIP BOARD

VISIT OUR WEBSITE AND LINK TO OUR EDUCATIONAL RESOURCE CENTER:

www.mds-foundation.org

INTERNATIONAL WORKING GROUP FOR PROGNOSIS IN MDS

This international group of physicians, coordinated through the MDS Foundation, is dedicated to the revision and refinement of the International Prognostic Scoring System (IPSS).

THANK YOU TO OUR SPONSORS FOR THEIR SUPPORT
MDS Italy Patient Support Group Meetings
Reggio Calabria and Rome, Italy

A special thank you to AIL Pazienti for their collaboration!

The inaugural meeting in conjunction with AIL Pazienti was held on November 25, 2011 in Reggio Calabria. It was a huge success – almost fifty patients attended. Patients were stunned and emotional because of all of the attention they were receiving from our collaboration.

The second one was held in Rome on January 19, 2012. Almost 100 people attended. AIL will support future meetings as much as possible, and are organizing our next meetings in Florence & Treviso.

Thank you to Professor Mandelli, Drs. Oliva and Latagliata, and Maria Rita Grattarola for their hard work and contributions. Well done AIL. Thank you all for making this happen in Italy!
Inaugural MDS Belgium Patient Support Group Meeting

February 11, 2012

A special thank you to our guest speakers: Dr. Dominik Selleslag and Nurse Vanessa Prockl and AZ Sint-Jan AV in Brugge for hosting this event!
Mark Your Calendars!

2012 MDS Patient-Caregiver Education Forum Dates

After our huge successes with our past signature events, the MDS Foundation is happy to announce the dates of our 2012 Patient-Caregiver Forums.

This year, we are holding conferences in:

- Tampa, FL: February 29, 2012
- Palo Alto, CA: March 24, 2012
- San Antonio, TX: April 11, 2012
- Columbus, OH: May 12, 2012
- Minneapolis, MN: TBD
- Milwaukee, WI: TBD
- Durham, NC: TBD
- Pittsburgh, PA: TBD
- Long Island, NY: TBD
- Boston, MA: TBD

For more information on our upcoming forums, please visit www.mdsfoundation.org.

We are thrilled to have been able to reach so many members of the MDS community in 2011, and look forward to continuing doing so in 2012!

Thank You to Our Pharmaceutical Supporters

We would like to thank our pharmaceutical supporters for their commitment to the Foundation and its work. They have contributed in the form of educational grants, which maintain not only this newsletter but also the development of the MDS homepage on the World Wide Web, the Center of Excellence program, continuing medical education programs, and the dissemination of patient information.
Would you like to join a local support group in the Philadelphia, PA area?

It is our goal to initiate and meet on a regular basis to:
- Bring individuals together including patients and caregivers
- Meet others with similar challenges
- Share hopes and frustrations, gather information
- Provide information to better understand MDS treatment options
- Listen to physician and nurse presentations
- Socialize

If you are interested in joining a support group for patients who have MDS, please contact Audrey Hassan at 1-800-MDS-0839 or email ahassan@mds-foundation.org.

We have found that family members and caregivers will benefit as much as patients!

National Doctors’ Day
A Holiday Established in 1990 to Honor Physicians

March 30th of every year is National Doctors’ Day—a special day set aside to honor the skill and commitment of the dedicated men and women who devote their lives to providing hope and healing.

A tribute gift has been made to the MDS Foundation in your honor by someone who appreciates your skill, care, and commitment:

Dr. Erica Warlick
Wayne Sether, St. Paul, MN

Dr. Gary Grad
John W. Morris, Rolling Meadows, IL

Dr. Michael K. Gornet
Carolyn M. Long, Anchorage, AK

Dr. John Adamson
Harvey and Dr. Randi Heisel
San Diego, CA

Dr. Theodore Braich
Ray Gann, Bend, OR

Dr. M. Thirman
David Hensel, Oak Forest, IL

Dr. Bart Scott
Steve and Carolyn Kessler, Bellevue, WA

Dr. E. Randolph Broun
Evelyn D. Forney, Cincinnati, OH

Dr. Sushma Nakka
Donald and Kathe Dempster
Lakeland, FL

Dr. Mark Moskowitz
Mary Roberts, Naples, FL

Dr. A. Tom Andrews
Harold C. Ryder
Mechanicsburg, PA

Dr. Kelly McCaul
Lucille B. Nase, Centerville, SD

Dr. Luigi F. Bertoli
Lois Smith, Clanton, AL

Dr. Stuart Goldberg
Michael & Mary Ann Maher
Summit, NJ

Dr. Ajay Dar
Sheila Martin, Fairfax, VA

Dr. Aftab Mahmood
Robert E. Forest
Corpus Christi, TX

Dr. Alan List
Joan Weidenfeld
Boca Raton, FL

Dr. Suzanne Fanning
Harriet Brenner, Greenville, SC

Dr. Douglas Testori
Page Wingfield, Hampstead, NC

Dr. Kathleen Stewart
Dorotha Friar
Three Churches, WV

Dr. Paramjeet Singh
Roselyn B. Woolord, Raleigh, NC

Dr. Timothy J. Ernst
Phyllis Simons, Natick, MA

Dr. Hussain Saba
William Hamilton, Lake Como, NJ

Dr. Georgia I. Karp
Herbert Vine, East Brunswick, NJ

Dr. Jane Brooks
Elizabeth Benso, Matamoras, PA

Dr. Alan List
Arthur G. Lipman, Northbrook, IL

Dr. Virginia Klimek
Marjorie Brittenham and Family
Poughkeepsie, NY

Dr. Michael Duggan
David Pressley, Terre Haute, IN

Dr. Valeria Santini
Roberto Degli’Innocenti, Miami, FL

Dr. Stephen D. Nimer
Barry & Naomi Cooper, Brooklyn, NY
Hematopoietic Stem Cell Transplantation: A Therapeutic Option for Selected Patients with Myelodysplastic Syndromes

Erik Aerts, RN
Sandra Kurtin, RN, MS AOCN, ANP-C
On behalf of the MDS Foundation Nursing Leadership Board

Hematopoietic stem cell transplantation (HCT) remains the only potentially curative treatment option for the myelodysplastic syndromes.1 The pathobiology of MDS includes abnormalities within the myeloid clone which can only be completely eliminated by treating the disease aggressively with high dose chemotherapy followed by a stem cell rescue using donor stem cells. This is known as an allogeneic stem cell transplant. Autologous HCT (use of the patients own stem cells) is used infrequently for the treatment of MDS due to inferior long-term relapse-free periods. However, not all patients with MDS will be eligible for HCT based on commonly used criteria for patient evaluation and selection: 1) performance status (ability to perform daily task independently); 2) major organ function (liver, heart, kidneys, lungs); 3) the presence of co-morbidities (number and how well controlled); 4) response to disease modifying treatments (hypomethylating agents, immunomodulating agents, chemotherapy, clinical trials); 5) the availability of a suitable donor; 6) availability of a consistent caregiver; 7) age; and 8) patient wishes after informed consent.2,4

The best outcomes for patients undergoing HCT for MDS are felt to be in those patients who meet these eligibility criteria and who have had effective treatment for their MDS using disease modifying therapies. The use of disease modifying treatments prior to HCT is recommended to reduce the tumor burden and improve the potential for a favorable outcome. Disease that is not responsive to standard therapies is more likely to relapse early after HCT or not respond to the HCT preparative regimen. Patients with lower risk MDS (IPSS low or Intermediate 1) are less likely to transform early to acute leukemia and may be more effectively treated with disease modifying therapies. Due to the high risk for morbidity and mortality with HCT in a predominantly older population, careful evaluation of the individual patient, their disease, personal attributes, and resources for support is critical. The type of donor available is also a critical consideration. Matched sibling donors offer reduced post-transplant complications such as severe graft-vs-host disease (GVHD) and other organ failure. Matched unrelated donor (MUD) HCT carries much greater risk of transplant related morbidity and mortality. Given the majority of patients diagnosed with MDS are 70–75 years of age, this is not a feasible option for most patients due to common co-morbidities with secondary organ damage, the lack of a suitable matched donor, and the risk associated with the procedure. The probability of locating a HLA matched sibling donor is approximately 25%. If there is no sibling donor, a search will be initiated for the worldwide marrow donor registry which has approximately 8 million HLA typed volunteers. The probability of finding a matched donor is 40–60% for the general population, but under 10% for ethnic minorities.

For those patients who are deemed eligible for HCT, the timing of the HCT and what type of preparative regimen should be used is another consideration. The majority of data describing the timing for transplant has been based on retrospective analyses.4 Koerth and colleagues conducted a prospective analysis of 513 MDS patients’ ages 60–70 years who received reduced intensity chemotherapy (RIC) Allogeneic HCT.5 Early RIC HCT in lower-risk MDS patients was associated with inferior life expectancy 38 months vs 77 months) quality adjusted life expectancy (35 months vs 65 months) than patients who did not have an early RIC HCT. However, early RIC HCT was associated with superior overall life expectancy (36 months vs 28 months) and quality adjusted life expectancy (33 months vs 15 months) in patients with higher risk MDS. Transfusion independent patients in both groups did better than their transfusion dependent counterparts. A retrospective analysis of 291 patients with MDS undergoing allogeneic HCT from the Spanish MDS registry found that high risk cytogenetics, higher risk IPSS category, and lack of benefit from disease modifying treatments prior to transplant were associated with inferior survival outcomes.6 The OS rate after 2.6 years of follow-up was 33%, and infection (61%) represented the largest cause of transplant-related mortality (41%). These data stress the importance of a complete diagnostic evaluation including calculation of the IPSS category and the importance of disease modifying treatments to achieve transfusion independence early in the course of disease and prior to HCT. Although RIC HCT may limit treatment-related morbidity and mortality, the risk of early relapse is increased. The selection of pre-transplant disease modifying therapies will vary by region throughout the world based on approved agents and current practice guidelines for each country.7

For those patients found to be eligible for HCT, the pre-transplant evaluation will be very thorough to confirm adequate organ function, social support, psychological health, and financial resources. Immediately prior to the transplant, the patient and their designated caregiver(s) will have a meeting to obtain informed consent for the treatment. Support of the patient and their family during the transplant evaluation, the preparative treatment and stem cell infusion, and the post-transplant period requires a well-organized multidisciplinary team including medical oncologist, oncology nurse specialists, dieticians, social workers, spiritual counselors, financial counselors, and a number of other health care providers as needed for individual patients. The majority of patients will spend several weeks...
in the inpatient setting and once discharged will be followed closely at the transplant center outpatient clinic. Careful monitoring is required to detect early or late onset of toxicities including GVHD or other organ dysfunction. With early intervention, many of these potential toxicities can be effectively treated. Treatment as a part of a registered clinical trial is recommended to allow further characterization of the best treatment approaches and supportive care strategies for patients with MDS.

References:
Would you like your treatment center to become part of the referral system for MDS patients and be designated as a Center of Excellence? To be recognized as a Center of Excellence, an institution must have the following:

- An established university (or equivalent) program
- Recognized morphologic expertise in MDS
- Available cytogenetics and/or molecular genetics
- Ongoing research, including Institutional Review Board–approved clinical trials
- Documentation of peer-reviewed publications in the field
- The ability and intention to register patients in the MDS International Registry database

Please contact the Foundation for further information and an application form for your center.

The following centers have qualified as MDS Centers of Excellence:

**UNITED STATES**

**ARIZONA**
- Mayo Clinic Hospital
  - Phoenix, Arizona
  - Ruben Mesa, MD, James Slack, MD
- University of Arizona Arizona Cancer Center
  - Tucson, Arizona
  - Daruka Mahadevan, MD, PhD

**CALIFORNIA**
- Cedars-Sinai Medical Center
  - Los Angeles, California
  - H. Phillip Koehlert, MD
- City of Hope National Medical Center
  - Duarte, California
  - Stephen J. Forman, MD
- Stanford University Medical Center
  - Stanford, California
  - Peter L. Greenberg, MD
- UCLA Center for Health Sciences
  - Los Angeles, California
  - Gary J. Schiller, MD
- University of Southern California Keck School of Medicine
  - Los Angeles, California
  - Casey L. O’Connell, MD

**FLORIDA**
- All Children’s Hospital
  - St. Petersburg, Florida
  - Gregory Hale, MD
- Mayo Clinic
  - Jacksonville, Florida
  - Alvaro Moreno-Aspitia, MD
- University of Florida Shands Hospital
  - Gainesville, Florida
  - Christopher R. Cogle, MD
- University of South Florida H. Lee Moffitt Cancer Center
  - Tampa, Florida
  - Alan F. List, MD

**GEORGIA**
- Emory Winship Cancer Institute
  - Atlanta, Georgia
  - Amelia Langston, MD

**ILLINOIS**
- Loyola University Chicago Cardinal Bernardin Cancer Center
  - Maywood, Illinois
  - Scott E. Smith, MD, PhD
- Robert H. Lurie Comprehensive Cancer Center of Northwestern University
  - Chicago, Illinois
  - Olga Frank, MD
- Rush University Medical Center
  - Chicago, Illinois
  - Stephanie A. Gregory, MD
  - Jamile Shammo, MD
- University of Chicago Medical Center
  - Chicago, Illinois
  - Richard A. Larson, MD

**INDIANA**
- Indiana University Medical Center
  - Indianapolis, Indiana
  - Larry Crive, MD

**MARYLAND**
- Johns Hopkins University School of Medicine
  - Baltimore, Maryland
  - Steven D. Gore, MD
  - Charles S. Hesdorffer, MD
- University of Maryland Greenebaum Cancer Center
  - Baltimore, Maryland
  - Maria R. Baer, MD

**MASSACHUSETTS**
- Children's Hospital Boston
  - Boston, Massachusetts
  - Inga Hofmann, MD
- Dana-Farber Cancer Institute
  - Boston, Massachusetts
  - Richard M. Stone, MD, David P. Steensma, MD
- Tufts University School of Medicine
  - Boston, Massachusetts
  - Kellie Sprague, MD

**MICHIGAN**
- Mayo Clinic
  - Rochester, Minnesota
  - Mark R. Litzow, MD
- University of Minnesota Medical Center
  - Fairview University of Minnesota Medical School
  - Minneapolis, Minnesota
  - Erica D. Warlick, MD

**MISSOURI**
- Washington University School of Medicine
  - St. Louis, Missouri
  - John F. DiPersio, MD, PhD

**NEBRASKA**
- University of Nebraska Medical Center
  - Omaha, Nebraska
  - Lori Maness, MD

**NEW JERSEY**
- The Cancer Center of Hackensack University Medical Center
  - Hackensack, New Jersey
  - Stuart Goldberg, MD

**NEW YORK**
- Albert Einstein College of Medicine Cancer Center
  - Bronx, New York
  - Amit Verma, MD
- Columbia University Medical Center
  - New York, New York
  - Azra Raza, MD
- Memorial Sloan-Kettering Cancer Center
  - New York, New York
  - Virginia M. L’Hermite, MD

**OHIO**
- Cleveland Clinic Foundation Taussig Cancer Center
  - Cleveland, Ohio
  - Jaroslaw Maciejewski, MD, PhD
- The Ohio State Comprehensive Cancer Center
  - Columbus, Ohio
  - Allison R. Walker, MD
**Announcing New Clinical Trials**

**NAME OF INSTITUTION:** Novartis Pharmaceuticals  
**TRIAL NUMBER:** NCT00940602  
**Title of Trial or Description:** Myelodysplastic Syndromes (MDS) Event-Free Survival With Iron Chelation Therapy Study (TELESTO)  
A Multi-center, Randomized, Double-blind, Placebo-controlled Clinical Trial of Deferasirox in Patients With Myelodysplastic Syndromes (Low/Int-1 Risk) and Transfusional Iron Overload  
Currently Recruiting Participants.  
The primary purpose of this study is to prospectively assess the efficacy and safety of iron chelation therapy with deferasirox compared to placebo in patients with myelodysplastic syndromes (low/int-1 risk) and transfusional iron overload.  
Contact the Novartis Clinical Trials Hotline at 800-340-6843 or go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for additional information and to view the active sites.

**NAME OF INSTITUTION:** Celgene Corporation  
**TRIAL NUMBER:** NCT01029262  
**Title of Trial or Description:** A Study of Lenalidomide Versus Placebo in Subjects With Transfusion Dependent Anemia in Low Risk Myelodysplastic Syndrome (MDS-005)  
Currently Recruiting Participants.  
The primary purpose of this study is to compare the efficacy of Lenalidomide (Revlimid®) versus placebo in achieving red blood cell transfusion independence in the overall study population and in a pre-specified subgroup of patients with an erythroid differentiation gene expression signature predictive of Lenalidomide response.  
Access [www.clinicaltrials.gov](http://www.clinicaltrials.gov) for additional information.

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**Clinical Trials: Economic Value, supported by Clinical Efficacy**

With the emergence of new methods of treatment for myelodysplastic syndromes (MDS), comes the realization that new treatment options support the opportunity for life extending and cost effective alternatives for patients, especially the relapsed or refractory patient to presently approved drug therapies versus the cost of supportive care.

**Economic Analyses in Clinical Trials**

Health economics are rarely the primary purpose of an experimental study, yet these economic attributes are measured today in the common design of the latest studies, ensuring that the trial will provide the data necessary for a high quality economic analysis of the study outcome.

Carrying out an economic evaluation within a controlled-randomized trial allows detailed information to be collected, including:

- Description and analysis of treatment related costs to health care systems, payers, and society
- Measurement of costs and consequences (clinical, economic, and humanistic) of medications, devices, and services

**Health economic measurements are an important area of evaluation within the ONTIME trial (ON 01910.NA) Trial In Myelodysplastic syndrome**

The primary purpose of the ONTIME study is to compare overall survival (OS) in patients receiving rigosertib plus best supportive care (BSC), to the OS of patients receiving BSC alone. This MDS patient population has excess blasts (5% to 30% bone marrow blasts) and have failed, or become intolerant too, or relapsed after treatment with azacitidine or decitabine.

**Consider the ONTIME Trial for the treatment of MDS—Accrual of patients is ongoing**

If you would like additional information regarding ONTIME or would like to refer a patient for enrollment into this clinical trial OR if you are an MDS patient who has failed, become intolerant, or relapsed after Vidaza® (azacitidine) or Dacogen® (decitabine) treatment, please call the ONTIME Trial Help Line at 1-855-609-6564.

**Learn More**

More information can be found at www.mdstrial.com or clinicaltrials.gov, the identifier is NCT01241500.
follows: (a) megaloblastoid changes and oligonuclearity in erythropoiesis, (b) pseudo Pelger Huet cells and hypogranularity in granulopoiesis and (c) micromegakaryocytes and mononuclear megakaryocytes.


The study showed increased levels of serum ferritin in non-transfused MDS patients as compared to healthy individuals. Among the MDS patients, the serum ferritin levels were higher in high risk categories of IPSS, and in patients with cytogenetic abnormalities. A significantly higher leukemia free survival and overall survival rates were noted if the serum ferritin levels were <500 ng/mL.


A study based on Israel’s nationwide health plan data showed MDS incidence of 3.32 per 100,000, which increases significantly among the anemic individuals over 40 years of age (56.7 per 100,000). The study also highlighted that only 44% of MDS patients had bone marrow examination recorded in the database and that the time taken to reach diagnosis of MDS from the first indication of anemia was 3.5 years.


This pivotal study assessed 2902 patients from four large MDS patient databases to propose a new and comprehensive cytogenetic scoring system. Approximately 45% patients had cytogenetic abnormalities with del(5q) and trisomy 8 being the most frequently noted abnormalities. In total 19 cytogenetic categories were defined to construct five prognostic subgroups with significant differences in median overall survival, ranging from very good—61 mo, good—49 mo, intermediate—26 mo, to poor—16 mo and very poor—6 mo. The majority of patients (65.7%) with cytogenetics

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**Online Search Tool for Clinical Trials**

**TrialCheck**

Clinical trials information and products powered by:
Coalition of Cancer Cooperative Groups

TrialCheck is another online search tool that helps you gather information about cancer clinical trials to discuss with your doctor. This user-friendly tool allows you to search for trials according to your type of cancer and according to your zip code. This will help you locate physicians and hospitals near your home that offer trials.

TrialCheck searching is based on nine simple questions. Depending upon the answers you provide, TrialCheck generates a list of trials in which you may be eligible to enroll.


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**New Research Protocol Listings**

The MDS Foundation wants you to know about clinical trials of investigational treatment options for patients with MDS and has updated its International Clinical Trials list on our website and for distribution.

Please contact us for a detailed listing featuring new protocols:

**Website:** www.mds-foundation.org

**Email:** patientliaison@mds-foundation.org or call 800-MDS-0839 and the current clinical trials will be sent to you.

Clinical trials often have very specific eligibility requirements. Please talk with your doctor to help decide which, if any, trials might be right for you. Please note that the information is provided strictly as a resource and is not an endorsement of any physician, institution, or treatment.

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**Educational Resources**

**Highlights of Latest Literature in MDS**

*Suneel D. Mundle, PhD*

*Anuj Marathe*

Listed below are citations of some new publications relevant to MDS (pathogenesis, clinical characterization, management, etc.). To access the complete article log on to [www.pubmed.gov](http://www.pubmed.gov).

**DIAGNOSIS/PROGNOSIS:**


This study extensively assessed dysplastic features in peripheral blood and bone marrow of 3156 Düsseldorf MDS registry patients to demonstrate most common features of dysplasia in the three hematopoietic lineages as follows: (a) megaloblastoid changes and oligonuclearity in erythropoiesis, (b) pseudo Pelger Huet cells and hypogranularity in granulopoiesis and (c) micromegakaryocytes and mononuclear megakaryocytes.


The study showed increased levels of serum ferritin in non-transfused MDS patients as compared to healthy individuals. Among the MDS patients, the serum ferritin levels were higher in high risk categories of IPSS, and in patients with cytogenetic abnormalities. A significantly higher leukemia free survival and overall survival rates were noted if the serum ferritin levels were <500 ng/mL.


A study based on Israel’s nationwide health plan data showed MDS incidence of 3.32 per 100,000, which increases significantly among the anemic individuals over 40 years of age (56.7 per 100,000). The study also highlighted that only 44% of MDS patients had bone marrow examination recorded in the database and that the time taken to reach diagnosis of MDS from the first indication of anemia was 3.5 years.


This pivotal study assessed 2902 patients from four large MDS patient databases to propose a new and comprehensive cytogenetic scoring system. Approximately 45% patients had cytogenetic abnormalities with del(5q) and trisomy 8 being the most frequently noted abnormalities. In total 19 cytogenetic categories were defined to construct five prognostic subgroups with significant differences in median overall survival, ranging from very good—61 mo, good—49 mo, intermediate—26 mo, to poor—16 mo and very poor—6 mo. The majority of patients (65.7%) with cytogenetics...
abnormalities in this study group were classified under “Good” prognostic group within the newly proposed cytogenetic scoring system.

**TREATMENT:**

**Reviews and Perspectives**

The following two articles provide significant perspective on the current therapeutic landscape of MDS and identify need for additional prospective studies.


**Transfusions:**


An Italian 5 year study (2006–2010), reveals feasibility of using a dedicated home care program for blood transfusions to MDS patients. Authors suggest that such a service helps maintain quality of life and provides a comfortable treatment option to the elderly and frail MDS patients.

**IMiDs:**

1. Wei W et al. A combination of thalidomide and arsenic trioxide is effective and well tolerated in patients with myelodysplastic syndromes. Leukemia Research. 2012, Jan 23 [Epub ahead of print].

Twenty-two patients each were assessed on treatment with a combination of thalidomide plus arsenic trioxide (ATO) or supportive care. The treatment arm demonstrated 18.2% CR and 68.2% hematopoietic improvement rate which were significantly higher than in those receiving only supportive care on the control arm. The progression free- and overall survival were also significantly higher with the active treatment than the controls (26 vs. 10 months and 36 vs. 16 months respectively). No severe AEs were noted.


Thirty-one consecutive lower risk non-del(5q) MDS cases refractory to ESA received lenalidomide with or without ESA. Erythroid response was noted in 48% patients (37% transfusion independence), median response duration was 2 years. The erythroid response was higher in patients receiving lenalidomide +ESA than lenalidomide alone (55% vs. 36%).

**Demethylating Agents:**


A retrospective study of 282 higher risk MDS patients treated with azacitidine in combination with ESA (n=32) or alone (n=250) demonstrated significantly higher rate of erythroid response, transfusion independence rate, and improved survival with the addition of ESA to azacitidine.

**Other Agents:**


This post-hoc analysis of the EPIC trial with deferasirox (Exjade™) demonstrated hematologic responses in all three hematopoietic lineages (erythroid—21.5%, platelets—13% and neutrophil—22%) with a trend of greater ferritin reduction in responding patients as compared to the non-responders. The authors concluded that treatment with deferasirox up to 1 year may yield hematopoietic responses in some MDS patients.


Intravenous clofarabin was evaluated in high-risk MDS patients at 15 mg/m² vs. 30 mg/m² daily x 5 days. Among the total of 58 patients, the ORR was 41% vs. 29% with 15 and 30 mg doses respectively. The median survival for all patients was 7.4 months (21.7 months in those with CR). Hepatic and renal AE >grade 2 were seen with 30 mg dose and in general myelosuppression and infections were frequent with treatment.

**PATHOBIOLOGY:**

1. Yoshida A et al. Marked up-regulation of Survivin and Aurora-B kinase are associated with disease progression in the myelodysplastic syndromes. Haematologica. 2012, Mar 14 [Epub ahead of print].

Survivin is apoptosis inhibitor and, Survivin and Aurora-B kinase play an important role in maintaining genomic stability. This study reports assessment of Survivin and Aurora-B kinase m-RNA expression in CD34+ cells from 64 MDS or in leukemia blasts from 50 de novo AML cases. The expression of both genes was increased in RAEB-1/2 and 1AAML patients as compared to normal controls and correlated with disease progression. The authors suggest that the role of increased expression of these two genes in evolution of complex karyotypic abnormalities in MDS needs to be explored further.


**SF3B1, SRSF2, ZRSR2, and U2AF35 gene mutations were analyzed in a cohort of 221 MDS patients. The total incidence of these mutations was approximately 43% and these were mutually exclusive. The report describes that each genotype corresponded with unique clinicopathologic features.**


Mutations in the genes of the splicing machinery are increasingly assessed in MDS. The present study assessed 193 MDS patients. Mutations were detected in a total of 34.7% patients in SRSF2, U2AF1, ZRSR2 and SF3B1 genes of which SRSF2 was the one shown to have a negative prognostic impact on leukemic transformation and overall survival.


Increased risk of leukemia was previously shown amongst the survivors of atomic bomb radiation exposure. Recent analysis suggests persistence of this risk even after six decades since the initial exposure. High-risk MDS and complex karyotypes were found to be more frequent in patients with higher dose radiation exposure.


The authors constructed specific algorithms based on four claims databases to estimate the incidence of myeloid malignancies and compared the outcome with that reported by the SEER national registry of the USA. The study revealed over 50% underreporting of the incidence of myeloid malignancies in SEER database.

We would like to thank Suneel Mundle, a member of the MDS Foundation, for his assistance in monitoring these important peer-review publications on MDS.
Thank You!

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A memorial fund has been established in the name of Ms. Ruth Glogow Lublin
Donations have been made in Ms. Lublin’s memory by:
- Danny and Eileen Alva, Philadelphia, PA
- Ronald and Sydney Beifeld, Conshohocken, PA
- Jerry and Marilyn Segal, Dresher, PA
- Joanne Marchionni, Philadelphia, PA
- Jackie Nitzberg, Wynnewood, PA
- Allan and Suzanne Jaspian, Aventura, FL

A memorial fund has been established in the name of Mr. Anthony Massone
Donations have been made in Mr. Massone’s memory by:
- Jeff Fosole, Forest Hills, NY
- Tim and Trish Kaufman, Fairlawn, OH

A memorial fund has been established in the name of Mrs. Marlene Maunder
Donations have been made in Mrs. Maunder’s memory by:
- Charles and Carol Cox, Carlisle, MA
- Yvonne Bynes, Ammandale, VA

A memorial fund has been established in the name of Ms. Lena McNellis
Donations have been made in Mrs. McNellis’ memory by:
- Laura Nagonsky, Arlington Heights, IL
- Linda and Terry Mainiero, Arlington Heights, IL
- Barbara Wilton, Palatine, IL
- Cheryl Heater, Crest Hill, IL
- Thomas and Geraldine Piatt, Marengo, IL
- Bill and Mary Ann Spaletto, Inverness, IL

A memorial fund has been established in the name of Captain RET Richard Keith Meadow, Sr.
Donations have been made in Captain Meadow’s memory by:
- James and Kathryn Stanley, Naples, FL
- Joseph and Kay Wilson, San Francisco, CA
- Allen Lang, Montgomery, AL

A memorial fund has been established in the name of Mr. Wayne Meling
Donations have been made in Mr. Meling’s memory by:
- Patricia Meling, Arlington Heights, IL
A memorial fund has been established in the name of Mr. Allan Moberg
Donations have been made in Mr. Moberg’s memory by:
Keith Kaminsky, Dale City, VA

A memorial fund has been established in the name of Mr. Garvin Morris
Donations have been made in Mr. Morris’ memory by:
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A memorial fund has been established in the name of Mrs. Lillian M. Morris
Donations have been made in Mrs. Morris’ memory by:
John W. Morris, Naperville, IL
Rolling Meadows, IL

A memorial fund has been established in the name of Dale Neuman
Donations have been made in Mr. Neuman’s memory by:
City & County Credit Union
Joe and Karen Hines
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A memorial fund has been established in the name of Ms. Rory Jean Nimon
Donations have been made in Ms. Nimon’s memory by:
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A memorial fund has been established in the name of Mr. John Nole
Donations have been made in Mr. Nole’s memory by:
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A memorial fund has been established in the name of Mrs. Arlene O’Donnell
Donations have been made in Mrs. O’Donnell’s memory by:
James J. O’Donnell, Ill, Ocean City, NJ

A memorial fund has been established in the name of Mr. Donato Parisi
Donations have been made in Mr. Parisi’s memory by:
Parker, Pollard, Wilton & Peaen P.C.
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Wilton, CT
Jerry & Gloria Anderson
Manchester, NJ
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Raymond & Santa Banach
Kristy Buileri
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A memorial fund has been established in the name of Mr. Harold R. Parkinson
Donations have been made in Mr. Parkinson’s memory by:
Mary K. Parkinson, Annapolis, MD

A memorial fund has been established in the name of Mr. Harvey Adam Pearlman
Donations have been made in Mr. Pearlman’s memory by:
Ken and Cynthia Eckstein
Bridgewater, CT

A memorial fund has been established in the name of Mrs. Marna Pedersen
Donations have been made in Mrs. Pedersen’s memory by:
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Palm Springs, CA
Don and Eileen Malstrom
Palm Springs, CA
Walter Farrell & Jerry Gerken
Palm Springs, CA
Gayle Hodges
Palm Springs, CA
George Pohle
Palm Springs, CA
Addionio Family
Summit, NJ
Erik and Suzanne Christensen
Palm Springs, CA

A memorial fund has been established in the name of Mr. Ronald F. Pientka
Donations have been made in Mr. Pientka’s memory by:
Tangie, Robin, Diane, Ike Biggs and Family
Beaver, OH

A memorial fund has been established in the name of Mr. Louis F. Posillico
Donations have been made in Mr. Posillico’s memory by:
Rasheed and Nicole Epps
Havertown, PA

A memorial fund has been established in the name of Mrs. Claudia Calello Pugliese
Donations have been made in Mrs. Pugliese’s memory by:
Theresa Lobosco
Totowa, NJ
Beniamino Varricchio
Wallington, NJ
M.M. Sieber
Pugliese Family
Clifton, NJ

A memorial fund has been established in the name of Mrs. Edna Rashkin
Donations have been made in Mrs. Rashkin’s memory by:
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Boca Raton, FL

A memorial fund has been established in the name of Mr. Rudy Rodriguez, Jr.
Donations have been made in Mr. Rodriguez’ memory by:
Shawn and Keili Doherty
The Woodlands, TX

A memorial fund has been established in the name of Mrs. Norma Rolando
Donations have been made in Mrs. Rolando’s memory by:
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Rocky Hill, CT
Sophie and Christa Mariner
Rocky Hill, CT
Dina Pizzoferrato
Rocky Hill, CT
Joseph and Rosemarie Zapulla
Windsor Locks, CT
Lola Zinolfi
Enfield, CT

A memorial fund has been established in the name of Mr. Abraham (Abe) Rosenthal
Donations have been made in Mr. Rosenthal’s memory by:
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League City, TX
Harry and Beverly Bloom
Houston, TX
Stuart Bernoff, Bronx, NY
Steve and Lana Royal
Birmingham, AL
Ray and Ruth Eagle
Houston, TX

A memorial fund has been established in the name of Mrs. Enid Rottenberg
Donations have been made in Mrs. Rottenberg’s memory by:
Edward Biodnick, Garden City, NY

A memorial fund has been established in the name of Ms. Jill Schmitt
Donations have been made in Ms. Schmitt’s memory by:
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A memorial fund has been established in the name of Mrs. Joyce McSwain Shugart
Donations have been made in Mrs. Shugart’s memory by:
Council of Chief State School Officers—Former Members
New Haven, CT
Texas Police Athletic Federation Inc.
The Reeses
Plainview, TX

A memorial fund has been established in the name of Mr. Agustin Sierra
Donations have been made in Mr. Sierra’s memory by:
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Alexandria, VA

A memorial fund has been established in the name of Mr. Raymond Simon
Donations have been made in Mr. Simon’s memory by:
Arline C. Muntner, Boca Raton, FL

A memorial fund has been established in the name of Mrs. Sandra K. Smith
Donations have been made in Mrs. Smith’s memory by:
John and Mary Jane Glaze
Greencastle, IN

A memorial fund has been established in the name of Mr. John A. Snyder
Donations have been made in Mr. Snyder’s memory by:
Jeanette Snyder
The Gerber Foundation
Novi, MI

A memorial fund has been established in the name of Mr. Thomas Soudrette
Donations have been made in Mr. Soudrette’s memory by:
Susanne M. Soudrette
Lawrenceburg, IN
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Donations have been made in Mr. Spear’s memory by:
Vince and Karin Carson  Kaz USA, Inc.
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Gwen Stamps, Las Cruces, NM

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Howard Stephenson, Lakeside, MI

A memorial fund has been established in the name of Mr. Oliver D. Strampher
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A memorial fund has been established in the name of Ms. Ressie Marie Strange
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A memorial fund has been established in the name of Mr. Donald Stuart
Donations have been made in Mr. Stuart’s memory by:
Wilma Wilt, Claremont, CA

A memorial fund has been established in the name of Mr. Mark Swanson
Donations have been made in Mr. Swanson’s memory by:
Debby Herron, Brentwood, TN

A memorial fund has been established in the name of Mrs. Doris Kjersgaard Thomas
Donations have been made in Mrs. Thomas’ memory by:
Class of 1944, Perth Amboy High School
Perth Amboy, NJ

A memorial fund has been established in the name of Mr. Ned Tito
Donations have been made in Mr. Tito’s memory by:
James and Carol Fujimoto, Chicago, IL

A memorial fund has been established in the name of Mrs. Faith Darlene Togami
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Wheaton, IL  DiPasquale and Family
Neil and Joyce Thedford  Northbrook, IL
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A memorial fund has been established in the name of Mr. Kenneth Tomczik
Donations have been made in Mr. Tomczik’s memory by:
Susan Tomczik, Brooklyn Park, MN

A memorial fund has been established in the name of Mrs. Jeanette Toth
Donations have been made in Mrs. Toth’s memory by:
Joseph Toth  Donna, Dave, Davy Bunton
Manalapan, NJ  Arlington, VA

A memorial fund has been established in the name of Ms. Marjorie Ruth Tyson
Donations have been made in Ms. Tyson’s memory by:
Michael Tyson, Fort Worth, TX

A memorial fund has been established in the name of Mr. Peter Urquiaga
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Rita Ennis  Millville, DE
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A memorial fund has been established in the name of Mr. Sanford Howard Wittin
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A memorial fund has been established in the name of **Mr. Nello Lewis Zanett**

Donations have been made in Mr. Zanett’s memory by:

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- Louise Shephard, North Adams, MA
- Mickey and Janet O’Neill, North Adams, MA
- Greylock Community Club, North Adams, MA
- Ellen Casey, Hinsdale, MA
- John Devio, North Adams, MA
- Greylock Community Club, North Adams, MA
- Dan McGinnis, Dalton, MA
- Bill and Sheryl Morehouse, North Adams, MA
- Sandy Morehouse, North Adams, MA

A memorial fund has been established in the name of **Mrs. Joan Zimetbaum**

Donations have been made in Mrs. Zimetbaum’s memory by:

- Stephen Goldberger, Boston, MA
- Bruce and Sally Levy, West Roxbury, MA
- Steve and Randi Schwartz, Hartsdale, NY
- Rina Schunk, Ardsley, NY
- Beth Zelin, Ardsley, NY
- Jay and Lois Ibes, Hartsdale, NY
- Rita Spriro and Family, Greenacres, FL
- Richard and Susan Aitn, Hartsdale, NY
- Robert and Roberta Yeshion, Hartsdale, NY
- Corey Friedlander, Tarrytown, NY
- Caryn Donocoff, Hartsdale, NY

A memorial fund has been established in the name of **Dr. Marcel Zimetbaum**

Donations have been made in Dr. Zimetbaum’s memory by:

- Joseph Ganger, Oakdand Gardens, NY
- Dr. and Mrs. Asao Hirano, Irvington, NY
- Judith Wachs, Baldwin, NY
- Kenny and Bernice Strauss, Yonkers, NY
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A Living Endowment

Many families are affected by living with the reality of MDS. There is an extraordinary way to contribute to the MDS Foundation and support our mission of working as a resource for patients, families, and healthcare professionals.

A commitment to donate to the Foundation on occasions of loss, birthdays, and anniversary remembrances can be made. Honor your friends or family members on these occasions with a donation, and the MDS Foundation will send an acknowledgment to the recipient, recognizing the occasion.

**A Living Endowment donation has been made in honor of:**

**Kenny Steinback**

This donation was submitted by:

Geoff and Sandy Goldworm
Jupiter, FL

**A Living Endowment donation has been made in honor of:**

**Marilyn S. Gould**

This donation was submitted by:

Marilyn S. Gould
St. Petersburg, FL

**A Living Endowment donation has been made in honor of:**

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This donation was submitted by:

Ron and Suzanne Hoffman
Sumner, ME

**A Living Endowment donation has been made in honor of:**

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This donation was submitted by:

Ted and Shirley Levy, Naples, FL
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**A Living Endowment donation has been made in honor of:**

**Cousin living with MDS**

This donation was submitted by:

R.L. Proctor
Leeds, AL

**A Living Endowment donation has been made in honor of:**

**Dr. Stephen Nimer**

This donation was submitted by:

Barry and Naomi Cooper
Brooklyn, NY

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**Robert W. Cook, Jr.**

This donation was submitted by:

Suzanne Demartini
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**A Living Endowment donation has been made in honor of:**

**Gloria Schwartz**

This donation was submitted by:

Arnold Schwartz
Woodland Hills, CA

**Suzanne Fleischman Memorial Fund for Patient Advocacy**

A fund has been established by the MDS Foundation in memory of Suzanne Fleischman. Contributions may be sent to the Foundation with a notation designating the Suzanne Fleischman Memorial Fund for Patient Advocacy.

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