

Diversity, Equity, and Inclusion in Multiple Myeloma: A Call to Action

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Abstract

Background: Although advancements in multiple myeloma therapy have rapidly evolved, pervasive racial and social inequities prevent uniform benefit across diverse patient populations. This affects access to US Food and Drug Administration–approved treatments and to clinical studies. The impact of health-care inequities is not well understood and thus, the development of effective strategies is inadequate. We identify different disparities including race, age, socioeconomic status, and sexual preference/orientation and their effect on patient care. We explore recommendations for the advanced practitioner to overcome underrepresentation and increase access in myeloma care. **Method:** We performed a literature review using online databases including PubMed and CINAHL to identify different disparities, barriers to clinical studies, and recommendations to improve access. The following terms were used to identify the most relevant articles: myeloma, bias, diversity, racial disparity, inequity, socioeconomic factors, trial, elderly, sexual orientation, and sexual preference. **Findings:** Racial and socioeconomic inequities largely affect the survival and quality of care available to underrepresented populations as well as elderly patients. Existing inequities negatively affect study enrollment leading to real world consequences. Structural, clinical, and attitudinal factors further compound the issue of equitable trial engagement. Current recommendations for the advanced practitioner include addressing systemic issues to increase understanding of inequities to mitigate socioeconomic factors that deter equitable access. **Conclusion:** Understanding the issue of inequities is vital in ensuring myeloma patients are provided appropriate care. Recommendations are rooted in education and improving treatment access. Illuminating the issues of treatment disparities can remove barriers to ensure a more equitable future.

Multiple myeloma (MM) is the second most common hematologic malignancy. It is a B-cell cancer affecting the plasma cells (Faiman & Tariman, 2022). It is the leading hematologic malignancy in African Americans (National Black Caucus of State Legislators, 2022). In fact, African Americans represent 20% of all MM patients diagnosed with this incurable cancer (National Black Caucus of State Legislators, 2022). Extensive inequities, which often correlate with race, can be further compounded by other factors including socioeconomic status (SES) and sexual preference/orientation that may affect the access and availability of treatments. To date, there is an underrepresentation of racially/ethnically marginalized patients and a lack of inclusivity of the Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ+) patient population enrolled in clinical trials (CTs). This underrepresentation of diverse populations is problematic as it leads to inconsistent and inequitable patient outcomes. While there are many influences that affect equitable care delivery for MM, this article will focus on inequities based on race, age, SES, and sexual preference/orientation that affects access to treatment and CTs.

BACKGROUND

Multiple myeloma contributes to 17% of all hematologic malignancies. Over 35,000 new cases are diagnosed in the United States each year (Siegel et al., 2021). With over 12,500 deaths from MM annually, recent studies have found significant racial inequities in overall survival (OS) since the introduction of novel therapies (Ailawadhi et al., 2012; Costa et al., 2017). This disease is characterized by the presence of myeloma-specific biomarkers (clonal plasma cells in the bone marrow > 60%, involved to uninvolved serum free light chain ratio > 100, or > one focal lesion on MRI studies) and the presence of at least one myeloma-defining feature, also known as the CRAB criteria (high Calcium [hypercalcemia], Renal insufficiency, Anemia, and osteolytic Bone lesions). Although incurable, the past 15 to 20 years has seen a significant improvement in the OS of myeloma patients due to a variety of medical and technological advancements, including greater scientific understanding of the disease biology, the development of novel

therapies, and increased capabilities in the field of genetic sequencing (Dingli et al., 2017; Kumar & Rajkumar, 2018; Rajkumar, 2020).

Historically, treatment consisted of agents such as melphalan, cyclophosphamide, doxorubicin, and steroids followed by autologous stem cell transplant. Proteasome inhibitors (PIs) and immunomodulatory drugs (IMiDs) that were approved in 2003 and 2007, respectively, changed the treatment landscape, and since then, many therapies have been approved (see Table 1). In recent years, two chimeric antigen receptor (CAR) T-cell therapies (idecabtagene vicleucel and ciltacabtagene autoleucel) and more recently a bispecific antibody (BiAb), teclistamab, have been US Food and Drug Administration (FDA)-approved, allowing patients to have greater avenues of therapeutic options (FDA, 2022).

IDENTIFYING INEQUITIES IN UNDERREPRESENTED POPULATIONS

Although advances in MM have surged especially in recent years, benefit across diverse patient populations are not observed. While the reason for this is not well understood, treatment inequities across racial lines are well documented (Fiala et al., 2015). Health-care inequities refer to unfair and unjust disparities in health care, encompassing avoidable differences that predominantly impact systematically marginalized groups of people (U.S. Department of Health and Human Services, 2021). Enrollment of non-White populations to clinical trials is staggering and is half of what is expected (Kazandjian, 2016). Additionally, socioeconomic factors (SEF) have long been thought to pose a significant barrier to access and may serve as an independent barrier or as an added impediment further deepening current racial inequities (Kazandjian, 2016). Although the median age of MM diagnosis is 69, the elderly population remains underrepresented in CTs (Duma et al., 2018). Elderly representation is vital in the development of new treatments, as they constitute a distinct group with advanced physiologic changes, greater comorbidities, and subsequently, increased likelihood of polypharmacy (Gross et al., 2022).

Racial diversity in clinical trials is beneficial in various ways and serves as a measurement of health-care access and equality, while determining

Table 1. Approvals in Multiple Myeloma

Date of initial approval	FDA-approved treatment agent	Treatment combinations
1959	Cyclophosphamide	PCd, VTD-PACE
1964	Melphalan	MVP, MPT
1999	Thalidomide	Dara + VTd
2003	Bortezomib (SQ admin)	VRD, Vd
2005	Lenalidomide	VRD, Rd
2011	Bendamustine	BRd, BVd
2012	Carfilzomib	KRd, Kd, DKd, IsaKd
2013	Pomalidomide	Pd, DPd, EPd, PCd, Isa-Pd
2015	Daratumumab	DRd, DVd, DPd, D-VMP, DKd
2015	Ixazomib	IRd
2015	Elotuzumab	ERd, EPd
2015	Panobinostat	Panobinostat + Vd
2019	Selinexor	Sd
2020	Isatuximab	Isa-Pd, Isa-Kd
2020	Belantamab mafodotin ^a	Belmaf
2021	Melphalan flufenamide ^a	
2021	Idecabtagene vicleucel	
2021	Ciltacabtagene vicleucel	
2022	Teclistamab	

Note. Information from Brigle et al. (2022); Faiman et al. (2016); FDA (2022); Rajkumar (2020).
^aWithdrawn from FDA approval

efficacy of medications in various populations (Loree, et al., 2019). The effect of race on biology and patient outcomes of MM is an important area of investigation. Patients of African American descent are often found to have standard-risk cytogenetic abnormality of translocation (t)(11;14) and high-risk cytogenetics abnormalities of t(14;16) and t(14;20) (Gormley et al., 2021). African American patients are less likely to have high-risk cytogenetic findings of 17p/TP53 compared with White patients (Gormley et al., 2021). Hispanic patients are found to share a similar incidence of cytogenetic risk when compared with White patients, and like African American patients, are more likely to present with renal dysfunction (Kaur et al., 2021).

Treatment Inequities

Although different factors may affect a patient's treatment course, there is not a significant difference in the overall response of patients of varying races when provided the same MM treatment in the United States or worldwide (White 66%, African American 57%, Asian 75%, non-White Hispanic 67%; Kanapuru et al., 2022). The Surveillance, Epidemiology, and End Results (SEER) Medicare database has been widely used to assess epidemiological trends and is the main platform used by many studies. Retrospective studies using SEER show that when African American and White patients were given similar treatment regimens, the OS of African American patients was found to be similar or even greater than that of White patients, which suggests that poor outcomes in non-White populations are related to other factors (Dong et al., 2022).

Equitable access is essential as it provides researchers greater knowledge of how a drug affects a patient in a particular group, but unfortunately, this is often not the case, as African American patients were less likely than White patients to utilize novel agents such as PIs, IMiDs, and autologous stem cell transplant (ASCT; Table 2; Dong et al., 2022). Racial inequities were also noted at the time of treatment with novel agents as African American and non-White Hispanic populations receive novel therapies much later (5.2 months and 4.6 months, respectively) than White counterparts (2.6 months), with non-White Hispanic patients half as likely as White patients to receive ASCT (Table 2; Ailawadhi et al., 2019). This study also examined the use of novel regimens within 6 months of MM diagnosis by these three racial groups from 2007 to 2009 and 2012 to 2013. The trends show a general increase of novel therapy use in all three groups; however, the rate of White patient participation in novel therapies still exceeded that of African American and non-White Hispanic patients (Table 2; Ailawadhi et al., 2019).

Fiala and colleagues (2015) found similar results when investigating the utilization of stem cell transplant by race, reporting that White patients were more likely to undergo SCT than African American patients (Table 2). However, they did not find that SES accounted for the racial

Table 2. Utilization of Novel Agents by Race

	Caucasian	African American	Hispanic
Proteasome inhibitors	32.7% (Dong et al., 2022) 67% (Fiala et al., 2015)	28.3% (Dong et al., 2022) 45% (Fiala et al., 2015)	-
Immunomodulatory drugs	21.3%	16.4%	-
Autologous stem cell transplant	6.4%	3.8%	3.2%
Novel therapies	72.8%	65.4%	62.7%

Note. Information from Ailawadhi et al. (2019); Dong et al. (2022); Fiala et al. (2015)

inequities seen, which suggests that other barriers such as patient/physician biases may adversely affect participation rate. While there is an apparent gap in ASCT participation across races, the OS and progression-free survival (PFS) of African American and White patients who underwent ASCT were comparable, with 5-year OS at 47% vs. 52% and PFS at 21% vs. 19%, respectively (Majhail et al., 2012). This further demonstrates that equal access to treatments may improve survival benefits regardless of race or ethnicity.

Clinical Trial Inequities

More equitable representation in clinical studies is crucial to advance treatment and improve survival for all patients. However, diminished representation of elderly patients and the lack of diversity in CT enrollment are barriers to understanding how the disease and treatment of MM affects diverse populations. A study by Jayakrishnan and colleagues (2021) determined that a significant number of clinical trial participation lacked elderly and diverse representation compared to real-world populations. Hence, the limited diversity in trial participants can constrain the generalizability of findings when applying them to real-world scenarios.

A review of 177 MM trials from 2000 to 2016 found that only 32% of participants were over 65 years of age, even though 62% of MM patients are over 65 years of age (Duma et al., 2018). Additionally, there was a lack of clinical data and research outcomes reported on patients over 75 years due to a deficiency of trial participation, and of the 177 trials that were reviewed, only five trials included data on patients aged over 75 (Duma et al., 2018). The reasons for diminutive elderly participation on trial may be due to a variety of barriers that will be discussed later in this article.

While racial representation is well noted, many studies do not report on racial and ethnic characteristics of a patient (Jayakrishnan et al., 2021). A review of FDA drug approvals occurring from July 2007 to July 2019 found that of 261 CTs, 85.4% reported race while 14.6% did not, and this reporting did not improve significantly over time. Another study reviewing 230 FDA-approved oncology trials conducted from July 2008 to June 2018 showed similar results. Of the total number of studies reviewed, 145 studies reported on the race of the patient enrolled. The results further demonstrate that racial minorities (Asian 18.3%, non-White Hispanic 6.1%, and African American patients 3.1%) enrolled at a much lower rate compared with White patients (76.3%; Loree et al., 2019). A systematic review of 37 phase II and III clinical drug trials in patients with MM showed an average non-Hispanic White enrollment of 83%, whereas the average enrollment for non-Hispanic African American patients was only 5.3% (Adams et al., 2018). An analysis of FDA-approved treatments from 2006 and 2019 for MM correlated with similar racial demographics. Of 10,157 patients who were enrolled across 19 clinical studies, White (84%) representation remained prevalent, followed by Asian (7%), African American (4%), non-White Hispanic (4%), then finally American Indian or Alaska Native (0.04%; Kanapuru et al., 2022). Retrospective studies have found that between 2003 and 2017, the median African American population enrolled in pivotal MM studies was only 4.9% compared with 9.3% across studies (Bhatnagar et al., 2017). An analysis of significant MM studies (Table 3) examines the findings regarding underrepresentation in people from historically marginalized racial/ethnic groups and deficiencies in race reporting. While underrepresentation in the elderly population occurred in some studies,

Table 3. Landmark MM Studies and Enrollment Data by Race and Ethnicity

Trial	Treatments	Race/Ethnicity/Age, %						Age, %	
		Caucasian	African American	Asian	Other	Unknown	Hispanic	< 60 < 65 < 75	> 60 ≥ 65 > 75
FIRST Benboubker et al., 2014	Rd vs. MPt	89.00	1.20	7.82	1.35	0.55	ND	5.70 67.00	94.30 33.00
ASPIRE Stewart et al., 2015	KRd vs. Rd	95.20	2.90	0.50	1.40	ND	ND	50.40	49.60
ENDEAVOR Dimopoulos et al., 2016a	Kd vs. Rd	75.45	2.00	12.37	ND	10.22	ND	46.60	53.39
SIRIUS Lonial et al., 2016	Dara	79.00	14.00	4.00	ND	3.00	ND	55.00 88.70	45.00 11.3
CASTOR Palumbo et al., 2016	DVd vs. VD	ND	ND	ND	ND	ND	ND	53.61 88.36	45.77 11.64
POLLUX Dimopoulos et al., 2016b	DRd vs. Rd	69.06	2.81	19.33	10.54	ND	ND	47.97 88.76	52.02 11.24
TOURMALINE-MM1 Moreau et al., 2016	IRd vs. Rd	85.00	ND	ND	ND	ND	ND	48.00	52.00
PANORAMA-1 San-Miguel et al., 2016	Pano VD vs. VD	64.97	2.86	30.2	1.95	ND	ND	57.94 91.30	42.05 8.70
MAIA Facon et al., 2019	D-Rd vs. Rd	91.58	ND	ND	ND	ND	ND	1.08 56.45	98.91 43.55
ELOQUENT-2 Dimopoulos et al., 2018a	ERd vs. Rd	84.00	4.00	10.00	2.00	ND	ND	42.72	52.27
ELOQUENT-3 Dimopoulos et al., 2018b	EPd vs. Pd	ND	ND	ND	ND	ND	ND	37.60 78.64	62.00 21.36
STORM Chari et al., 2019	Selinexor	ND	ND	ND	ND	ND	ND	49.18 85.00	50.81 15.00
OPTIMISM Richardson et al., 2019	PVd vs. Vd	ND	ND	ND	ND	ND	ND	43.47 83.37	56.52 16.63
ENDURANCE Kumar et al., 2020a	KRd vs. VRd	81.96	11.68	ND	2.00	0.04	ND	68.35	31.20
GRIFFIN Voorhees et al., 2020	D-RVd vs. RVd	78.00	15.00	ND	ND	ND	ND	72.90	28.10
CANDOR Dimopoulos, 2020	DKd vs. Kd	ND	ND	ND	ND	ND	ND	51.50 89.27	48.49 10.72
BELLINI Kumar et al., 2020b	VenVd vs. Vd	ND	ND	ND	ND	ND	ND	45.02	54.98
DREAMM-2 Lonial et al., 2020	BelMaf	79.08	13.78	ND	ND	ND	ND	41.32 84.70	58.67 15.30
KarMMa Munshi et al., 2021	Ide-cel	ND	ND	ND	ND	ND	ND	64.84	35.16
CARTITUDE-1 Berdeja et al., 2021	Cilta-cel	71.00	18.00	1.00	2.00	8.00	6.00	ND	ND
DETERMINATION Richardson et al., 2022	VRd>ASCT >maint len	74.79	18.28	2.77	2.49	1.67	4.84	69.00	31.00

other studies did report near equivalent or greater levels of participation, although there may be other factors contributing to this.

Challenges to enrollment are indeed multifactorial and include a variety of other barriers including SEF, access, perceptions, and practices. An examination of clinical trial data from nine national cooperative groups focusing on newly diagnosed MM consistently shows a higher enrollment rate of White participants in studies involving novel agents, in contrast to non-White races who tend to prefer trials without novel agents (Ailawadhi et al., 2018). When response rates of individuals who participated in CTs were compared across racial groups, there was no significant difference in overall response (Ailwadhi et al., 2018).

Socioeconomic Inequities

Socioeconomic status is multidimensional and can further deepen inequities and affect the outcomes of MM patients. Socioeconomic status may increase the risk of many cancers and deeply affect the patient's ability to access treatment once diagnosed (Marinac et al., 2020). Socioeconomic status can be attributed to a variety of factors, but most often refers to an individual's level of education, income status, or occupational status (Williams et al., 2016). Treatments for MM are often complex, time consuming, and costly, and the SES of a patient, even without taking race/ ethnicity into account, correlates with the patient's OS (Jain & Chang, 2019). In a study conducted in Korea where the population is generally racially uniform, the patient's income and regional status were two significant factors that were found to determine OS in cancer patients (Jain & Chang, 2019). Out-of-pocket expenditures may be especially high in patients receiving cancer treatment as it involves frequent hospital visits, continuous chemotherapy, and even radiation and other associated charges. Patients may additionally incur added costs that include housing and travel, further increasing financial burden. Regionally disadvantaged locations are a major deterrent to patient access to adequate health care. Low income and disadvantageous regional status are negative prognostic indicators for overall survival (Jain & Chang, 2019).

Socioeconomic status may occur independently but is found to be associated with race, de-

creasing the OS of African American and White patients (Dong et al., 2022). Asian and White patients were found to have the highest education levels compared with African American and non-White Hispanic patients and subsequently, also had higher household incomes (Williams et al., 2016). However, White patients were found to have greater net worth compared with all other races (Williams et al., 2016). The effect of SES on treatment access and disease management was noted in a retrospective study using data from the National Cancer Database. Patients who received treatment for MM between 1998 to 2010 were evaluated based on education level, income, and location. Patients with lower levels of education and income were less likely to undergo ASCT, which is the gold standard in induction therapy, when compared with patients with higher levels of education and income (Ailawadhi et al., 2018).

Studies evaluating SES have examined different SEF and in evaluating SEER data of patients younger than 65 between 2007 and 2012, marital status, income, education, and insurance status were significant factors impacting mortality rates of patients with MM (Costa et al., 2016). Individuals without insurance, who were single, or resided in a county with a lower income level were at a higher risk of death (Costa et al., 2016). Individuals with no adverse SEF had a 4-year OS of 71.1%, and this decreased with the addition of more adverse SEFs (one SEF 63.2%, two SEF 53.4%, three SEF 46.5%), which further establishes its impact on patient outcomes (Costa et al., 2016).

LGBTQ+ Inequities

The LGBTQ+ community is an underserved and understudied patient population. It makes up approximately 3% to 12% of individuals with hematologic malignancies (Smith-Graziani & Flowers, 2021). This group has historically faced persistent social discrimination, which continues to affect their ability to access affordable health insurance and establish trust with their health-care providers for fear of stigma. Sexual minorities have specific health needs that most health-care providers are ill equipped to manage due to a lack of education and training (Jowett & Peel, 2009). Despite being an underserved population with a distinct and unique set of psychosocial challenges, few

studies have examined the specific needs of the LGBTQ+ patient population in relation to cancer care (Smith-Graziani & Flowers, 2021). Patient-centered care is essential in oncology; however, the LGBTQ+ community reports lower satisfaction with the health care they receive. This may suggest that health care may not be personalized and could affect the patient's experience across the cancer care continuum (Sutter et al., 2021).

Education of the health-care provider is necessary to overcome barriers in order to provide culturally competent cancer care for LGBTQ+ patients. Without the proper training and education, health-care providers can face challenges in caring for LGBTQ+ patients (Ussher et al., 2022). Sexual minorities are found to exhibit more cancer-related risk factors. These risk factors have not been found to decrease even after cancer treatment (Gibson et al., 2017). As such, they are more vulnerable to negative outcomes that may affect their physical and mental health, such as increased feelings of isolation or depression (Gibson et al., 2017). The LGBTQ+ group is a complex amalgamation of individuals with diverse backgrounds including differences in race, socioeconomic status, and gender. There are many unanswered questions on how best to serve the individuals of this group and yet, a paucity of data persists (Gibson et al., 2017). Though the National Institutes of Health has provided funding on projects related to sexual minorities, it was found that 75% of these projects focused on HIV/AIDS and only 1.8% were related to cancer. Research involving transgender populations was even less. Better understanding of sexual minorities may help to address these issues and identify strategies to improve access and decrease social stigma. Clinicians' education and training on the needs and perspectives of LGBTQ+ patients with cancer are more necessary now than ever (Berner et al., 2020; Kamen et al., 2019; Schabath et al., 2019).

BARRIERS TO CLINICAL TRIALS IN MULTIPLE MYELOMA

The advantages of CTs are well established and essential in developing novel therapies vital in the treatment of oncologic patients. Retrospective studies found that the reduction of mortality is directly related to the rate of clinical trial enrollment

as faster trial enrollments lead to quicker treatment advances (Unger et al., 2016). Historically, pediatric cancer trial engagement and enrollment has occurred at a greater pace than adult participation (> 50%), and subsequently the decrease in pediatric mortality has been observed much earlier since the 1970s as compared to improvement in adult mortality rates, which started much later in the 1990s (Unger et al., 2016).

Barriers to enrollment in clinical studies have been widely studied and have been found to be multifactorial including cost, location, education, awareness, cultural representation, opportunity, and specific exclusionary criteria (Vuong et al., 2020). Identifying barriers to access is vital in formulating strategies to increase access and improve clinical trial participation lest disparate populations continue to suffer from the consequences of delayed access to treatment (Pierre & Williams, 2020). Since these barriers are numerous and multifactorial, they may be divided into three main categories: structural, clinical, and attitudinal (Unger et al., 2016).

Structural Barriers

Structural barriers are defined as factors that directly relate to access to a cancer center (issues related to geography, transportation, costs, and social support) or the actual availability of a trial (Unger et al., 2016). Geography can pose a challenge as there are implications involving distance from the nearest cancer institute and costs sustained from travel. A study found that vulnerable populations enrolled in phase I studies were more inclined to travel longer distances as they were likely to have fewer options for treatment. Furthermore, the accessibility to CTs of patients from lower income neighborhoods was lower as clinical trial availability was greater in higher income neighborhoods. As a result, patients from lower income neighborhoods traveled greater distances and sustained more travel-associated costs (Borno et al., 2018). Conversely, the elderly were less likely to participate in clinical studies due to logistic challenges with patients aged between 60 to 70 years twice as likely to refuse consent when compared with their younger counterparts (Boquoi et al., 2022).

The ascent of CAR T-cell and BiAb therapies has revolutionized myeloma treatment options by

improving OS and introducing new fields of investigation, but access to such therapies commercially and on study has been a major deterrent for patients (Alqazaqi et al., 2022). It is well known that African American participation in clinical studies is inadequate, which is further compounded by the fact that access to studies and novel treatments are affected by availability and distance (Alqazaqi et al., 2022). In a study investigating the availability of CAR T-cell therapy and BiAb treatment, it was found that 17 states (34%) did not offer any CAR T-cell or BiAb trials, and in 21 (41%) states where these studies were available, it was accessible to only 30% of African American residents (Alqazaqi et al., 2022).

Clinical Barriers

Clinical barriers to trial may also deter enrollment with too stringent eligibility criteria that excludes populations that may be more representative of the real world (Unger et al., 2016). While eligibility criteria serve to protect patients and ensure they are stable enough to participate in CTs, it also helps ensure that the patient profiles are similar for consistency, which may unwittingly affect representation of underserved populations (Shah et al., 2017). The elderly population may suffer more from study-imposed restrictions due to the greater likelihood of having several coexisting comorbidities, which may not only pose safety concerns, but the elderly may also require greater support or more medical care and attention that may deter participation (Boquoi et al., 2022). It is estimated that with less stringent eligibility criteria surrounding functional status, elderly participation in studies could approach 60% (Boquoi et al., 2022)

There is a paucity of available data evaluating stringent eligibility criteria and its effect on underserved MM patients, but some indirect conclusions can be drawn from retrospective studies that analyze eligibility criteria between eligible and ineligible patients. Analysis of the CoMMpass (Relating clinical outcomes in MM to Personal Assessment of Genetic Profile) study found that meeting any one or more of the following criteria resulted in the exclusion of prospective MM patients considering clinical study: ECOG (Eastern Cooperative Oncology Group) score of 3 or 4, ab-

solute neutrophil count $< 1 \times 10^9/L$, platelet count $< 50,000 \times 10^9/L$, or creatinine level ≥ 2 or receiving dialysis (Shah et al., 2017). As most patients suffering from MM may have some degree of cytopenias or renal insufficiency, trials using these criteria may often fail to represent MM with advanced disease (Shah et al., 2017). A misrepresentative population on study is already concerning to investigators, and this does not include the lack of representation with consideration to underprivileged populations. Underserved populations (groups that included individuals of lower SES, historically marginalized race and ethnicities, and the elderly) were found to be both directly and indirectly excluded due to eligibility criteria in a study examining enrollment of participants to breast cancer clinical studies (Moloney & Shiely, 2022). Furthermore, evaluation of the Connect Registry determined that patients found to be ineligible for clinical studies were more likely to have more comorbid conditions and advanced disease compared with patients who were eligible (Shah et al., 2017). African American patients are known to have a greater rate of comorbidities than other population subgroups, which may contribute indirectly to their ability to participate in studies (Pierre & Williams, 2020). Indirect exclusion of patients based on sexual orientation may be more common than recognized, as HIV positivity is often cited as an exclusion criterion, and HIV may be more pervasive in homosexual males (Moloney & Shiely, 2022).

Attitudinal Barriers

Patient perceptions to clinical studies may serve as a major proponent or deterrent in participation. While some populations may consider studies to be necessary and exciting, others may view trials with distrust, perceiving more harm than benefit (Loree et al., 2019). Trust has been found to be a major contributing factor in recruitment to CTs as it may not only affect a patient's willingness to participate in study, but also their compliance to study requirements (Amorrortu et al., 2018). Moreover, the recruitment process for clinical studies can be impacted by the presence of health-care providers from similar racial/ethnic backgrounds as the patients they serve. Some patients may have a higher level of trust and

confidence in such providers who present them with a clinical study opportunity (Pierre & Williams, 2020; Grant et al., 2022). A commonly cited reason negatively affecting the patient's perception of clinical study is the fear of uncertainty. Clinical studies involve experimentation, and some studies may require randomization, which may contribute to the patient's unease with participating in trials compared with the more certain and predictable course of commercial products (Unger et al., 2016). Indeed, some evidence shows that newly diagnosed patients are more inclined to participate on study compared with the relapsed or refractory patient who may value more control over their disease course (Boquoi et al., 2022). As trials require frequent monitoring and more obligations than standard-of-care options, practical barriers affecting patient participation may include concerns of greater time commitment, increased costs, and increased travel burden (Unger et al., 2016). Furthermore, patient perception regarding goals of treatment may be different, thus affecting the willingness to enroll in clinical study. Older adults have been found to prioritize quality of life and may opt for disease control compared with depth of response. In contrast, younger adults are more likely to prioritize longevity and opt for intensive treatments for greater depth of response, which may result in greater participation to trials with novel therapies (Boquoi et al., 2022).

Provider attitudes and perceptions may also deter the consideration of underserved populations to clinical study. Since CTs are investigational, providers may anticipate the patient's anxiety and uncertainty with this treatment option and may thus avert the discussion of trials completely lest they compromise the trust their patients have in them (Unger et al., 2016). There is also a worry that offering CTs may break trust and thus negatively affect the patient/provider relationship (Nipp et al., 2019). Some studies have found that some providers may suffer from the implicit bias of believing non-White patients to be "poorer" trial candidates and fear they may be less likely to be compliant with treatment requirements (Hamel et al., 2016). Furthermore, providers may be more reluctant to enroll elderly patients on clinical studies for fear of an in-

creased risk of toxicities, presence of comorbidities that could affect treatment, and compliance issues (Aapro et al., 2005). Practical barriers that affect a provider's ability to offer CTs include a provider's knowledge and awareness of available trials (Hamel et al., 2016). Some providers may refrain from discussing clinical studies as they believe trial involvement is too restrictive and time consuming, possibly resulting in more paperwork, follow-up visits, and time in discussion (Unger et al., 2016).

RECOMMENDATIONS FOR ADVANCED PRACTITIONERS

Over the past decade, there have been several position statements, whitepapers, and guidelines released by notable organizations to address inequities in health care. One notable whitepaper from Integrated, Coordinated, Open, Networked (ICON) Science addressed the lack of inclusion and diversity in CTs (ICON, 2021). This whitepaper describes several factors of social determinants of health that should be considered when recommending strategies to improve inclusion and diversity. These factors include the following: economic stability, education, access and quality, health-care access and quality, neighborhood and established environment, inclusive language, and social and community context.

To address negative patient perceptions to CTs, it is important to cultivate community relationships with trust and conduct treatment discussions with open dialogue, shared decision-making, and genuine respect (ICON, 2021). When distrust occurs, individuals feel exploited (ICON, 2021).

Health economics and access to health-care facilities should also be considered when addressing inequities in health care. Access and location of the health-care facility is an important factor to enroll participants in a trial. There is often a tendency for organizations and industry to sponsor trials in an established clinical setting, and thus overlook community established health-care facilities. Transportation, geographic location, and multiple clinic visits can deter patients from participating in a trial and should be considered in the early protocol development stages (Habr & Corsaro, 2022).

A strategic plan should be incorporated in every oncology clinic as well as in health-care industries to address inclusivity and diversity in MM treatment and protocol enrollment. The themes of a strategic plan should include increasing the provider's education of health-care inequities, forming community and institutional patient awareness of CTs, and broadening access of CTs in various community settings. Table 4 describes specific recommendation interventions. The success of implementing a strategic plan can only be accomplished with agreement of all stakeholders involved in caring for MM patients on CTs (Habr & Corsaro, 2022). There is also an unmet need to incorporate inclusive language in the recruitment and retention of clinical drug trial participants, welcoming older LGBTQ+ patient participation through inclusion of gender affirming terminolo-

gies in the research demographic questionnaire and the study informed consent. The inclusion of terminologies such as transgender woman, transgender man, gender fluid, and nonbinary categories for the study participants' gender conveys cultural competence and an inclusive environment (Chaiyasit & Lutz, 2020). Moreover, ageism, heterosexism, and cisgenderism emerged as cross-cutting themes that negatively impact access to health care for LGBTQ older adults (Boggs et al., 2017). In sum, health-care providers need more education and training (Berner et al., 2020; Kamen et al., 2019; Schabath et al., 2019) to gain more knowledge, attitudes, and skills in sexual- and gender-specific minority cancer research and health-care advocacy (Kano et al., 2022). This would facilitate the active inclusion of LGBTQ+ patients in clinical drug trials for MM.

Table 4. Recommendations for Interventions

Healthcare Provider Education About Existing Inequities in CTs

- Ongoing educational information about inequities in MM trials.
- Ongoing education and training for oncology clinicians on LGBTQ cancer-related needs, issues, and perspectives.
- Provide information to health-care professionals that will enhance communication and promote a trusting patient/provider relationship.
- Consider the barriers that prevent individuals from participating in trials and develop a plan to address these issues (economics, education, health-care access, community context, mistrust of researchers).
- Consider hiring a nurse navigator to support trial participants and educate health-care professionals.
- Involve patient's family or support system if it increases patient comfort and encourage shared decision-making as warranted.
- Provide website information for current and future trials.
- Provide list of MM organizations that provide information about diversity and inclusivity such as the International Myeloma Foundation, Oncology Nursing Society, American Society of Clinical Oncology, Multiple Myeloma Research Foundation.

Community and Institutional Patient Education Awareness of CTs

- Provide community-directed clinical trial education.
- List of websites that for trial information.
- Provide an environment that encourages open dialogue and shared decision-making.
- Improve patient trust by working closely with community healthcare providers.
- Provide information about the logistics of the trial such time spent at the clinic, community transportation schedules, maps of the health-care facility, calendars that includes schedule, required scans and data to participate in the study.
- Provide list of MM organizations that provide information about diversity and inclusivity such as International Myeloma Foundation, Oncology Nursing Society, American Society of Clinical Oncology, Multiple Myeloma Research Foundation.
- Conduct self-assessment of practice sites and gather trial screening, offering, and enrollment data by race and ethnicity to enhance DEI in clinical drug trials.
- Implement implicit bias training program for all stakeholders of the clinical drug trial enterprise.

Broaden Access of CTs in Various Community Settings

- Develop outreach community programs to provide CTs by expanding access of CTs in the community.
- Consider using local laboratories and health-care facilities for bloodwork and scans.
- Consider telehealth visits when appropriate.
- Work with sponsors to provide financial support for participants to take part in the trial (transportation, overnight stay in hotel, employment compensation).
- Clinical barriers to trial may also deter enrollment with too stringent eligibility criteria that excludes populations that may be more representative of the real world.

Note. Information from Barrett et al. (2023); Guerra et al. (2023); Gormley et al. (2021); Habr & Corsaro (2022); ICON (2021).

CONCLUSION

More equitable representation in clinical studies is needed to advance MM treatment and improve survival for all patients. Barriers to enrolling non-White patient populations on trials is multifactorial and includes social determinants of health, mistrust of the researchers, and access to health care. The formidable task of improving cancer clinical trial diversity is a shared responsibility of all stakeholders, which include health-care professionals, administrators, organizations, and the pharmaceutical industries. The allocation of funding resources for oncology clinicians' education and training on implicit bias, cultural competence, and LGBTQ+ issues and perspectives are imperative. ●

Disclosure

The authors have no conflicts of interest to disclose.

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