Overcoming Barriers to Effective Treatment and Enrollment in Clinical Trials for Black and Underserved Patients with Multiple Myeloma

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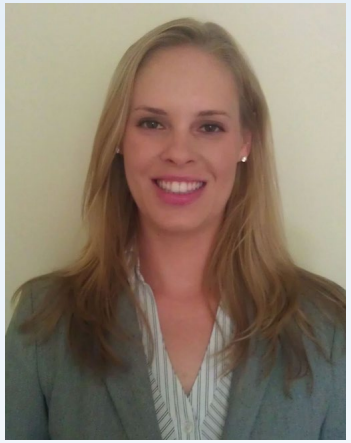

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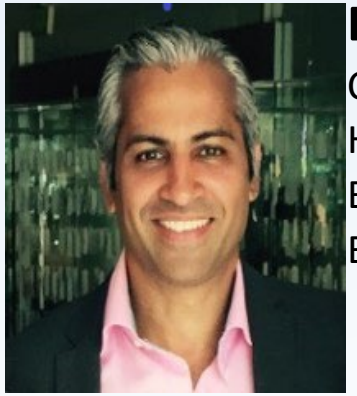

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Learning Objectives

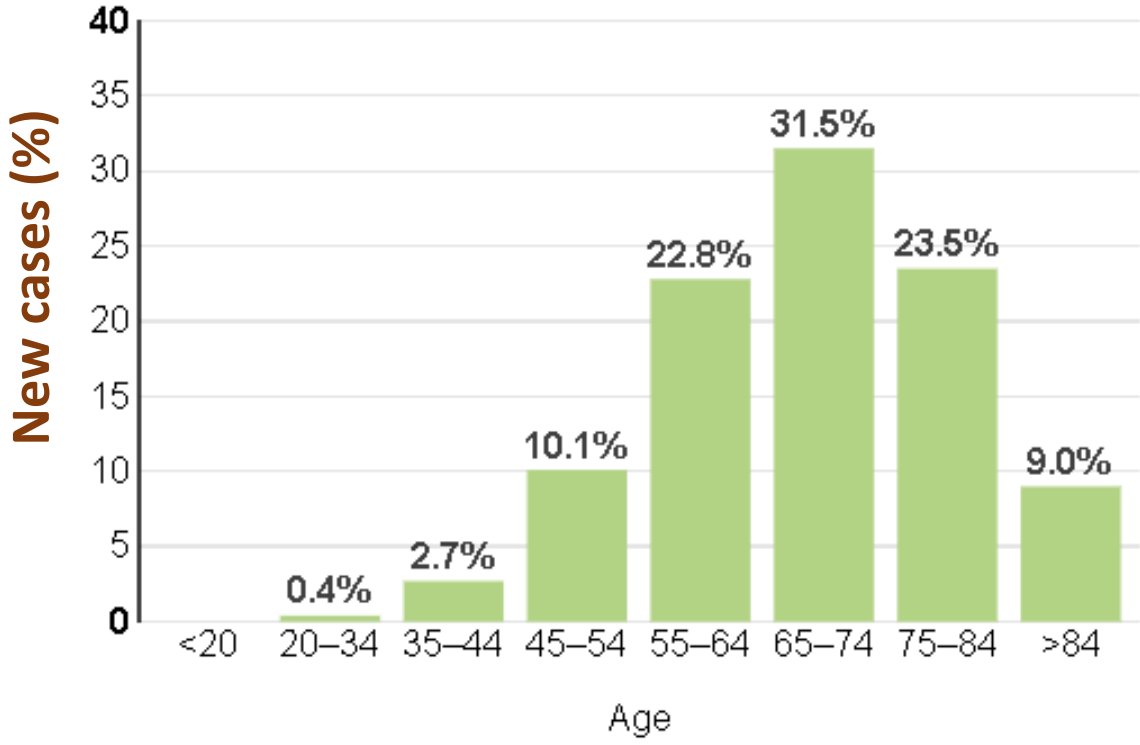
1. Discuss health inequities and racial disparities in multiple myeloma.
2. Describe racially unique adverse drug events associated with treatment for Black patients with multiple myeloma.
3. Discuss multiple myeloma treatment risks with Black patients to support shared decision-making regarding treatment and manage expectations.
4. Develop strategies to mitigate the multiple barriers to clinical trial enrollment and appropriate clinical care in Black and underserved patients with multiple myeloma.
5. Identify appropriate use of BCMA-targeted therapies for all patient populations with multiple myeloma.

Multiple Myeloma and Racial Disparities

Multiple Myeloma

- Multiple myeloma is a plasma-cell malignancy occurring in more than 34,000 people in US annually
- It is responsible for more than 12,600 deaths each year in US alone
- Median age at diagnosis is 69 years, with most patients presenting between the ages of 65 and 74

Percent of new cases by age group



Siegel RL, et al. *CA Cancer J Clin.* 2022;72:7-33. National Cancer Institute (NCI). Cancer Stat Facts: myeloma. 2022 (https://seer.cancer.gov/statfacts/html/mulmy.html).

General Presentation/Identification of MM

Common Characteristics

- Bone pain (often affecting the back)
- Malaise
- Anemia
- Renal insufficiency
- Hypercalcemia
- Bone disease
- Bone marrow infiltration

Differential Diagnosis

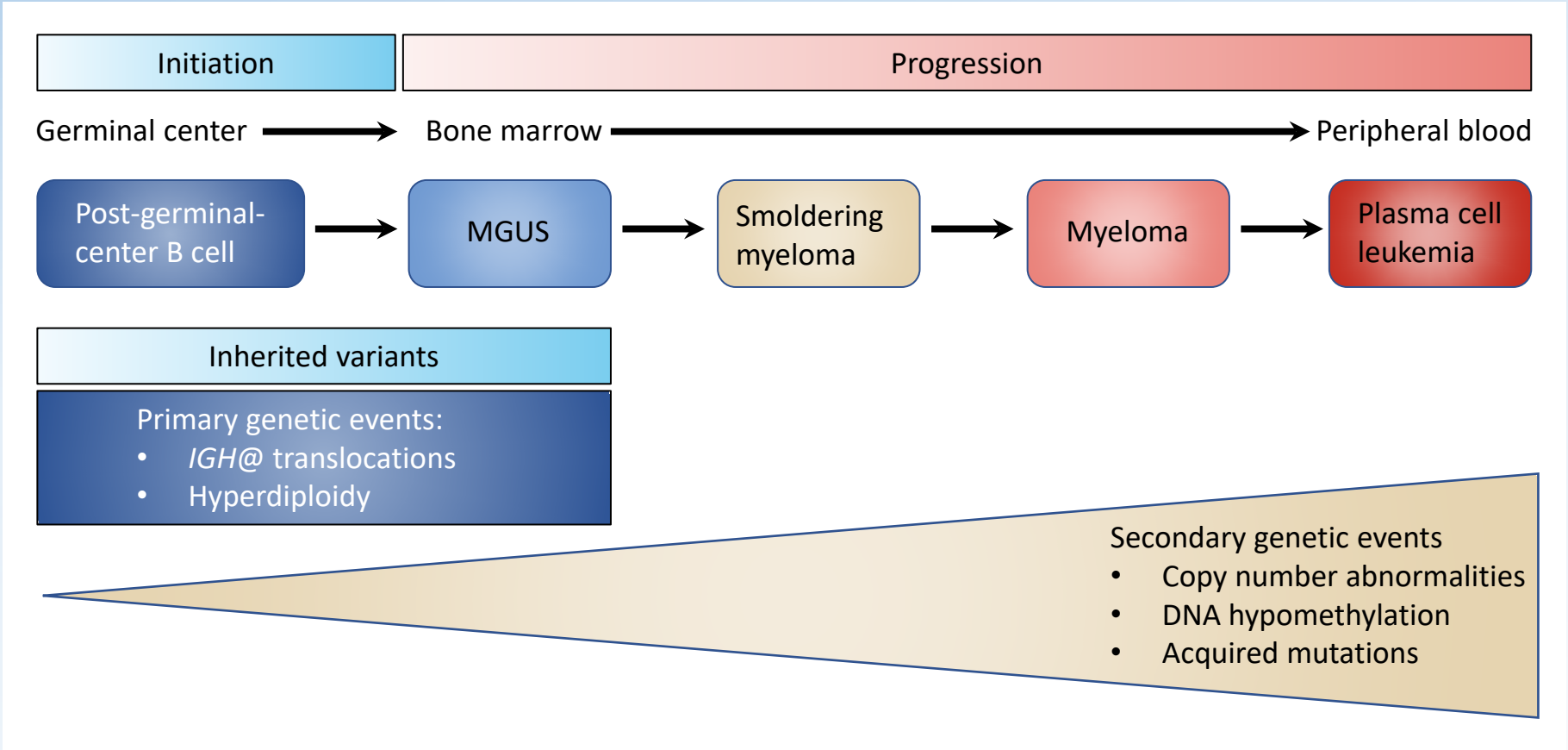
- MGUS
- Smoldering (asymptomatic) and symptomatic MM
- Amyloidosis
- B-cell non-Hodgkin lymphoma
- Waldenstrom macroglobulinemia
- Rare plasma cell leukemia and heavy chain diseases

Incidental discovery on comprehensive laboratory panels is common!

MGUS: monoclonal gammopathy of uncertain significance

Nau K, et al. *Am Fam Physician*. 2008;78(7):853-9.

Multiple Myeloma is a Multi-step Progressive Disease



Morgan, G. et al. *Nat Rev Cancer.* 2012;12(5);335-48. Cohen H, et al. *Am J Med.* 1998;104(5):439-44.

Myeloma Evolution Over the Clinical Course

Short-term

Maximal response

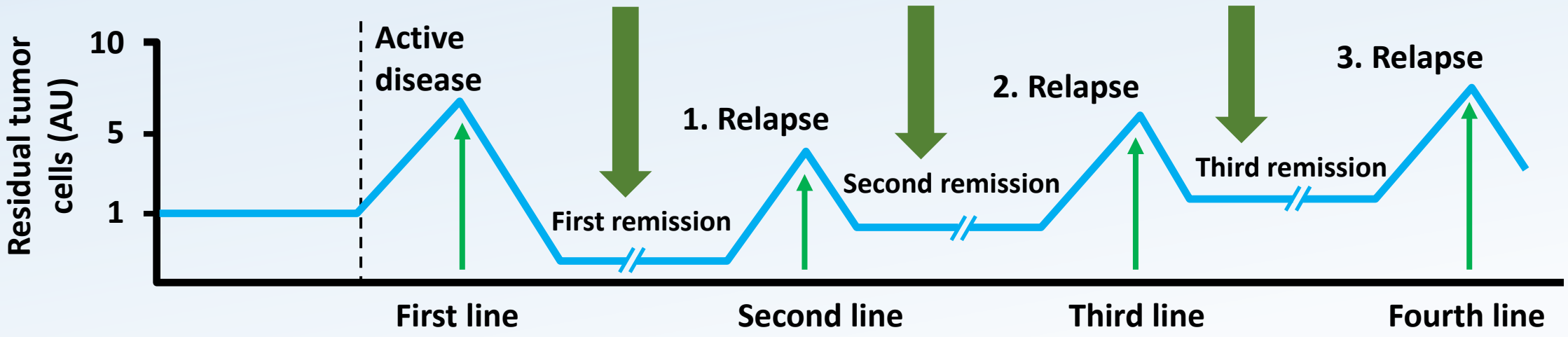
Throughout…

- Limited toxicity
- Maintained QoL

Long-term

Prolonged PFS and OS

Maintain and deepen response with long-term efficacy and QoL



QoL = quality of life; PFS = progression-free survival; OS = overall survival; AU = absorbance unit.

Sonneveld P, et al. *Crit Rev Oncol Hematol.* 2017;112:153-170. Sonneveld P, Broijl A. *Haematologica.* 2016;101:396-406. Guglielmelli T, Palumbo A. *Expert Rev Hematol.* 2015;8:253-256. Borrello I. *Leuk Res.* 2012;36(suppl 1): S3-12.

Disparities in Multiple Myeloma

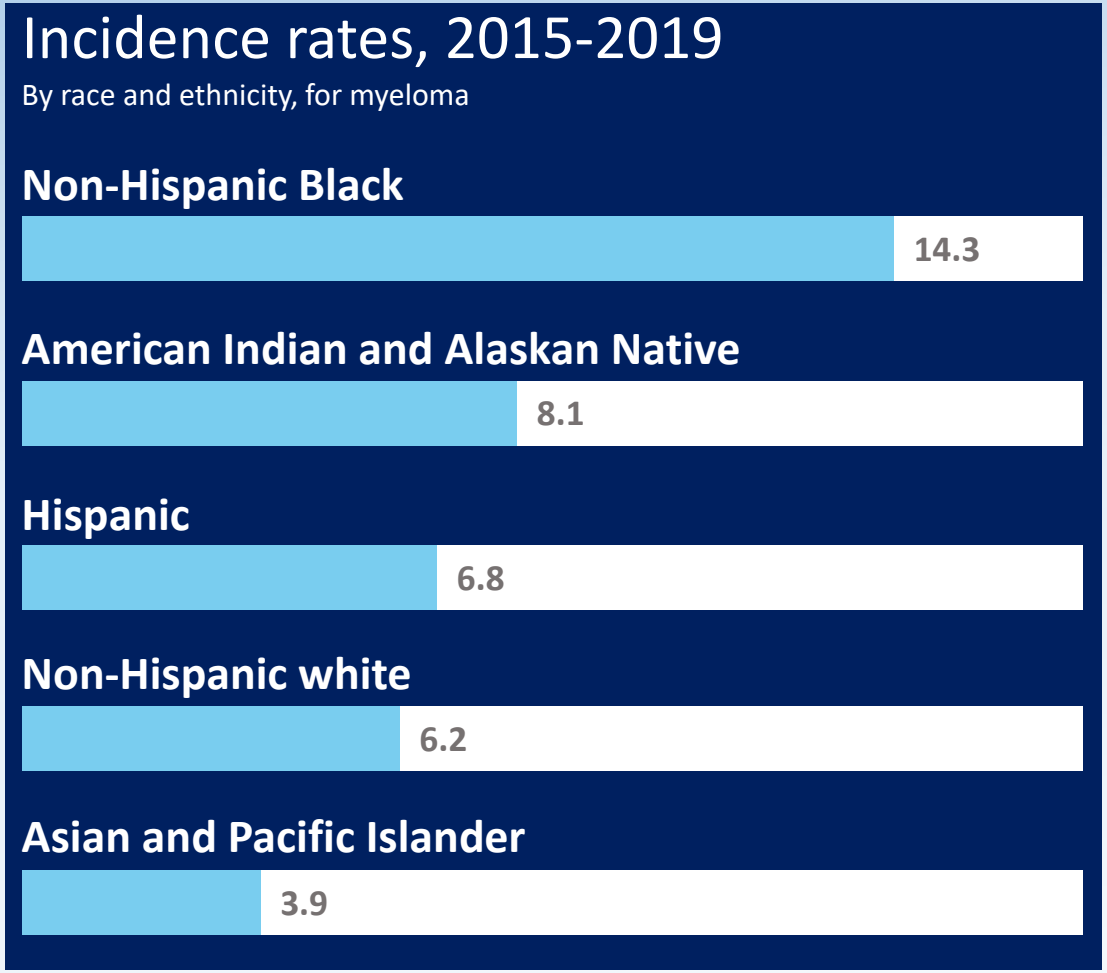
- *Incidence and Death Rates*
- *Age and Cytogenetic Differences*
- *Clinical Presentation*
- *Access to Care*
- *Treatment Patterns and Outcomes*
- *Adverse Drug Events*
- *Costs*

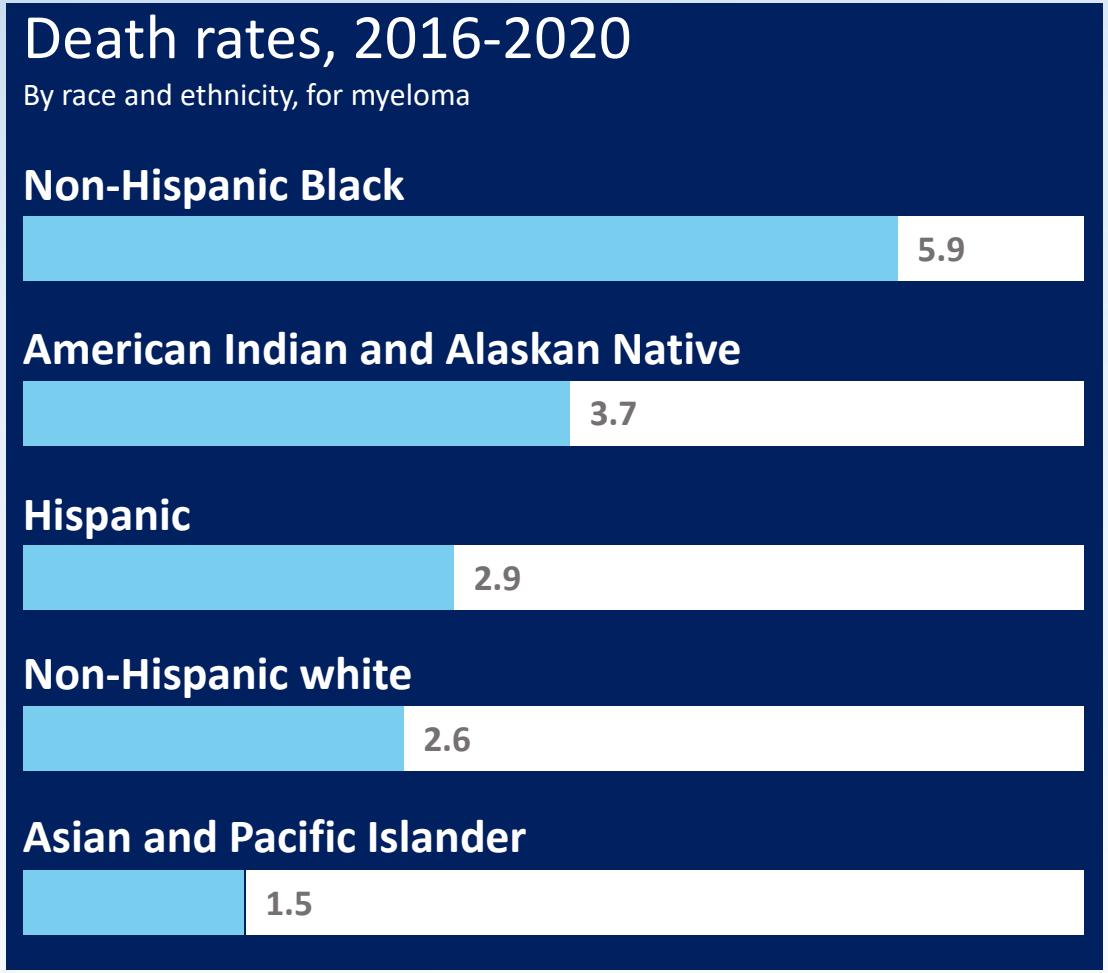
Audience Polling Question

Compared to white patients with multiple myeloma, which of the following is associated with non-white race, as evidenced from clinical data and observations in practice?

1. Lower MM incidence rate; similar MM death rate
2. Lower rates of use of novel agents, but similar use of combination therapy
3. Similar overall and progression-free survival
4. Higher rates of several adverse drug reactions

Incidence and Death Rates of MM by Ethnicity

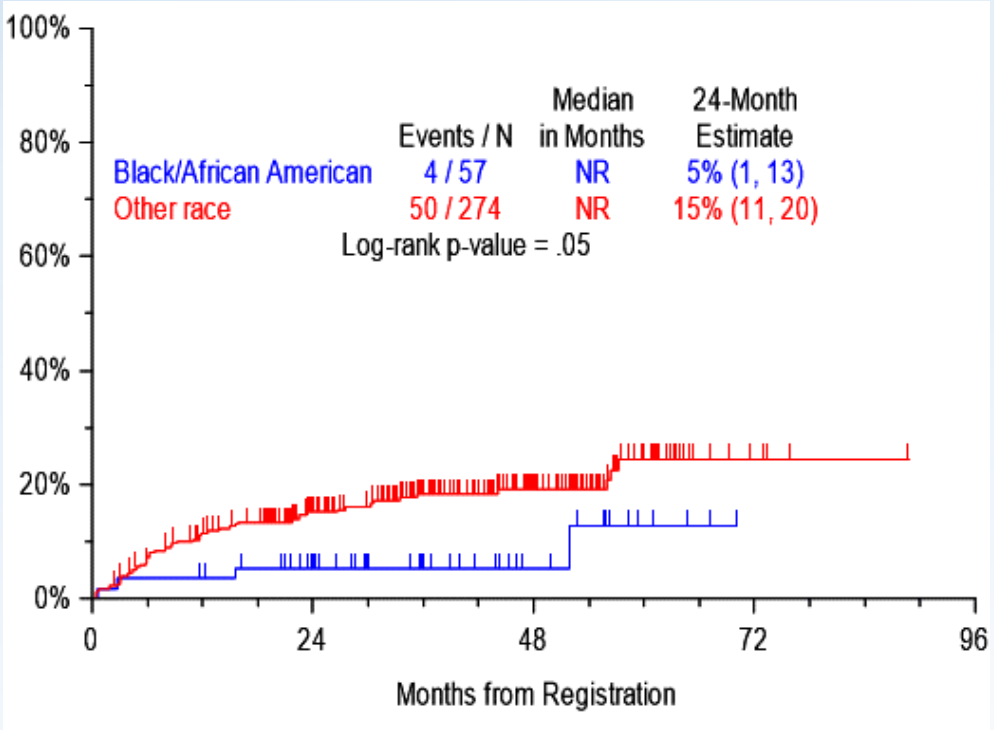




American Cancer Society. *Myeloma*. 2023. Available at: https://cancerstatisticscenter.cancer.org/#!/cancer-site/Myeloma

Racial Disparities in MGUS

- MGUS is detected **twice as frequently in men** compared with women and **3 times more often in patients of African descent**.
- MGUS in Black patients is associated with lower M-protein levels, higher rate of abnormal FLC ratio, younger mean age distribution, and lower IgM gammopathy prevalence.
- Although the prevalence of MGUS is higher in Black patients, the rate of progression to MM is the same.



SWOG S0120*: Race-dependent Differences in Risk of Transformation to Clinical MM

*SWOG S0120 was a US cooperative group prospective, observational clinical trial.

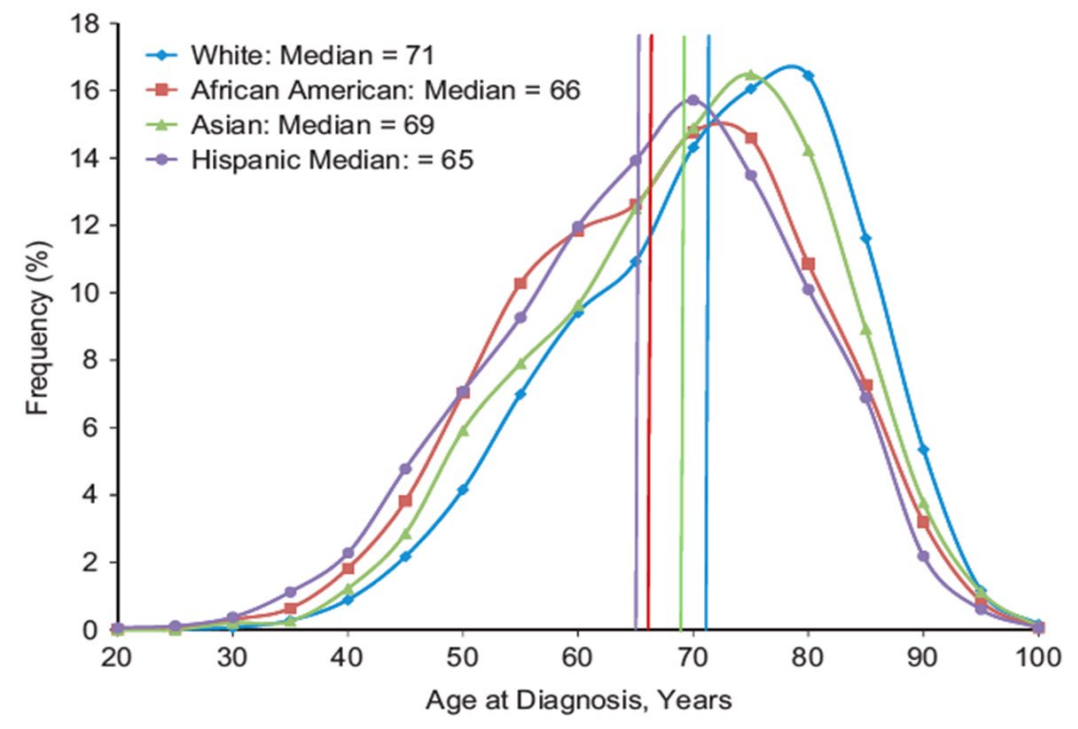
FLC = free light chains

Slide courtesy: Madhav Dhodapkar. Dhodapkar et al. *Clin Can Res. 2020;26:5814-9.*

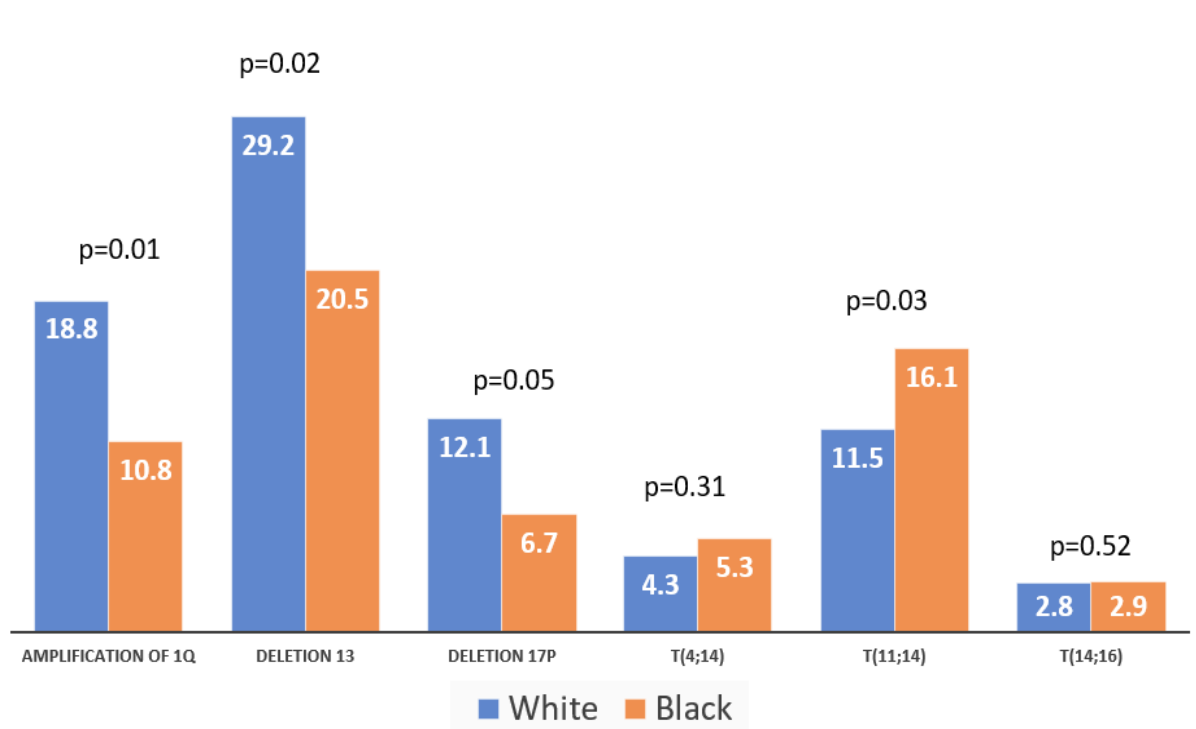
Cohen H, et al. *Am J Med.* 1998;104(5):439-44. Reproduced with permission from CLINICAL CANCER RESEARCH-via Copyright Clearance Center.

MM Racial Disparities in Blacks

Age



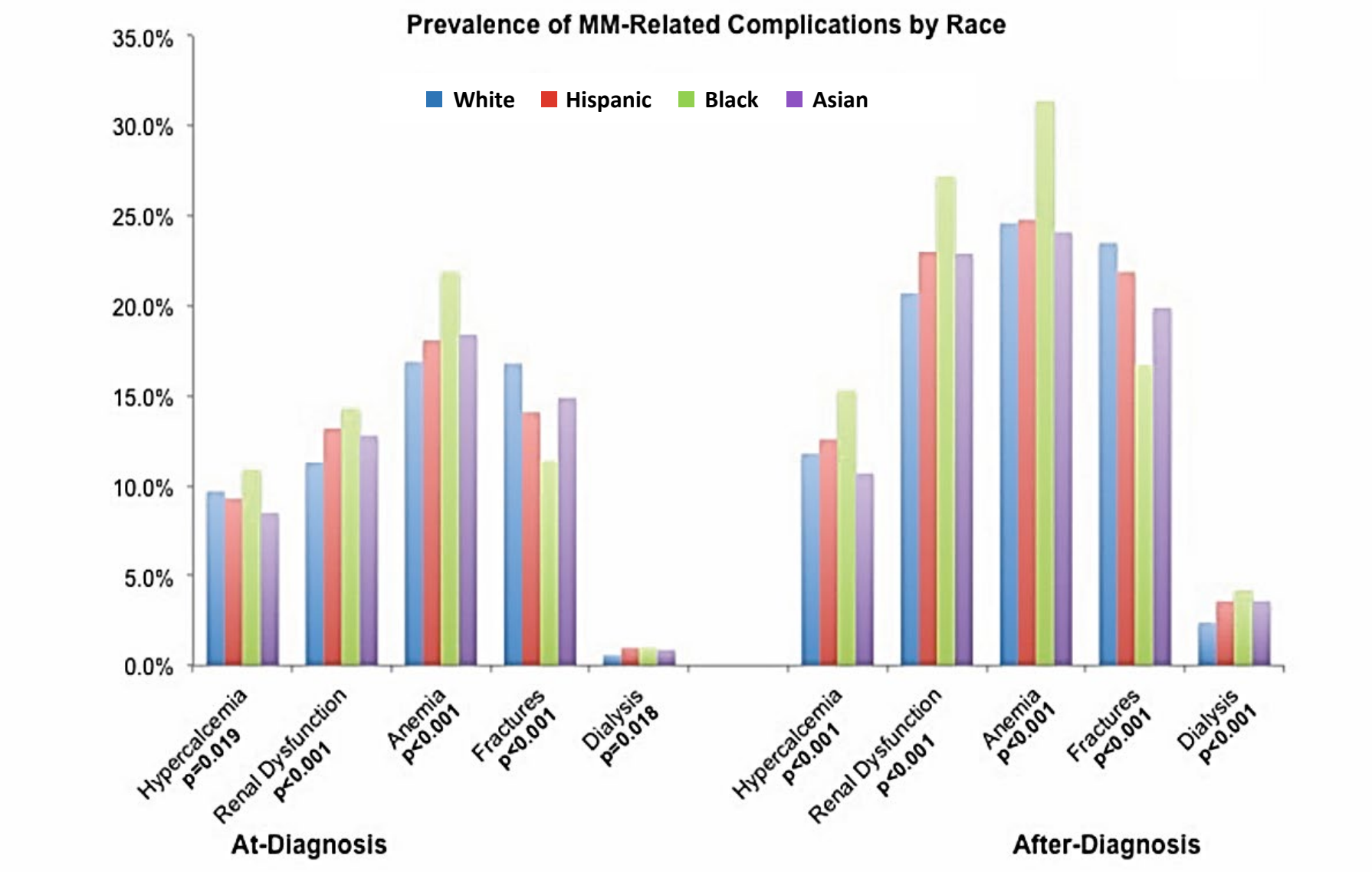
Cytogenetics



Percentage of Cytogenic Abnormalities By Race
(n=1000 patients treated at Emory University, 35% AA)

Ailawadhi S et al. *Br J Haematol*. 2012;158(1):91-8. Reproduced with permission from the BRITISH JOURNAL OF HAEMATOLOGY-via Copyright Clearance Center.
Joseph N. *JCO.* 2020;38(17)1928-37.

Clinical Presentation by Race in MM



Ailawadhi S et al. *Cancer*. 2018;124(8):1710-1721. Reproduced with permission from CANCER-via Copyright Clearance Center.

Access To Treatment

Racial Disparities in Treatment and Access to Care

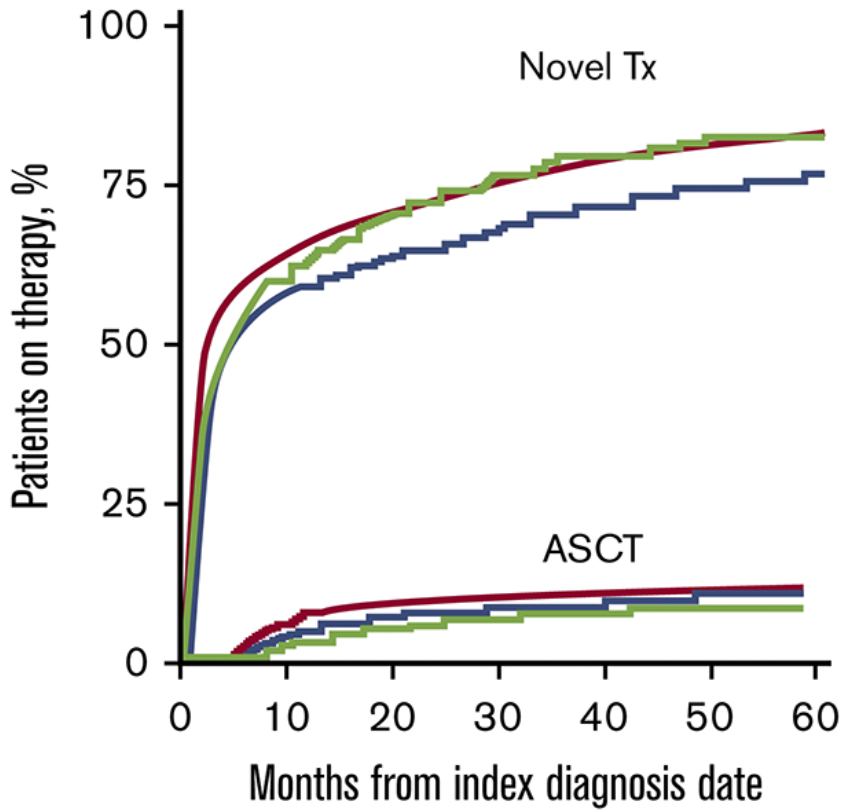
- Treatment with novel agents and use of ASCT has become standard of care for newly diagnosed MM[1]
  - However, racial/ethnic minorities receive these at a lower rate than whites[1,2,3]
- Patients of African descent: fewer transplants; more blood product transfusions; fewer palliative care consults; less inpatient chemotherapy; higher intensive care utilization[4]
- Patients of African descent with MM have the *potential* to experience similar or better survival than white pts[5,6]
- Patients of African descent have similar response rates/survival to white pts when enrolled in clinical trials[7,8]

ASCT, autologous stem cell transplant; SMM, smoldering multiple myeloma.

1: Fiala MA, et al. *Clin Lymphoma Myeloma Leuk.* 2020;20(10):647-651.
2: ASH 2021, Abstract 4118. https://www.myeloma.org/blog/studies-disparities-myeloma-presented-ash
3: ASH 2021, Abstract 566. https://www.myeloma.org/blog/studies-disparities-myeloma-presented-ash
4: Al Hadidi S, et al. *Leuk Lymphoma*. 2021;62(13)3256-63.
5: Marinac CR, et al. *Blood Cancer J* 2020;10(2):19.
6: Joseph N, et al. *JCO.* 2020;38(17):1928-37.
7: Ailawadhi S, et al. *Blood Cancer J* 2018;8(7):67.
8: Ailawadhi S, et al. *Blood Adv* 2019;3(20):2986-2994.

Patient Vignette – Delayed Diagnosis

Racial Disparity in Treatment Patterns: SEER-Medicare Analysis



Cohort	N	Mean age (y)	Mean CCI
White	3,504	75.8	2.2
AA	858	71.8	3.2
HISP	468	72.7	2.7

Novel Tx	Median (months)	Log-rank *P* value (vs White)
White	2.7	–
AA	5.2	<0.001
HISP	4.6	<0.05

ASCT	Median (months)	Log-rank *P* value (vs White)
White	Not reached	–
AA	Not reached	0.08
HISP	Not reached	<0.05

AA, African American; HISP, Hispanic; CCI, Charlson Comorbidity Index; ASCT, autologous stem cell transplant

Racial Differences in Treatment and Outcomes in MM: The CoMMpass Trial Data

Characteristics of MMRF Patients

	White *(n = 526)*	Black *(n = 113)*	*P*-value
Age, median *(range)*	65 (38-89)	63 (34-87)	0.2
Male gender	319 (61%)	69 (61%)	0.9
Induction therapy			0.001
Any triplet	384 (73%)	62 (55%)	<0.001
PI+IMiD triplet	240 (46%)	40 (35%)	0.05
Alkylator-based triplet	144 (27%)	22 (20%)	0.1
Doublet	118 (22%)	46 (41%)	<0.001
Other	24 (5%)	5 (4%)	1
Best response to induction therapy, n	512	109	0.2
<VGPR	290 (57%)	69 (63%)	
≥VGPR	222 (43%)	40 (37%)	
Received triplet + ASCT	231 (44%)	37 (33%)	0.04
Received first line ASCT	260 (49%)	44 (39%)	0.04
+Post-ASCT maintenance	157 (60%)	26 (59%)	0.9

Derman B, et al. *Blood Cancer J*. 2020;10(8):80. MMRF = Multiple Myeloma Research Foundation

Racial Differences in Treatment and Outcomes in MM: The CoMMpass Trial Data

OS by Race

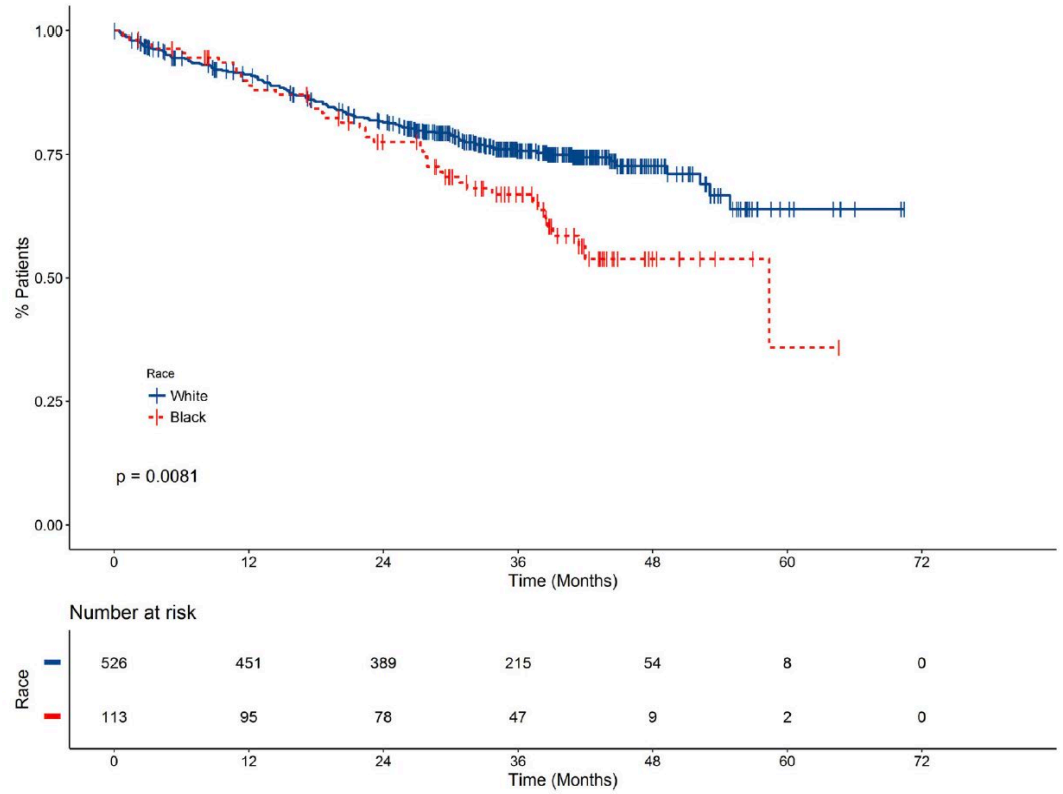


Fig. 1 Overall survival stratified By race. Overall survival was shorter for Blacks compared with Whites, with an age-adjusted hazard ratio of 1.7 (95% confidence interval 1.2–2.4, $p = 0.003$).

OS by Race For Those Receiving Triplet Therapy

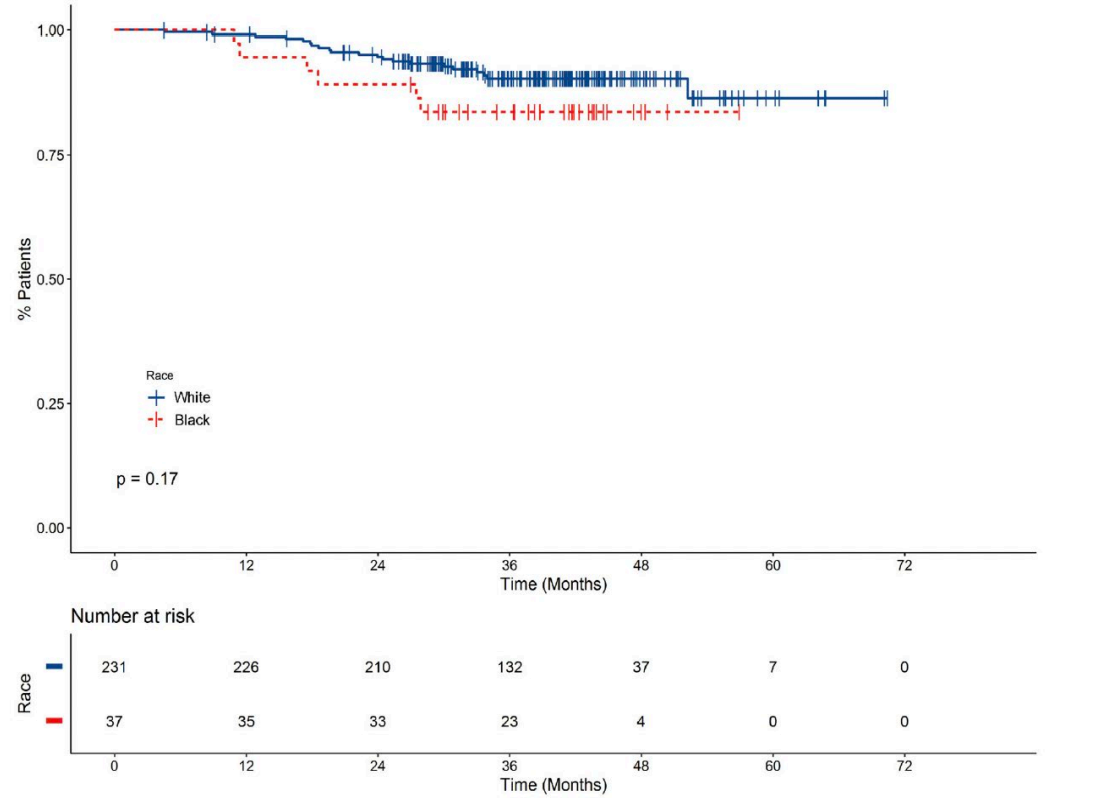
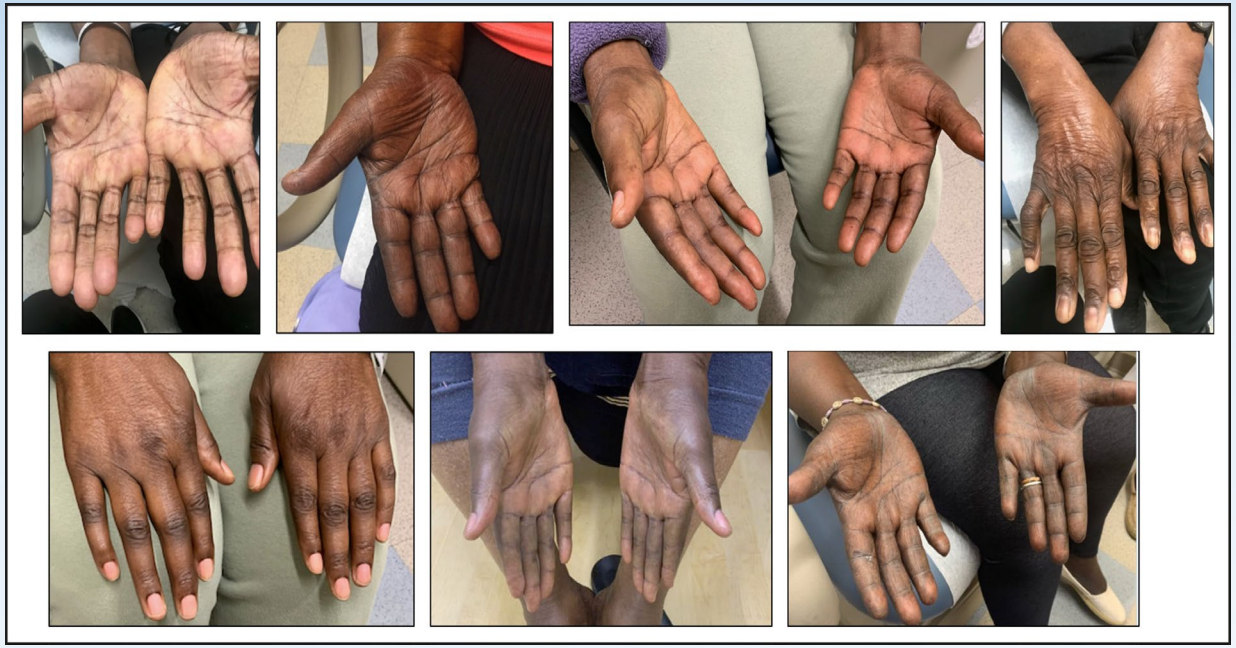


Fig. 2 Overall survival of patients receiving triplet therapy and autologous transplant stratified by race. The difference in OS between races was partly attenuated in patients receiving triplet therapy and autologous stem cell transplant.

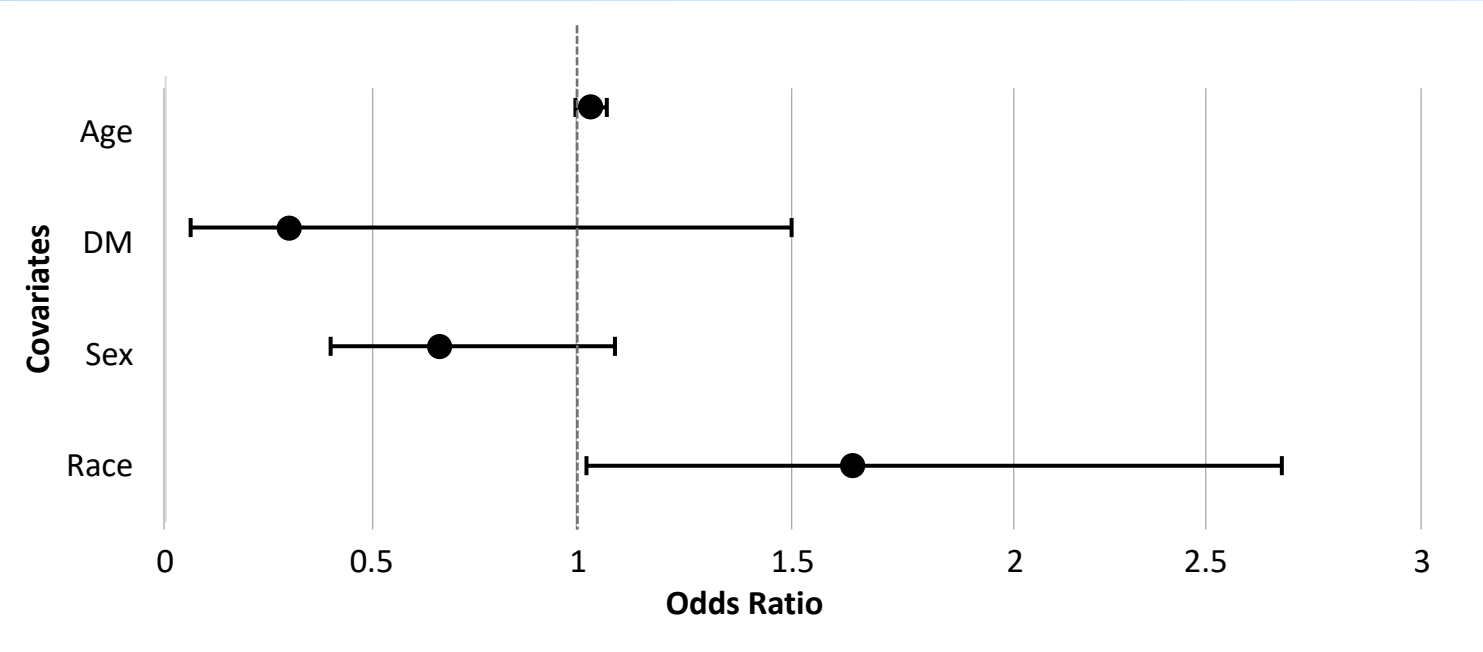
Adverse Drug Events

Skin Hyperpigmentation in Black Patients Receiving Treatment with Immunomodulatory Drugs



Milrod C, et al. *Blood*. 2021;137(21):2987-9. Milrod C, et al. *Crit Rev Oncol Hematol*. 2022;172:103644.

Black Patients: Risk Factor for Peripheral Neuropathy w/ Bortezomib Induction in Newly Diagnosed MM



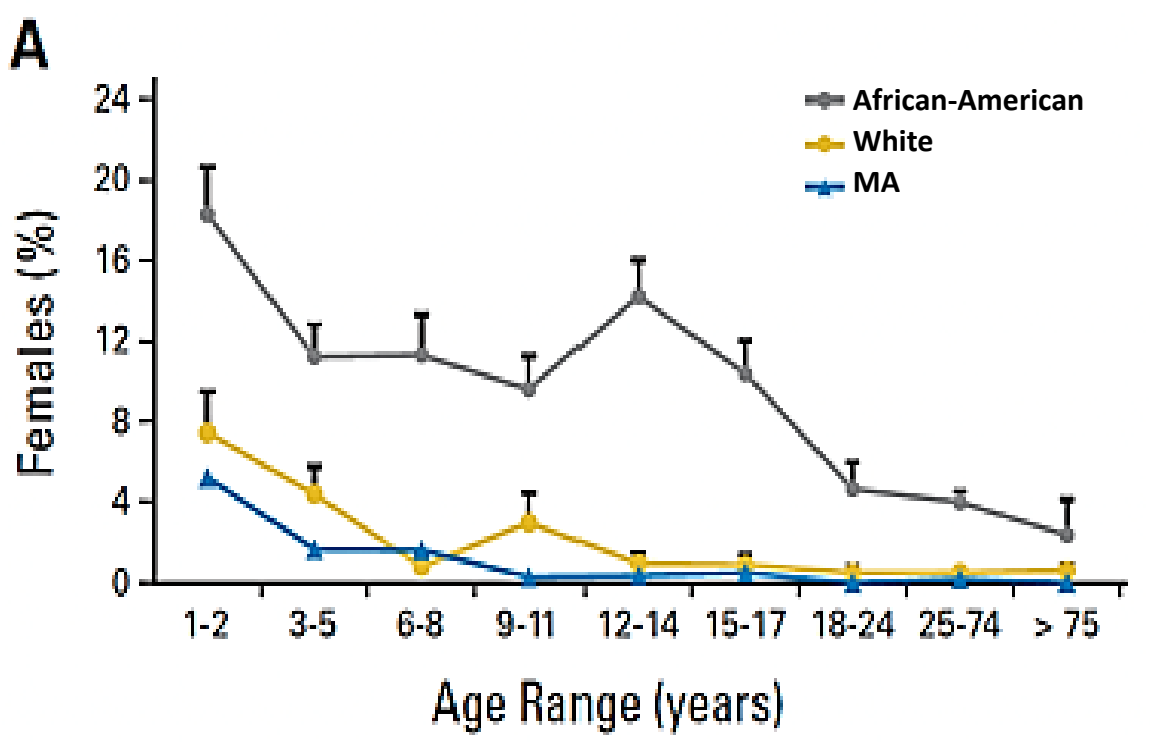
Impact of age, pre-existing DM diagnosis, sex and race on risk of BIPN using multivariate logistic regression model.

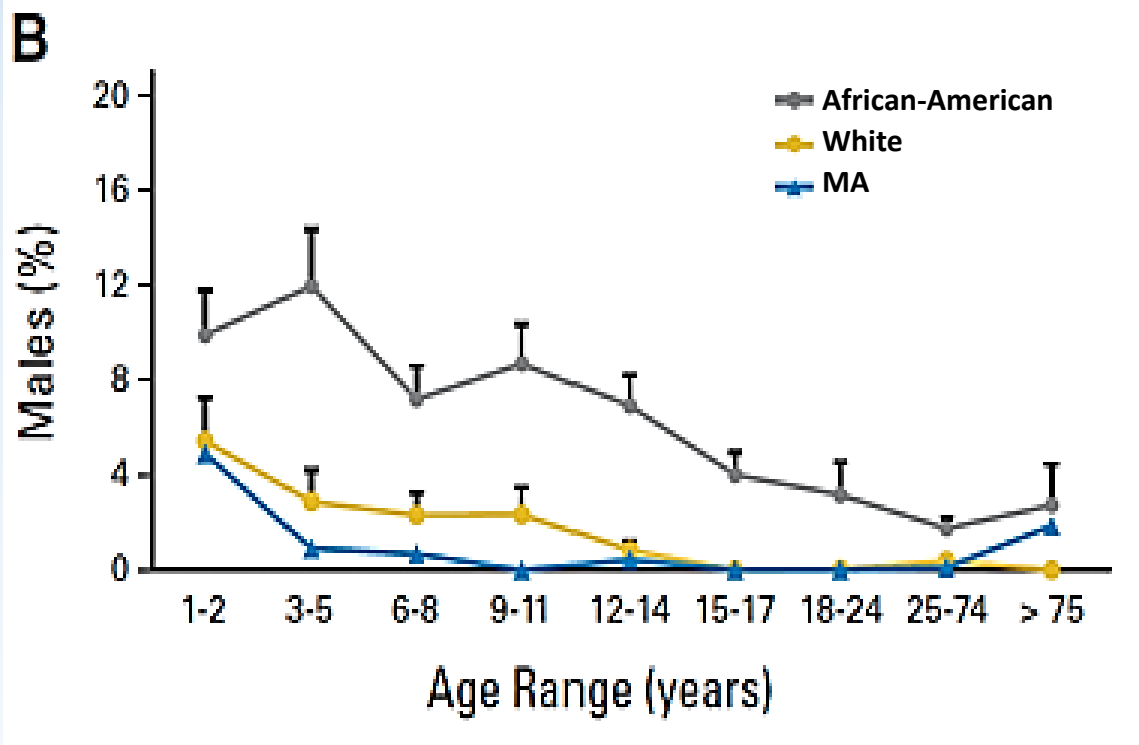
Odds ratios (ORs) and 95% confidence intervals for risk of BIPN (bortezomib-induced peripheral neuropathy with age, pre-existing DM diagnosis, seax and race using multivariate logistic regression model are shown. ORs for AA patients were compared to non-AA patients; patients with pre-existing DM diagnosis were compared to those without; male were compared to female patients. A significant increased risk of BIPN was observed in AA patients. In contrast, no statistically significant risk for BIPN was observed with other covariates.

Sun L, et al. *Blood.* 2022;140(Supplement 1):7131–2.

Neutrophil Count in African-Americans

Percent of Female and Male Participants with Neutrophil Count <1.5x10^9 cells/L in NHANES 1999-2004





Racial Disparity in Cost of Care: Healthcare Resource Utilization

Black patients have more MM complications and need more focused care:

- Baseline neutropenia
- Higher utilization of healthcare resources
- Delays in diagnosis
- More blood transfusions/anemia

ASH 2022 Study - higher financial toxicity for:

- African Americans
- No college education
- Lower SES
- Private insurance
- Oral/no treatment (vs IV)

SES = socioeconomic status

Silberstein A, et al. *Blood*. 2021;138(suppl 1);4027.

MM Racial Disparities in Blacks

- Difference in biology
  - Diagnosed 5 years younger
  - More likely to have standard risk cytogenetics and less likely to have high risk cytogenetic feature (del17)
  - 10% of Blacks over age of 40 have MGUS
- Racial/socioeconomic status
  - Higher financial toxicity, food and housing insecurities and lack of trust in health care system
  - Black patients withhold information such as side-effects to white providers
  - Most are more comfortable sharing with Black staff to whom they relate
- Access to Innovative treatment
  - Less likely to get triplet therapy, transplants, access to innovative clinical trials and CAR T-cell therapies

International Myeloma Foundation. Available at: https://www.myeloma.org/IMF-Diversity-Equity-Inclusion-Policy/disparities-african-americans#:~:text=In%20the%20U.S.%2C%20African%20Americans,will%20be%20of%20African%20descent accessed 1/22/23.

Audience Polling Question

Compared to white patients with multiple myeloma, which of the following is associated with non-white race, as evidenced from clinical data and observations in practice?

1. Lower MM incidence rate; similar MM death rate
2. Lower rates of use of novel agents, but similar use of combination therapy
3. Similar overall and progression-free survival
4. Higher rates of several adverse drug reactions

Overcoming Healthcare Disparities in Multiple Myeloma and Improving Access to Care

What Affects Access to Treatment in MM?

Patient Factors:

- Age
- Comorbidities
- Gender
- Year/Period of Diagnosis

Socioeconomic Factors:

- Race/Ethnicity
- Health Insurance
- Geographical Location
- Socioeconomic Status
- Access to Healthcare

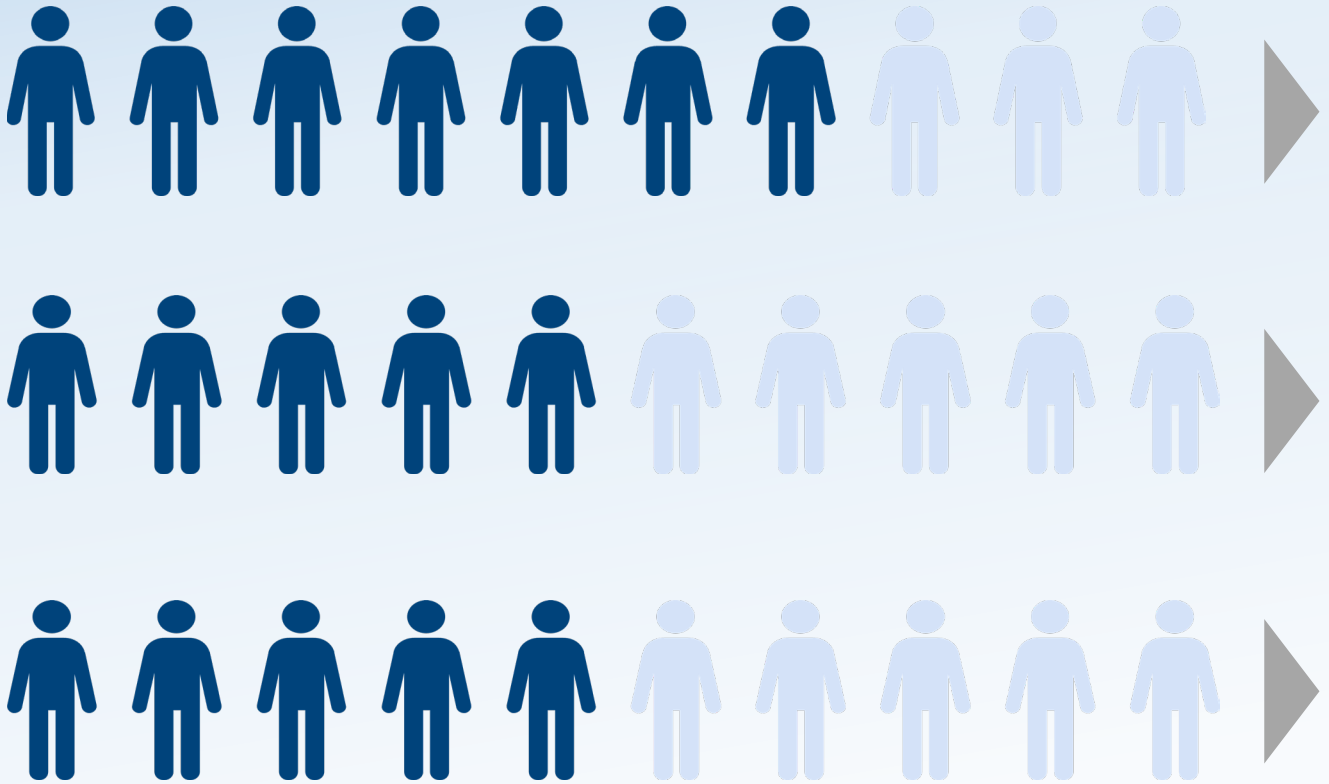
Disease Factors:

- Disease Stage
- Prognostic Risk Category
- Presence of Kidney Dysfunction
- Presence of Bone Disease
- Associated Amyloidosis
- Disease Subtype

Ganguly S, et al. *ASCO Educ Book*. 2019;39:519-29.

Boston Medical Center (BMC)

Our Patient Population is Racially, Culturally, and Linguistically Diverse: Promotion of Health Equity is Imperative



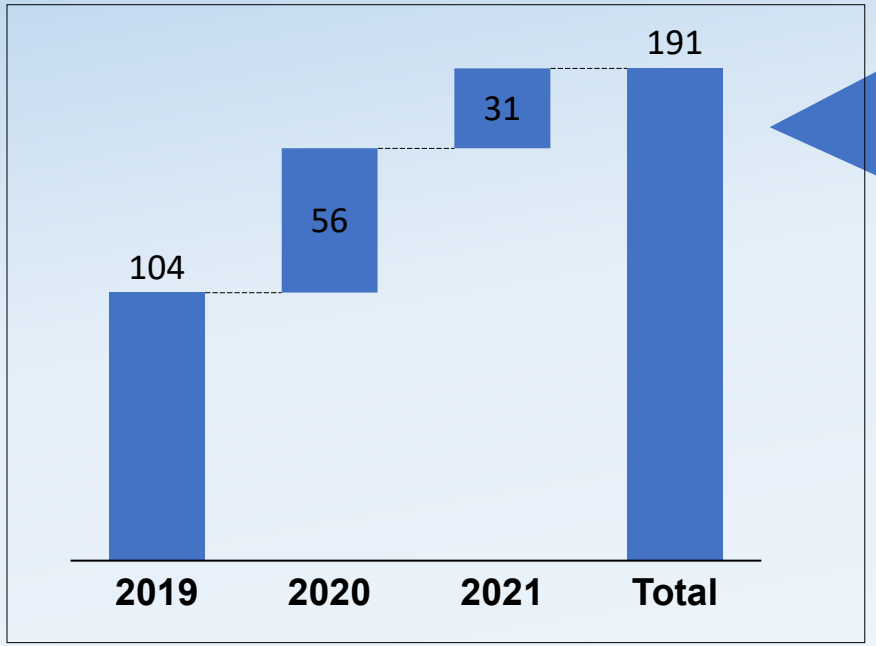
~70% of our hospital patients identify as **people of color**

~50% of our hospital patients live at or **below the federal poverty level**

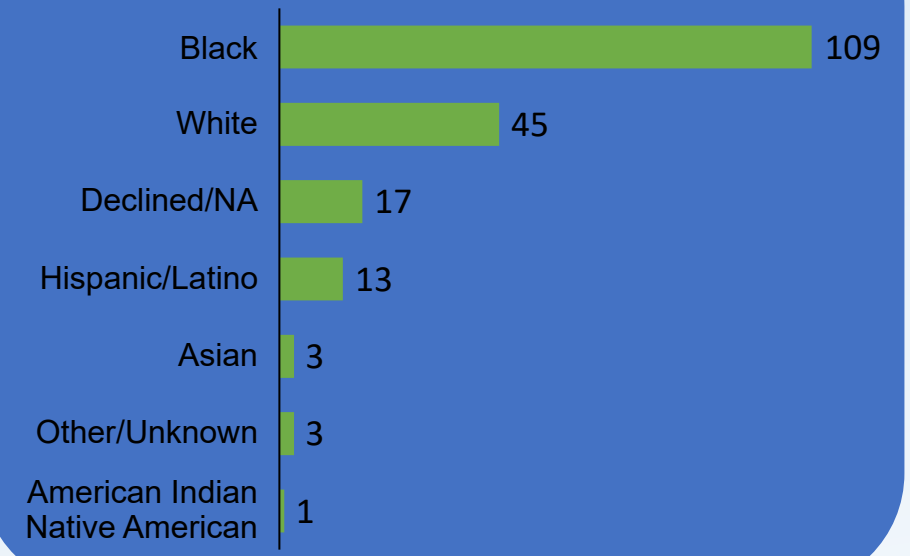
~50% of our Health Plan members have a **mental health and/or substance use disorder**

Among 191 MM Patients Seen at BMC Since 2019, >66% Are From Ethnic Minority Groups; >50% are Black

Unique Multiple Myeloma Patients Seen Across BMC
2019/1/1-2021/8/31, n=191



BMC Multiple Myeloma Patients by Race
2019/1/1-2021/8/31, n=191[1]



Multiple Myeloma Patients Seen at Hematology Department by Year
2019/1/1-2021/8/31, n=191

Year	Established Patients	New Patients	Total
2019	27	12	39
2020	18	18	36
2021	9	8	17

BMC EHR Data; patients identified by first time cancer diagnosis code is dropped in relevant department; 8 months data included for 2021. BMC = Boston Medical Center

Screening/Intervention for Social Determinants of Health in MM

Housing

Food

Medications

Transportation

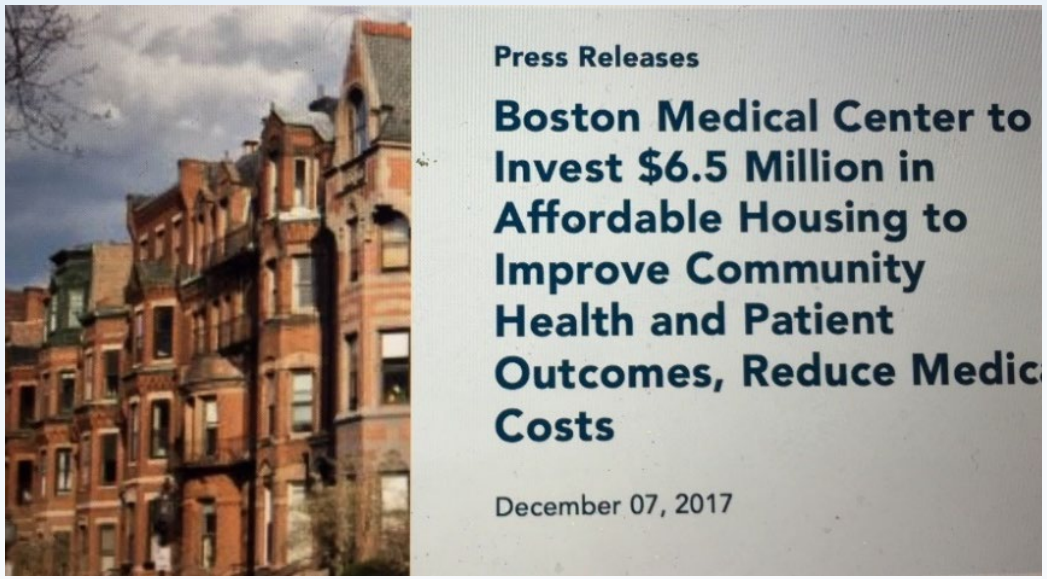
Utilities

Child or Adult Care

Employment

Education

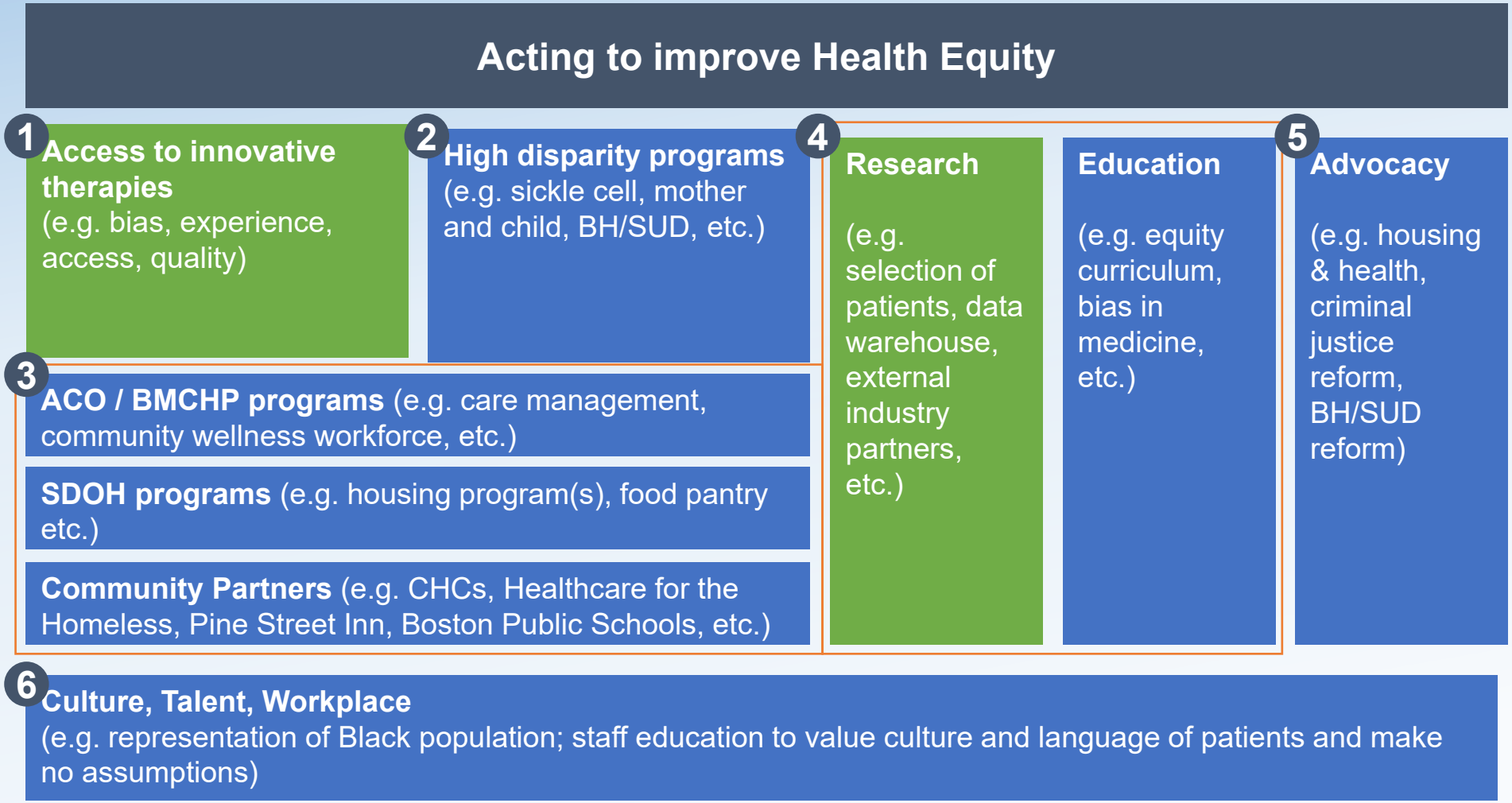
BMC Rooftop Farm



Date range: Sep 2017 to March 2021

Patient Vignette – Support Groups

Case Example:
Boston Medical Center's Mission of Improving Health Equity



BH/SUD = behavioral health/substance use disorder; CHC = community health center; SDOH = social determinant of health

How Can Pharmaceutical Companies Help Overcome Barriers to Health Care Access

- Prioritize access to innovative clinical trials with top racial inclusivity ranked institutions for research
- Develop patient support programs around social determinants of health for MM
- Work with providers on innovative population health projects to improve education, access to early diagnostics and timely connection in care with specialists for patients in underserved communities

TOP 50 HOSPITALS, RACIAL INCLUSIVITY

RANK	HOSPITAL
1	Metropolitan Hospital Center New York, NY
2	Boston Medical Center Corporation Boston, MA
3	St. Charles Madras Madras, OR
4	Newark Beth Israel Medical Center Newark, NJ
5	Little Colorado Medical Center Winslow, AZ

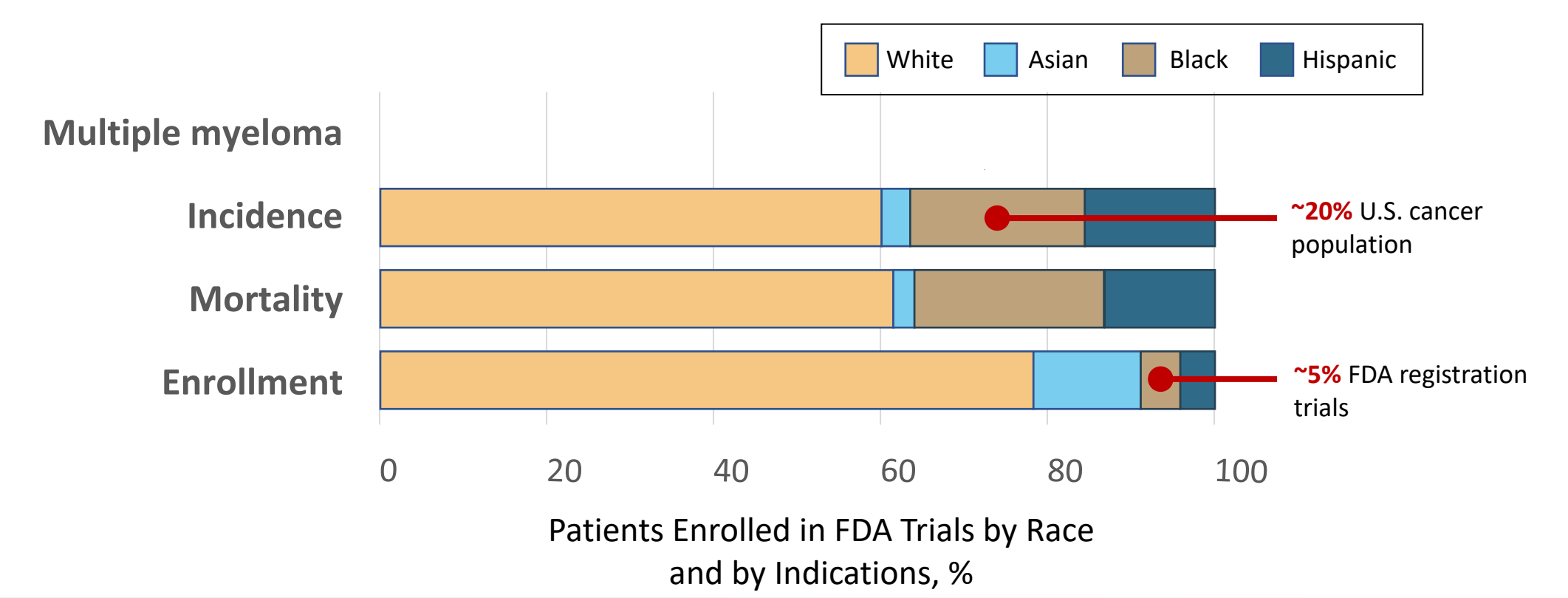
Underrepresentation of Black Patients with MM in Clinical Trials

Audience Polling Question

Which of the following statements is true?

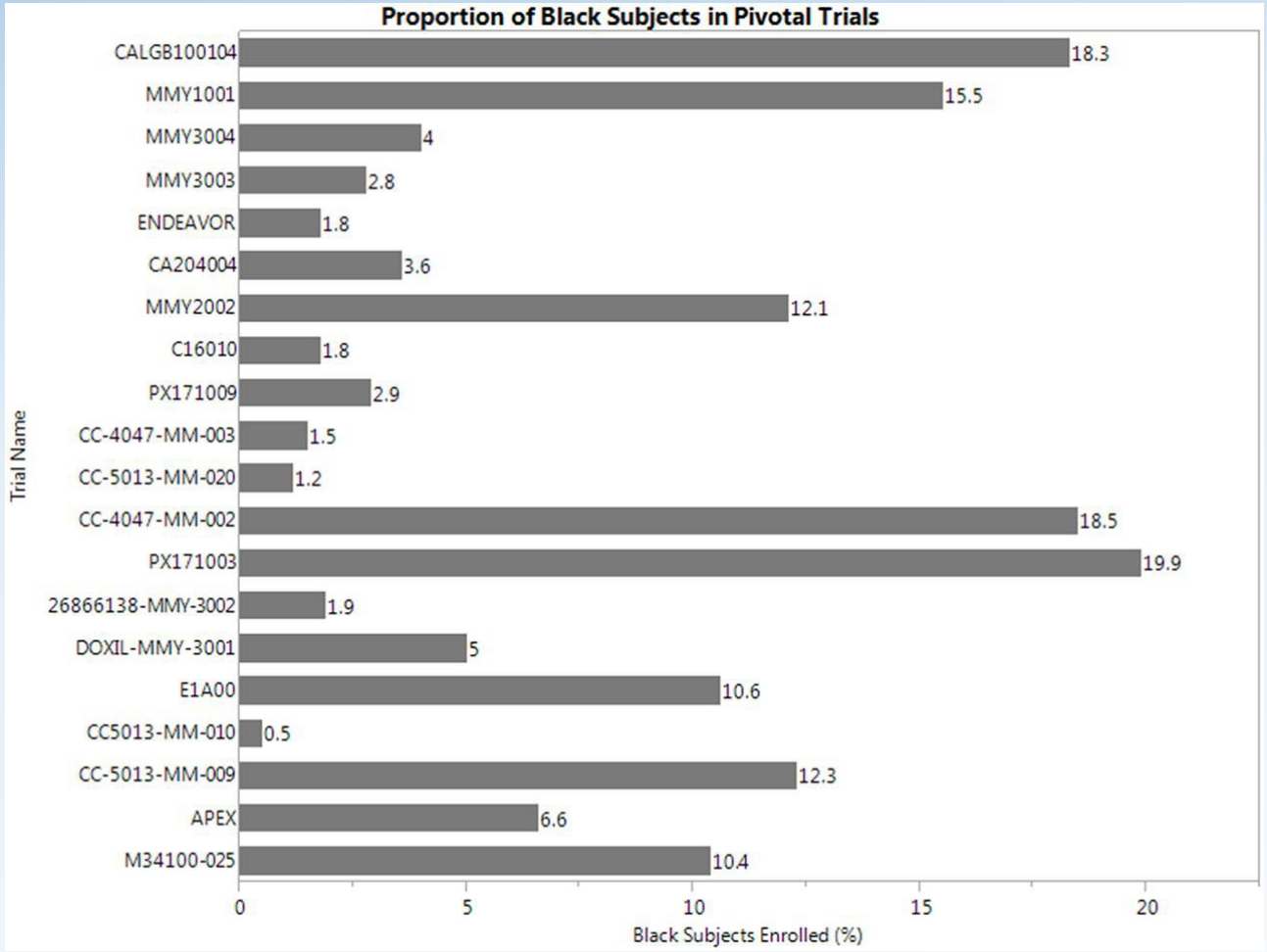
1. Blacks represent around 20% of the population enrolled in MM clinical trials
2. Blacks represent 20% of the MM population, but only 5% of clinical trial enrollment
3. Enrollment of Blacks in drug trials submitted to the FDA is generally representative of the population affected by MM

Realities of Clinical Trial Enrollment



Loree JM et al. *JAMA Oncol.* 2019;5(10):e191870.

FDA Analysis of Racial Demographics in MM Trials

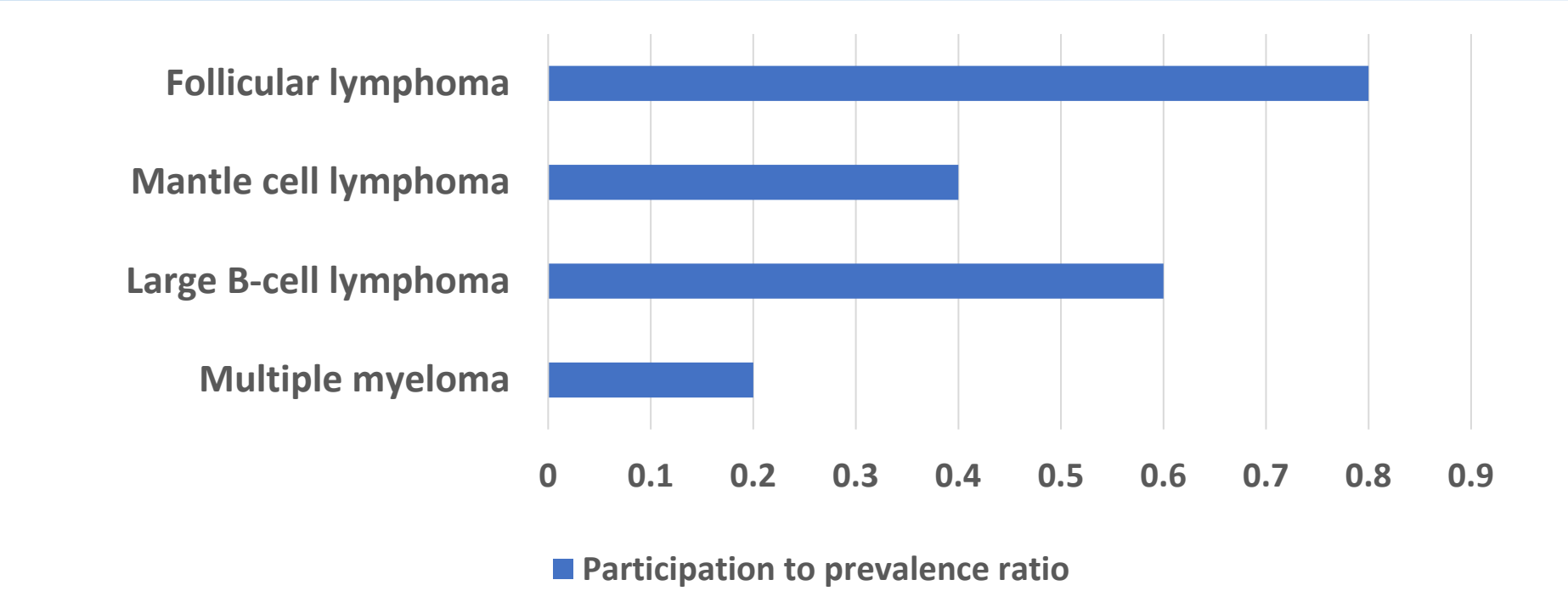


- The median percentage of Blacks enrolled in pivotal MM cinical trials was 4.5% while Black patients represent 20% of the MM population
- Enrollment of Black subjects in pivotal trials submitted for U.S. regulatory approval is not representative of the population affected by MM
- UK Study: Ethnic distribution across 5 RCTs over 18 yrs:
  - White: 93.8%
  - Black: 2.2%
  - Asian 1.8%
  - Other/unknown: 2.2%

Bhatnager V, et al. *Blood.* 2017;130(Suppl 1):4352. Popat R, et al. *Blood*. 2021;138(suppl 1):4118.

Enrollment of Blacks in Pivotal Clinical Trials of CAR–T Therapy for Hematological Malignant Neoplasms

Participation to Prevalence Ratio of Blacks Enrolled in Clinical Trials of CAR-T Cell Therapy in Various Hematological Malignant Neoplasms



Al Hadidi S, et al. *JAMA Netw Open*. 2022;5(4):e228161.

FDA Analysis of Racial Demographics in MM Trials

2014 SEER data: Blacks represent 20% of MM population.
In MM trials, the median % of Blacks was only 4.5%.

Enrollment of Black subjects in trials is <u>not</u> representative of the population affected by MM!

Benefits of increasing enrollment of Black subjects:

- Improved access to novel therapies for underserved
- Trials would be more representative of the US population
- Further understanding of MM disease biology in Black patients
- Identify molecular subtypes that could be targeted by established or novel drugs
- Identification of potential race-associated side effects

Bhatnager V, et al. *Blood*. 2017;130(Suppl 1):4352.

Patient Vignette – Clinical Trial Participation

Barriers to Clinical Trial Enrollment

- Trial Issues:
  - Eligibility criteria
  - Site selection
  - Geographic access
  - Clinicians not asking patients
- Social/Cultural Issues:
  - Social support
  - Cultural sensitivities
  - Uncertainty about risk may reduce patient willingness to participate
  - Structural racism
  - Broken down by fear of past injustices
- Financial Issues:
  - Routine care costs (copayments, coinsurance, deductibles)
  - Time away from work
  - Lodging, meals, dependent care, and transportation burden
  - Unknown adverse effects of investigational agent and resulting expenses (e.g., supportive care medications, urgent care visits, hospitalizations)

Nipp RD et al. *Am Soc Clin Oncol Educ Book*. 2019;39:105-114

Potential Solutions

- Overcoming Trial Issues:
  - Broaden eligibility criteria
  - Include trial design/study plan to encompass disease subtypes commonly seen in Blacks
  - Appoint a diversity officer for local trial site operations
  - Enhance role of patient navigators in improving enrollment
  - Need consistent staff education on valuing different ethnicities in relation to their culture
  - Focus on effective communication with all medical staff; take a team-based approach and patient-centered focus

- Overcoming Social/Cultural Issues:
  - Establish strong patient/doctor relationships by acknowledging and addressing patient concerns
  - Forge partnerships through outreach to include social groups not traditionally approached for trial enrollment (e.g., churches, medical societies, etc.)
  - Engage with patient advocacy groups.
  - Have patients share trial experiences with others to help alleviate fears/concerns
  - Develop programs that make resources available to support clinical trial infrastructure in locations that are race/ethnicity rich

Gormley N et al. *Blood Cancer Discov.* 2021;2:119–24
Nipp RD et al. *Am Soc Clin Oncol Educ Book*. 2019;39:105-114

Potential Solutions

- Overcoming Financial Concerns:
  - Clarify definitions of routine care costs
  - Provide patients with clear and transparent information about potential trial-related financial burden along with resources to help
  - Allow for ethically appropriate financial assistance for trial-related expenses
  - Conduct additional research to help recognize and address the financial burden of clinical trials

Gormley N et al. *Blood Cancer Discov.* 2021;2:119–24
Nipp RD et al. *Am Soc Clin Oncol Educ Book*. 2019;39:105-114

Integration of BCMA-targeted Therapies in Underrepresented Populations

BCMA-Targeted Therapies for MM

Myeloma cell

BCMA

Antibody-drug conjugates

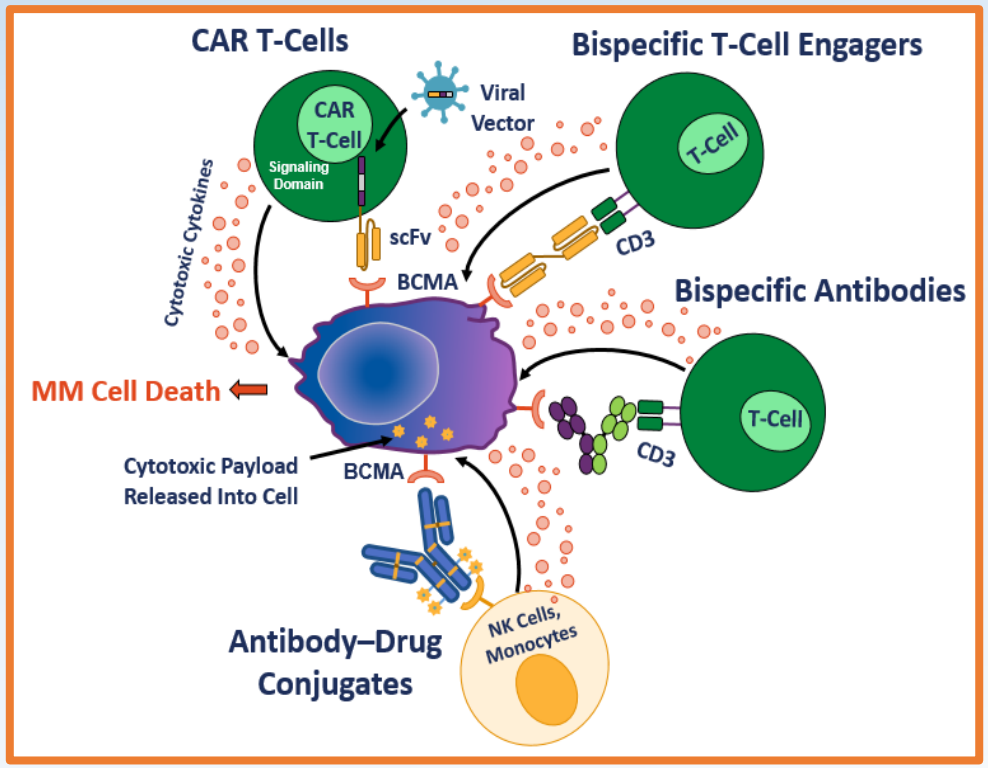
Belantamab mafodotin (discontinued)
MEDI2228*
CC-99712

Bispecific antibodies/BiTEs

Teclistamab
Elranatamab
Linvoseltamab (REGN5458)
Pavurutamab (discontinued)
Alnuctamab (cc-93269)
TNB-383B
RO7297089

CAR-T therapies

Idecabtagene vicleucel
Ciltacabtagene autoleucel
Orvacabtagene autoleucel*
Zevorcabtagene autoleucel (CT053)
ALLO-715
bb21217*
P-BCMA-101*
P-BCMA-ALLO1
CT103A
C-CAR088
PHE885
CART-ddBCMA



*Development halted.

BiTEs = bispecific T-cell engagers.

Progress in AA Enrollment in BCMA and Newer Targeting Agents Trials

Characteristics of the Patients at Baseline

Characteristic	Phase 1 (N=29)	Phase 2 (N=68)	Total (N=97)
Median age, years	60 (57 -67)	62 (55-70)	61 (56-68)
Sex			
Male	14 (48%)	43 (63%)	57 (59%)
Female	15 (52%)	25 (37%)	40 (41%)
Race			
White	20 (69%)	49 (72%)	69 (71%)
Black or African American	5 (17%)	12 (18%)	17 (18%)
Asian	1 (3%)	0	1 (1%)
American Indian or Alaska Native	1 (3%)	0	1 (1%)
Native Hawaiian or other Pacific Islander	0	1 (1%)	1 (1%)
Not Reported	1 (7%)	6 (9%)	8 (8%)

Cilta-Cel

Characteristic	Phase 1 (N=40)	Phase 2 (N=125)	Total (N=165)
Age			
Median (range) – years	62.5 (39-84%)	64 (33-83%)	64 (33-84%)
≥75 yr	5 (12.5%)	19 (15.2%)	24 (14.5%)
Sex			
Male	26 (65%)	70 (56%)	96 (58.2%)
Female	14 (35%)	55 (44%)	69 (41.8%)
Race			
White	34 (85%)	100 (80%)	134 (81.2%)
Black or African American	1 (2.5%)	20 (16%)	21 (12.7%)
Asian	0	3 (2.4%)	3 (1.8%)
Other	5 (12.5%)	2 (1.6%)	7 (4.2%)

Teclistamab

Characteristic	Subcutaneous Talquetamab, 405 µg Weekly (N=30)	Subcutaneous Talquetamab, 800 µg Every 2 Weeks (N=44)	Subcutaneous Talquetamab, All Doses (N=130)	Subcutaneous Talquetamab, All Doses (N=102)
Age				
Median (range) – years	62 (46-80%)	64 (47-84%)	64 (39-84%)	65 (33-79%)
≥75 yr	7 (23%)	15 (34%)	37 (28%)	32 (31%)
Sex				
Male	19 (63%)	21 (48%)	75 (58%)	57 (56%)
Female	11 (37%)	23 (52%)	55 (42%)	45 (44%)
Race				
White	25 (83%)	35 (80%)	107 (82%)	82 (80%)
Black or African American	4 (13%)	4 (9%)	13 (10%)	14 (14%)
Asian	0	3 (7%)	4 (3%)	2 (2%)
Other	1 (3%)	2 (5%)	6 (5%)	4 (4%)

Talquetamab

Moreau P, et al. *N Engl J Med*. 2022;387(6):495-505. Berdeja J, et al. *Lancet*. 2021;398(10297):314-24. Chari A, et al. *N Engl J Med*. 2022;387(24):2232-44.

Audience Polling Question

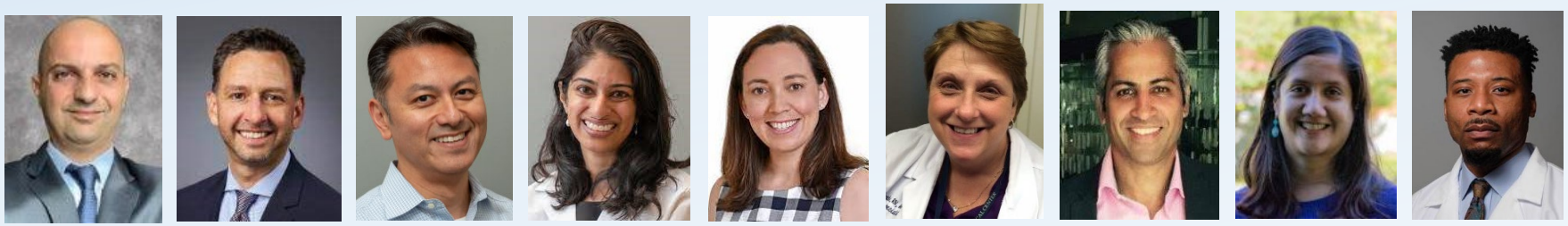
Which of the following would be a good proposition for overcoming racial disparities in multiple myeloma care?

1. Implement a “one-size-fits-all” program to standardize how to effectively communicate with minorities
2. Broaden the number of health care workers involved in the treatment of a given patient
3. Narrow clinical trial eligibility criteria
4. None of the above

A Coordinated Multidisciplinary Approach for MM Care

Boston Medical Center's CAR-T Program

- Oncology
- Critical Care
- Neurology
- Oncology Clinical Nursing
- Pharmacy
- Laboratory /Apheresis



The Multidisciplinary Clinical team provides integrated care between **hematology, critical care, neurology, cardiology, pharmacy and emergency department** with dedicated **social work and patient navigator** support

This program will become an **integral part of the Boston cell therapy development ecosystem**; consolidate the clinical program and **build translational research capabilities** to advance new cell therapy product concepts into clinical testing

Summary

- Disparities along racial lines exist due, in part, to differences in biology, socioeconomic status, and healthcare access
- Adverse drug reactions can often occur along racial lines; hyperpigmentation and peripheral neuropathy are two that more frequently affect Blacks
- Overcoming barriers to clinical trial enrollment include addressing trial, financial, social/cultural issues
- Enhanced care of MM across races requires:
  - Recognition of racial disparities
  - Care that is tailored to a specific race or culture
  - A coordinated multidisciplinary approach
  - Improved patient/clinician and clinician/clinician communication

Thank you for your attention.

Please complete the evaluation and posttest in order to claim your statement of credit.