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Update on Transplant Outcomes Using Different Donor Sources

Steven Devine
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Disclosures

Full time employee of NMDP

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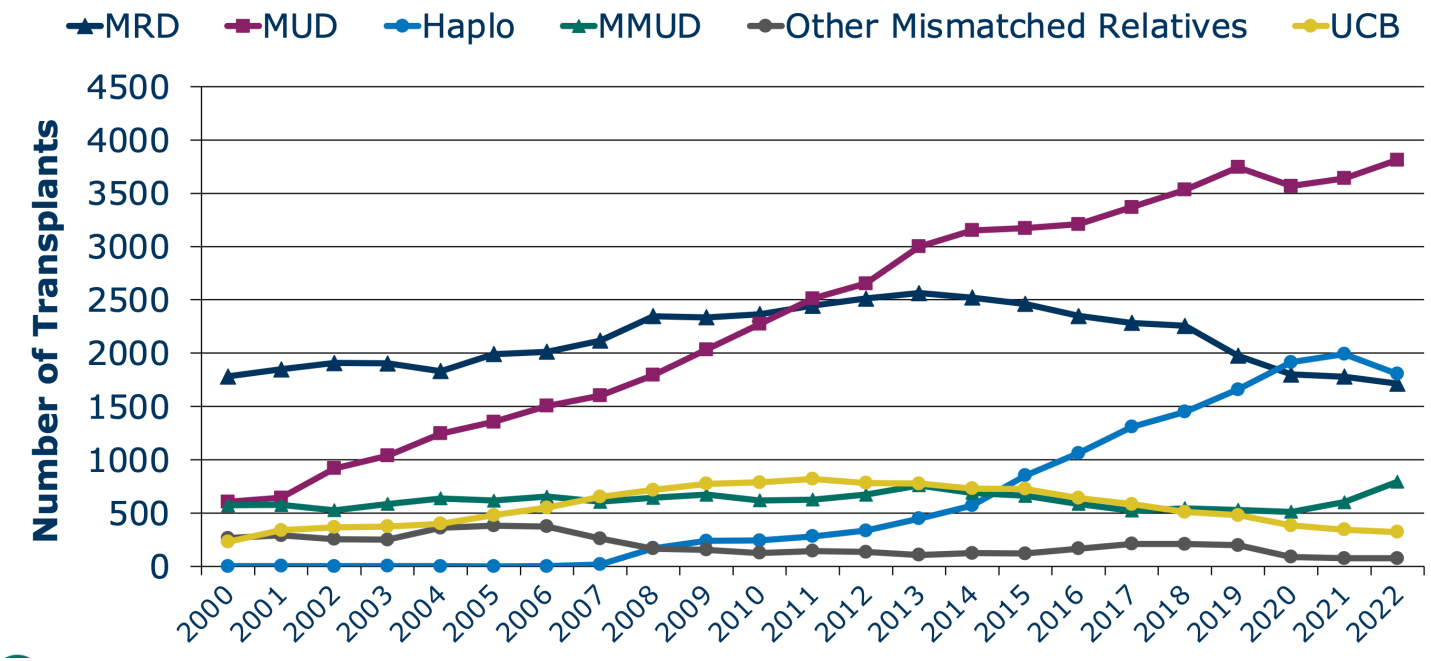
High Level Overview in the U.S.

- There has been a progressive decline in the use of matched related donors
- About 60% of donors are not related to the recipient
- More than a third of all donors are HLA-mismatched with the recipient
- More racially/ethnically diverse patients are being transplanted than ever before
- Much of the change has been driven by the advent of PTCy for GVHD prophylaxis
- Mobilized peripheral blood is by far the most common graft source, particularly in adults
- A suitable donor can now be identified for virtually all patients
- **Overall survival continues to improve**

Donor source: Over 20 years of data

Number of Allogeneic HCTs in the US by Donor Type



21st Century Trends in Donor Source

MRD: In decline since 2013 due to concerns about donor age and clonal hematopoiesis.

MUD: Rapid growth through 2013 curtailed by Haplo and Pandemic, but now experiencing regrowth

UCB: Growth continued through 2011, spurred by 2004 NEJM publications followed by decline, particularly in adults for a variety of reasons

Haplo: Rapid growth following initial publications of efficacy of PTCy and BMT CTN studies; growth curtailed recently by increase in MMUD use

MMUD: No growth or small decline for most of 21st century followed by rapid growth since 2020 due to PTCy and to lesser degree abatacept approval

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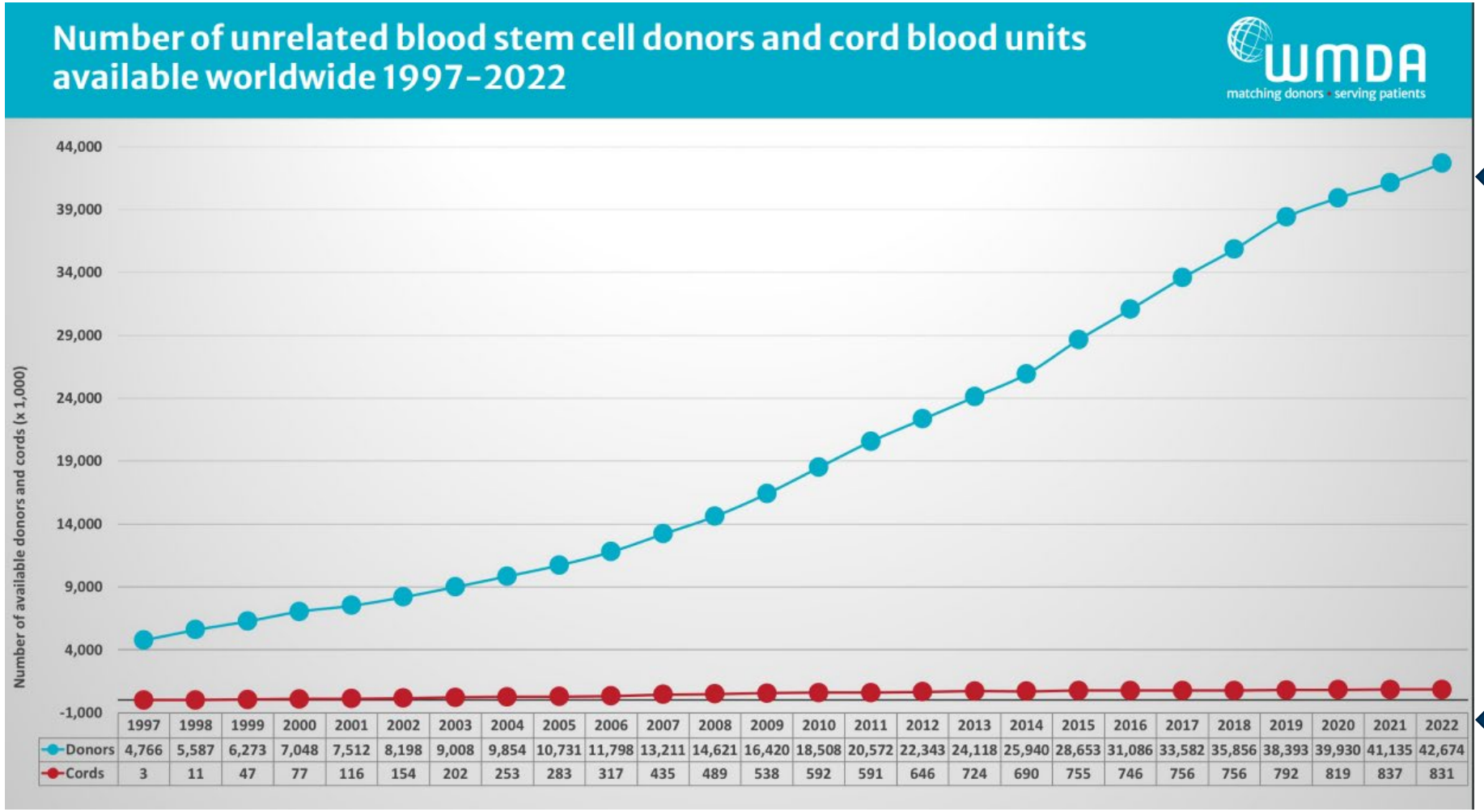
Source: CIBMTR Summary slides

Growth in worldwide unrelated donor and cord blood registries



	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Donors	4,766	5,587	6,273	7,048	7,512	8,198	9,008	9,854	10,731	11,798	13,211	14,621	16,420	18,508	20,572	22,343	24,118	25,940	28,653	31,086	33,582	35,856	38,393	39,930	41,135	42,674
Cords	3	11	47	77	116	154	202	253	283	317	435	489	538	592	591	646	724	690	755	746	756	756	792	819	837	831

>41 Million registered donors worldwide

>800K banked umbilical cord blood units worldwide

WMDA Global Trends Report-2022

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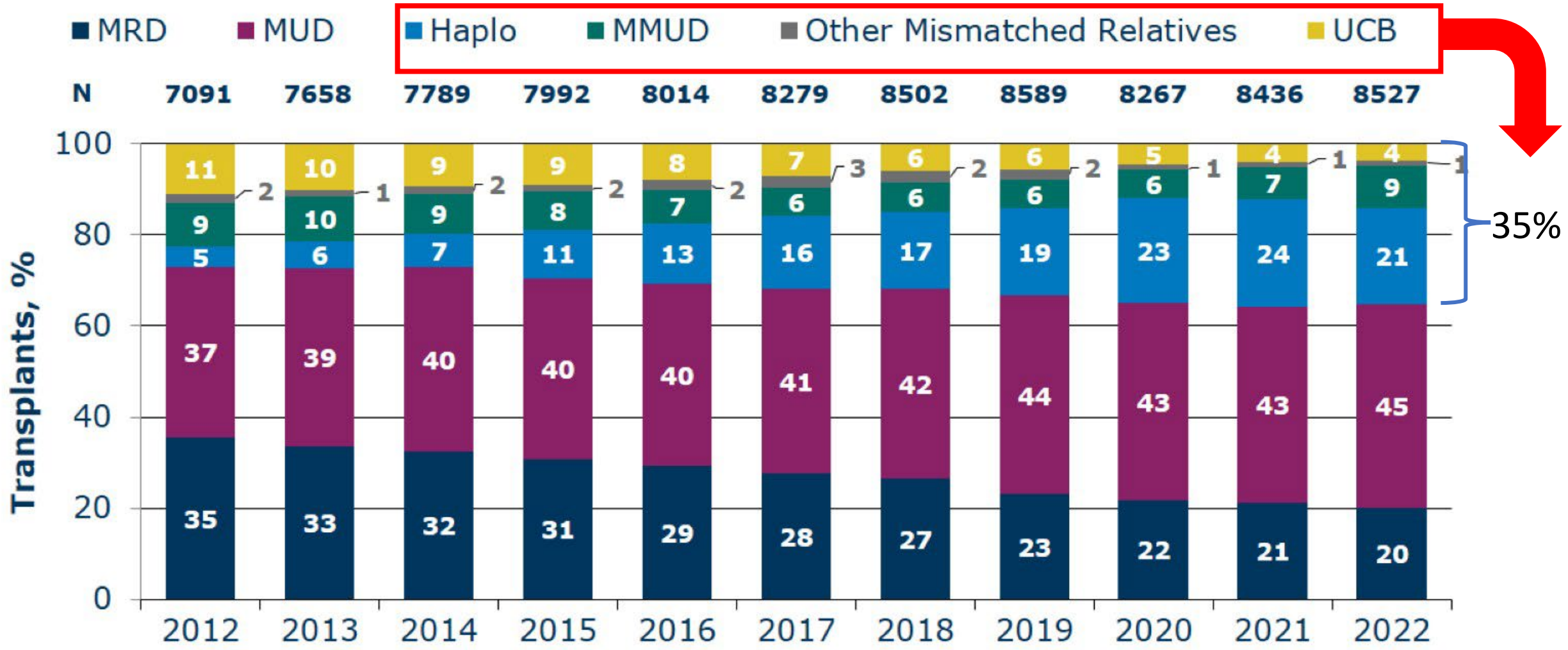
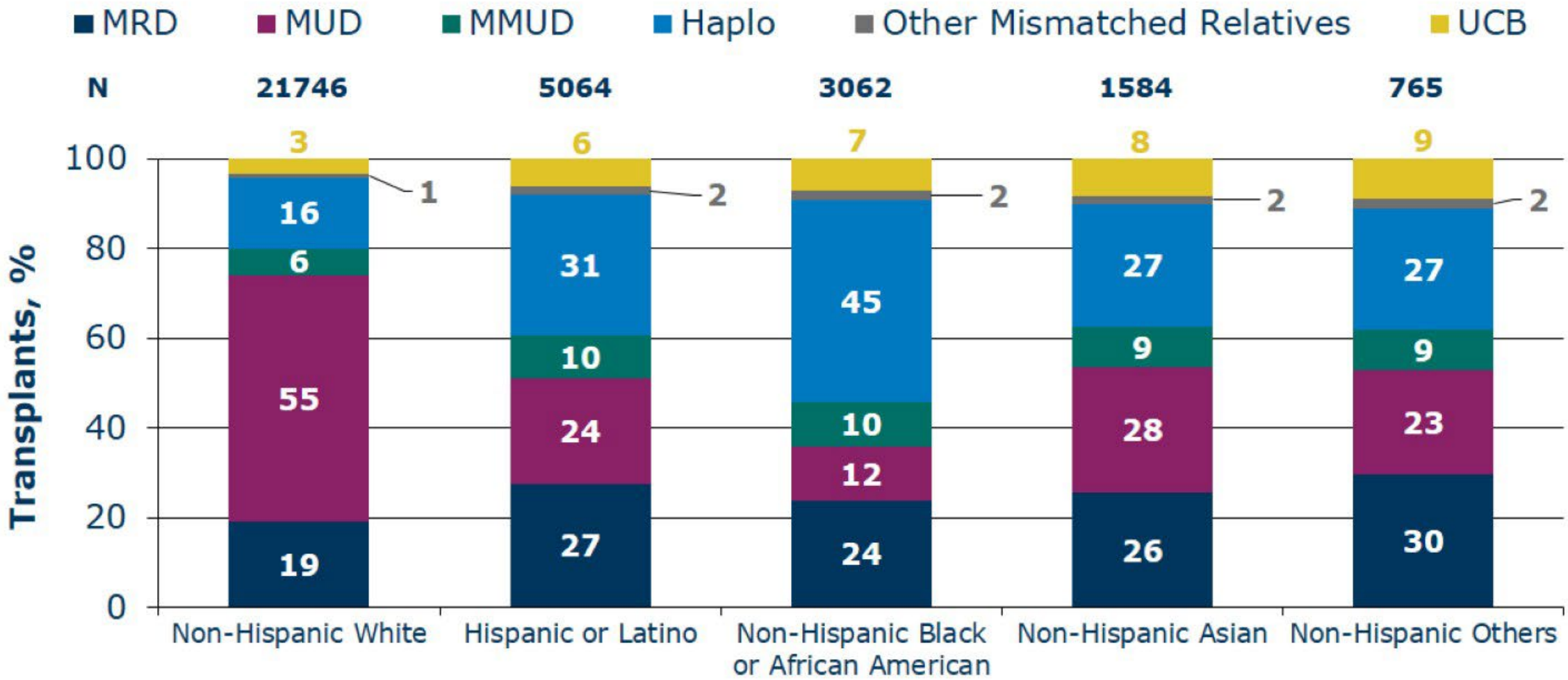
Relative Proportion of Allogeneic HCTs in the US by Donor Type



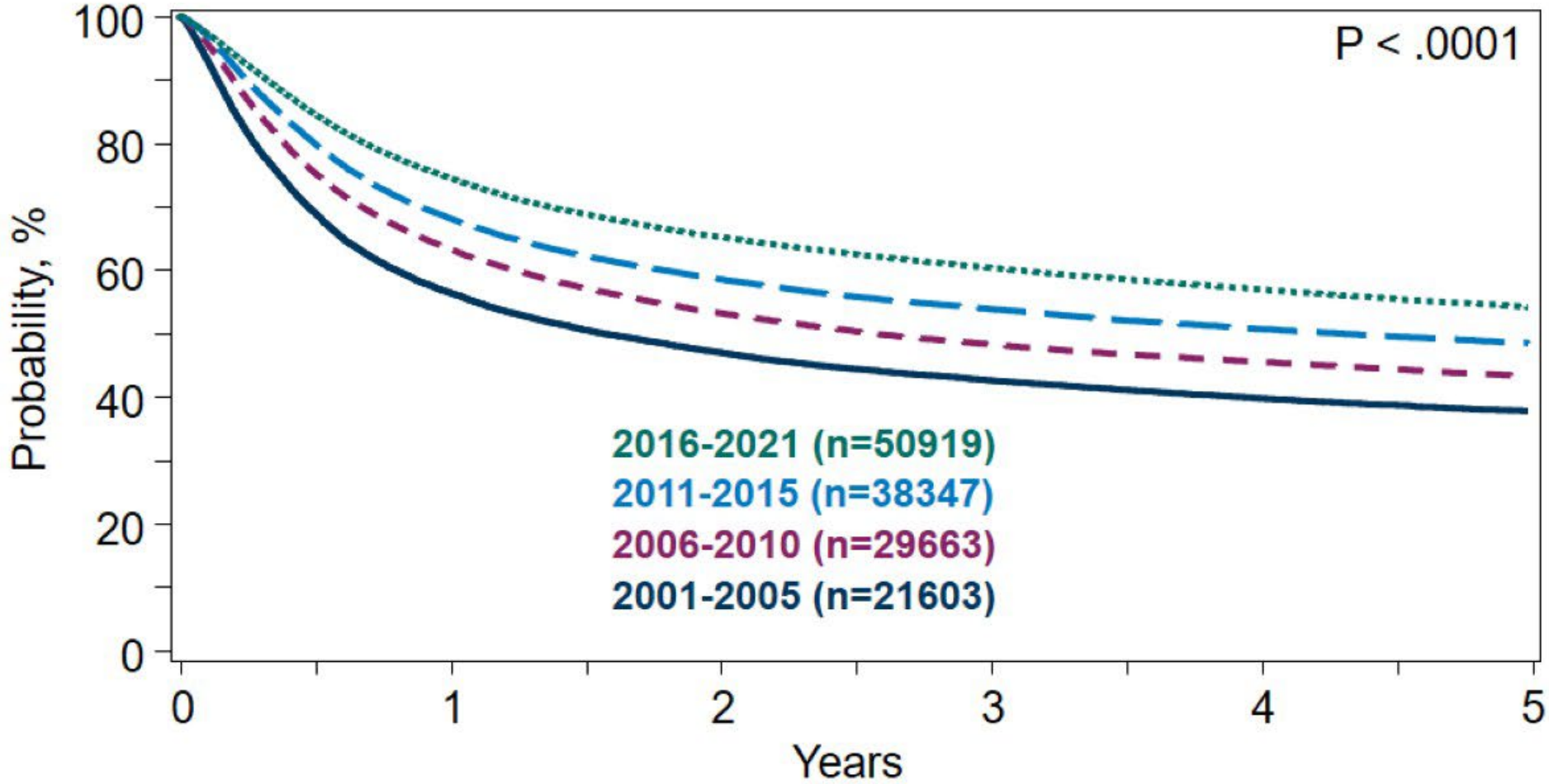
Abbreviations: MRD, matched related donor; MUD, matched unrelated donor; Haplo, ≥ 2 HLA antigen mismatch; MMUD, mismatched unrelated donor ≤ 7/8 HLA allele match; UCB, umbilical cord blood

Allogeneic HCTs in the US by Race and Ethnicity and Donor Type, 2019-2022



Abbreviations: haplo, includes ≥ 2 HLA antigen mismatch donors; MMUD, mismatched unrelated donor ≤ 7/8 HLA allele match; MRD, matched related donor; MUD, matched unrelated donor; UCB, umbilical cord blood.
Note: Other race includes Native Hawaiian or other Pacific Islander (n=76); American Indian or Alaska Native (n=131); more than one race (n=236); and not a US resident (n=322).

Trends in Survival after Allogeneic HCTs, in the US, 2001-2021



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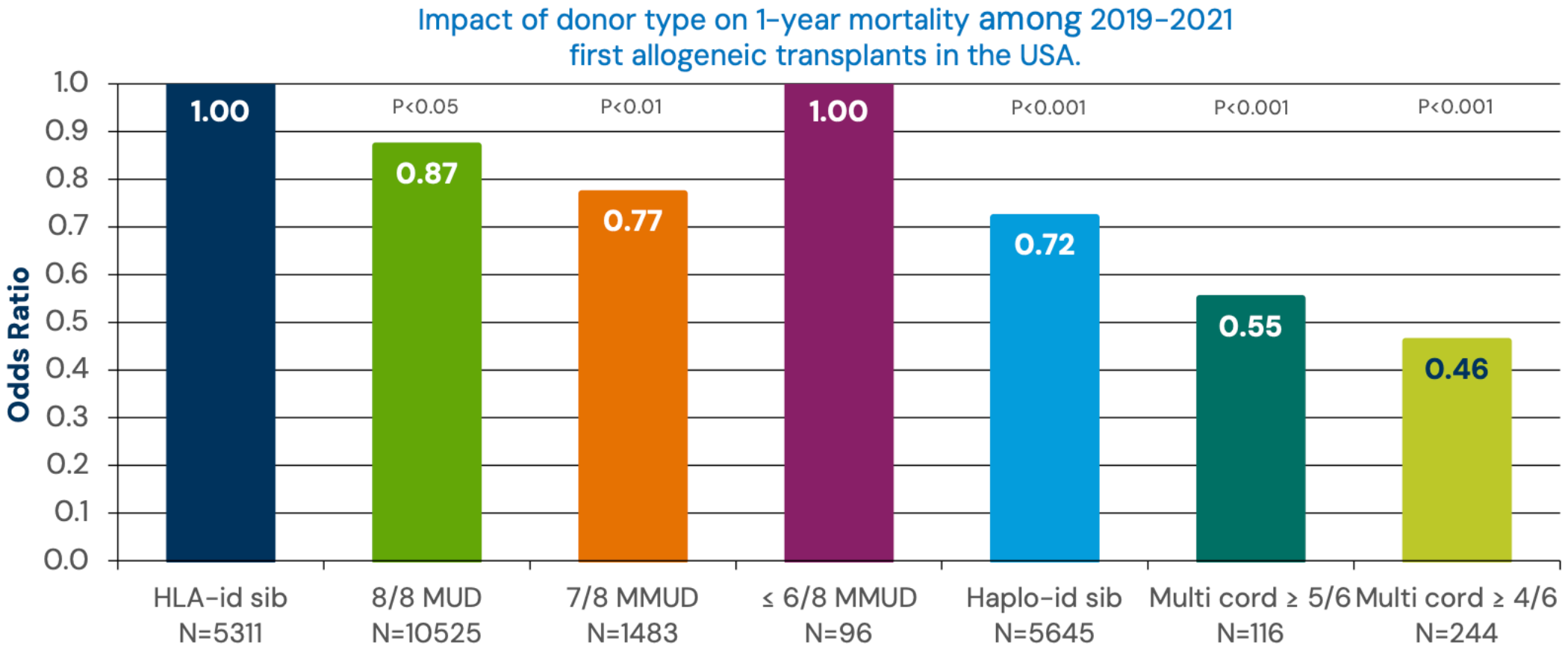
Impact of Donor Type on One-year mortality after HCTs done in 2019-2021



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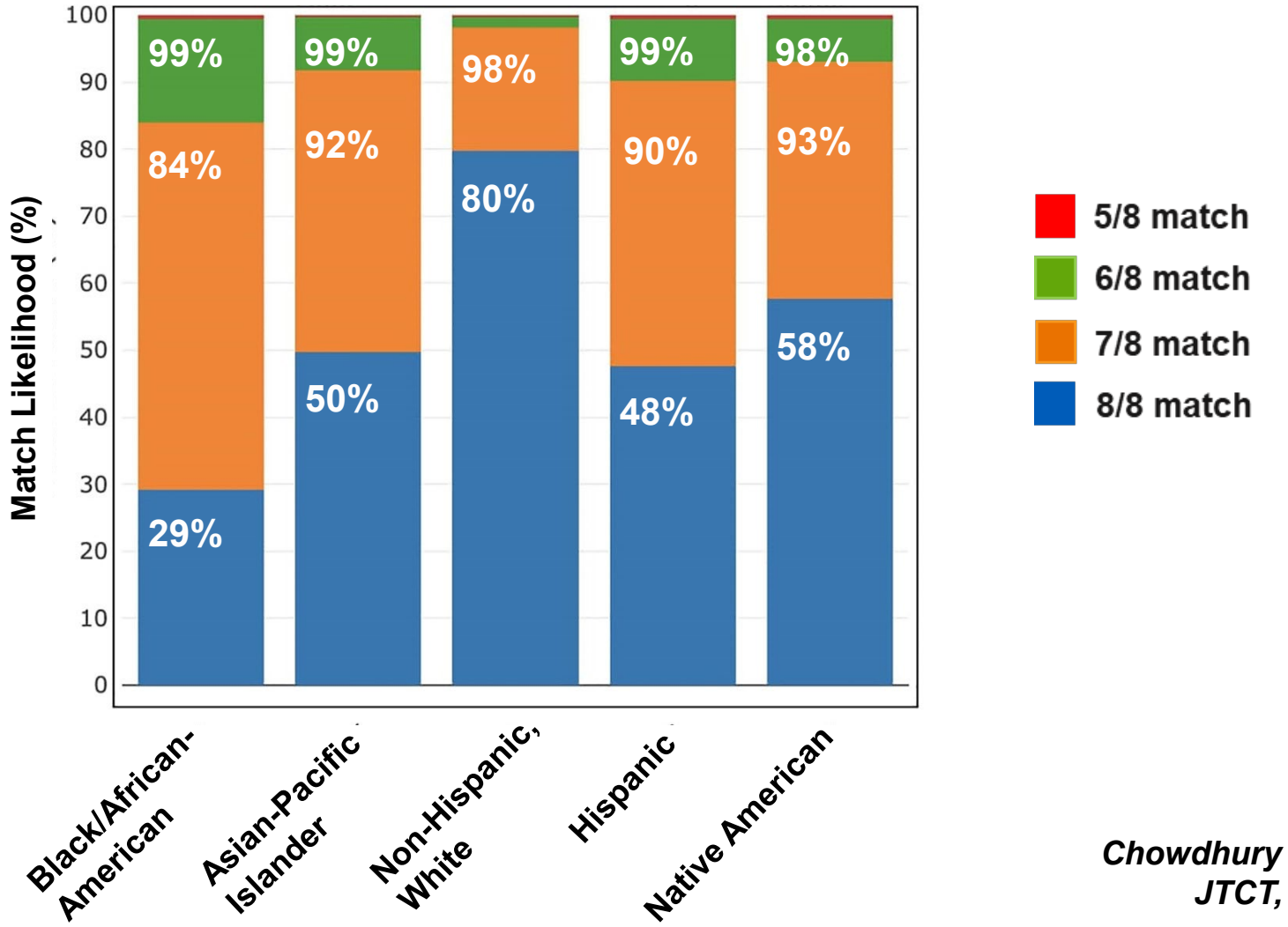
Source: 2023 Center specific analysis of US transplants

8/8 unrelated donor unlikely for many patients, but 7/8 mismatched unrelated donor (MMUD) donors are likely

HLA match likelihoods (%) at 5/8-8/8 levels with donors of all ages in 5 broad race/ethnic groups



Chowdhury et al, JTCT, 2023

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original reports

Phase II Trial of Costimulation Blockade With Abatacept for Prevention of Acute GVHD

Benjamin Watkins, MD[1]; Muna Qayed, MD[1]; Courtney McCracken, PhD[2]; Brandi Bratrude, BA[3]; Kayla Betz, BS[3]; Yvonne Suessmuth, PhD[1]; Alison Yu, PhD[3]; Shauna Sinclair[4]; Scott Furlan, MD[5]; Steven Bosinger, PhD[6]; Victor Tkachev, PhD[3]; James Rhodes, PharmD[7]; Audrey Grizzle Tumlin, BS[7]; Alexandria Narayan, BA[5]; Kayla Cribbin, BS[4]; Scott Gillespie, MS[2]; Ted A. Gooley, PhD[5]; Marcelo C. Pasquini, MD[8]; Kyle Hebert, MS[8]; Urvi Kapoor, MD[9]; Andre Rogatko, PhD[10]; Mourad Tighiouart, PhD[10]; Sungjin Kim, MS[10]; Catherine Bresee, MS[10]; Sung W. Choi, MD[11]; Jeffrey Davis, MD[12]; Christine Duncan, MD[3]; Roger Giller, MD[13]; Michael Grimley, MD[14]; Andrew C. Harris, MD[15]; David Jacobsohn, MD[16]; Nahal Lalefar, MD[17]; Maxim Norkin, MD[18]; Nosha Farhadfar, MD[19]; Michael A. Pulsipher, MD[20]; Shalini Shenoy, MD[21]; Aleksandra Petrovic, MD[4]; Kirk R. Schultz, MD[12]; Gregory A. Yanik, MD[11]; Edmund K. Waller, MD[22]; John E. Levine, MD[9]; James L. Ferrara, MD[9]; Bruce R. Blazar, MD[23]; Amelia Langston, MD[22]; John T. Horan, MD[3]; and Leslie S. Kean, MD, PhD[3]

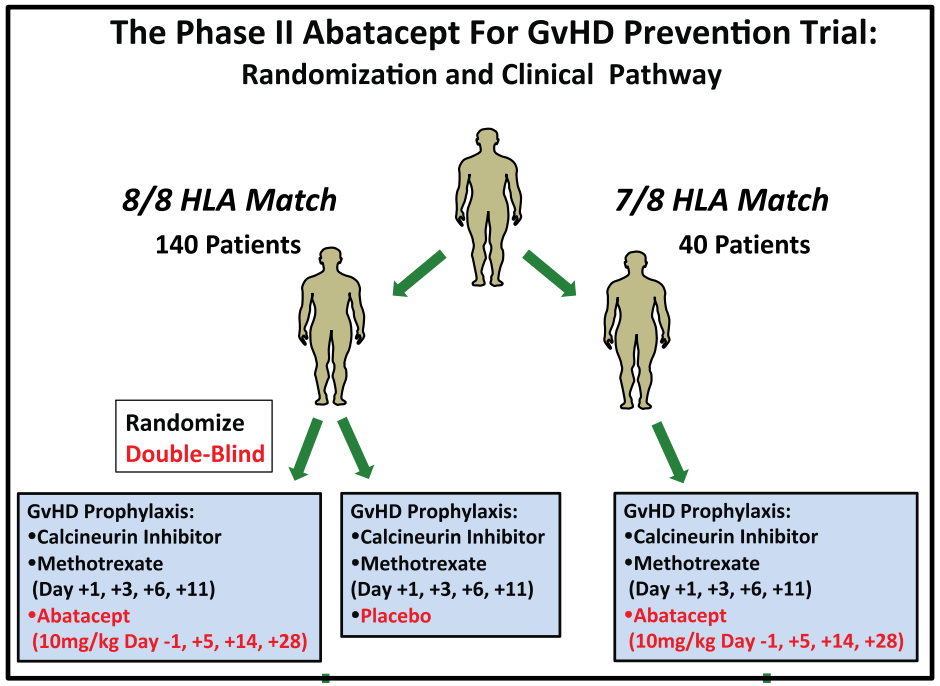
December 15, 2021

U.S. FOOD & DRUG ADMINISTRATION

FDA Homepage

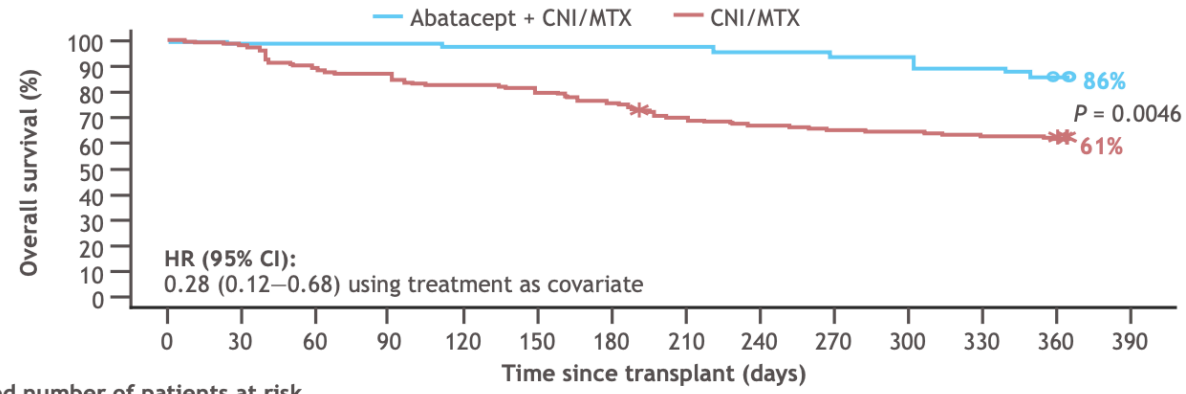
← Home / Drugs / Development & Approval Process | Drugs / Drug Approvals and Databases / Resources for Information | Approved Drugs / FDA approves abatacept for prophylaxis of acute graft versus host disease

FDA approves abatacept for prophylaxis of acute graft versus host disease



7/8 MMUD recipients

OS



Weighted number of patients at risk

Abatacept + CNI/MTX	54	53	53	53	53	53	53	53	52	51	51	48	45
CNI/MTX	161	158	144	140	133	131	122	112	107	104	103	100	98

Day 180 FDA prespecified primary endpoint: abatacept, 98% vs CNI/MTX, 75%; HR (95% CI): 0.06 (0.01–0.27); *P* = 0.0028; using treatment as covariate

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Watkins et al, J Clin Oncol, 2021

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Impact of PTCy on Patient Outcomes

Updated CIBMTR Analysis of US data

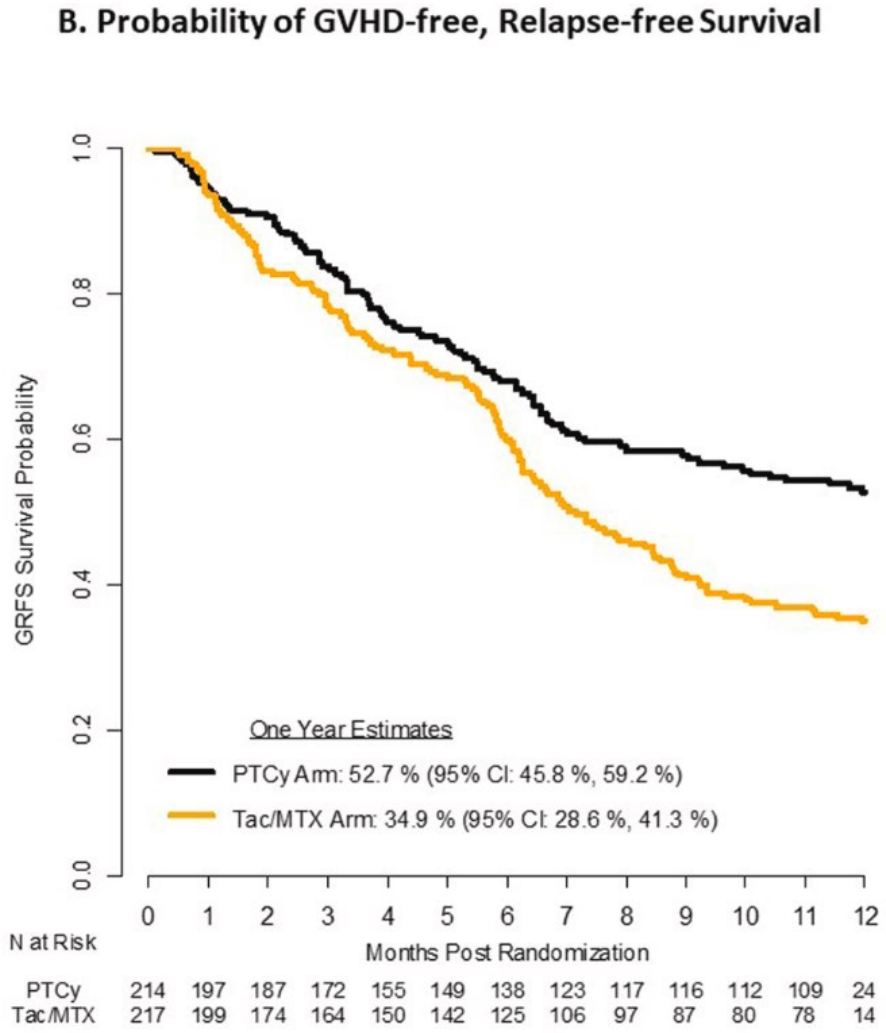
PTCy-based GVHD prophylaxis as the new standard in RIC HCT using HLA-matched donors

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Post-Transplantation Cyclophosphamide-Based Graft-versus-Host Disease Prophylaxis

J. Bolaños-Meade, M. Hamadani, J. Wu, M.M. Al Malki, M.J. Martens, L. Runaas, H. Elmariah, A.R. Rezvani, M. Gooptu, K.T. Larkin, B.C. Shaffer, N. El Jurdi, A.W. Loren, M. Solh, A.C. Hall, A.M. Alousi, O.H. Jamy, M.-A. Perales, J.M. Yao, K. Applegate, A.S. Bhatt, L.S. Kean, Y.A. Efebera, R. Reshef, W. Clark, N.L. DiFronzo, E. Leifer, M.M. Horowitz, R.J. Jones, and S.G. Holtan, for the BMT CTN 1703 Investigators*



Bolanos-Meade et al, NEJM, 2023

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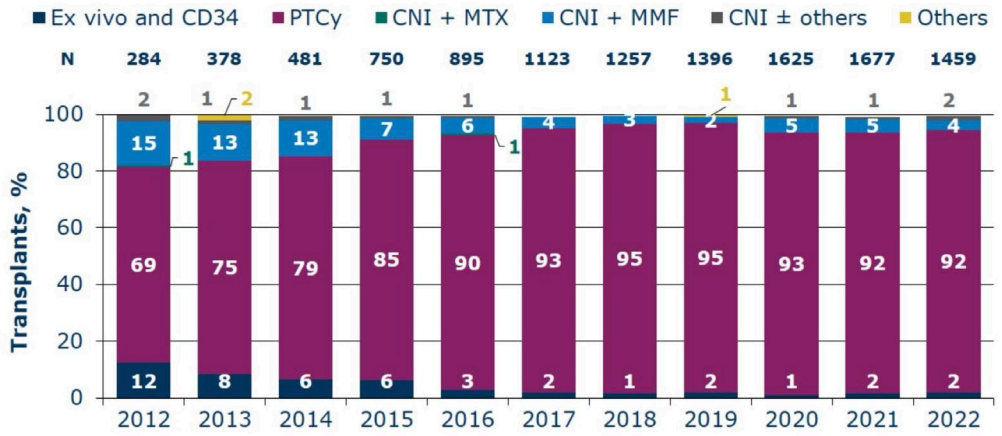
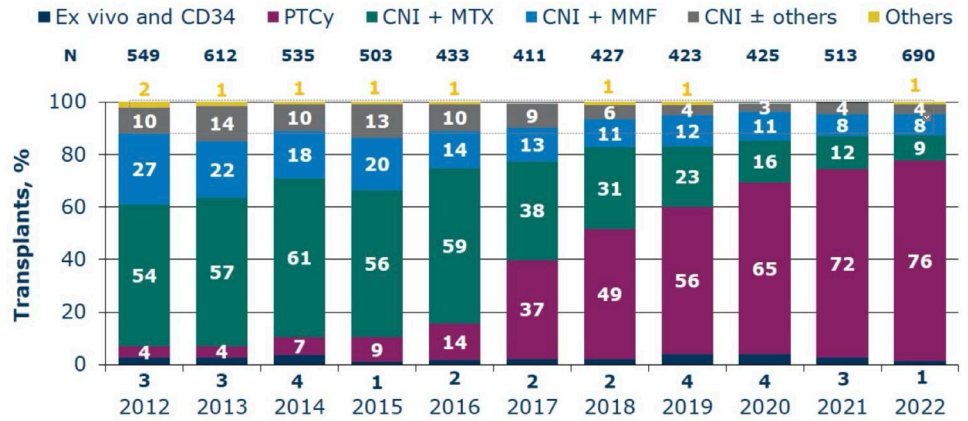
US GVHD Prophylaxis use by Donor Source

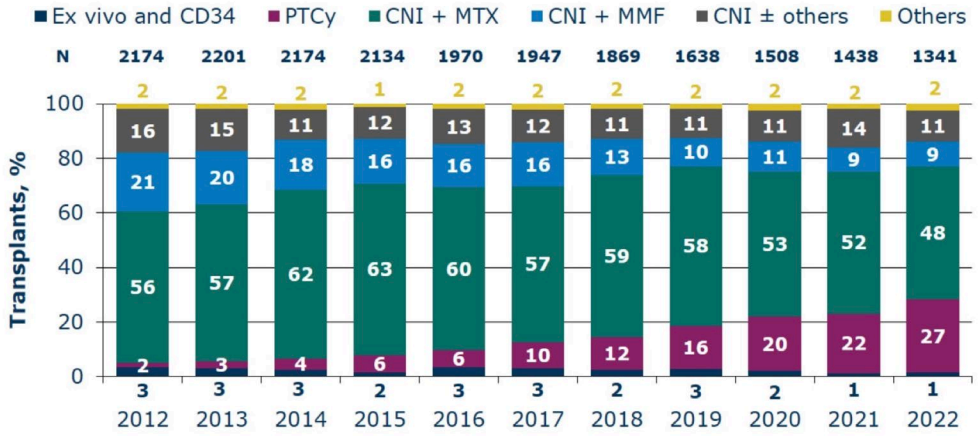
GVHD Prophylaxis of Haplo Donor HCTs in the US, Adults



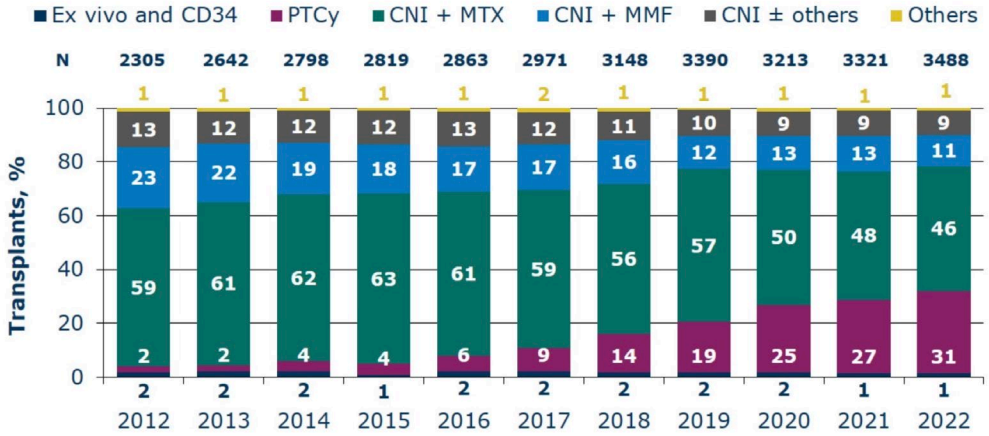
GVHD Prophylaxis of Mismatched Unrelated Donor HCTs in the US, Adults



GVHD Prophylaxis of Matched Related Donor HCTs in the US, Adults



GVHD Prophylaxis of Matched Unrelated Donor HCTs in the US, Adults



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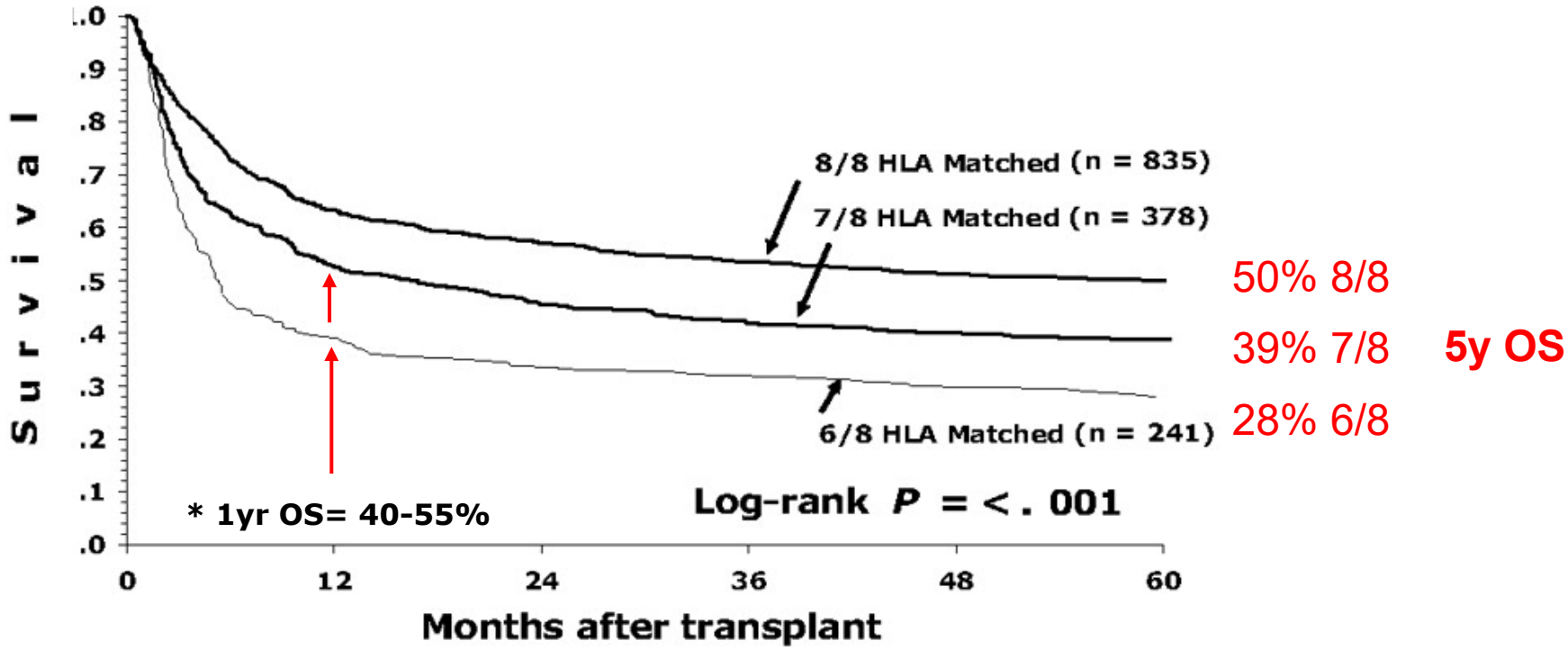
Historically, overall survival (OS) has been inferior following MMUD (6-7/8) vs. MUD (8/8) HCT using CNI-based GvHD prophylaxis

Patient cohort:

- N=3,857
- ALL, AML, CML, MDS
- 1st alloHCT 1988-2003
- 84% MAC
- 94% BM grafts
- 78% T-cell replete
- **CNI GvHD prophylaxis**
- Median follow-up = 5y



50% 8/8
39% 7/8 **5y OS**
28% 6/8

Early stage-disease OS is shown.
Similar survival trends for intermediate and advanced-stage disease.

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CNI = calcineurin inhibitor

Lee at al, Blood 2007;110(13):4576

What is the gap in matched and mismatched URD outcomes in the PTCy era?

- Primary Objective:
  - To compare OS and GRFS* between 8/8 and 7/8 URD HCT
    - By GvHD prophylaxis regimen (CNI vs. PTCy)
    - By PTCy GvHD prophylaxis only
- Secondary Objective:
  - To compare GRFS, OS, and other clinical outcomes among 8/8 and and haploidentical-related donor (Haplo) HCT
    - By PTCy GvHD prophylaxis

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GRFS = Graft-versus-host disease (GvHD)-free, relapse-free survival, OS = Overall survival
*Survival without grade 3-4 acute GvHD, systemic therapy-requiring chronic GvHD, or relapse

PTCy reduces differences in outcomes between matched and mismatched unrelated donor recipients

Original Reports | Hematologic Malignancy

Post-Transplant Cyclophosphamide–Based Graft-Versus-Host Disease Prophylaxis Attenuates Disparity in Outcomes Between Use of Matched or Mismatched Unrelated Donors

Brian C. Shaffer, MD, MS[1]; Mahasweta Gooptu, MD[2]; Todd E. DeFor, MS[3]; Martin Maiers, MS[3]; Javier Bolaños-Meade, MD[4]; Ramzi Abboud, MD[5]; Adrienne D. Briggs, MD[6]; Farhad Khimani, MBBS[7]; Dipenkumar Modi, MD[8]; Richard Newcomb, MD[9]; Elizabeth J. Shpall, MD[10]; Caitrin Bupp, MPH[3]; Stephen R. Spellman, MBS[3]; Heather E. Stefanski, MD, PhD[3]; Bronwen E. Shaw, MD, PhD[11]; Jeffery J. Auletta, MD[3,12]; Steven M. Devine, MD[3]; Antonio M. Jimenez Jimenez, MD, MSc[13]; and Monzr M. Al Malki, MD[14]

DOI https://doi.org/10.1200/JCO.24.00184

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Patient selection

7/8 vs. 8/8 URD HCT outcomes: CNI vs. PTCy

- Adult patients (age≥18y) with ALL, AML, or MDS receiving first URD HCT using CNI- or PTCy-based GvHD prophylaxis between Jan 2017- Jun 2021
- **Study groups (N=10,025)**
  - 8/8 URD PTCy (n=1681)
  - 7/8 URD PTCy (n=613)
  - 8/8 URD CNI (n=7272)
  - 7/8 URD CNI (n=459)
- Minimum median follow-up = 3y
- Data completeness index >90%

7/8 vs. 8/8 URD (1^0) vs. Haplo (2^0) HCT outcomes: Focus on PTCy

- Adult patients (age≥18y) with ALL, AML, or MDS receiving first URD or Haplo HCT using PTCy-based GvHD prophylaxis between Jan 2017 – Dec 2020
- **Study groups (N=4,829)**
  - 8/8 URD (n=1517)
  - 7/8 URD (n=540)

  } Overlap CNI vs. PTCy
  - Haplo (n=2772)
- Minimum median follow-up = 3y
- Data completeness index >90%

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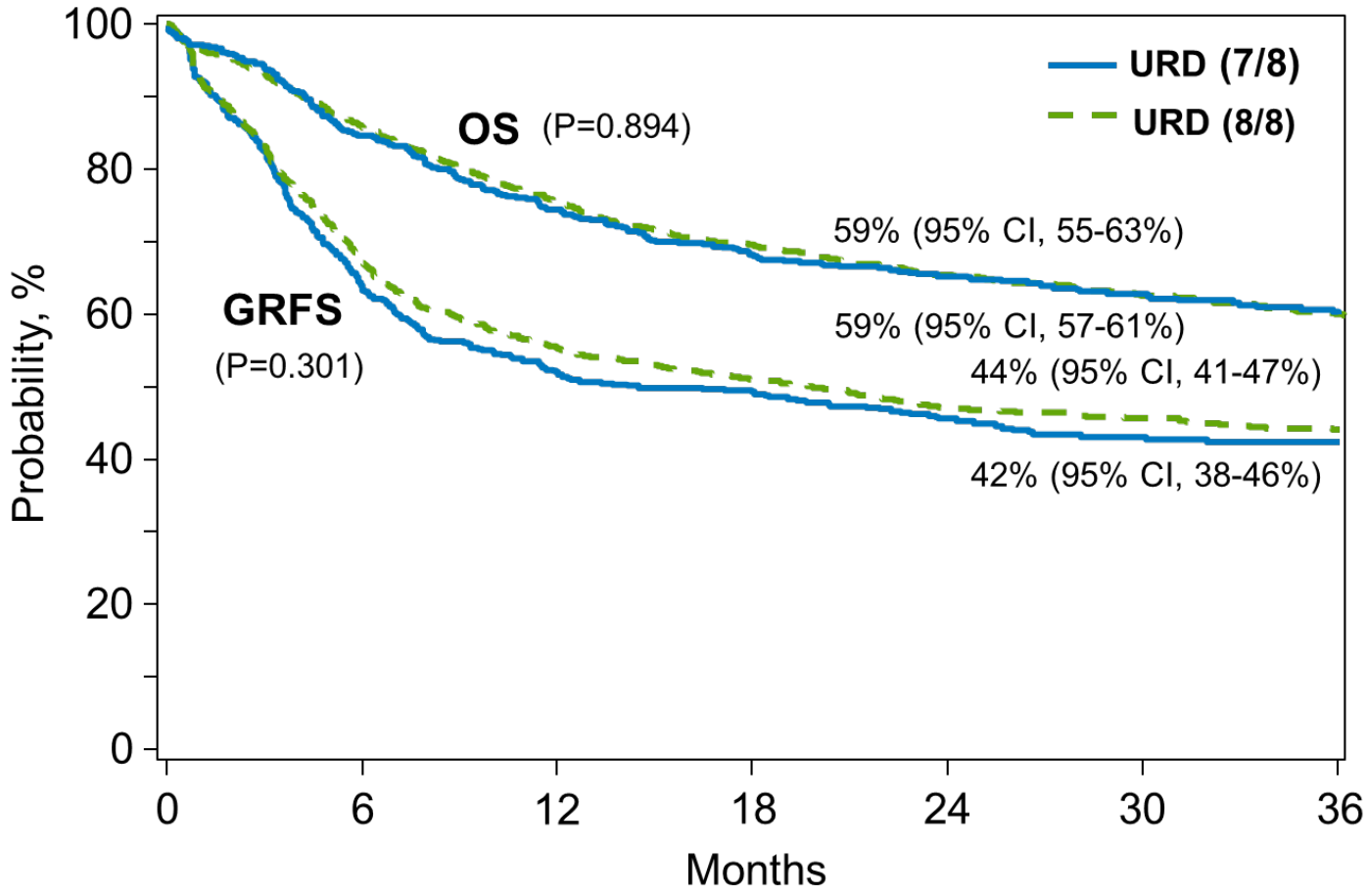
No difference between 8/8 and 7/8 URD HCT with PTCy: Adjusted 3y OS and GRFS

First allogeneic HCT in adults with ALL, AML or MDS using PTCy GvHD prophylaxis (2017-2021)



7/8: N= 613
8/8: N=1,681

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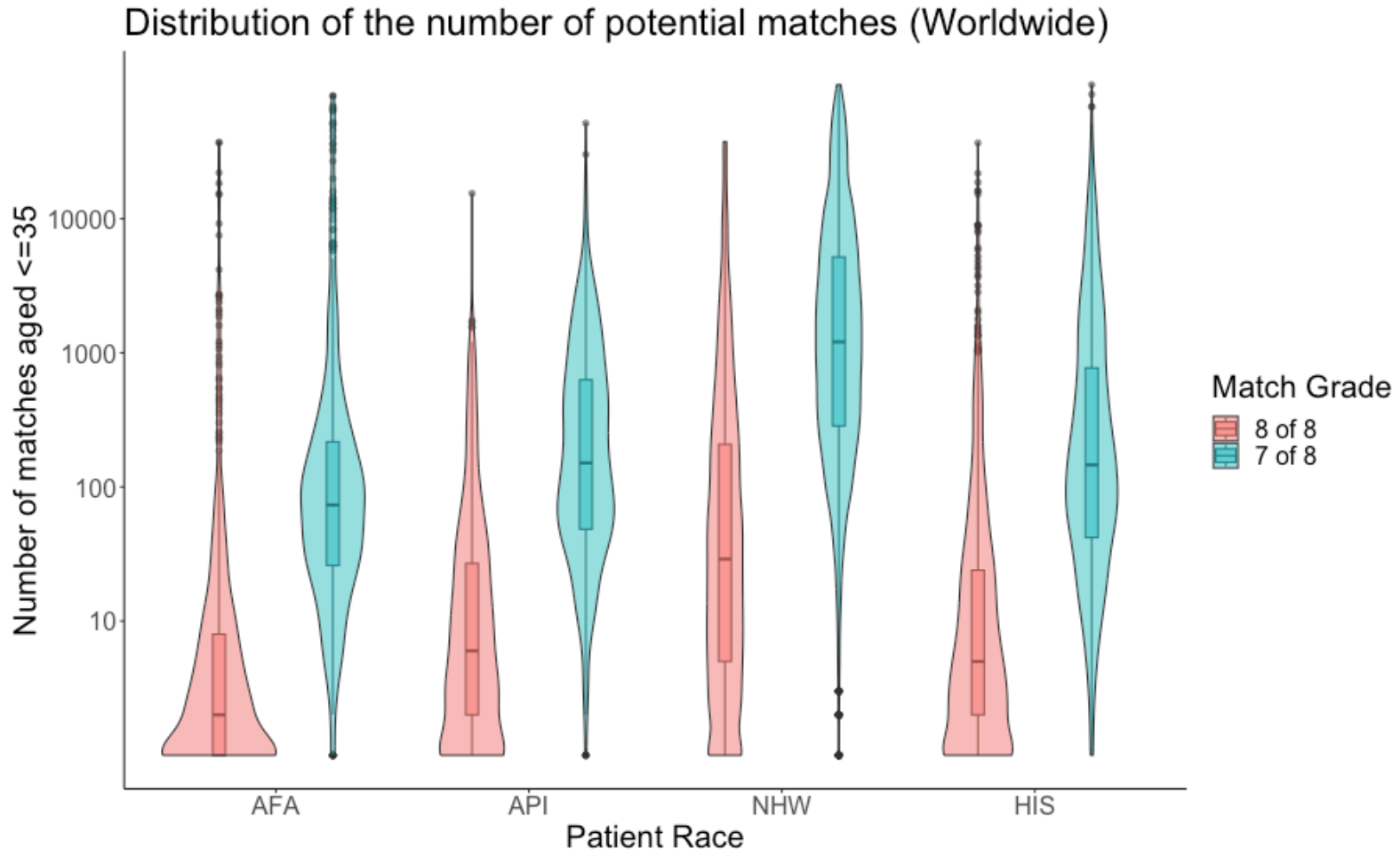
Shaffer et al, J Clin Oncol, online

Effect of MMUD on Donor Existence



Median:	**2**	**74**	**6**	**151**	**29**	**1226**	**5**	**147**

Shaffer et al, J Clin Oncol, online

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Post-Transplant Cyclophosphamide-Based Graft-versus-Host Disease Prophylaxis Following Mismatched Unrelated Donor Peripheral Blood Stem Cell (PBSC) Transplantation (the ACCESS Study)

Monzr M. Al Malki, Stephanie Bo-Subait, Brent Logan, Janelle Olson, Erin Leckrone, Juan Wu, Heather E. Stefanski, Jeffery J. Auletta, Stephen R. Spellman, Craig Malmberg, Brian C. Shaffer, Dipenkumar Modi, Farhad Khimani, Mahasweta Gooptu, Mehdi Hamadani, Larisa Broglie, Bronwen E. Shaw, Steven Michael Devine, Antonio Martin Jimenez Jimenez

Study Sponsored by:

nmdp
FIND CURES. SAVE LIVES.

NCT04904588

ACCESS Study Design

Adults stratified by intensity and analyzed separately with one pediatric MAC stratum

Stratum 1	•Adult subjects undergoing HCT with a **PBSC** graft source and receiving a myeloablative conditioning **(MAC) regimen** and PTCy-based GVHD prophylaxis
Stratum 2	•Adult subjects undergoing HCT with a **PBSC** graft source and receiving a non-myeloablative (**NMA**) or reduced-intensity conditioning **(RIC) regimen** and PTCy-based GVHD prophylaxis
Stratum 3	•Pediatric and young adult subjects undergoing HCT from a **BM** graft source and receiving a **MAC** regimen and PTCy-based GVHD prophylaxis

- Initial design planned for for 70 adults in each strata
- Accrual in RIC stratum far exceeded expectations, leading to protocol amendment to increase to 190 in order to analyze impact of donors matched at <7/8
- Study activated August 2021
- Enrollment RIC cohort completed September 2022
- Follow-up completed September 2023
- **Initial statistical analysis plan included first 70 RIC patients**

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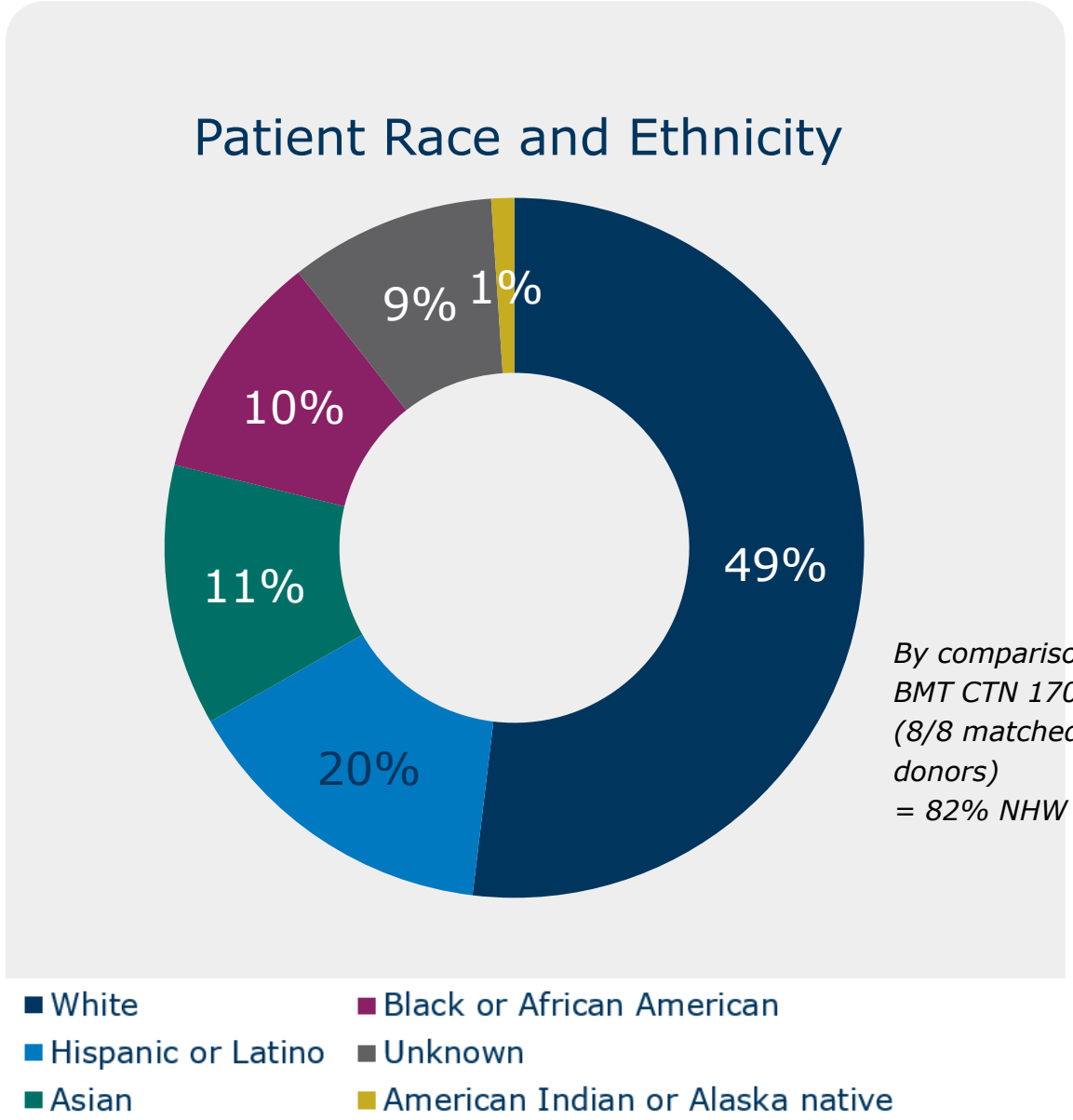
**Prospective, multi-center Phase II study (NCT04904588) to assess the impact of PTCy-based GVHD prophylaxis on transplantation in adults and children with advanced hematological malignancies.*

Results – Patient Demographics

Characteristic	n (%)
No. of patients	70
No. of centers	13
Age at HCT	
Median (min-max)	**65.0** (24.0-77.0)
Sex	
Male	35 (50.0)
Female	35 (50.0)
Cryopreservation	
Cryopreserved	60 (85.7)
Fresh	10 (14.3)



By comparison: BMT CTN 1703 (8/8 matched donors) = 82% NHW

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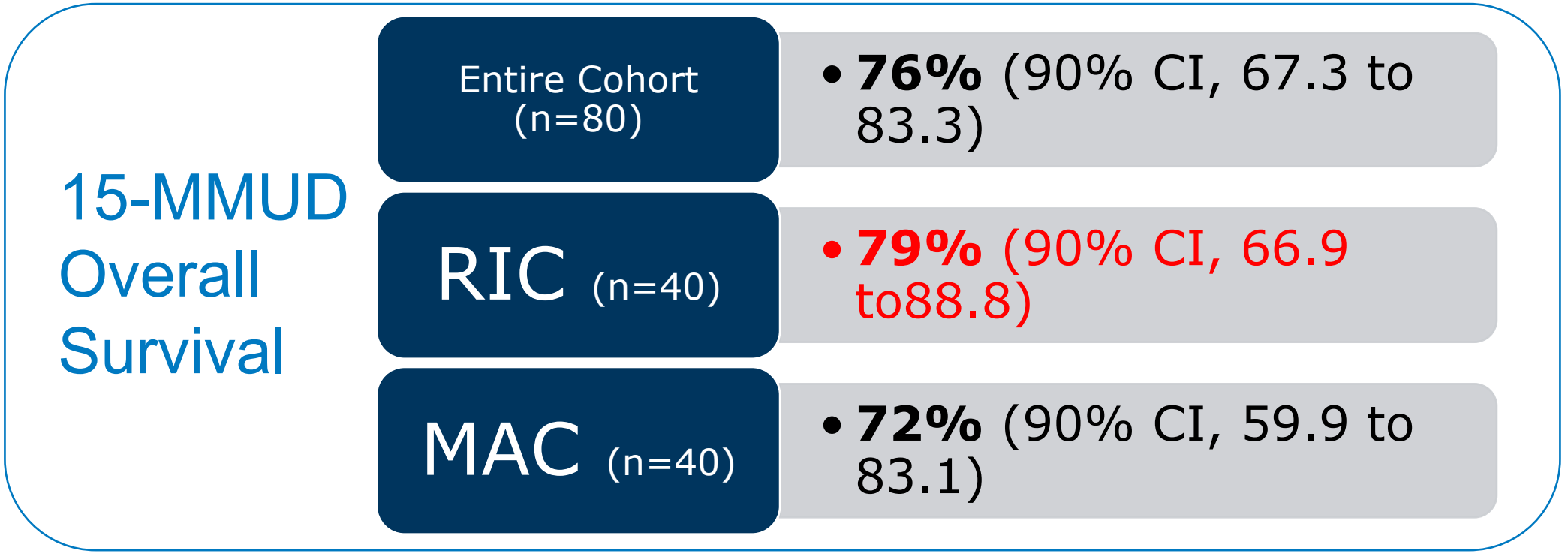
Hypothesis Testing for ACCESS Study

Transplantation of a PBSC product from a MMUD using PTCy-based GVHD prophylaxis will be safe and feasible and will result in a high likelihood of overall survival at one year following HCT.



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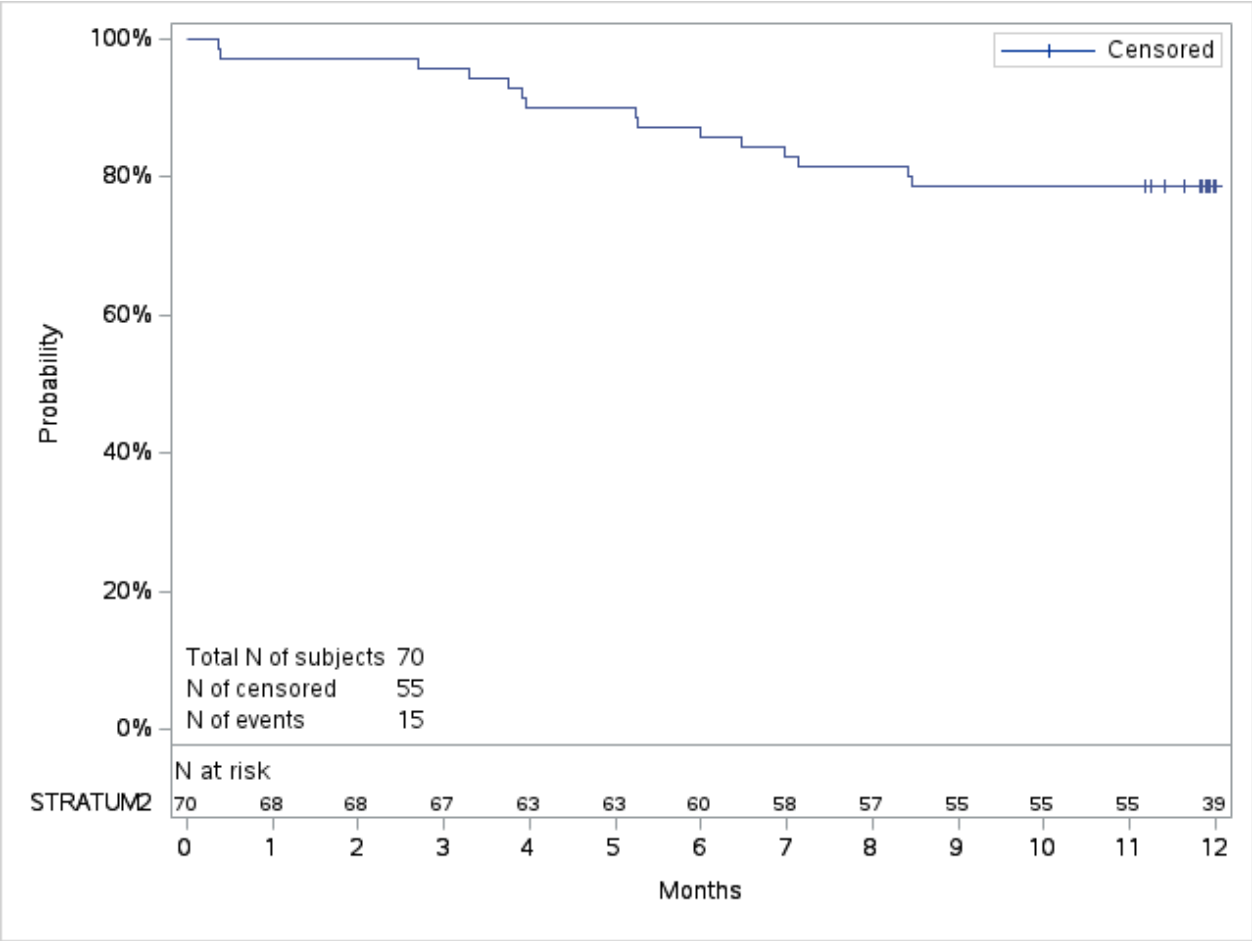
Shaw et al, J Clin Oncol, 2021

Primary Endpoint: Overall Survival



Kaplan-Meier estimates and 95% confidence intervals for overall survival

Outcomes	N/n eval	Prob (95% CI)
OS[1]	70	
1-year	39	79 (68-87) %

[1] Median follow-up (min-max), months: 12.0 (0.4-12.9)
Median follow-up (min-max) of survivors, months: 12.1 (11.2-12.9)

Impact of degree of HLA match (7/8 Vs <7/8) on OS

	HLA match: 7/8		HLA match: <7/8		
Outcomes	N/n eval	Prob (95% CI)	N/n eval	Prob (95% CI)	P-value[1]
OS	47		23		0.580
1-year	27	77 (64-87)%	12	83 (65-95)%	

[1] P-value from log-rank test.

Impact of donor age (above vs below median of 25) on OS

	> Median		≤ Median		
Outcomes	N/n eval	Prob (95% CI)	N/n eval	Prob (95% CI)	P-value[1]
OS	35		35		0.813
1-year	18	77 (62-89)%	21	80 (65-91)%	

[1] P-value from log-rank test.

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Results: comparison to BMT CTN 1703

Clinical Endpoint	ACCESS Study (RIC Stratum; N=70)	BMT CTN 1703 PTCy Arm[1]
Overall Survival	79% (68-87%)	77% (71-82%)
GVHD-free, relapse free survival (GRFS)	51% (36-59%)	53% (46-39%)
Primary graft failure by Day 28	6% (2-14%)	3% (not reported)
Non-relapse mortality (NRM)	13% (6-22%)	12% (8-17%)
Relapse	21% (13-32%)	21% (16-27%)
Acute GVHD grade II-IV	43% (31-55%)*	56% (49-62%)*
Acute GVHD grade III-IV	9% (3-16%)*	8% (5-12%)*
NIH moderate/severe chronic GVHD	9% (3-17%)	7% (not reported)

One-year estimates (%) (95% CI); *6-month estimate

OS and GRFS using Kaplan-Meier method; NRM, relapse, and GVHD using cumulative incidence method.

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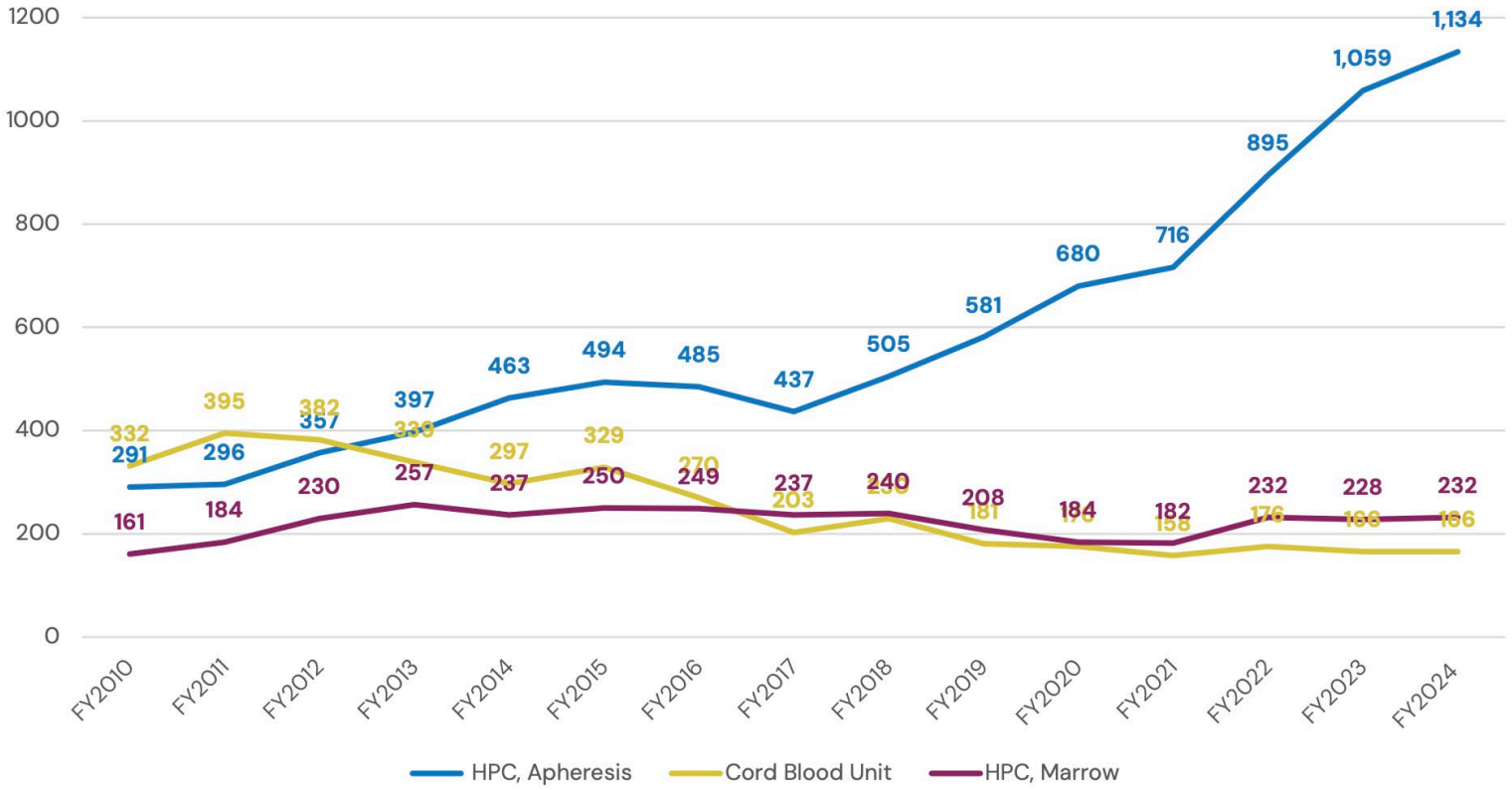
1. Bolanos-Meade et al, New Engl J Med, 2023

Ethnically diverse patient transplants in US facilitated by NMDP



Substantial growth driven mainly by MMUD HCTs, and shift to PBSC

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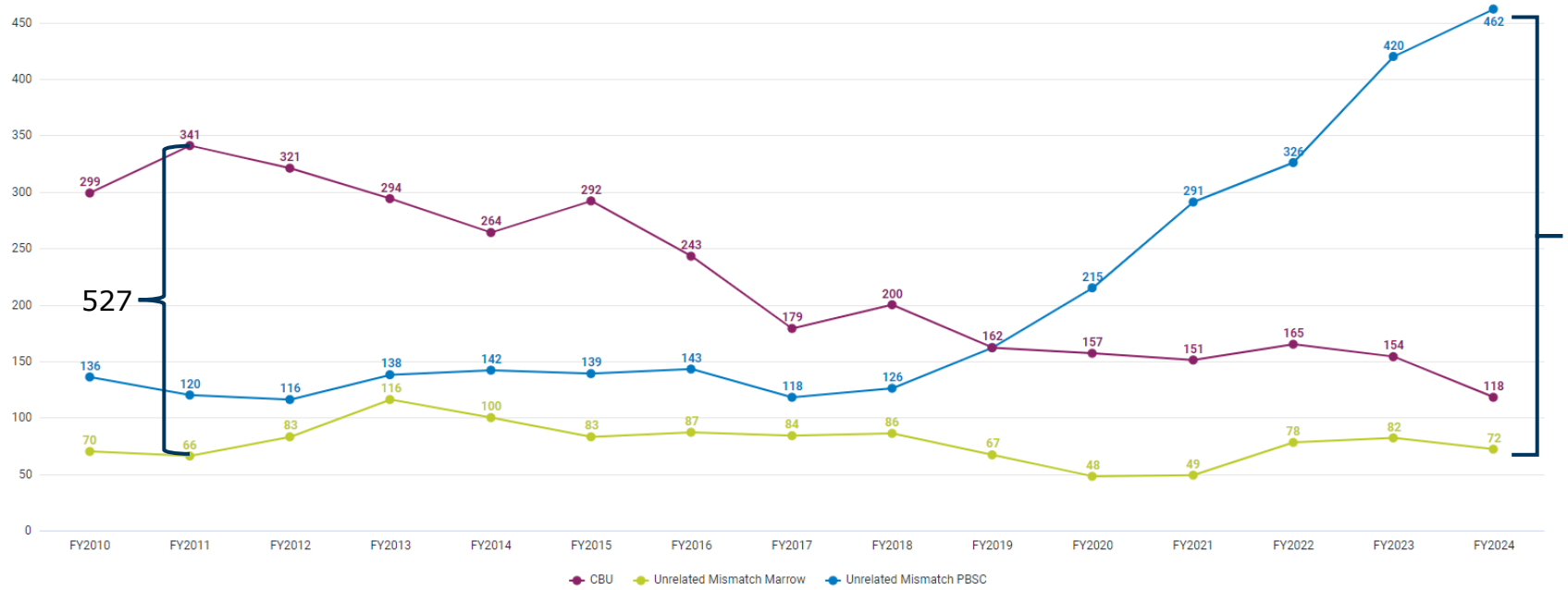
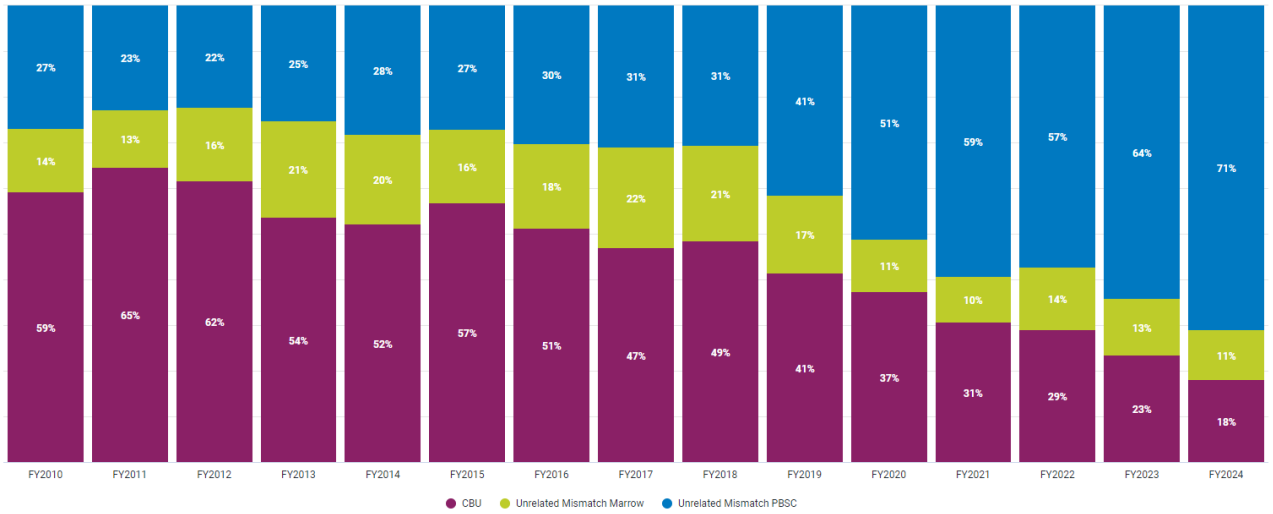
Source: NMDP Looker dashboard

NMDP Facilitated Transplants for Ethnically Diverse HCT Recipients in the US by graft source over time



24% increase relative to 2011



= PBSC

= BM

= UCB

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Source: NMDP Looker Dashboard

Does HLA Matching Matter in any Setting if PTCy is used?

Updated CIBMTR analysis comparing outcomes of HCT using 8/8 URD or Haplo Related: Restricted to PTCy

- First US Adult HCT from January 2017-Dec 2021
- Limited to AML/ALL/MDS
- BM and PBSC
- 8/8 URD and Haplo only
- PTCy-combos only
- No ATG or Abatacept
- 5,873 total patients
  - Haplo = 3900
  - 8/8 URD= 1973
- Primary endpoints
  - OS and GRFS

- Differences in Patient Characteristics:
  - Donor age; 28 v 36
  - Race/ethnicity: 86% vs 59% NHW
  - More high risk MDS in URD
  - More BM in Haplo
  - More transplants in 2017/18 in Haplo
- Median follow up in both cohorts:
  - 36 months
  - Major contrast to Gooptu et al, Blood, 2021

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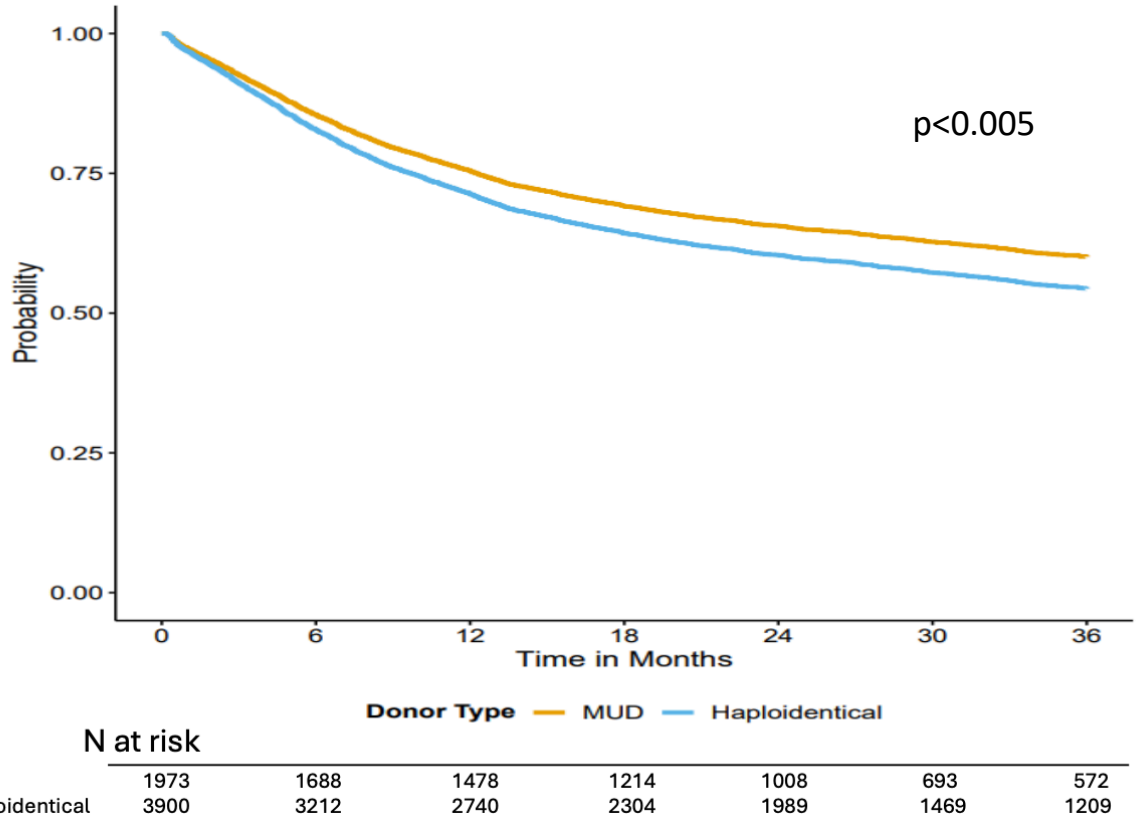
Auletta et al, ASH 2023

*Focus on MUD vs. Haplo: 3y Adjusted OS & GRFS**

First allogeneic HCT in adults with ALL, AML or MDS using PTCy GvHD prophylaxis only (2017-2021)

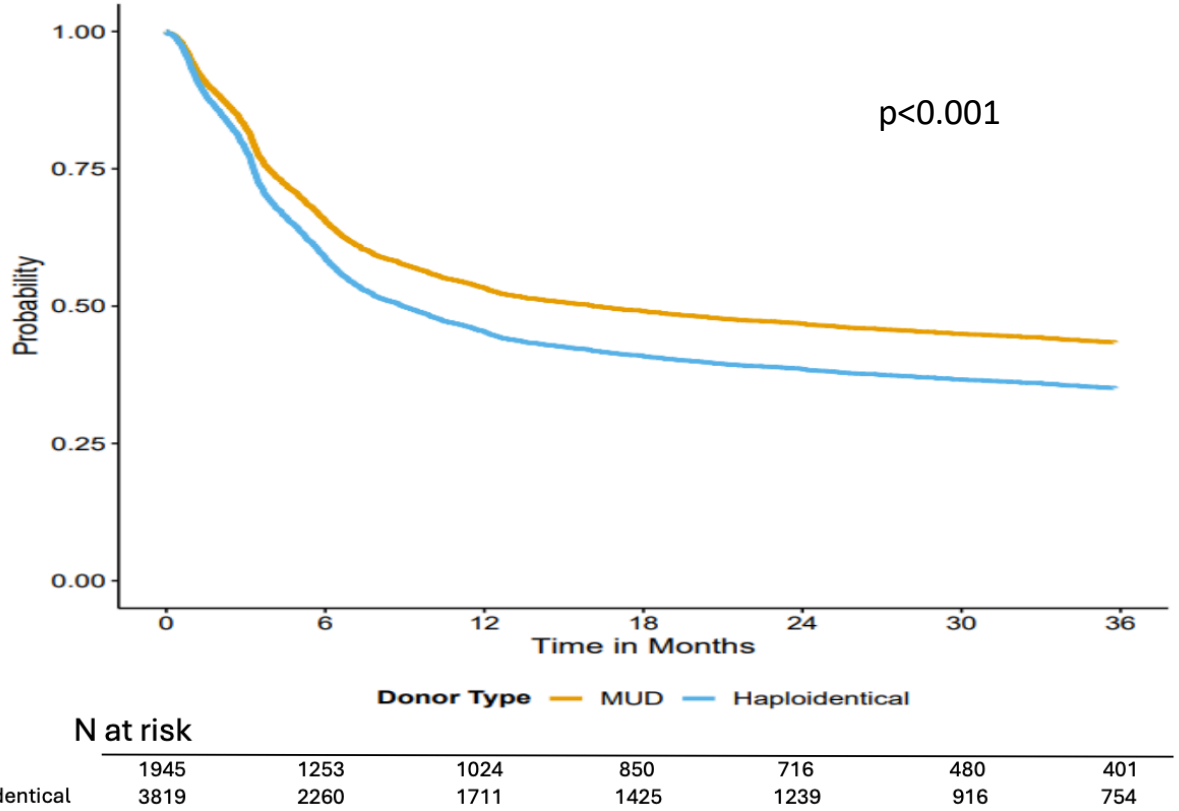
3y Adjusted Overall Survival



N at risk

MUD	1973	1688	1478	1214	1008	693	572
Haploidentical	3900	3212	2740	2304	1989	1469	1209

3y Adjusted GvHD-free, Relapse-free Survival



N at risk

MUD	1945	1253	1024	850	716	480	401
Haploidentical	3819	2260	1711	1425	1239	916	754

OS & GRFS Adjusted for: Refined DRI, HCT-CI, age at transplant, donor age at transplant, race, graft source (BM or PBSC), D/R CMV, year of transplant

OS Adjusted for: Above + gender

nmdp FIND CURES. SAVE LIVES.

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Auletta et al, ASH 2023

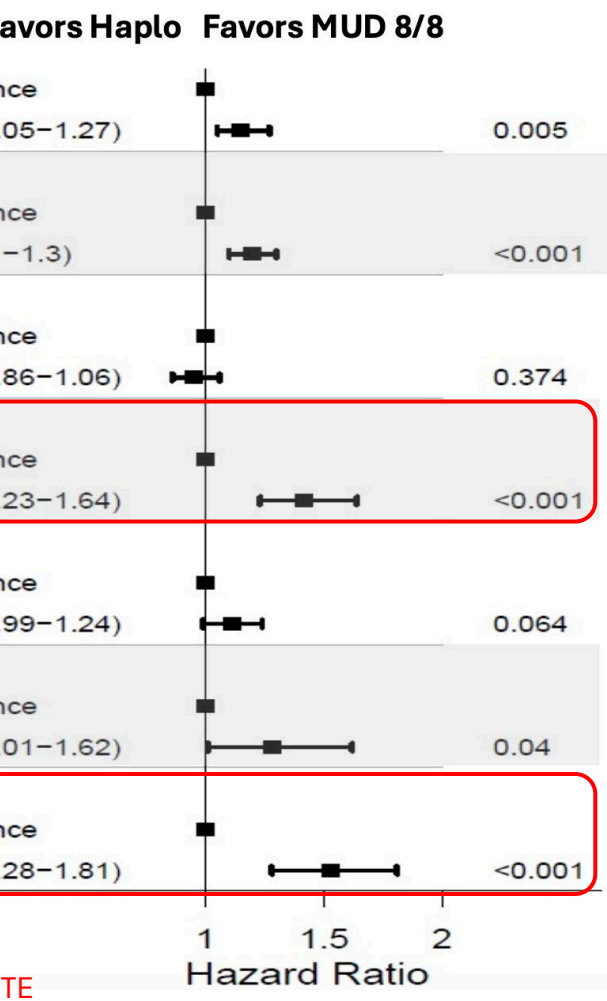
With MUD, lower risk NRM, Gr3-4 aGvHD, cGvHD

First allogeneic HCT in adults with ALL, AML or MDS using PTCy GvHD prophylaxis only (2017-2021)

Hazard ratio comparisons relative to 8/8 URD through 3y post-HCT

Forest plot of Regression Analyses

Comparator Group	N Patients	HR (95% CI)	P-value
Overall Survival			
8/8 HLA URD	1973	Reference	
Haploidentical	3900	1.15 (1.05-1.27)	0.005
GVHD-Free, Relapse-Free Survival			
8/8 HLA URD	1945	Reference	
Haploidentical	3819	1.2 (1.1-1.3)	<0.001
Relapse			
8/8 HLA URD	1963	Reference	
Haploidentical	3863	0.95 (0.86-1.06)	0.374
Non-Relapse Mortality			
8/8 HLA URD	1963	Reference	
Haploidentical	3863	1.42 (1.23-1.64)	<0.001
Grade II-IV Acute GvHD			
8/8 HLA URD	1959	Reference	
Haploidentical	3875	1.11 (0.99-1.24)	0.064
Grade III-IV Acute GvHD			
8/8 HLA URD	1959	Reference	
Haploidentical	3875	1.28 (1.01-1.62)	0.04
Moderate/Severe Chronic GVHD			
8/8 HLA URD	1956	Reference	
Haploidentical	3860	1.53 (1.28-1.81)	<0.001



Conclusions

- NMDP realized that disparities in access to HLA-matched donors based on race/ethnicity could not be solved **just** by increasing registry size or diversity

- This required committing resources to prospective clinical research designed to close the gap in outcomes between matched and mismatched URDs

- CIBMTR led studies sponsored by NMDP demonstrate that PTCy-based GVHD prophylaxis has mitigated impact of HLA-mismatching, and both Haplo and MMUD are being used increasingly for patients unlikely to find an HLA-matched donor
    - 7/8 Donors using PTCy-prophylaxis now a standard of care at US transplant centers

- PTCy and other forms of T-cell depletion have enabled more ethnically diverse patients to receive HCT
- Between MRD, MUD/MMUD, Haploidentical, and UCB options, access to a life saving HCT has increased for all patients regardless of ancestry

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