Multicenter Biologic Assignment Trial Comparing Reduced-Intensity Allogeneic Hematopoietic Cell Transplant to Hypomethylating Therapy or Best Supportive Care in Patients Aged 50 to 75 with Intermediate-2 and High-Risk Myelodysplastic Syndrome: Blood and Marrow Transplant Clinical Trials Network #1102 Study Rationale, Design, and Methods

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ABSTRACT
The introduction of reduced-intensity conditioning (RIC) regimens made it possible to offer allogeneic hematopoietic cell transplantation (alloHCT) to older patients with myelodysplastic syndromes (MDS). However, the relative risks and benefits of alloHCT compared with novel nontransplant therapies continue to be the source of considerable uncertainty. We will perform a prospective biologic assignment trial to compare RIC alloHCT with nontransplant therapies based on donor availability. Primary outcome is 3-year overall survival. Secondary outcomes include leukemia-free survival, quality of life, and cost-effectiveness. Four hundred patients will be enrolled over roughly 3 years. Planned subgroup analyses will evaluate key biologic questions, such as the impact of age and response to hypomethylating agents on treatment effects. Findings from this study potentially may set a new standard of care for older MDS patients who are considered candidates for alloHCT.

INTRODUCTION
Myelodysplastic syndromes (MDS) represent a heterogeneous group of acquired malignant bone marrow disorders characterized by high rates of apoptosis leading to ineffective hematopoiesis [1]. An acquired bone marrow failure picture ensues and leads to varying degrees of peripheral blood cytopenias and potentially fatal complications, including infection and bleeding [1,2]. MDS is most often diagnosed in elderly individuals with a median age of 76 years at diagnosis [3,4]. Overall, about 30% of individuals with MDS progress to acute myeloid leukemia (AML), although the probability of progression is largely determined by disease risk at presentation [4,5] (eg, the 2-year risk of progression to AML is 80% for those with high-risk disease but only 10% among those with low-risk disease [6]).

The most widely used prognostic classification system for MDS is the International Prognostic Scoring System (IPSS), which takes into account the number of bone marrow blasts, cytogenetic abnormalities, and cytopenias [5]. The IPSS classifies patients into low-risk, intermediate-1, intermediate-2, and high-risk stages. The median survival ranges from 5.7 years for those with low-risk disease to only months for
those with high-risk disease [5]. A newer IPSS was published (IPSS-R) [7], but to date most clinical experience and conduct of investigative clinical trials for MDS have used the original IPSS.

A wide range of therapeutic approaches exists for patients with MDS, which are typically selected based on the patient’s estimated risk of death [5-9]. Also, treatment guidelines have been developed by independent groups [10,11]. Introduction of hypomethylating agents (HMAs) prolongs progression-free survival [12] and overall survival (OS) [13,14] and delays transformation to AML [12-14]. However, to date, allogeneic hematopoietic cell transplantation (alloHCT) remains the only curative therapeutic modality available. Despite its curative potential, because of the risk of nonrelapse mortality with alloHCT in a population of mostly older individuals, many patients with MDS are still not referred for transplant evaluation [15]. A query of transplantation activity reported to the Center for International Blood and Marrow Transplant Research (CIBMTR) showed that of 3101 alloHCTs performed in the United States between 2000 and 2010 for MDS, only 232 (7.5%) were among persons aged 65 years and older (unpublished data; W.S., personal communication, June, 2012). Studies have shown, however, that among patients who were considered to be candidates for alloHCT and were referred to the transplant programs, age was not an important predictor of post-transplant outcomes [16-18]. With the introduction of reduced-intensity conditioning (RIC) alloHCT, shown to be associated with promising results in MDS [19-21], as well as expanded coverage for alloHCT by Medicare under the Coverage with Evidence Development (CED) mechanism [22], more patients are now undergoing this curative therapy [23].

To better define the value of alloHCT, comparative analyses are needed. Few such analyses have been performed. In a retrospective cohort analysis, alloHCT (N = 103) recipients were 70% less likely to die (P = .007) compared with patients that only received HMAs [24]. However, this particular study did not control for lead time bias [24], and therefore the results should be interpreted with great caution [25]. In a recent retrospective analysis, the investigators used a multistate statistical model to define the optimal timing of alloHCT for MDS patients aged 60 to 70 years (N = 514) [26]. This analysis demonstrated that among those with low-risk MDS (IPSS low risk/intermediate-1), nontransplant therapies provided a higher life expectancy, whereas among those with high-risk MDS (IPSS intermediate-2/high risk), proceeding immediately to alloHCT was associated with higher life expectancy than nontransplant approaches [26]. A small prospective study compared alloHCT with nontransplant approaches using a “donor versus no donor” comparison [27]. One hundred sixty-three patients with intermediate/high-risk MDS were enrolled. The distribution of donor status was as follows: 34 had no donors, 115 had HLA-matched donors (identical sibling or well-matched [HLA 10/10] unrelated donor), and 14 had partially matched (HLA 9/10) unrelated donors. The primary outcome (OS at 48 months) was significantly different among the 3 groups (P = .01). The corresponding survival probabilities were 17% (95% confidence interval [CI], 6% to 43%), 35% (95% CI, 26% to 49%), and 8% (95% CI, 1% to 55%). Whether the difference between the no donor arm and the HLA-matched donor group was significant is unclear, however. Given the wide CIs around these estimates, these results need to be confirmed in larger studies.

Given the lack of definitive prospective data evaluating the relative risks and benefits of alloHCT compared with nontransplant approaches among older MDS patients and as a response to the Centers for Medicare & Medicaid Services (CMS) CED for National Coverage Determination of Stem Cell Transplantation, the Blood and Marrow Transplant Clinical Trials Network (BMT CTN) has launched the BMT CTN 1102 prospective study to address this knowledge gap [28]. In this article we discuss the design of the BMT CTN 1102 and steps taken to address potential sources of bias.

STUDY OVERVIEW

The fundamental question being addressed is whether patients aged 50 to 75 years with high-risk MDS referred to transplantation centers and for whom a suitable donor is available have a 3-year survival advantage with RIC alloHCT compared with nontransplant-based therapies (offered to those without a suitable donor but transplant eligible). Other key outcomes include leukemia-free survival, quality of life, and cost-effectiveness.

Figure 1 depicts the overall study schema. Subjects are enrolled at the referral visit to the transplant center. Subjects for whom a search for an unrelated donor was initiated before their referral to the transplant center will not be eligible for participation in this study. However, subjects for whom sibling tissue typing was initiated before their referral will be allowed to participate. All subjects are initially assigned to the no donor arm at the time of enrollment. Subjects with a suitable donor will be reassigned to the donor arm when a donor is identified. A suitable donor is defined as either an HLA-matched related donor or an 8/8 (HLA-A, -B, -C, and

Figure 1. Study schema. QOL indicates quality of life.
-DRB1) matched unrelated donor (by confirmatory typing). If no suitable donor is identified during a 90-day interval (from enrollment), subjects will be permanently assigned to the no donor arm. The 90-day interval was chosen based on prior experience from the National Marrow Donor Program that if a donor is not found in this time frame, the subsequent likelihood of finding a donor is very small.

KEY ISSUES IN STUDY DESIGN
Randomization versus Biologic Assignment

Randomized controlled trials represent the gold standard design when one wishes to compare 2 therapies. However, among patients who are referred for transplant evaluation and for whom an HLA-matched donor has been identified, it is generally viewed as not feasible to conduct a true randomized controlled trial (ie, randomize patients with HLA-matched donors to alloHCT versus nontransplant) [29,30]. An alternative approach is to conduct a biologic assignment trial, which means that patients with a suitable HLA-matched donor are assigned to the alloHCT arm, whereas patients who do not have such a donor are assigned to the nontransplantation arm. Biologic assignment trials have been used successfully to evaluate the role of alloHCT across multiple hematologic malignancies [31-36]. With this design, accrual is significantly enhanced, and therefore this is a more feasible design compared with randomized controlled trials [37]. Given prior beliefs and misconceptions regarding the value of alloHCT among those with a donor, a biologic assignment design provides a reasonable platform upon which the study can be performed [37]. The BMT CTN 1102 is designed as a prospective, comparative biologic assignment study of RIC alloHCT from related and unrelated donors versus hypomethylating therapy or best supportive care among patients with intermediate-2/high-risk de novo MDS.

Although selection bias can arise in biologic assignment, it is the most feasible design for this trial. The study was carefully designed and adjusted analysis planned to minimize potential bias as discussed below.

Enrolling at Referral to Transplant Program versus Other Time Points (eg, at Diagnosis or at Complete Remission)

Because most newly diagnosed MDS patients are treated by community oncologists, it is difficult to recruit patients at diagnosis before they have received therapy. Unlike acute leukemias where a complete remission is the objective of induction chemotherapy (and therefore an ideal time to enroll patients onto a study that evaluates consolidative strategies), induction chemotherapy is rarely used at the time of initial MDS diagnosis, and a complete remission occurs in few MDS patients on HMAs, rendering enrollment at complete remission neither a clinically meaningful nor feasible time point [12,14]. The BMT CTN 1102 addresses the fundamental question of whether RIC alloHCT offers a survival advantage compared with nontransplant therapies among older MDS patients who are believed to be transplant candidates. Therefore, enrolling patients at the time of referral would seem to be a reasonable approach.

Enrollment Bias and Prognostic Factor Imbalances

Given the lack of randomization, biologic assignment trials are inherently vulnerable to enrollment bias and prognostic factor imbalances. A detailed discussion of enrollment bias in the setting of biologic assignment trials has been published elsewhere [37]. To reduce bias and assemble the proper control group for the “donor arm,” it is critical to enroll patients without knowledge of whether a donor is available or not. Therefore, patients whose tissue typing for unrelated donors was initiated before referral will not be eligible. Patients whose tissue typing for a sibling donor was initiated before referral will still be eligible. The latter should not risk enrollment bias, because patients in whom the tissue typing rules out available sibling donors will still be considered for an HLA-matched unrelated donor transplant. Additionally, a multivariate analysis is planned that will adjust for any serious imbalances in baseline characteristics.

Potential Bias Introduced During Donor Search

Excessive early deaths (“early” indicates no suitable donor is identified and the 90-day window is not yet reached) could potentially bias the study in favor of the RIC alloHCT arm, because subjects who die before a donor is identified will be analyzed in the no donor arm. Conversely, subjects with an already identified sibling donor (which means immediate assignment to the donor arm) referred to the transplant center who experience early death (“early” indicates death occurring less than 90 days from enrollment and before RIC alloHCT is actually performed) are analyzed in the donor group, which could bias the study in favor of the nontransplant arm. The protocol team will monitor the rates of early death carefully and will report them to the Data Safety Monitoring Board. The protocol team expects that these early deaths rates will be very small given that these patients were believed to be eligible to undergo alloHCT within the preceding 2 to 3 months.

Eligibility Criteria

Patients with de novo MDS are eligible irrespective of how long they had MDS [38]. Patients must have (or previously had) an intermediate-2 or high-risk IPSS stage [5]. Our intent is to include patients in whom a RIC alloHCT is preferred based on physician’s assessment. Patients younger than 50 years of age typically undergo high-intensity conditioning alloHCT [23]. Therefore, subjects aged 50 to 75 years will be eligible to participate.

For subjects to be assigned to the donor arm, a suitable donor must be identified, which as previously stated is defined as either HLA-matched related donor or 8/8 HLA well-matched unrelated donor. Two analyses informed the decision to restrict donor types to only these 2. First, we recently reported outcomes of 701 MDS patients (median age 53 years [range, 22 to 78]) after HLA-identical sibling versus 8/8 (HLA-A, -B, -C, and DRB1) matched unrelated donor versus 7/8 HLA partially matched unrelated donor alloHCT [39]. In the multivariate analysis, HLA-identical sibling HCT recipients had similar survival compared with 8/8 matched unrelated donor HCT recipients, and both HLA-identical sibling and 8/8 matched unrelated donor groups had superior survival compared with 7/8 HLA partially matched unrelated donor alloHCT recipients (Table 1) [39]. Second, using data from the CIBMTR, we conducted an exploratory analysis to determine the impact of different donor sources on post-alloHCT outcomes in patients with MDS (unpublished data, June, 2012). We selected patients who were at least 21 years of age who received an alloHCT for MDS between 2000 and 2010 in the United States. Donor sources were HLA-identical sibling (n = 1458), well-matched unrelated donors (n = 1091), partially matched unrelated donors (n = 273), cord blood (n = 153), and haploidentical donors (n = 95). Median age at HCT was 54 (range, 21 to 81), and
Survival was not significantly different between HLA-identical sibling and well-matched unrelated donors. Therefore, only patients with suitable donor is not available, and therefore patients with therapy-related MDS are excluded from this study.

**Feasibility**

Based on historical CIBMTR data and assuming an accrual rate of 40%, we expect annual enrollment of 84 patients to the RIC alloHCT arm. The length of time required to accrue the targeted sample size for this study depends on the proportion of enrolled patients with a suitable donor. Supplemental Table 4 provides estimated annual accruals for various proportions of donor availability. Based on these assumptions, it is estimated that 2.5 to 3.5 years of accrual will be necessary to enroll the targeted sample size.

**Data Collection for Subjects Assigned to the No Donor Arm**

Subjects assigned to the no donor arm will continue to be followed by their primary hematologists. The HCT centers that enrolled and registered the patients will be responsible for periodic contact (every 3 months for Years 1 and 2, every 6 months in Year 3, ±1 month) with the primary hematologists. Documentation of transformation to AML will be requested, as well as treatment history. Vital status (death or alive) and date of the last follow-up or death will be recorded.

**Data Collection for Subjects Assigned to the Donor Arm**

The schedule of follow-up for subjects assigned to the donor arm but had not yet undergone alloHCT will follow the same schedule outlined above for the no donor arm. Once transplanted, the follow-up will be through submission of CIBMTR pre- and post-transplant comprehensive Report Forms. In the event that patients with donors do not undergo transplantation, the follow-up will remain the responsibility of the transplant center, with the same schedule outlined above for the no donor arm.

### Table 1
Multivariate Analysis of a Cohort of Adult MDS Patients Who Underwent HLA-Identical Sibling HCT or 8/8 or 7/8 Matched Unrelated Donor (MUD) HCT From 2002 to 2006

<table>
<thead>
<tr>
<th>Transplant-Related Mortality</th>
<th>RR (95% CI)</th>
<th>P</th>
<th>Relapse</th>
<th>RR (95% CI)</th>
<th>P</th>
<th>Treatment Failure (Death or Relapse)</th>
<th>RR (95% CI)</th>
<th>P</th>
<th>Mortality</th>
<th>RR (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>8/8 MUD vs. MRD</td>
<td>1.43 (1.06-1.95)</td>
<td>.02</td>
<td>.85 (0.60-1.18)</td>
<td>.33</td>
<td>1.13 (0.91-1.42)</td>
<td>.26</td>
<td>1.24 (0.98-1.56)</td>
<td>.06</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7/8 MUD vs. MRD</td>
<td>1.80 (1.23-2.63)</td>
<td>.002</td>
<td>1.02 (0.66-1.60)</td>
<td>.91</td>
<td>1.47 (1.10-1.96)</td>
<td>.008</td>
<td>1.62 (1.21-2.17)</td>
<td>.001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7/8 MUD vs. 8/8 MUD</td>
<td>1.25 (0.91-1.72)</td>
<td>.16</td>
<td>1.21 (0.81-1.81)</td>
<td>.35</td>
<td>1.29 (1.00-1.66)</td>
<td>.04</td>
<td>1.30 (1.01-1.68)</td>
<td>.03</td>
<td></td>
<td></td>
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</tbody>
</table>

MRD indicates matched related donor; RR, relative risk. Adapted from Saber et al. [39].

The actual choice of regimen is left to the discretion of the treating physician. However, regimens must be declared by the physician. However, regimens must be declared by the treating physician, with the same schedule outlined above for the no donor arm. Once transplanted, the follow-up will be through submission of CIBMTR pre- and post-transplant comprehensive Report Forms. In the event that patients with donors do not undergo transplantation, the follow-up will remain the responsibility of the transplant center, with the same schedule outlined above for the no donor arm.

**Ric alloHCT Regimens**

The protocol does not mandate particular nontransplant therapies. However, we expect most patients will be treated with HMAs. We acknowledge that nontransplant treatments used for patients in the control arm may vary. However, no nontransplant therapies produce cures in patients with high-risk MDS, and most nontransplant patients will receive the few US Food and Drug Administration–approved and available therapies when appropriate. The poor outcomes associated with these therapies are demonstrated in Supplemental Table 3. Data on the type of nontransplant therapies will be captured (ie, whether HMAs were received or not, number of cycles, duration of therapy).

**Nontransplant Regimens**

The actual choice of regimen is left to the discretion of the treating physician. However, regimens must be declared by the treating physician, with the same schedule outlined above for the no donor arm. Once transplanted, the follow-up will be through submission of CIBMTR pre- and post-transplant comprehensive Report Forms. In the event that patients with donors do not undergo transplantation, the follow-up will remain the responsibility of the transplant center, with the same schedule outlined above for the no donor arm.

**Key Issues in Study Analysis**

**Intention-to-Treat versus As-Treated Analysis**

To minimize bias that may occur after assignment, intention-to-treat analysis is planned as the primary analysis. Table 2 gives examples that illustrate how the intention-to-treat principle will be maintained when events occur during the 90-day interval and beyond. Additional sensitivity analyses excluding patients who died or dropped out before 90 days from enrollment as well as a secondary analysis using as-treated principles will also be conducted.

**Statistical Power**

Secondary analyses of published data from the CIBMTR for high-risk MDS patients older than age 50 suggest 3-year OS estimates between 35% and 40% [39]. Based on data from a compassionate use program of DNA HMAs, the 3-year OS probabilities for the nontransplant arm are estimated to range between 20% and 25% [41]. Based on these data, we expect to observe an absolute difference of 15% in 3-year OS probabilities in favor of patients assigned to the RIC alloHCT.
Table 2
Examples of Treatment Arm Assignment and Subsequent Analysis Based on Suitable Donor Identification

<table>
<thead>
<tr>
<th>Scenario</th>
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<tbody>
<tr>
<td>A transplant donor is identified 30 days from consent. The subject undergoes transplantation 70 days from consent.</td>
</tr>
<tr>
<td>A transplant donor is identified 30 days from consent. The subject receives 4 cycles of hypomethylating therapy and undergoes transplantation 200 days from consent.</td>
</tr>
<tr>
<td>A transplant donor is identified 30 days from consent. The subject receives 4 cycles of hypomethylating therapy and dies related to an infection before transplantation.</td>
</tr>
<tr>
<td>The patient has an identified sibling donor on the date of consent. The subject eventually declines transplantation.</td>
</tr>
<tr>
<td>A donor search is begun after enrollment, and the subject begins hypomethylating therapy. The subject dies 80 days after consent without a donor being identified.</td>
</tr>
<tr>
<td>A donor search is begun after enrollment, and the subject begins hypomethylating therapy. No donor is identified after a 90-day search. The subject continues on hypomethylating therapy.</td>
</tr>
<tr>
<td>A donor search is begun after enrollment, and the subject begins hypomethylating therapy. No donor is identified after a 90-day search. The subject progresses and undergoes alternative donor transplantation 150 days from consent.</td>
</tr>
</tbody>
</table>

Supplemental Table 5 gives the estimated sample size and power (at least 80% power) for various combinations of baseline survival probability and donor availability. It is expected that 60% to 70% of patients will have a donor. The required sample size increases with higher percentage of donor availability.

Planned Subgroup Analyses

The value of HMA therapy pre-HCT—and, more specifically, the “optimal” timing to refer a patient on HMA therapy for transplantation evaluation—remains unknown. Retrospective analyses have examined the impact of pre-HCT HMA therapy on post-HCT outcomes. The largest study included 163 individuals who underwent HCT after azacitidine and after leukemia-type induction chemotherapy. There were no differences in post-HCT outcomes [42]. A smaller study from Seattle demonstrated a slight advantage of pre-HCT therapy with azacitidine over induction chemotherapy, potentially because of reduced toxicity [43]. Both studies, however, lacked the size of the original patient population initially considered for transplantation—the actual denominator—without which it is impossible to determine the role of one pre-HCT approach versus another. Other retrospective analyses compared pre-HCT HMA therapy with no treatment and showed no benefit to HMA therapy. These studies were affected by similar selection biases as mentioned above [44,45]. Predefined subgroup analyses to determine the impact of pre-HCT HMA therapy (including response to HMA therapy) on the study outcomes will be performed to address this important question. Additional predefined subgroup analyses will examine the impact of the following factors on treatment effect: patient age (<65 years versus ≥65 years), disease duration, and IPSS and IPSS-R.

DISCUSSION

Understanding the relative risks and benefits of alloHCT can move the field significantly forward. We believe the current study design affords the best practical approach to achieving this goal in a relatively unbiased fashion. Despite the potential limitations discussed above, the strength of the current design is that it is likely to result in successful accrual by (1) having eligibility criteria that will capture a large segment of the patients referred for transplantation, (2) allowing flexibility in both transplant and nontransplant therapies administered, (3) minimizing the data collection burden, and (4) providing the optimal comparator groups given the constraints discussed above. It also allows for quality-of-life and cost-effectiveness studies, which are being planned in a “real world” population of patients. Recently, a Data Safety Monitoring Board recommended that the National Heart, Lung, and Blood Institute prematurely terminate BMT CTN 0901 (ClinicalTrials.gov identifier: NCT01339910 [46]) because preliminary data suggested that high-intensity regimens were associated with superior outcomes compared with RIC regimens permitted in the study among patients with AML and MDS who were eligible to get either regimen intensities. Because the data were not sufficiently mature to perform subgroup analysis based on disease type, it is not known currently whether these preliminary findings are consistent among AML versus MDS patients. These analyses will be performed in the future. We acknowledge that these preliminary results might lead some physicians to prefer higher intensity regimens in some patients otherwise eligible for BMT CTN 1102. However, we believe the proportion will be relatively low, because the eligibility criteria for BMT CTN 1102 from the start were only patients believed to be candidates for RIC alloHCT and not high-intensity regimens (because of comorbidities or age). Patients who are candidates for higher intensity regimens are not currently eligible for enrollment onto BMT CTN 1102.

The results of the BMT CTN 1102 have the potential to change practice. If this study demonstrates a significant survival advantage with alloHCT, we expect the number of patients transplanted would increase significantly, setting the stage for more refined studies. In fact, emerging data from an ongoing single-arm prospective study conducted at the CIBMTR to evaluate safety of alloHCT for older MDS patients [18], also made possible by the expanded coverage for the alloHCT by Medicare under the CED mechanism [22], clearly show that under this coverage mechanism the number of HCTs have risen dramatically (Figure 2). These data strongly support that barriers to access to alloHCT care is affecting the decision to refer patients for transplant evaluation. The BMT CTN 1102 has recently gained approval by the CMS, and therefore costs of alloHCT for Medicare

![Figure 2](image-url)

Figure 2. US alloHCTs for MDS patients older than 65 years from 2005 to 2013. BMT indicates bone marrow transplant.
beneficiaries enrolled onto this study will be covered. If the study demonstrates survival advantage with alloHCT, this will have significant implications with respect to coverage of costs of alloHCT for MDS by the CMS for all Medicare beneficiaries in the future. Alternatively, if the study fails to show an advantage to allogeneic HCT, it will make us dramatically rethink how we approach the problem of MDS in this patient population. Finally, if the study fails to accrue adequate numbers of patients for completion in a timely manner, there is the definite risk that Medicare will choose to no longer continue coverage and we will never know the answer.

ACKNOWLEDGMENTS

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SUPPLEMENTARY DATA

Supplementary data related to this article can be found online at http://dx.doi.org/10.1016/j.bbmt.2014.06.010.

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