PROJECTED IMPACT OF OMIDUBICEL ON RACIAL AND ETHNIC DISPARITIES IN ALLOGENEIC HEMATOPOIETIC CELL TRANSPLANT ACCESS AND OUTCOMES FOR PATIENTS WITH HEMATOLOGIC MALIGNANCIES IN THE US

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BACKGROUND

- The majority of patients with hematologic malignancies (HM) who are eligible for allogeneic hematopoietic cell transplant (allo-HCT) lack human leukocyte antigen (HLA)-matched related donors (MRD) and rely on donor registries to identify matched- or mismatched-unrelated donor (MUD, MMUD), or umbilical cord blood (UCB)[1]
- The likelihood of finding a match in donor registries differs by race and contributes to racial disparities in health outcomes[2]
- Omidubicel, an advanced cell therapy for allo-HCT patients, demonstrated superior hematopoietic recovery and decreased early transplant-related mortality compared with standard UCB HCT in a phase III clinical trial (NCT02730299)
- More than 40% of patients in the trial were minorities, and consistent clinical benefit was demonstrated across race groups. Thus, access to omidubicel may reduce racial and ethnic health disparities for allo-HCT–eligible patients
- In this analysis, we hypothesized that access to omidubicel may reduce racial and ethnic health disparities for allo-HCT–eligible patients

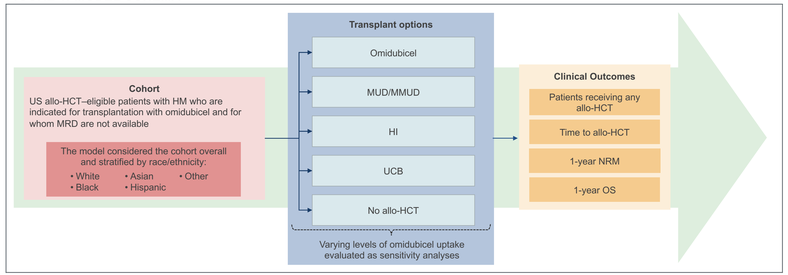
OBJECTIVE

- To quantify the expected effects of access to omidubicel on health disparities in allo-HCT access and outcomes for patients with HM in the United States

METHODS

- A decision tree model was developed to project allo-HCT access and clinical outcomes in a hypothetical population of 10,000 allo-HCT–eligible patients in the US with HM lacking MRD (**Figure 1**)
  - The model assigned patients to receive MUD/MMUD, haploidentical (HI), UCB transplant, or no transplant according to probabilities sourced from real-world evidence and based on assumptions[2,3]
  - A status quo scenario including 0% omidubicel use was treated as the reference case. Scenarios with omidubicel use of 10%, 15%, 20%, and 30% were modeled based on proportional reductions in use of other allo-HCT donor types or no transplant, drawing evenly among racial subgroups
  - Weighted average outcomes, across transplant donor types, were calculated for the overall population and by race groups
    - Studied outcomes were time to allo-HCT, 1-year non-relapse mortality (NRM), and 1-year overall survival (OS)
    - Average time to allo-HCT and NRM outcomes were modeled among patients receiving transplant in each scenario. 1-year OS was modeled in the entire patient cohort, inclusive of those not receiving a transplant
- Clinical inputs for each allo-HCT type were drawn from clinical trials,[4-6] public data from the Center for International Blood and Marrow Transplant Research (CIBMTR),[3] and published studies and assumptions (**Table 1**)[7-11]
  - The distribution of patients receiving each modeled transplant type was sourced from the CIBMTR and the US Department of Health and Human Services[3]
  - Average time from establishment of transplant eligibility to transplant procedure was sourced from published studies and assumptions
  - Efficacy for each transplant type was assumed to apply to all patients receiving the transplant—ie, differences in transplant efficacy by race were not considered

FIGURE 1. MODEL SCHEMA



Allo-HCT: allogeneic hematopoietic cell transplantation; HI: haploidentical; HM: hematologic malignancies; MRD: matched related donor; MUD: matched-unrelated donors; MMUD: mismatched-unrelated donor; NRM: non-relapse mortality; OS: overall survival; UCB: umbilical cord blood; US: United States.

TABLE 1. KEY CLINICAL INPUTS

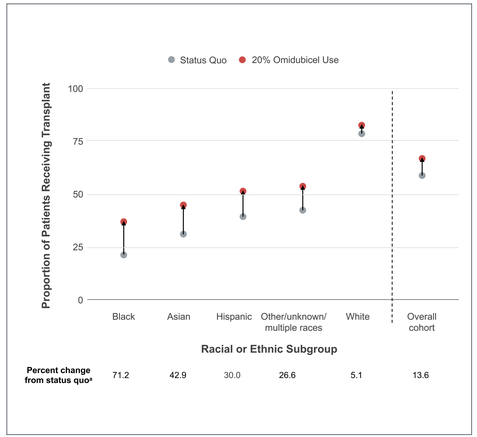
	Omidubicel	MUD/MMUD	HI donor	UCB transplant	No transplant	*Sources*
Patients receiving each transplant option at status quo (%)	-	39.9	14.7	5.0	40.4	CIBMTR US HHS Data[3]
Average time to transplant procedure (weeks)	4.0	15.1	4.3	3.7	-	Omidubicel: Assumption MUD/MMUD: Mayani 2020[11] HI: Ciurea 2018[9] UCB: Gamida Cell Trial Data
1-year NRM (%)	15.4	23.7	24.1	28.6	-	Omidubicel: Gamida Cell Trial Data MUD/MMUD: Baker 2016[7] HI: Baker 2016[7] UCB: Gamida Cell Trial Data
1-year OS (%)	73.0	70.8	62.0	60.0	52.5	Omidubicel: Gamida Cell Trial Data MUD/MMUD: CIBMTR HI: Brunstein 2011[5] UCB: Gamida Cell Trial Data No transplant: Lerch 2009,[8] Goldstone 2008[6]

CIBMTR: Center for International Blood and Marrow Transplant Research; HI: haploidentical; MUD: matched-unrelated donor; MMUD: mismatched-unrelated donor; NRM: non-relapse mortality; OS: overall survival; UCB: umbilical cord blood; US HHS: United States Department of Health and Human Services.

RESULTS

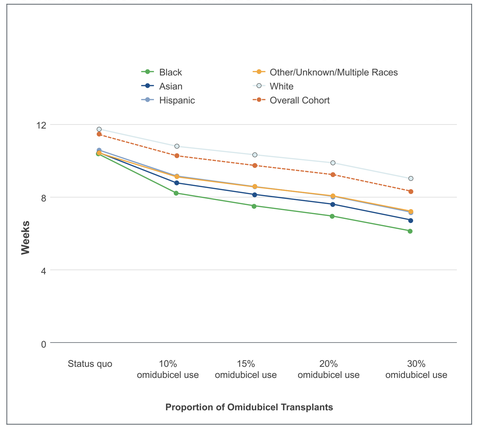
- In a modeled population of 10,000 patients for whom MRD were unavailable, 5956 (60%) were estimated to receive allo-HCT using current comparator donor sources (MUD, MMUD, HI, UCB) under the status quo scenario without omidubicel. 4044 patients (40%) in the status quo population did not receive allo-HCT
  - Among transplanted patients, 80% of White patients underwent allo-HCT, whereas only 40% of Hispanic, 32% of Asian, and 22% of Black patients received an allo-HCT
  - Mean times from transplant assignment to transplant procedure and 1-year NRM were 11.5 weeks and 24%, respectively, among transplanted patients. Including those not transplanted, 1-year OS was 62% overall, ranging from 56% (Black) to 65% (White)
- Modeled increases in omidubicel use in eligible patients were associated with higher proportions of patients undergoing allo-HCT, decreased time to allo-HCT, decreased 1-year NRM, and increased 1-year OS. Improvements were greater among racial minorities but their results generally lagged behind those of White patients. In a scenario evaluating 20% omidubicel uptake:
  - The proportion of Black patients receiving allo-HCT increased by 71%, with significant increases also noted in non-Black minorities (Asian [43%], Hispanic [30%], other [27%]), and a modest increase in White patients (5%) (**Figure 2**)
  - Modeled time to allo-HCT improved 19% among all transplanted patients, with improvements ranging from 33% in Black patients to 16% in White patients (**Figure 3**)
  - Similarly, 1-year NRM decreased 11%, with a 9% reduction among White patients, 20% reduction among Black patients, and 14%–17% reductions among Asian, Hispanic, and other racial or ethnic subgroups (**Figure 4**)
  - 1-year OS increased by 4% in the overall population, including non-transplanted patients, with improvements ranging from 3% among White patients to 6% among Black and Asian patients (**Figure 5**)

FIGURE 2. PROPORTION OF PATIENTS RECEIVING ALLO-HCT



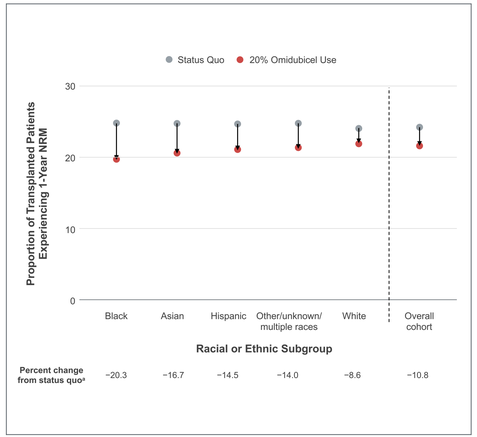
[a]The status quo scenario is defined as 0% omidubicel use. Allo-HCT: allogeneic hematopoietic cell transplantation.

FIGURE 3. AVERAGE TIME FROM ALLO-HCT DECISION TO PROCEDURE



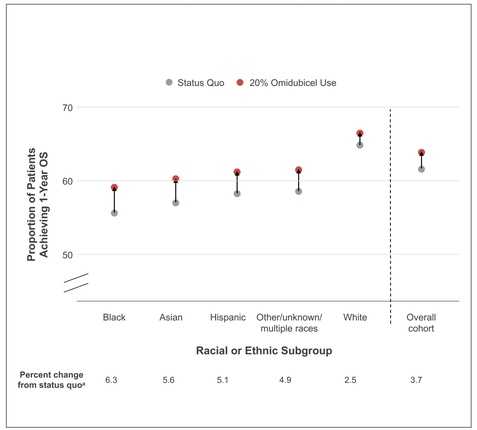
Allo-HCT: allogeneic hematopoietic cell transplantation.

FIGURE 4. PROPORTION OF TRANSPLANTED PATIENTS EXPERIENCING 1-YEAR NRM



[a]The status quo scenario is defined as 0% omidubicel use. NRM: non-relapse mortality.

FIGURE 5. PROPORTION OF PATIENTS ACHIEVING 1-YEAR OS



[a]The status quo scenario is defined as 0% omidubicel use. OS: overall survival.

LIMITATIONS

- Utilization and outcomes data are from historic studies/registries/clinical trials and assumptions
- Projections are based on assumed levels of omidubicel uptake and translation of clinical trial results to real-world results
- The present study focused on racial disparities in finding suitable donor tissue for allo-HCT. Other possible contributors to inequity, such as differences in socioeconomic status, health insurance status, care-seeking challenges, or geographical hurdles should also be studied and addressed

CONCLUSIONS

- We project that omidubicel will extend access to allo-HCT–eligible HM patients, decrease time to transplant, and improve clinical outcomes
  - The greatest benefits were seen among racial and ethnic groups with worse status quo outcomes
- Higher levels of modeled omidubicel uptake were associated with greater improvements in clinical outcomes and greater reductions in racial disparities

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DISCLOSURES

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