International Bone Marrow Transplant Registry / Autologous Blood & Marrow Transplant Registry

IBMTR/ABMTR newsletter

Volume 9 Issue 1 February 2002

CONTENTS

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Mary M Horowitz, MD, MS

IBMTR/ABMTR Scientific Director,
Professor of Medicine,
Medical College of Wisconsin

The first successful allogeneic bone marrow transplants in humans were carried out in 1968. Since then, use of allogeneic or autologous hematopoietic stem cell transplantation (HSCT) has increased dramatically, with an estimated 40–50,000 HSCTs worldwide in 2001. Concomitant with this development the IBMTR and ABMTR have coordinated an international effort to collect and analyze data on transplant outcome. Efforts of participating centers and IBMTR/ABMTR Statistical Center staff have resulted in establishment of a unique resource of data and statistical expertise for studying HSCT. The Registries now have data for more than 150,000 transplants. This issue of the IBMTR/ABMTR Newsletter brings you our annual report on the "State of the Art" in HSCT. A tradition for the past 15 years, this report uses the Registry database to summarize current use and outcome of HSCT. The report is written by Dr Mary Eapen, who joined the Statistical Center in 2000 as an Assistant Scientific Director from the University of Minnesota. Dr Eapen is a pediatric hematologist/oncologist who also holds a Master's degree in Clinical Research. Under her guidance, this year's summary report includes expanded information on HSCT results in children.

This report, distributed widely through our web site (www.ibmtr.org), this Newsletter and a compact disc provided free of charge to participating centers, represents a part of the Statistical Center's effort to make the data contributed by IBMTR/ABMTR centers accessible to the transplant community. We hope you find it useful and we welcome suggestions to make future editions even better.

continued on page 2

Report on state of the art in blood and marrow transplantation

– the IBMTR/ABMTR Summary slides with guide

Since 1972 the International Bone Marrow Transplant Registry (IBMTR) has collected and analyzed outcome data from blood and marrow transplant centers worldwide. More than 450 centers now participate in the IBMTR. The IBMTR database has information for about 40% of allogeneic transplants done since 1970. In 1991, the Autologous Blood & Marrow Transplant Registry (ABMTR) began collecting outcome data on autotransplants from centers in North and South America. More than 200 autotransplant centers now participate. The ABMTR database has information for about 60% of autotransplants carried out in North and South America since 1989.

Using these data, the Statistical Center periodically prepares and distributes graphics summarizing current use and outcome of allogeneic and autologous hematopoietic stem cell transplants (SCT). This year's Summary Slides are described on pages 4–11.

continued on page 4

see page 3 for **IBMTR/ABMTR data management update**

see page 4 for **Summary Slides 2002**

International Bone Marrow Transplant Registry / Autologous Blood & Marrow Transplant Registry
IBMTR/ABMTR newsletter
Volume 9 Issue 1 February 2002

M. Horowitz – continued from page 1

In addition to this report, the IBMTR/ABMTR continues its efforts to improve the outcome of HSCT recipients through careful collection and analysis of clinical data. Observational databases such as the one maintained by the IBMTR/ABMTR may facilitate understanding of transplant outcomes by addressing questions difficult to address in randomized trials or single center series. These include descriptions of transplant results in various disease states and patient groups, analysis of prognostic factors, evaluation of new regimens, comparison of transplant with non-transplant therapy, studying late effects, developing analytic approaches to evaluating transplant outcome and evaluation of quality of life. An observational database can also be an asset in designing clinical trials by providing more precise and unbiased estimates of baseline outcome rates, ascertaining availability of patients under varying eligibility criteria and allowing simulation of various statistical designs.

Clinical investigators are increasingly seeking help from the Statistical Center in clinical trial design. Registry data are now also being used to explore the impact of specific center characteristics on clinical outcome (see Dr Loberiza's article below). As always, we welcome proposals for novel uses of the database and encourage participants to contact us with questions that might be effectively addressed by IBMTR/ABMTR data.

IBMTR/ABMTR initiates center effects study

With the aid of funding from the Agency for Healthcare Research and Quality and the Medical College of Wisconsin, the IBMTR/ABMTR has begun to collect data on the characteristics of allogeneic and autologous transplant centers in the United States. These data will be used to examine whether variances in center-related factors such as transplant center volume and experience, transplant unit bed capacity and geographic location affect transplant outcomes. This study is being coordinated by Fausto R. Loberiza, Jr., MD, MS, Assistant Scientific Director of the IBMTR/ABMTR and Assistant Professor of Health Policy Research at the Medical College of Wisconsin.

Recent efforts in this area by our European colleagues suggest that outcomes are better in larger centers (Frassoni *et al., Lancet* 2000; 355), as did a previous IBMTR study (Horowitz *et al., Blood* 1992; 79). However, those studies did not consider many other potentially important institutional characteristics, e.g. nurse–physician ratio, medical center organization, physician training and many patient and disease factors that may vary significantly among centers. We think it is important to reexamine this issue in an independent population, taking into consideration these and other factors in addition to center size. Additionally, as all centers face pressures to decrease costs and increase efficiency, it would be interesting to have data on which institutional resources are most closely associated with clinical outcome.

The study will examine the effect of center transplant volume and other factors on patient outcomes, specifically 100-day and one-year treatment-related mortality and overall survival after allogeneic and autologous transplantation for malignant hematologic disorders after adjusting for identified patient-, disease-, and treatment-related prognostic factors. The study aims to determine whether transplant procedure volume is a surrogate for other factors that actually determine the quality of care among transplant recipients. Increasing transplant volume may be difficult in some geographic areas where a small center may offer an important service to its constituents, but other characteristics of large centers that correlate with better outcomes may be adoptable by small centers.

Center data has been requested from selected transplant centers in the USA. Centers are encouraged to participate in this annual survey; collaboration will hopefully provide helpful information for improving patient treatment and outcomes.

IBMTR/ABMTR data management update

This column is dedicated to keeping those who complete IBMTR/ABMTR data collection forms up-to-date on registration and reporting procedures, including how to report new transplant techniques. These are common queries received at the Statistical Center. For more information, complete registration instructions can be found on the IBMTR/ABMTR web site at http://www.ibmtr.org/datacollec/RegInst.PDF.

Q: What is non-myeloablative conditioning?

A: Non-myeloablative conditioning regimens are less intensive regimens, also known by the terms NST (non-ablative stem cell transplants), reduced intensity, or "mini" transplants. Please consult with your Team Leader if you are unsure whether the patient received a non-myeloablative conditioning regimen. Non-myeloablative conditioning is only used in allogeneic transplantation.

Q: What if a patient's ethnicity is not known?

A: No tick box for "unknown" was provided on the form, as in most instances this ethnic information should be available. If it is truly "unknown" by your team, report as "other" and specify "unknown", or if only known as "other", but not otherwise specified, report as "other-NOS."

Q: How are patients selected for submission of a comprehensive Report Form?

A: Using Registration data, patients are randomly selected for comprehensive Report Form completion, although new therapies and rare diseases may also trigger "Form Due = Yes." It is possible that a Report Form may be due on a patient for whom a Disease Specific Insert does not yet exist (check www.ibmtr.org for the latest insert releases and versions.) In those instances, complete the 2002-Day 100 CORE Form and Graft Insert. When the Disease Insert is developed, you will receive a request to complete one at that time.

Q: How do I assign IUBMID numbers?

A: The present system allows for six digits. If your unique numbering system includes more than six digits, please contact the Registry before submitting any patient data: snell@mcw.edu or janer@mcw.edu

Q: What should I do if a patient is pre-registered prior to the start of conditioning, but never receives a transplant?

A: Please DO NOT re-number the patients, even when the patient does not receive the first dose of conditioning. "No conditioning received" can be recorded to document that no further follow-up is required. We've developed a fax form, CancelTX, in which you convey whether the first dose of conditioning was received, if the transplant is postponed or cancelled and whether the patient is alive. Please request "CancelTX" from Jane Rebro (janer@mcw.edu). An M-TED form *is still due* per the usual schedule if the patient **received the first dose of conditioning** but expired before receiving the transplant.

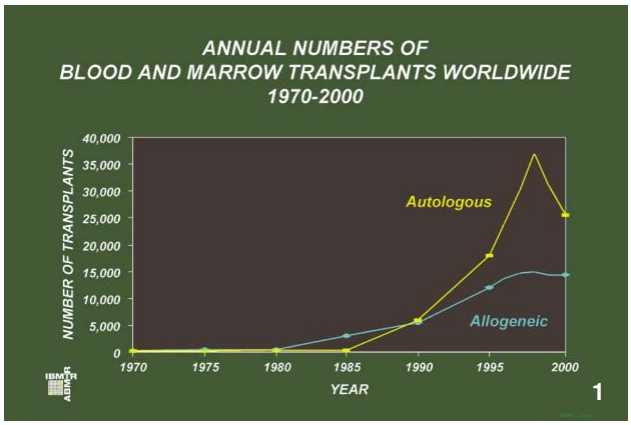
Q: When must a separate Pre-Reg or TED form be completed, i.e., what constitutes a separate transplant?

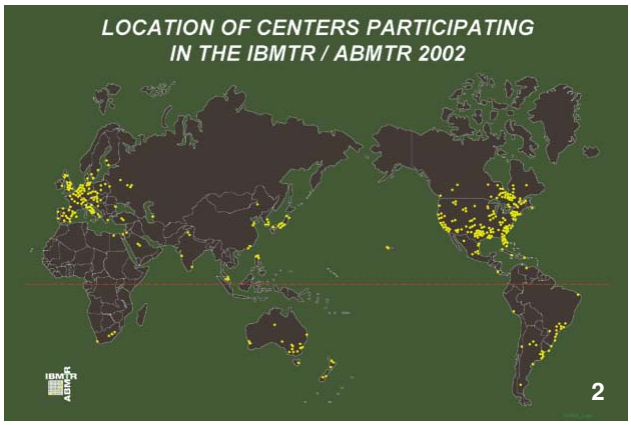
A: The definitions of a reportable transplant or infusion are given on 2002 Day 100 CORE pages 16 & 34 (available on www.ibmtr.org). These same definitions can be applied to the Pre-Reg/TED process (see also Day 100 CORE page 39: vii–xi). A new Pre-Reg/TED form would be completed under the same circumstances as a subsequent Report Form. Do not attempt to report two reportable TX/infusions on one form; this will only delay the reporting process for all. Record subsequent–**blood or marrow infusion** on Day 100 CORE page 34 when the infusions are more than fourteen days from the first infusion. If less than fourteen days apart, this is considered "multiple infusions" for the same transplant. **Peripheral blood leukocyte or T-lymphocyte infusions (DLI) from the original donor** recorded on Day 100 CORE page 16 are considered "multiple infusions" for the same transplant if received less than twenty-eight days from the first infusion. **Additional cell therapy** refers to cells given to provoke an immune response (Day 100 CORE page 16: Q242 prophylaxis options), somewhat analogous to a vaccine program in that these are planned to occur, not based upon the occurrence of a posttransplant event such as graft failure, disease recurrence or viral infection. Lymphocytes, dendritic or mesenchymal cells are possible options for cellular therapy. When in doubt please contact the Registry. The soon-to-be-completed Donor Cellular Infusion Form (2002 Day 100 DCI Report Form) will contain an algorithm to aid in determining exactly how various infusion regimens should be reported.

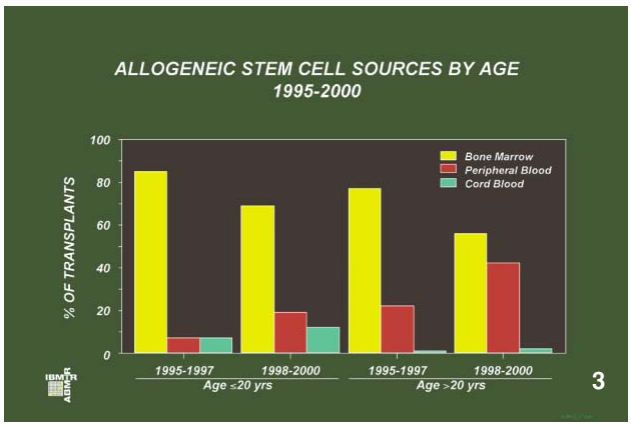
International Bone Marrow Transplant Registry / Autologous Blood & Marrow Transplant Registry
IBMTR/ABMTR newsletter
Volume 9 Issue 1 February 2002

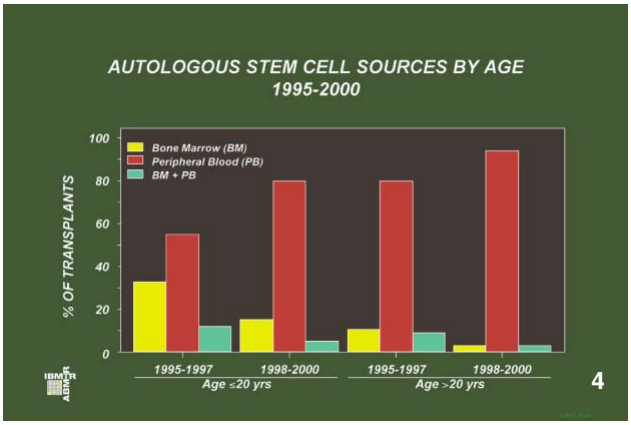
Summary slides 2002

Report on state of the art in blood and marrow transplantation – the IBMTR/ABMTR Summary slides with guide, continued from page 1







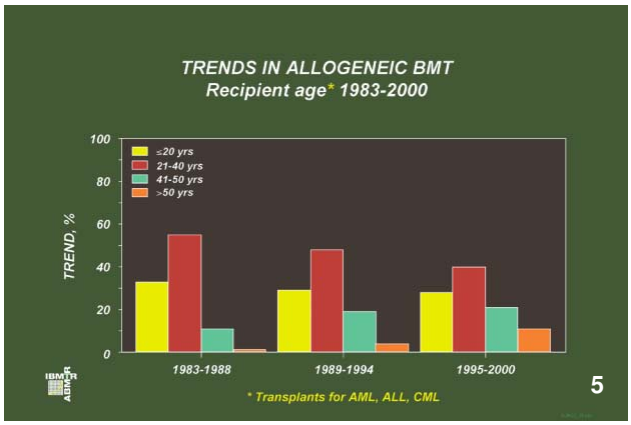


Slide 1: The rate of growth for autologous and allogeneic transplants appears to be slowing. In 1998–2000 there was a leveling off for allogeneic transplants and a steady decline in autologous transplants. Lack of growth in transplants may represent limited availability of suitable donors (related or unrelated), limited success to date with HLA-disparate donors, and increasing availability of competing therapies such as STI-571. The decline in autotransplants relates to the dramatic reduction in the use of this procedure for breast cancer. We estimate that 15,000 allogeneic and over 25,000 autologous transplants were carried out in 2000.

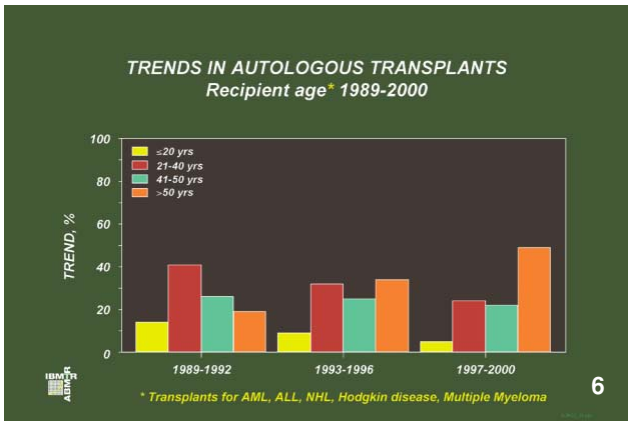
Slide 2: Currently, 492 centers participate in the IBMTR/ABMTR. The number of participating centers continues to increase.

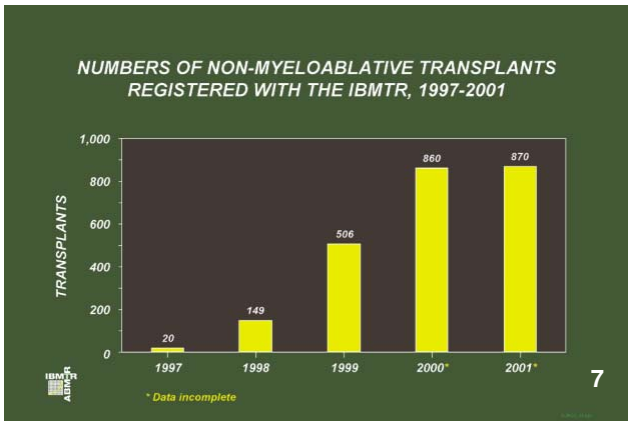
Slide 3: Most allogeneic transplants use bone marrow grafts. However, in 1998–2000 there was a steady increase in use of peripheral blood stem cells, especially in older recipients. There was also an increase in use of umbilical cord blood stem cells in recipients aged ≤ 20 years, but very few cord blood transplants in older recipients.

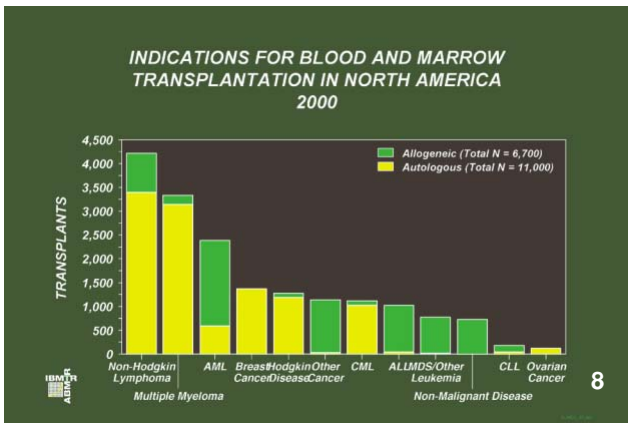
Slide 4: Over 95% of autotransplants in adults and 80% in children and adolescents use hematopoietic progenitor cells collected from blood. The remainder use bone marrow alone or in combination with cells collected from blood.

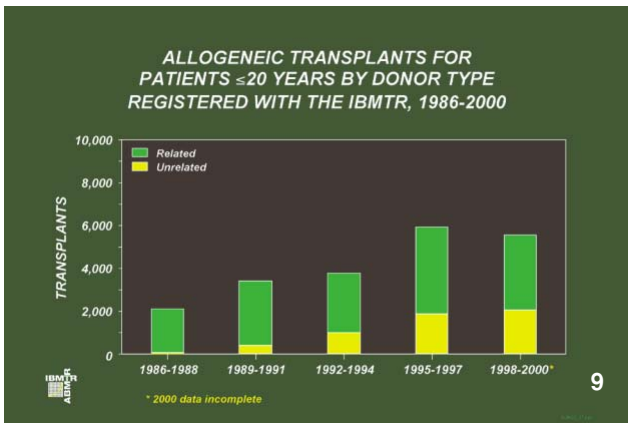


Slides 5 & 6: For both allo- and autotransplants, the proportion of recipients aged > 40 years continues to increase. This may reflect advances in supportive care with a resultant decrease in transplant-related toxicity (TRM) and the increased application of transplantation to diseases affecting older patients (e.g. multiple myeloma [MM]). Patients aged > 50 years now account for more than 10% of allograft recipients and 50% of autograft recipients.







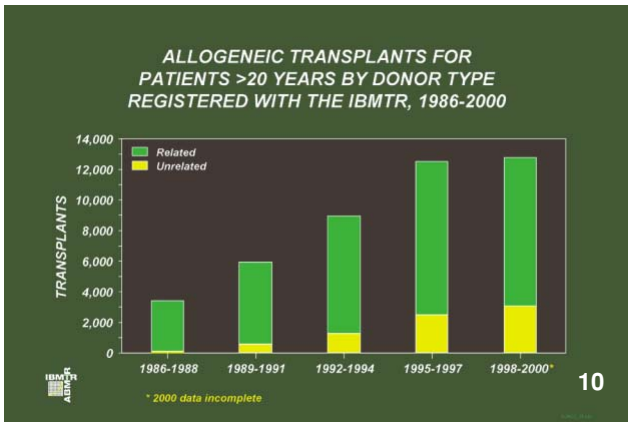


Slide 7: There was a steady increase in the number of non-myeloablative transplants being carried out between 1997 and 2001. These less intensive conditioning regimens are now used in about 25% of allotransplants.

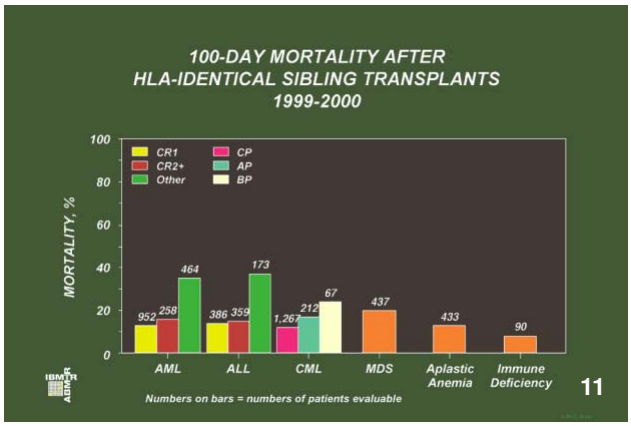
Slide 8: This slide illustrates indications for hematopoietic stem cell transplants in North America. The most common indications for allo- and autotransplants differ. The most common indications for allotransplants are acute and chronic leukemias, myelodysplasia (MDS), and non-malignant diseases (aplastic anemia, immune deficiencies, inherited metabolic disorders). Autotransplants are generally used for non-Hodgkin's lymphoma (NHL), MM, Hodgkin's lymphoma, and solid tumors. In 2000, NHL and MM were the most common indications for transplant in North America, accounting for over one third of all transplants.

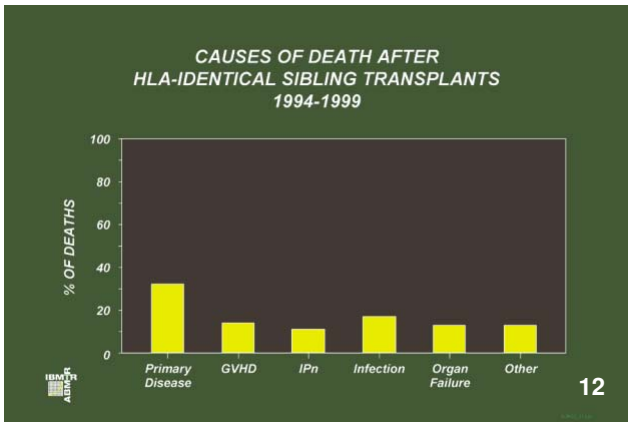
Slides 9 & 10: Most allotransplants are from HLA-identical sibling donors. However, only about 30% of transplant candidates have such a donor. Increasing availability of HLA-typed volunteer donors through large national and international registries has enabled increasing use of unrelated donors for transplantation. Transplants from unrelated donors now account for approximately 25% of allogeneic transplants.

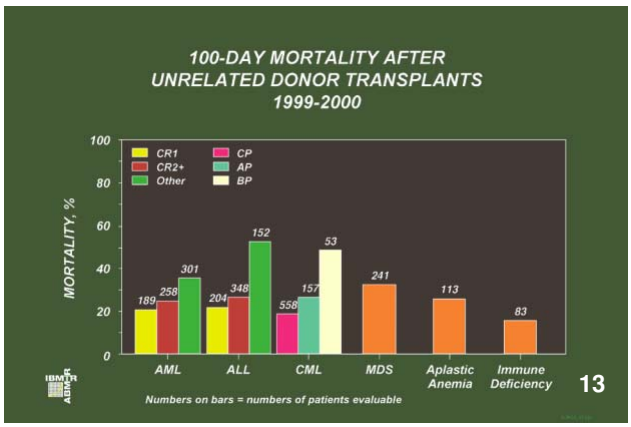
Slides 11 & 12: 100-day mortality rates are often used as a gauge of TRM. Allotransplants are associated with relatively high risks of graft-versus-host disease (GVHD), infections and liver

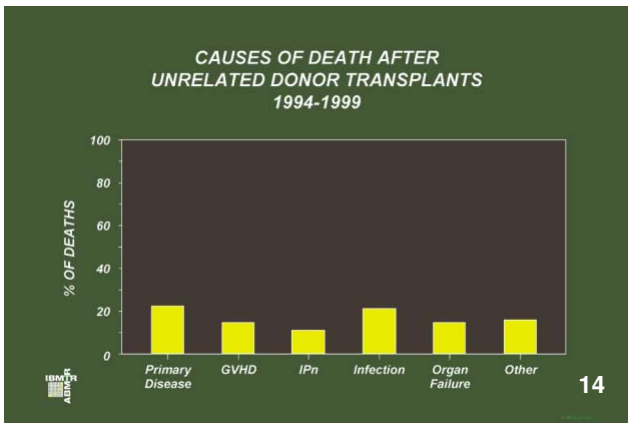


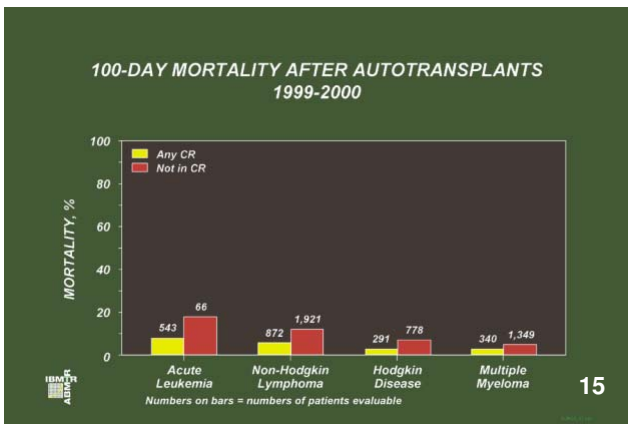
toxicity, resulting in high early mortality. Among HLA-identical sibling transplants carried out 1999–2000 and reported to the IBMTR, 100-day mortality rates ranged from about 10% for patients with acute leukemia in first remission to almost 40% for those with advanced leukemia. The 100-day mortality rates after transplants for aplastic anemia and immune diseases ranged between 10% and 15%. Recurrence or progression of the primary disease is responsible for over 30% of all deaths following HLA-identical sibling transplants, with GVHD and infection each responsible for approximately 20% of deaths.

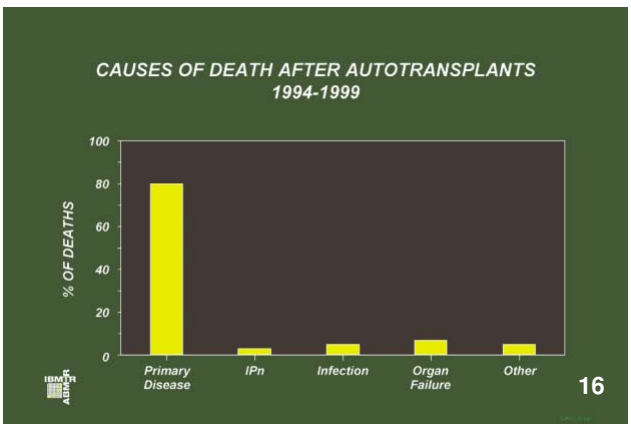






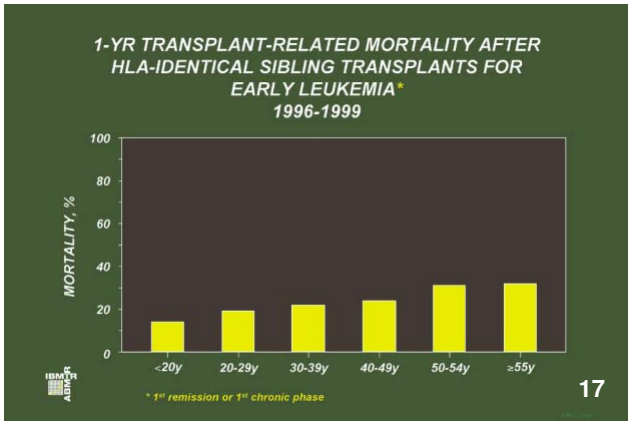


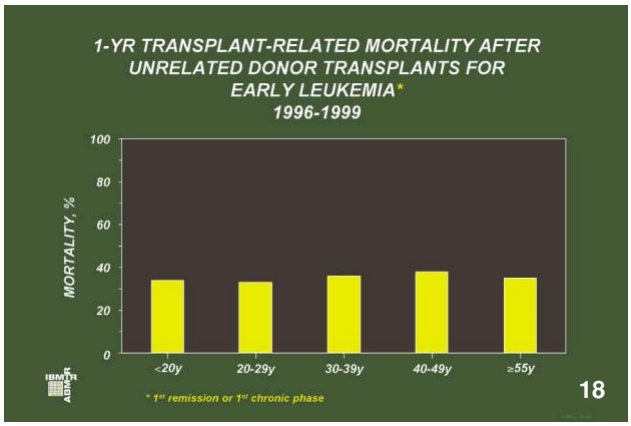


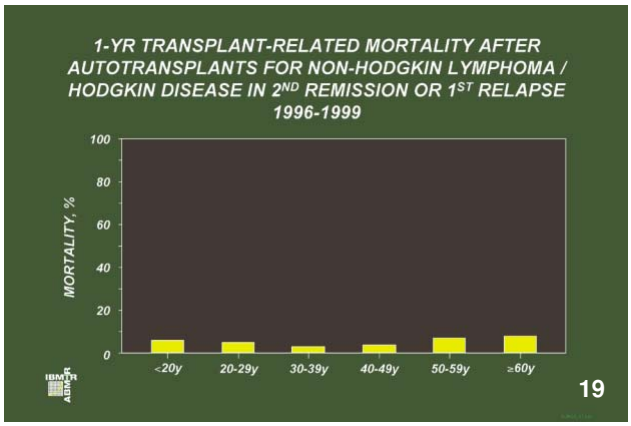


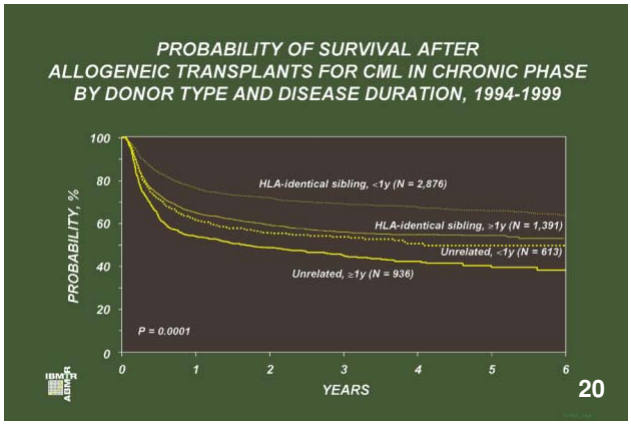
Slides 13 & 14: TRM is higher for recipients of unrelated donor transplants. The 100-day mortality ranged from about 20% for patients with acute leukemia in first remission to over 50% for those with advanced acute lymphocytic leukemia (ALL) and chronic myeloid leukemia (CML). The 100-day mortality rates after transplants for MDS, aplastic anemia and immune diseases ranged between 15% and 30%. Recurrence or progression of the primary disease and infections were the most common causes of mortality in this group.

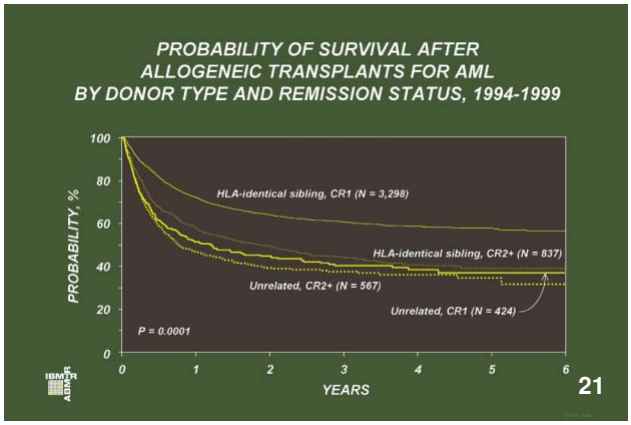
Slides 15 & 16: Early mortality is generally lower following autotransplants than for allotransplants. Among patients receiving autotransplants in 1999–2000, those transplanted for NHL or











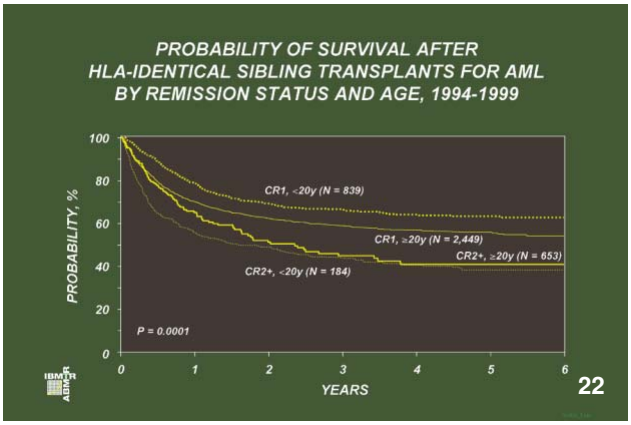
Hodgkin's lymphoma, MM or acute leukemia in remission had 100-day mortality of < 10%, while patients treated in relapse had higher early mortality. Recurrent disease continues to account for the overwhelming majority of deaths in autotransplant recipients.

Slide 17: The effect of age on TRM after HLA-matched sibling transplants is depicted in this slide. Increasing age is associated with increased 1-year TRM after allografts. TRM remains a significant problem, being higher than 30% for patients over 50 years of age.

Slide 18: TRM after unrelated transplants remains a significant problem at 35–40% even for young patients with good risk leukemia.

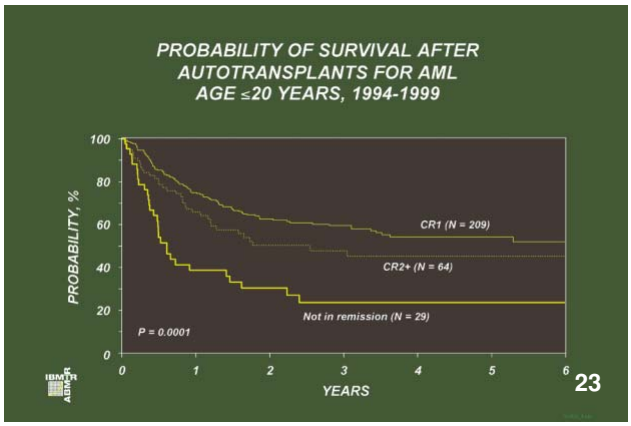
Slide 19: Less-intensive preparative regimens and absence of GVHD result in significantly less 1-year TRM after autotransplants. For good-risk Hodgkin's lymphoma and NHL patients TRM increases in patients aged ≥ 50 years.

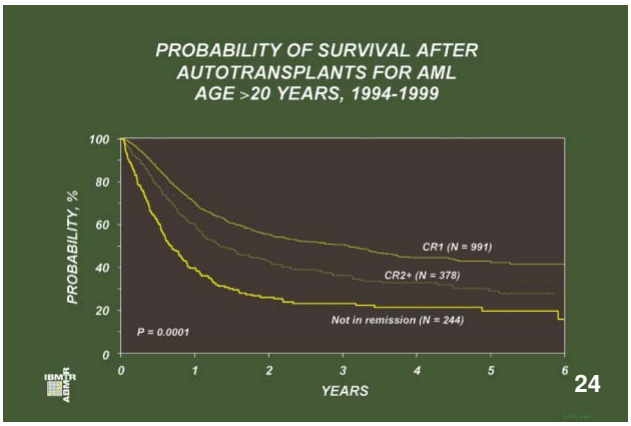
Slide 20: Allotransplants are an effective treatment for CML. Among 5,816 recipients of HLA-identical sibling transplants carried out for CML in chronic phase between 1994 and 1999, reported to the IBMTR, 3-year probabilities of survival were 69 ± 2% for 2,876 transplants carried out within 1 year of diagnosis and 57 ± 3% for 1,391 patients transplanted > 1 year after diagnosis. Unrelated donor transplants can cure CML but are associated with higher risks of GVHD and TRM. Additionally, unrelated donor transplants are often delayed because of the time required to identify a donor and reluctance to risk the higher TRM. Delaying transplantation may adversely affect outcome. For patients receiving unrelated transplants for CML in chronic phase, the 3-year probability of survival was 54 ± 5% for 613 patients

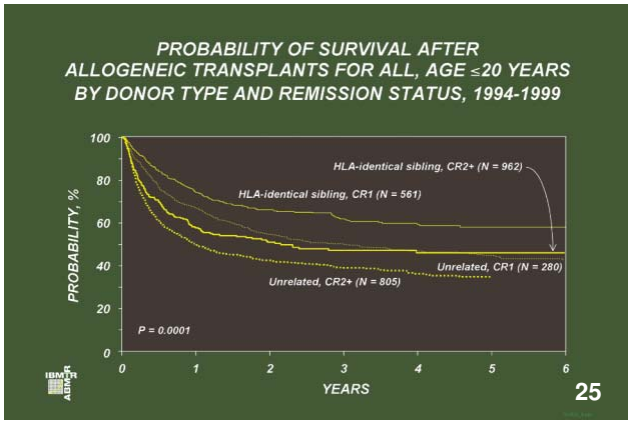


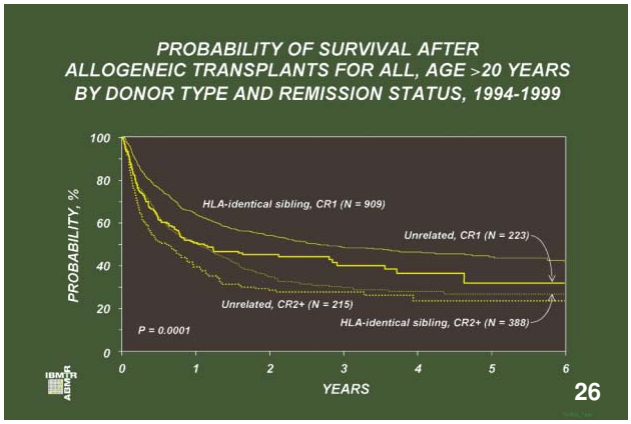
transplanted within the first year of diagnosis, and 46 ± 3% for 936 patients transplanted beyond the first year from diagnosis of CML.

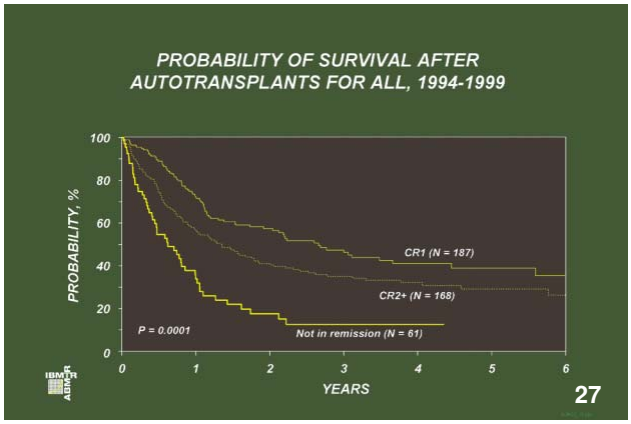
Slides 21 & 22: Among 5,126 recipients of allogeneic transplants for acute myeloid leukemia (AML) carried out between 1994 and 1999, reported to the IBMTR, 3-year probabilities of survival for recipients of HLA-identical sibling transplants were 60 ± 2% for 3,298 patients in first remission, and 44 ± 4% for 837 patients in second or subsequent remission. Survival was generally worse in 991 patients receiving transplants from unrelated donors. The 3-year probabilities of overall survival for recipients of unrelated donor transplants in first or second vs subsequent remission were 40 ± 5% and 37 ± 5%, respectively. There is an additional effect of age on survival following HLA matched sibling transplants independent of remission status. Younger patients (< 20 years of age) have superior survival to older patients.







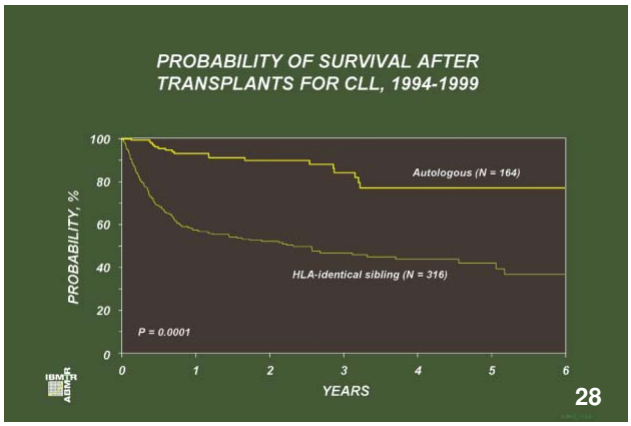


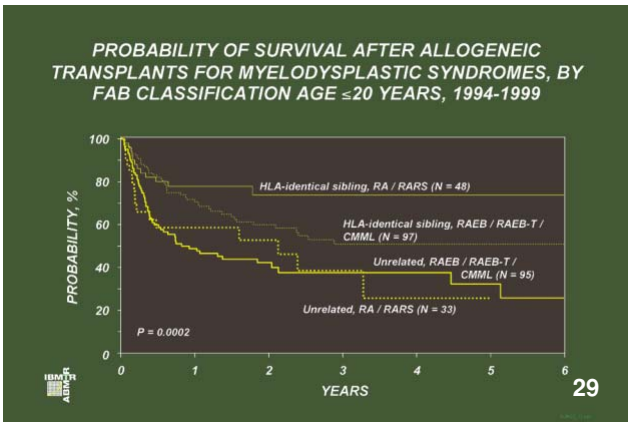


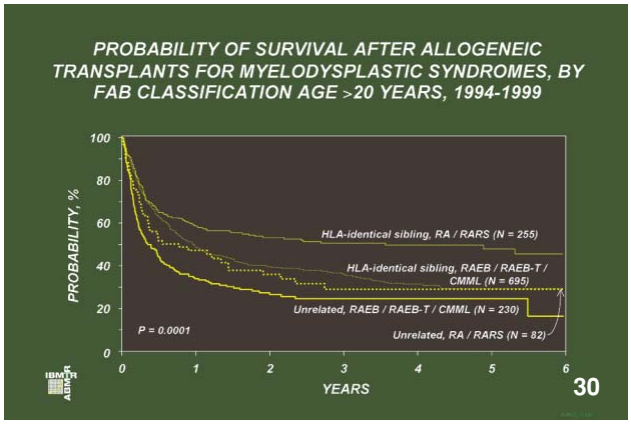
Slides 23 and 24: Among patients receiving autotransplants for AML between 1994 and 1999, reported to the ABMTR, the 3-year probability of survival was 59 ± 8% for 209 patients (≤ 20 years of age) and 50 ± 4% for 991 patients (> 20 years of age) transplanted in first remission; corresponding probabilities were 46 ± 13% for 64 patients ≤ 20 years of age and 38 ± 6% for 378 patients > 20 years of age in second remission. Patients transplanted in relapse or persistent disease did poorly, with 3-year probabilities of survival of 23 ± 18% for 29 patients ≤ 20 years of age and 24 ± 7% for 244 patients > 20 years of age.

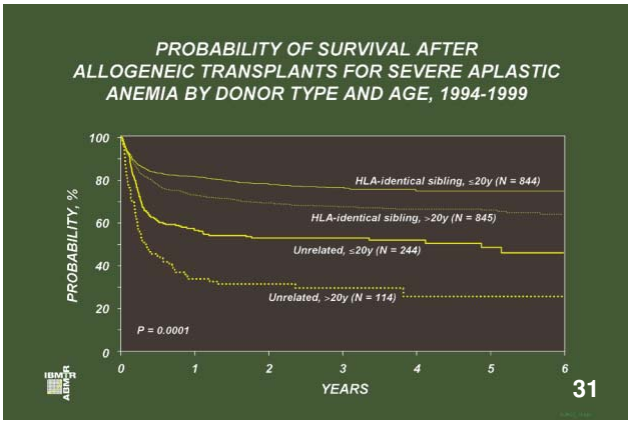
Slides 25 and 26: Most patients with ALL are cured with conventional chemotherapy. Consequently, bone marrow transplants are reserved for patients failing conventional therapy, i.e. in relapse or second or subsequent remission, or, patients in first remission with prognostic factors predicting a high risk of failure with conventional therapy. The most frequent indications for transplantation in first remission are older age, high leukocyte count at diagnosis, Philadelphia and other chromosome abnormalities and difficulty obtaining a first remission. Among 2,820 recipients of HLA-identical sibling transplants between 1994 and 1999, reported to the IBMTR, 3-year probabilities of survival were 61 ± 4% for 561 recipients ≤ 20 years of age and 48 ± 4% for 909 recipients > 20 years of age in first remission, and 47 ± 6% for 962 recipients ≤ 20 years of age and 30 ± 5% for 388 recipients > 20 years of age transplanted in second or subsequent remission. Although associated with higher TRM, unrelated donor transplants may be considered for patients with ALL unlikely to be cured by chemotherapy alone. Among 280 patients ≤ 20 years of age and 223 patients > 20 years of age who received unrelated donor transplants for ALL in first remission reported to the IBMTR, 3-year probabilities of survival were 50 ± 3% and 40 ± 8% respectively; among 805 recipients ≤ 20 years of age and 215 recipients > 20 years of age who received their transplant in second or subsequent remission, 3-year probabilities of survival were 39 ± 4% and 28 ± 7%, respectively.

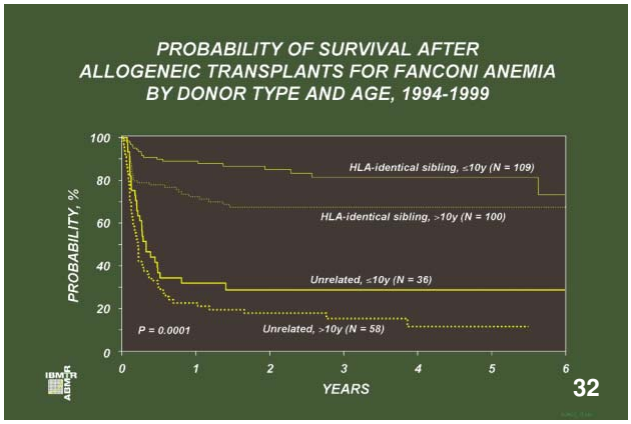
Slide 27: Among 416 recipients of autotransplants for ALL between 1994 and 1999, reported to the ABMTR, 3-year probabilities of survival were 44 ± 9% for 187 transplants carried out in first remission, 36 ± 9% for 168 transplants carried out in second or subsequent remission, and 12 ± 9% for 61 transplants carried out in relapse.









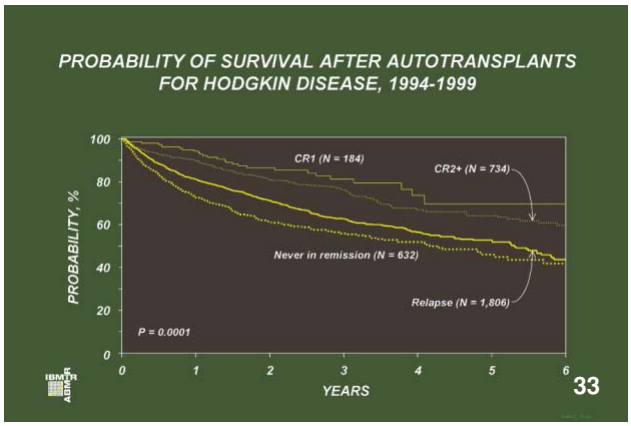


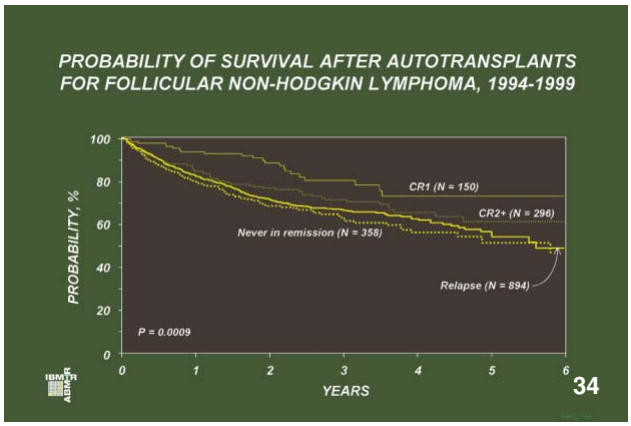
Slide 28: Interest in both allogeneic and autologous transplantation for chronic lymphocytic leukemia (CLL) is increasing. To date these transplants have primarily been carried out for poor prognosis patients failing other therapies. In 316 recipients of HLA-identical sibling transplants for CLL between 1994 and 1999, the 3-year probability of survival was 47 ± 7%. The experience with autologous transplantation for CLL is more limited. Among 164 recipients of autotransplants for CLL and reported to the ABMTR, the 3-year probability of survival was 84 ± 9%.

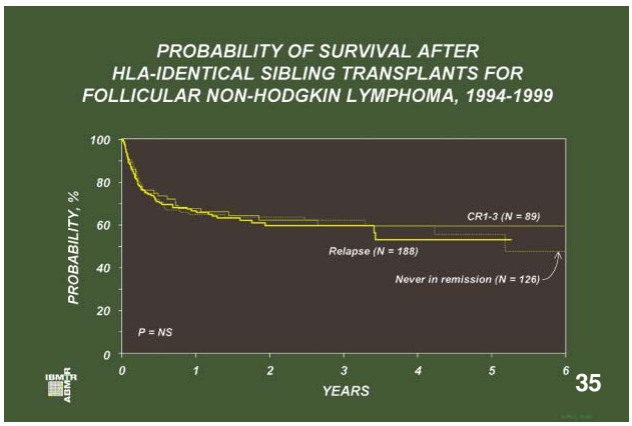
Slides 29 & 30: Allogeneic bone marrow transplantation can cure some patients with myelodysplastic syndromes. Among 1,095 recipients of HLA-identical sibling transplants between 1994 and 1999, reported to the IBMTR, 3-year probabilities of survival were 73 ± 15% for 48 recipients ≤ 20 years of age and 49 ± 7% for 255 recipients > 20 years of age with refractory anemia (RA) or refractory anemia with ringed sideroblasts (RARS). Among 97 recipients ≤ 20 years of age and 695 recipients > 20 years of age with refractory anemia with excess blasts (RAEB), refractory anemia with excess blasts in transformation (RAEB-T), or chronic myelomonocytic leukemia (CMML), the 3-year probabilities of survival were 52 ± 12% and 37 ± 4%, respectively. Among 440 recipients of unrelated donor transplants reported to the IBMTR, the 3-year probabilities of survival were 37 ± 11% for 33 recipients ≤ 20 years of age and 25 ± 7% for 82 recipients > 20 years of age with RA/RARS. Among 95 recipients ≤ 20 years of age and 230 recipients > 20 years of age with RAEB/RAEB-T/CMML the 3-year probabilities of survival were 38 ± 22% and 25 ± 7%, respectively.

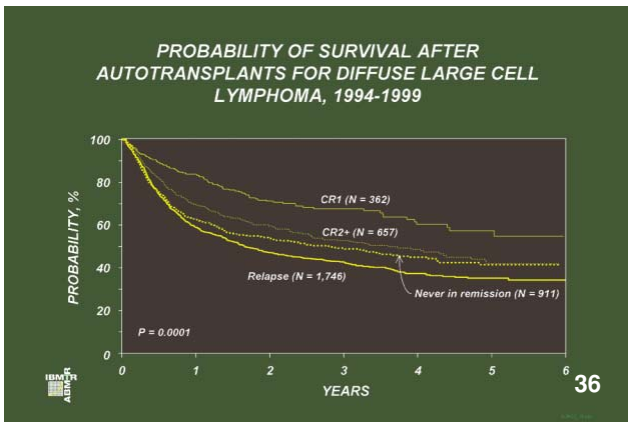
Slide 31: Allogeneic transplantation is the treatment of choice for young patients with aplastic anemia who have an HLA-identical sibling. Three-year probabilities of survival after 1,689 HLA-identical sibling transplants between 1994 and 1999, and reported to the IBMTR, were 76 ± 3% for 844 patients ≤ 20 years of age and 67 ± 3% for 845 older patients. Results were not as good in 358 recipients of unrelated donor transplants: 53 ± 6% in 244 patients ≤ 20 years of age and 32 ± 10% in 114 older patients.

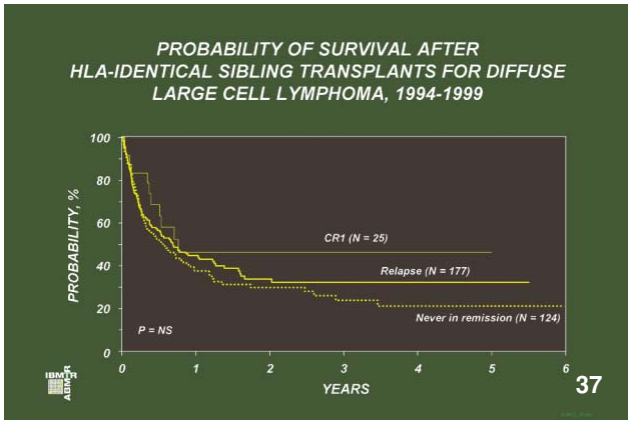
Slide 32: Allotransplants cure some patients with Fanconi anemia. Among 209 patients transplanted between 1994 and 1999 from matched siblings, the 3-year survival was 81 ± 9% in 109 patients aged < 10 years of age and 69 ± 10% in 100 older patients. Transplants from alternative donors have been less successful. Among 94 recipients of unrelated donor transplants, the 3-year probabilities of survival were 30 ± 16% in 36 patients aged < 10 years of age and 16 ± 10% in 58 older patients.

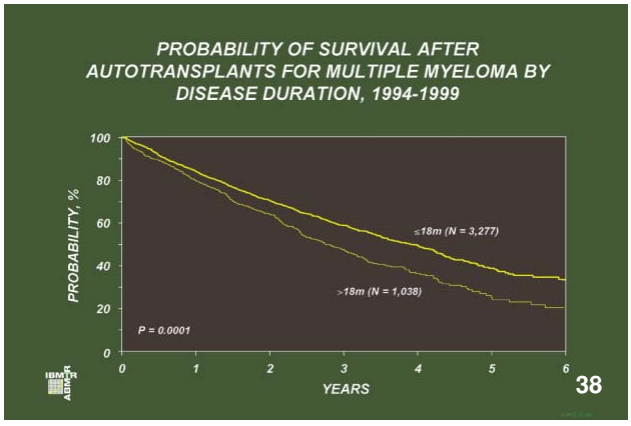








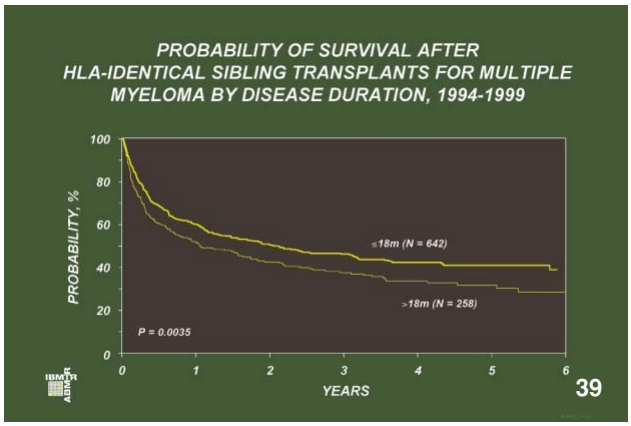


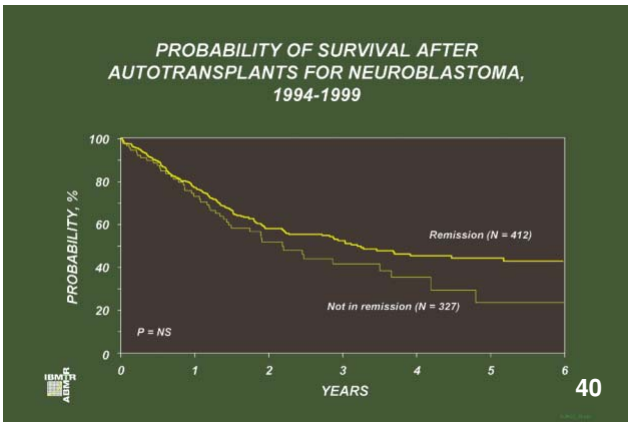


Slide 33: Most patients with Hodgkin's disease are cured with conventional chemotherapy. However, for the 20–30% failing conventional therapy, autotransplants are effective salvage therapy. Among 3,356 autotransplants between 1994 and 1999, reported to the ABMTR, 3-year probabilities of survival were 81 ± 8% for 184 transplants in first remission, 76 ± 4% for 734 transplants in second or subsequent remission, 63 ± 3% for 1,806 transplants in relapse, and 55 ± 5% for 632 patients with persistent disease.

Slides 34 & 35: NHL is the most common indication for hematopoietic stem cell transplantation. Most of these transplants use autologous cells. Among 1,698 patients receiving autotransplants for follicular lymphoma between 1994 and 1999, 3-year probabilities of survival were 81 ± 8% for 150 patients in first remission, 71 ± 6% for 296 in second remission, 66 ± 4% for 894 in relapse, and 63 ± 6% for 358 never achieving remission with standard chemotherapy. Relapse is less frequent but TRM is higher with HLA-identical sibling transplants. Among 403 patients with follicular lymphoma the 3-year probability of survival was approximately 60% regardless of remission status pre-transplant.

Slides 36 & 37: Among 3,676 patients receiving autotransplants for diffuse large cell lymphoma, 3-year probabilities of survival were 68 ± 6% for 362 patients in first remission, 53 ± 5% for 657 in second remission, 42 ± 3% for 1,746 in relapse and 49 ± 4% for 911 patients never achieving remission with conventional chemotherapy. Most failures after autotransplants for NHL are due to relapse. Higher TRM offsets the lower relapse rate seen with HLA-identical sibling transplants for these lymphomas. The





3-year survival rates among 326 patients transplanted between 1994 and 1999 from HLA-identical siblings for diffuse large cell lymphoma were 46 ± 23% in 25 patients in first remission, 32 ± 9% for 177 patients in relapse and 24 ± 9% for 124 patients with persistent disease.

Slides 38 & 39: Hematopoietic stem cell transplantation is now considered standard therapy for MM, a disease incurable with conventional therapy. Survival rates are better for patients transplanted early, compared to those transplanted more than 18 months from diagnosis. For 3,277 recipients of autotransplants who were transplanted < 18 months from diagnosis, the 3-year probabaility of survival was 59 ± 2%, compared to 48 ± 4% in 1,038 recipients who were transplanted > 18 months from diagnosis. The 3-year survival rate for recipients of HLA-identical sibling transplants was 47 ± 4% for 642 patients transplanted within 18 months from diagnosis compared to 38 ± 7% for 258 patients transplanted > 18 months from diagnosis. We do not have adequate long-term data to establish whether either strategy is truly curative for MM.

Slide 40: Neuroblastoma is the most common extracranial solid tumor of childhood. Approximately 60% of patients have high-risk tumors, incurable with conventional therapy alone. Autologous bone marrow transplantation may be effective therapy for these patients. Among 739 patients with neuroblastoma, transplanted between 1994 and 1999 and reported to the ABMTR, the 3-year probabilities of survival were 53 ± 7% in 412 patients in remission and 41 ± 8% in 327 patients with persistent disease.

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IBMTR ABMTR Statistical Center Personnel

Mary M. Horowitz, MD, MS
Scientific Director
John P. Klein, PhD
Statistical Director
Christopher N. Bredeson, MD, MSc, FRCPC
Assistant Scientific Director

Mary Eapen, MD, MS
Assistant Scientific Director, Pediatrics
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Research Scientist

J. Douglas Rizzo, MD
Assistant Scientific Director
Kathleen A. Sobocinski, MS
Associate Statistical Director
Mei-Jie Zhang, PhD
Associate Professor / Biostatistician

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Please address correspondence to:

IBMTR/ABMTR Statistical Center
Medical College of Wisconsin
8701 Watertown Plank Road
PO Box 26509
Milwaukee WI 53226, USA

Telephone: (414) 456-8325
Fax: (414) 456-6530
E-mail: ibmtr@mcw.edu

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Data Coordinator
Ruta Bajorunaite
Biostatistician
Kavita P. Bhavsar
Data Entry Assistant
Mita K. Desai
Data Entry Assistant
Sherry L. Fisher
Clinical Research Coordinator
Jane Gulla
Data Entry Assistant
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Data Entry Assistant
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