Randomized controlled trial of individualized treatment summary and survivorship care plans for hematopoietic cell transplantation survivors

Navneet S. Majhail
Cleveland Clinic

Let us know how access to this document benefits you.

Follow this and additional works at: https://escholarship.umassmed.edu/oapubs

Part of the Health Services Administration Commons, Hematology Commons, Hemic and Lymphatic Diseases Commons, Neoplasms Commons, Oncology Commons, and the Psychiatry and Psychology Commons

Repository Citation
Majhail NS, Cerny J. (2018). Randomized controlled trial of individualized treatment summary and survivorship care plans for hematopoietic cell transplantation survivors. Open Access Publications by UMMS Authors. https://doi.org/10.3324/haematol.2018.203919. Retrieved from https://escholarship.umassmed.edu/oapubs/3703

This material is brought to you by eScholarship@UMassChan. It has been accepted for inclusion in Open Access Publications by UMMS Authors by an authorized administrator of eScholarship@UMassChan. For more information, please contact Lisa.Palmer@umassmed.edu.
Randomized controlled trial of individualized treatment summary and survivorship care plans for hematopoietic cell transplantation survivors

by Navneet S. Majhail, Elizabeth Murphy, Purushottam Laud, Jaime M. Preussler, Ellen M. Denzen, Beatrice Abetti, Alexia Adams, RaeAnne Besser, Linda J. Burns, Jan Cerny, Rebecca Drexler, Theresa Hahn, Lensa Idossa, Balkrishna Jahagirdar, Naynesh Kamani, Alison Loren, Deborah Mattila, Joseph McGuirk, Heather Moore, Jana Reynolds, Wael Saber, Lizette Salazar, Barry Schatz, Patrick Stiff, John R. Wingard, Karen L. Syrjala, and K. Scott Baker

Haematologica 2018 [Epub ahead of print]

Citation: Navneet S. Majhail, Elizabeth Murphy, Purushottam Laud, Jaime M. Preussler, Ellen M. Denzen, Beatrice Abetti, Alexia Adams, RaeAnne Besser, Linda J. Burns, Jan Cerny, Rebecca Drexler, Theresa Hahn, Lensa Idossa, Balkrishna Jahagirdar, Naynesh Kamani, Alison Loren, Deborah Mattila, Joseph McGuirk, Heather Moore, Jana Reynolds, Wael Saber, Lizette Salazar, Barry Schatz, Patrick Stiff, John R. Wingard, Karen L. Syrjala, and K. Scott Baker. Randomized controlled trial of individualized treatment summary and survivorship care plans for hematopoietic cell transplantation survivors. Haematologica. 2018; 103:xxx
doi:10.3324/haematol.2018.203919

Publisher’s Disclaimer.
E-publishing ahead of print is increasingly important for the rapid dissemination of science. Haematologica is, therefore, E-publishing PDF files of an early version of manuscripts that have completed a regular peer review and have been accepted for publication. E-publishing of this PDF file has been approved by the authors. After having E-published Ahead of Print, manuscripts will then undergo technical and English editing, typesetting, proof correction and be presented for the authors’ final approval; the final version of the manuscript will then appear in print on a regular issue of the journal. All legal disclaimers that apply to the journal also pertain to this production process.
Randomized controlled trial of individualized treatment summary and survivorship care plans for hematopoietic cell transplantation survivors

Navneet S. Majhail¹; Elizabeth Murphy²; Purushottam Laud³; Jaime M. Preussler²,⁴; Ellen M. Denzen²,⁴; Beatrice Abetti⁵; Alexia Adams⁴; RaeAnne Besser⁴; Linda J. Burns²,⁴; Jan Cerny⁶; Rebecca Drexler⁴; Theresa Hahn⁷; Lensa Idossa²; Balkrishna Jahagirdar⁸; Naynesh Kamani⁹; Alison Loren¹⁰; Deborah Mattila⁴; Joseph McGuirk¹¹; Heather Moore²; Jana Reynolds¹²; Wael Saber³,¹³; Lizette Salazar¹⁴; Barry Schatz¹⁵; Patrick Stiff¹⁵; John R. Wingard¹⁶; Karen L Syrjala¹⁷; K Scott Baker¹⁷

¹Blood and Marrow Transplant Program, Cleveland Clinic, Cleveland, OH; ²National Marrow Donor Program/Be The Match, Minneapolis, MN; ³Medical College of Wisconsin, Milwaukee, WI; ⁴Center for International Blood and Marrow Transplant Research, Minneapolis, MN; ⁵Leukemia and Lymphoma Society, White Plains, NY; ⁶UMass Memorial Medical Center, Worcester, MA; ⁷Roswell Park Comprehensive Cancer Center, Buffalo, NY; ⁸Regions Hospital, St Paul, MN; ⁹AABB, Bethesda, MD; ¹⁰University of Pennsylvania, Philadelphia, PA; ¹¹University of Kansas Medical Center, Kansas City, KS; ¹²Baylor University Medical Center, Dallas, TX; ¹³Center for International Blood and Marrow Transplant Research, Milwaukee, WI; ¹⁴Haledon, NJ; ¹⁵Loyola University Medical Center, Chicago, IL; ¹⁶University of Florida, Gainesville, FL; ¹⁷Fred Hutchinson Cancer Research Center, Seattle, WA

Key Words: Survivorship; Autologous hematopoietic cell transplantation; Allogeneic hematopoietic cell transplantation; Late complications; Survivorship care plan
Running Title: Individualized care plans in HCT survivors

Submission Type: Original Article

Word Count: Abstract – 250 words; Text – 2669 words; Figures and Tables – 5; References – 56; Supplemental Figures and Table – 2

Clinical Trial Information: Clinicaltrials.gov registration number: NCT02200133

Research Support: Research reported in this publication was funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (CD-12-11-4062). The views in this publication are solely the responsibility of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee. K. Scott Baker, Navneet Majhail and Karen Syrjala are partially supported by a grant from the National Cancer Institute (R01-CA215134). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Conflict of Interest Statement: None of the authors has a relevant financial conflict of interest in relationship to this study.

Presentation: This study was presented in part at the American Society of Hematology annual meeting in December 2017 at Atlanta, GA

Address for Correspondence:
Navneet Majhail, MD, MS
Blood and Marrow Transplant Program
Cleveland Clinic
9500 Euclid Ave, CA60
Cleveland, OH 44195
Phone: 2164442199
Email: majhain@ccf.org
ARTICLE SUMMARY

- Individualized survivorship care plans can be generated using clinical data routinely submitted to a central registry of HCT recipients

- These care plans reduced cancer and treatment distress and improved mental domain of QOL in a randomized study of long-term HCT survivors
ABSTRACT

Survivorship care plans may facilitate long-term care for cancer survivors, but their effectiveness has not been established in hematopoietic cell transplantation recipients. We evaluated the impact of individualized survivorship care plans on patient-reported outcomes among transplant survivors. Adult (≥18 years at transplant) survivors who were 1-5 years post-transplantation, proficient in English, and without relapse or secondary cancers were eligible for this multicenter randomized trial. Care plans were developed based on risk-factors and treatment exposures using patient data routinely submitted by transplant centers to the Center for International Blood and Marrow Transplant Research and published guidelines for long-term follow-up of transplant survivors. Phone surveys assessing patient-reported outcomes were conducted at baseline and 6-months. Primary endpoint was confidence in survivorship information, and secondary endpoints included cancer and treatment distress, knowledge of transplant exposures, health care utilization and health-related quality of life. Of 495 patients enrolled, 458 completed a baseline survey and were randomized (care plan=231, standard care=227); 200 (87%) and 199 (88%) completed the 6-month assessments, respectively. Patient characteristics were balanced in the two arms. Participants on care plan arm reported significantly lower distress scores at 6-months and an increase in the Mental Component Summary quality of life score assessed by the SF12 instrument. No effect was observed on the endpoint of confidence in survivorship information or other secondary outcomes. Provision of individualized survivorship care plans generated using registry data was associated with reduced distress and improved mental domain of quality of life among 1-5 year hematopoietic cell transplantation survivors. (clinicaltrials.gov NCT02200133)
INTRODUCTION

It is estimated that there will be 250,000 hematopoietic cell transplantation (HCT) survivors in the United States (US) by 2020.1 Patients who survive the period of early complications and disease relapse, generally 1-2 years after transplantation, can expect high probability of subsequent long-term survival.2-7 Although potentially cured of their underlying disease, HCT survivors continue to be at risk for late complications that can cause substantial morbidity, mortality, and functional deficits, and contribute to psychosocial and quality of life impairments.8-23 Established survivorship guidelines provide a pragmatic approach to the long-term follow-up of autologous and allogeneic HCT survivors by recommending a minimum set of screening and preventive evaluations that need to be performed periodically post-transplantation.24,25

HCT survivors frequently do not receive or adhere to preventive care guidelines.26-28 Many barriers contribute to the inadequate provision of coordinated patient-centric survivorship care in this patient population.29-31 Among these barriers, lack of awareness of exposures and risks by patients is strongly associated with a lower likelihood of adherence to preventive care recommendations.26 Additionally, both transplant and non-transplant providers cite lack of knowledge of late complication risks and of awareness of guidelines as barriers to providing adequate preventive care.32 Finally, capacity limitations at transplant centers may impede provision and coordination of preventive care to HCT survivors.29,33-35 Interventions to enhance patient awareness of preventive care could potentially enhance appropriate healthcare utilization and adherence to survivorship guidelines, although, this approach has not been previously tested.
A treatment summary and survivorship care plan (SCP) is a tool that provides cancer survivors with information on their cancer type, treatments and potential consequences, and recommendations regarding follow-up and preventive care. SCPs are generally accepted as an important component of cancer survivorship care. Randomized trials of SCPs in cancer patients have primarily focused on providing information through in-person visit with patients or educating primary care providers, and evidence of their efficacy in enhancing various aspects of cancer survivorship care is generally negative. They are also frequently underutilized for many reasons, including insufficient resources for their generation and implementation, and a paucity of evidence regarding an impact on patient outcomes. The use and dissemination of SCPs in HCT survivors are hampered by similar challenges, and many transplant centers do not routinely provide patients with this tool. Furthermore, these barriers may be accentuated given the highly complex nature and unique exposures associated with the transplant procedure and challenges that exist in providing coordinated survivorship care.

We hypothesized that a patient centered approach with a personalized SCP based on published guidelines for prevention of HCT-related late complications, and generated using patient data routinely submitted by transplant centers in the US to an international clinical outcomes registry (Center for International Blood and Marrow Transplant Research [CIBMTR]) would increase patient awareness of recommended preventive care, which in turn would reduce distress, promote healthy behaviors, enhance healthcare utilization for appropriate preventive care, and improve health related quality of life (HRQOL). By using existing CIBMTR data, this approach would overcome several system-level barriers to providing survivorship care through transplant centers. Furthermore, it could serve as a template for a generalizable and efficient mechanism for
providing a patient-centric SCP to long-term HCT survivors who frequently are no longer under the care of transplant centers and are particularly vulnerable to gaps in preventive care. In a multicenter randomized controlled trial (RCT), we evaluated the efficacy of such an individualized SCP instrument generated using registry data and mailed to patients versus standard care on improving patient reported outcomes in adult HCT survivors who were 1-5 years after their transplantation.

METHODS

Supplemental materials detail study methods. Briefly, potentially eligible patients from 17 participating US centers were identified from the CIBMTR database and their data were used to generate a paper-based SCP that was personalized to their HCT specific exposures (see Supplemental Materials). Patient eligibility criteria were kept broad and included patients who were 1-5 years post-transplant, ≥18 years at the time of HCT, with no evidence of disease relapse/progression or second cancers, and fluency in English; patients were eligible irrespective of transplant type (autologous or allogeneic), diagnosis, donor source or conditioning regimen. None of the participating centers had an existing mechanism for routinely providing SCPs to their patients. The RCT used a multi-center design with patient-level randomization to treatment (Figure 1), and was approved by Institutional Review Boards at the NMDP and each participating site. A random order list of survivors was generated and released in blocks to centers, who confirmed patient survival and accuracy of SCP related data. Centers contacted and consented patients and then informed the CIBMTR, who proceeded with the rest of the study procedures. The CIBMTR Survey Research Group (SRG) conducted a phone assessment within 30 days of receiving participant enrollment form. Patients were randomized 1:1 to the SCP or
control arm (with delayed SCP). Patients randomized to the SCP arm were express mailed an information letter and their printed SCP while patients on the control arm received an information letter only. SRG then contacted all enrolled patients by phone between 7-28 days of mailing study materials to conduct a health literacy assessment using the Newest Vital Sign.44 During this contact, patients on the SCP arm were given the opportunity to address any questions about the content or use of their SCP. No further contact was made till the 6-month phone survey. The Confidence in Survivorship Information (CSI) was the primary endpoint (Supplemental Table 1).45 Secondary endpoints focused on Cancer and Treatment Distress (CTXD),20,46 as well as measures of Knowledge of Transplant Exposures, Health Care Utilization,26 and HRQOL using the SF-12.47 Patients on the intervention arm also received a 12-item assessment for qualitative feedback on SCP utilization. Sample size calculations were performed using a standard error formula that allowed for possible variability in treatment effect across centers and considered dropouts from baseline to 6 months. Our enrollment goal was 495 patients, which yielded adequate power to detect standardized effect sizes of ≥0.3, which are considered to be clinically meaningful, and anticipated a 10% drop-off from baseline to 6-months. An intention-to-treat approach was followed for analysis. A mixed model with center-level random effects and a fixed treatment effect was used to test whether a change in baseline and 6-month existed between the treatment and control groups for the primary and secondary endpoints. The 6-month assessment was used as a response variable and the baseline assessment was used as an explanatory variable in the regression models. If a treatment effect existed, we further evaluated whether the effect was modified by demographic variables or any interactions between variables.
RESULTS

Patient Characteristics

Among the 495 patients enrolled, 458 completed the baseline survey and were randomized (SCP=231, control=227); 200 (87%) and 199 (88%) completed 6-month assessments, respectively (Figure 2). The main reasons for dropout were loss to followup or patients not eligible for followup assessment due to interim disease relapse or progression. A greater proportion of patients who completed the 6-month assessment were White and reported higher health literacy scores; otherwise there were no significant differences in the demographic characteristics of patients who did and did not complete the 6-month assessments (Supplemental Table 2). Patient and transplant characteristics (including health literacy scores) were well balanced between the two arms, except for sex (49% males in SCP compared to 60% in controls, P=0.01) (Table 1). Median age was 59 years in both arms and enrolled patients were predominantly White (96% SCP and 92% controls). In the SCP and control arms, 48% and 44% had received allogeneic HCT; among allogeneic HCT recipients 63% and 67% had a history of acute GVHD and 60% and 66% had a history of chronic graft-versus-host disease (GVHD), respectively.

Analyses of Primary and Secondary Endpoints

Of the 458 patients randomized to the two arms, 399 completed 6-month assessments, including 398 who completed pre- and post-measurements for the primary endpoint (Table 2). We did not find any association between the SCP intervention and change in CSI scores from baseline to 6-months (P=0.223), even after assessing for the effect of demographic factors and interactions. However, we did observe a significant decrease in CTXD scores (P=0.004) and increase in
HRQOL Mental Component Summary (MCS) scores as assessed by SF-12 (P=0.003) among patients randomized to the SCP arm. There was no association between the SCP intervention and other secondary endpoints.

We further assessed the effect of demographic variables and interactions for the endpoints of CTXD and SF-12 MCS, where a significant treatment effect was observed. Age was significantly associated with CTXD scores (regression estimate -0.006, standard error 0.002; P=0.001), with lower distress among older patients. However, there was no significant interaction between age and SCP intervention and adjustment for age did not modify the treatment effect. The decrease in CTXD score for the SCP arm was independent of sex, health literacy, diagnosis, transplant type, and GVHD status (including acute and chronic GVHD). We also found a similar effect of age on MCS scores with older patients reporting significantly higher scores (estimate 0.03, standard error 0.034; P<0.001) and there was a significant interaction between age and SCP intervention (P=0.012). However, increase in mean MCS score in the SCP arm was independent of sex, health literacy, diagnosis, transplant type, and GVHD status.

Utilization of SCP

At their 6-month end-of-study assessments, patients on the intervention arm were asked questions about usefulness of the SCP for their survivorship care (Figure 3). A relatively large proportion of survivors reported that they found SCP somewhat or very useful for helping them better understand their HCT and related treatments (70%), side effects of HCT (65%), and managing their health (69%). The SCP helped survivors better communicate about HCT and its side effects with their medical providers. The 6-month interview included an open-ended
question about patients experience with the SCP; dominant themes identified on qualitative analyses included patients reporting that SCP helped survivors focus on their overall health, supported them in making care decisions with providers, and supported emotional health and coping.

**DISCUSSION**

In this large multicenter RCT of HCT survivors 1-5 years post-transplantation, we demonstrate that SCPs generated using a centralized clinical registry (CIBMTR), individualized to patient exposures, and without clinician contact to interpret or personalize their content and recommendations, are feasible and have desirable outcomes including lower treatment-related distress and improved mental health domain of HRQOL. Our results support further research towards broader implementation of our SCP instrument for facilitating care of HCT survivors and provides evidence to support a patient centered approach towards administration of SCPs.

SCPs have been endorsed as a tool for facilitating the care of cancer survivors with the goal of improving patient outcomes by promoting care-coordination, shared-decision making, self-management, and adherence to treatment recommendations. Evidence on their efficacy in impacting patients outcomes is mixed, and SCPs have not been universally adopted due to other barriers such as lack of standardized templates, need for extensive resources and time for their generation, and lack of reimbursement for their implementation. Similar challenges exist for transplant centers, and many programs have capacity limitations that frequently prevent provision of personalized comprehensive SCPs to their patients. Our SCP procedure provides several advantages to patients and transplant centers. It uses data that centers routinely submit
electronically to the CIBMTR and will provide a resource-effective mechanism for centers to generate the SCP for their recipients. Instead of receiving a generic SCP, patients can receive one that is specific to their treatment exposures. Our approach of facilitating patient ownership of survivorship care is different from the prevalent non-transplant cancer literature where SCPs have been largely tested in the setting of clinicians providing them to patients. Our SCP instrument was in a paper-based format and mailed to patients; more general dissemination would require its translation into an electronic format. Hence, further research is still needed to guide its implementation. An ongoing project funded by the National Cancer Institute is investigating its use in combination with an online health informatics platform to facilitate a self-management program for selected late complications among HCT survivors (NCT03125070; Syrjala, Baker and Majhail).

Of note, we did not observe any impact of the SCP intervention on our primary endpoint of CSI. Our study population consisted of HCT survivors who were relatively early post-transplantation (1-5 years) and enrolled by centers with an interest in providing survivorship care to their transplant recipients; it is possible our instrument may be more effective in enhancing knowledge and confidence about follow-up care among patients who are further out from transplantation or those who are not followed primarily or closely by their transplant centers. The CSI instrument has been validated in cancer survivors but not among HCT recipients, and it is also possible that it did not adequately measure the underlying construct in our patient population. The six-month pre- and post-intervention follow-up period was most likely too short to detect any significant associations with changes in healthcare adherence or utilization. We did not observe any interaction of GVHD with the intervention and study outcomes. This was most likely due to our
study population being relatively further out from transplantation and the short duration of the intervention. Furthermore, it is likely that patients with GVHD were under the active care of transplant centers and this may have impacted patient reported outcomes assessed in our study (e.g., greater confidence in recommended care, less distress, etc.). These same factors were probably responsible for some patients not finding the SCP tool to be useful for various aspects of survivorship care (see Figure 3; “I have not done this” and “Not at all useful” responses on SCP utilization survey administered as part of end-of-study assessments for the intervention arm).

The concordant findings of reduction in CTXD scores and improvement in SF-12 MCS scores cross-validate the overall effect of SCP on reducing distress and improving HRQOL in our study population of HCT survivors. It is important to note that these effects occurred over a relatively short period of time and did not require any additional clinical contact or intervention to facilitate the use of the SCP. Interestingly, we found an independent association between older age and lower CTXD scores, which is consistent with other literature where older adults are less distressed about cancer and survivorship.\textsuperscript{51-54} The SCP provided concise information on previous treatments and potential late effects, and practical guidance regarding recommended preventive care that survivors could easily understand and share, which may have empowered them in the CTXD domains (e.g., uncertainty, health burden and medical demands) and MCS domains (e.g., mental health, social functioning, role-emotional), leading to the improvement in those areas.\textsuperscript{55}

Some limitations of our study must be acknowledged. First, the treatment summary portion of our SCP primarily included HCT-related and post-transplant events and did not have detailed
information on pre-transplant exposures as those data are not captured comprehensively by the CIBMTR. However, transplant centers have the option to add information about those exposures to the basic template of the SCP. Participants who completed 6-month assessments were more likely White and had higher health literacy, which may limit the generalizability of our findings. However, this is reflective of the prevailing healthcare disparities in HCT and research on other interventions to facilitate SCP use in this underserved population is needed.\textsuperscript{56} Notwithstanding these limitations, the pragmatic nature of our study eligibility criteria and schema will make our results broadly applicable to transplant centers in the US.

An ideal mechanism to provide SCPs to HCT survivors would involve a dynamic, adaptable, and patient-specific shared-decision making approach between patients, their transplant centers, and other providers. However, several challenges prevent centers from providing this tool to facilitate survivorship care for their patients and SCPs that can be generated efficiently and without requiring significant center resources would be impactful for patient care. Our study supports further implementation of an individualized SCP generated using CIBMTR data in a population of HCT survivors that is at significant risk for late morbidity and mortality. Future research will examine the role of the SCP instrument in preventing specific late complications, in facilitating care coordination, and will serve as a platform for investigating novel methods for survivorship care delivery and implementation.
ACKNOWLEDGEMENTS

Key to the success of this patient-centered outcomes research study were the many contributions and engagement of our more than 40 stakeholder group representatives including: transplant recipients, caregivers, community hematology/oncology physicians, and transplant physicians, nurses, social workers, patient health educators, and patient advocates. We are deeply indebted to the National Marrow Donor Program’s Patient Services Advisory Group, which includes representation from many of these stakeholder groups, of whom several members participated in the protocol team for this study or provided feedback and guidance on study design and interpretation of results. The study investigators would like to the following transplant centers for enrolling patients on this study (site investigators are listed in parentheses): Baylor University, Dallas, TX (Jana Reynolds); Cleveland Clinic, Cleveland, OH (Navneet Majhail); Fred Hutchinson Cancer Research Center, Seattle, WA (K Scott Baker), Karmanos Cancer Institute, Detroit, MI (Abhinav Deol); Loyola University, Chicago, IL (Patrick Stiff); Mayo Clinic, Rochester, MN (Shahrukh Hashmi); Mayo Clinic, Scottsdale, AZ (Nandita Khera); Ohio State University, Columbus, OH (Samantha Jaglowski); Roswell Park Comprehensive Cancer Center, Buffalo, NY (Theresa Hahn); UMass Memorial Medical Center, Worcester, MA (Jan Cerny); University of Florida, Gainesville, FL (John R. Wingard); University of Kansas, Kansas City, KS (Joseph McGuirk); University of Minnesota, Minneapolis, MN (Shernan Holtan); University of North Carolina, Chapel Hill, NC (William Wood); University of Pennsylvania, Philadelphia, PA (Alison Loren); Vanderbilt University, Nashville, TN (Bipin Savani). We are especially grateful to study coordinators at all sites who worked tirelessly and often outside regular working hours to contact and enroll patients on our trial. We would also like to thank members of CIBMTR’s Health Services Research (HSR) Program and Resource for Clinical Investigation in Blood and
Marrow Transplantation (RCI BMT), including their Survey Research Group, who helped with study conduct, data collection and management, and performed patient interviews. This study was funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (CD-12-11-4062). The views in this publication are solely the responsibility of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee. K. Scott Baker, Navneet Majhail and Karen Syrjala are partially supported by a grant from the National Cancer Institute (R01-CA215134). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

AUTHOR CONTRIBUTIONS

Study Conception and Design: All authors

Collection and Assembly of Data: Jaime Preussler, Alexia Adams, RaeAnne Besser, Ellen Denzen, Deborah Matilla

Performed Statistical Analysis: Jaime Preussler, Purushottam Laud

Data Analysis and Interpretation: All authors

Drafting of Manuscript: Navneet Majhail, Jaime Preussler, Purushottam Laud

Critical Review and Final Approval of Manuscript: All authors
REFERENCES

1. Majhail NS, Tao L, Bredeson C, et al. Prevalence of hematopoietic cell transplant survivors in the United States. Biol Blood Marrow Transplant. 2013;19(10):1498-1501.

2. Wingard JR, Majhail NS, Brazauskas R, et al. Long-term survival and late deaths after allogeneic hematopoietic cell transplantation. J Clin Oncol. 2011;29(16):2230-2239.

3. Majhail NS, Bajorunaite R, Lazarus HM, et al. High probability of long-term survival in 2-year survivors of autologous hematopoietic cell transplantation for AML in first or second CR. Bone Marrow Transplant. 2011;46(3):385-392.

4. Majhail NS, Bajorunaite R, Lazarus HM, et al. Long-term survival and late relapse in 2-year survivors of autologous haematopoietic cell transplantation for Hodgkin and non-Hodgkin lymphoma. Br J Haematol. 2009;147(1):129-139.

5. Martin PJ, Counts GW, Jr., Appelbaum FR, et al. Life expectancy in patients surviving more than 5 years after hematopoietic cell transplantation. J Clin Oncol. 2010;28(6):1011-1016.

6. Bhatia S, Francisco L, Carter A, et al. Late mortality after allogeneic hematopoietic cell transplantation and functional status of long-term survivors: report from the Bone Marrow Transplant Survivor Study. Blood. 2007;110(10):3784-3792.

7. Bhatia S, Robison LL, Francisco L, et al. Late mortality in survivors of autologous hematopoietic-cell transplantation: report from the Bone Marrow Transplant Survivor Study. Blood. 2005;105(11):4215-4222.

8. Sun CL, Francisco L, Baker KS, Weisdorf DJ, Forman SJ, Bhatia S. Adverse psychological outcomes in long-term survivors of hematopoietic cell transplantation: a report from the Bone Marrow Transplant Survivor Study (BMTSS). Blood. 2011;118(17):4723-4731.
9. Armenian SH, Sun CL, Kawashima T, et al. Long-term health-related outcomes in survivors of childhood cancer treated with HSCT versus conventional therapy: a report from the Bone Marrow Transplant Survivor Study (BMTSS) and Childhood Cancer Survivor Study (CCSS). Blood. 2011;118(5):1413-1420.

10. Sun CL, Francisco L, Kawashima T, et al. Prevalence and predictors of chronic health conditions after hematopoietic cell transplantation: a report from the Bone Marrow Transplant Survivor Study. Blood. 2010;116(17):3129-3139; quiz 3377.

11. Baker KS, Ness KK, Weisdorf D, et al. Late effects in survivors of acute leukemia treated with hematopoietic cell transplantation: a report from the Bone Marrow Transplant Survivor Study. Leukemia. 2010;24(12):2039-2047.

12. Majhail NS, Ness KK, Burns LJ, et al. Late effects in survivors of Hodgkin and non-Hodgkin lymphoma treated with autologous hematopoietic cell transplantation: a report from the bone marrow transplant survivor study. Biol Blood Marrow Transplant. 2007;13(10):1153-1159.

13. Majhail NS, Douglas Rizzo J. Surviving the cure: long term followup of hematopoietic cell transplant recipients. Bone Marrow Transplant. 2013;48(9):1145-1151.

14. Battiwalla M, Hashmi S, Majhail N, Pavletic S, Savani BN, Shelburne N. National Institutes of Health Hematopoietic Cell Transplantation Late Effects Initiative: Developing Recommendations to Improve Survivorship and Long-Term Outcomes. Biol Blood Marrow Transplant. 2017;23(1):6-9.

15. Battiwalla M, Tichelli A, Majhail NS. Long-Term Survivorship after Hematopoietic Cell Transplantation: Roadmap for Research and Care. Biol Blood Marrow Transplant. 2017;23(2):184-192.
16. Majhail NS. Long-term complications after hematopoietic cell transplantation. Hematol Oncol Stem Cell Ther. 2017;10(4):220-227.

17. Syrjala KL, Artherholt SB, Kurland BF, et al. Prospective neurocognitive function over 5 years after allogeneic hematopoietic cell transplantation for cancer survivors compared with matched controls at 5 years. J Clin Oncol. 2011;29(17):2397-2404.

18. Kirchhoff AC, Leisenring W, Syrjala KL. Prospective predictors of return to work in the 5 years after hematopoietic cell transplantation. J Cancer Surviv. 2010;4(1):33-44.

19. Syrjala KL, Langer SL, Abrams JR, Storer BE, Martin PJ. Late effects of hematopoietic cell transplantation among 10-year adult survivors compared with case-matched controls. J Clin Oncol. 2005;23(27):6596-6606.

20. Syrjala KL, Langer SL, Abrams JR, et al. Recovery and long-term function after hematopoietic cell transplantation for leukemia or lymphoma. JAMA. 2004;291(19):2335-2343.

21. Majhail NS, Brazauskas R, Rizzo JD, et al. Secondary solid cancers after allogeneic hematopoietic cell transplantation using busulfan-cyclophosphamide conditioning. Blood. 2011;117(1):316-322.

22. Majhail NS. Secondary cancers following allogeneic haematopoietic cell transplantation in adults. Br J Haematol. 2011;154(3):301-310.

23. Sun CL, Kersey JH, Francisco L, et al. Burden of morbidity in 10+ year survivors of hematopoietic cell transplantation: report from the bone marrow transplantation survivor study. Biol Blood Marrow Transplant. 2013;19(7):1073-1080.
24. Majhail NS, Rizzo JD, Lee SJ, et al. Recommended screening and preventive practices for long-term survivors after hematopoietic cell transplantation. Bone Marrow Transplant. 2012;47(3):337-341.

25. Majhail NS, Rizzo JD, Lee SJ, et al. Recommended screening and preventive practices for long-term survivors after hematopoietic cell transplantation. Biol Blood Marrow Transplant. 2012;18(3):348-371.

26. Khera N, Chow EJ, Leisenring WM, et al. Factors associated with adherence to preventive care practices among hematopoietic cell transplantation survivors. Biol Blood Marrow Transplant. 2011;17(7):995-1003.

27. Bishop MM, Lee SJ, Beaumont JL, et al. The preventive health behaviors of long-term survivors of cancer and hematopoietic stem cell transplantation compared with matched controls. Biol Blood Marrow Transplant. 2010;16(2):207-214.

28. Armenian SH, Sun CL, Francisco L, et al. Health behaviors and cancer screening practices in long-term survivors of hematopoietic cell transplantation (HCT): a report from the BMT Survivor Study. Bone Marrow Transplant. 2012;47(2):283-290.

29. Hashmi SK, Bredeson C, Duarte RF, et al. National Institutes of Health Blood and Marrow Transplant Late Effects Initiative: The Healthcare Delivery Working Group Report. Biol Blood Marrow Transplant. 2017;23(5):717-725.

30. Majhail NS. Optimizing Quality and Efficiency of Healthcare Delivery in Hematopoietic Cell Transplantation. Curr Hematol Malig Rep. 2015;10(3):199-204.

31. Khera N, Martin P, Edsall K, et al. Patient-centered care coordination in hematopoietic cell transplantation. Blood Adv. 2017;1(19):1617-1627.
32. Mani S, Rybicki L, Carraway H, Moore H, Vakharia N, Majhail NS. Primary care physician preferences and perspectives on long-term care of survivors of hematologic malignancies and hematopoietic cell transplantation. Biol Blood Marrow Transplant. 2016;22(3 (Suppl)):S85-86.

33. Denzen EM, Majhail NS, Stickney Ferguson S, et al. Hematopoietic cell transplantation in 2020: summary of year 2 recommendations of the National Marrow Donor Program's System Capacity Initiative. Biol Blood Marrow Transplant. 2013;19(1):4-11.

34. Majhail NS, Mau LW, Chitphakdithai P, et al. National Survey of Hematopoietic Cell Transplantation Center Personnel, Infrastructure, and Models of Care Delivery. Biol Blood Marrow Transplant. 2015;21(7):1308-1314.

35. Majhail NS, Murphy EA, Denzen EM, et al. The National Marrow Donor Program's Symposium on Hematopoietic Cell Transplantation in 2020: a health care resource and infrastructure assessment. Biol Blood Marrow Transplant. 2012;18(2):172-182.

36. McCabe MS, Bhatia S, Oeffinger KC, et al. American Society of Clinical Oncology statement: achieving high-quality cancer survivorship care. J Clin Oncol. 2013;31(5):631-640.

37. Jacobsen PB, DeRosa AP, Henderson TO, et al. Systematic Review of the Impact of Cancer Survivorship Care Plans on Health Outcomes and Health Care Delivery. J Clin Oncol. 2018;36(20):2088-2100.

38. Salz T, Oeffinger KC, McCabe MS, Layne TM, Bach PB. Survivorship care plans in research and practice. CA Cancer J Clin. 2012;62(2):101-117.

39. Stricker CT, Jacobs LA, Risendal B, et al. Survivorship care planning after the institute of medicine recommendations: how are we faring? J Cancer Surviv. 2011;5(4):358-370.
40. Jacobs LA, Shulman LN. Follow-up care of cancer survivors: challenges and solutions. 
   Lancet Oncol. 2017;18(1):e19-e29.
41. Klemanski DL, Browning KK, Kue J. Survivorship care plan preferences of cancer survivors 
   and health care providers: a systematic review and quality appraisal of the evidence. J Cancer 
   Surviv. 2016;10(1):71-86.
42. Brennan ME, Gormally JF, Butow P, Boyle FM, Spillane AJ. Survivorship care plans in 
   cancer: a systematic review of care plan outcomes. Br J Cancer. 2014;111(10):1899-1908.
43. Denzen EM, Preussler JM, Murphy EA, et al. Tailoring a survivorship care plan: Patient and 
   provider preferences for recipients of hematopoietic cell transplantation Biol Blood Marrow 
   Transplant. 2018 Oct 10. [Epub ahead of print]
44. Weiss BD, Mays MZ, Martz W, et al. Quick assessment of literacy in primary care: the 
   newest vital sign. Ann Fam Med. 2005;3(6):514-522.
45. Palmer SC, Jacobs LA, Mao J, Stricker CT. Are cancer survivors confident in their 
   knowledge about their disease and care. Cancer Survivorship Research: Translating Science 
   to Care. 2012:A32.
46. Syrjala KL, Chapko ME. Evidence for a biopsychosocial model of cancer treatment-related 
   pain. Pain. 1995;61(1):69-79.
47. Ware J, Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of 
   scales and preliminary tests of reliability and validity. Med Care. 1996;34(3):220-233.
48. Mayer DK, Nekhlyudov L, Snyder CF, Merrill JK, Wollins DS, Shulman LN. American 
   Society of Clinical Oncology clinical expert statement on cancer survivorship care planning. 
   J Oncol Pract. 2014;10(6):345-351.
49. Blanch-Hartigan D, Forsythe LP, Alfano CM, et al. Provision and discussion of survivorship care plans among cancer survivors: results of a nationally representative survey of oncologists and primary care physicians. J Clin Oncol. 2014;32(15):1578-1585.

50. Hewitt ME, Bamundo A, Day R, Harvey C. Perspectives on post-treatment cancer care: qualitative research with survivors, nurses, and physicians. J Clin Oncol. 2007;25(16):2270-2273.

51. Acquati C, Kayser K. Predictors of psychological distress among cancer patients receiving care at a safety-net institution: the role of younger age and psychosocial problems. Support Care Cancer. 2017;25(7):2305-2312.

52. Head BA, Schapmire TJ, Keeney CE, et al. Use of the Distress Thermometer to discern clinically relevant quality of life differences in women with breast cancer. Qual Life Res. 2012;21(2):215-223.

53. Jacobsen PB, Shibata D, Siegel EM, et al. Evaluating the quality of psychosocial care in outpatient medical oncology settings using performance indicators. Psychooncology. 2011;20(11):1221-1227.

54. Zebrack B, Kayser K, Sundstrom L, et al. Psychosocial distress screening implementation in cancer care: an analysis of adherence, responsiveness, and acceptability. J Clin Oncol. 2015;33(10):1165-1170.

55. Syrjala KL, Sutton SK, Jim HS, et al. Cancer and treatment distress psychometric evaluation over time: A BMT CTN 0902 secondary analysis. Cancer. 2017;123(8):1416-1423.

56. Majhail NS, Nayyar S, Santibanez ME, Murphy EA, Denzen EM. Racial disparities in hematopoietic cell transplantation in the United States. Bone Marrow Transplant. 2012;47(11):1385-1390.
Table 1. Baseline characteristics of patients enrolled on the study

| Characteristic                                                | SCP (N=231) | Routine care (N=227) |
|---------------------------------------------------------------|-------------|----------------------|
| Age at HCT, years; Median (range)                             | 59 (19-81)  | 59 (20-77)           |
| Time from HCT to enrollment (months); Median (range)          | 42 (16-66)  | 45 (16-66)           |
| Age group at baseline survey, years; N (%)                    |             |                      |
| 18-29                                                         | 7 (3)       | 9 (4)                |
| 30-39                                                         | 10 (4)      | 14 (6)               |
| 40-49                                                         | 28 (12)     | 18 (8)               |
| 50-59                                                         | 55 (24)     | 58 (26)              |
| 60-69                                                         | 83 (36)     | 92 (41)              |
| ≥70                                                           | 48 (21)     | 36 (16)              |
| Sex; N (%)                                                    |             |                      |
| Male                                                          | 112 (49)    | 136 (60)             |
| Female                                                        | 119 (52)    | 91 (40)              |
| Ethnicity; N (%)                                              |             |                      |
| Hispanic/Latino                                               | 8 (3)       | 7 (3)                |
| Non-Hispanic/Latino                                          | 216 (94)    | 216 (95)             |
| Declined                                                     | 7 (3)       | 4 (2)                |
| Race; N (%)                                                   |             |                      |
| White                                                         | 222 (96)    | 208 (92)             |
| African-American                                             | 5 (2)       | 15 (7)               |
| Asian                                                         | 2 (1)       | 3 (1)                |
| Pacific Islander                                             | 1 (<1)      | 0 (0)                |
| Declined                                                     | 1 (<1)      | 1 (<1)               |
| Diagnosis; N (%)                                              |             |                      |
| Acute myeloid leukemia                                       | 52 (23)     | 46 (20)              |
| Acute lymphoblastic leukemia                                  | 10 (4)      | 8 (4)                |
| Myelodysplastic/myeloproliferative disorders                  | 19 (8)      | 23 (10)              |
| Chronic myeloid leukemia                                      | 2 (1)       | 3 (1)                |
| Hodgkin lymphoma                                              | 13 (6)      | 10 (4)               |
| Non-Hodgkin lymphoma                                         | 49 (21)     | 47 (21)              |
| Plasma cell disorder/multiple myeloma                        | 78 (34)     | 80 (35)              |
| Other                                                         | 8 (3)       | 10 (4)               |
| Time from diagnosis to HCT, months; Median (range)            | 7 (1-266)   | 8 (1-327)            |
| Year of transplant; N (%)                                     |             |                      |
| 2010                                                          | 11 (5)      | 22 (10)              |
| 2011                                                          | 67 (29)     | 61 (27)              |
| 2012                                                          | 48 (21)     | 53 (23)              |
| 2013                                                          | 81 (35)     | 64 (28)              |
| 2014                                                          | 24 (10)     | 27 (12)              |
|                      | SCP Arm | Routine Care Arm |
|----------------------|---------|-----------------|
| **Transplant type; N (%)** |         |                 |
| Allogeneic           | 111 (48)| 100 (44)        |
| Autologous           | 120 (52)| 127 (56)        |
| **Donor type; N (%)** |         |                 |
| Allogeneic, related  | 47 (20) | 36 (16)         |
| Allogeneic, unrelated/umbilical cord blood | 64 (28) | 64 (28) |
| Autologous           | 120 (52)| 127 (56)        |
| **Graft type; N (%)** |         |                 |
| Bone marrow          | 15 (7)  | 16 (7)          |
| Peripheral blood     | 207 (90)| 203 (89)        |
| Umbilical cord blood | 9 (4)   | 8 (4)           |
| **Number of transplants; N (%)** |         |                 |
| 1                    | 206 (89)| 191 (84)        |
| ≥2                   | 25 (11) | 36 (16)         |
| **Conditioning regimen intensity; N (%)** |         |                 |
| Myeloablative (including autologous regimens) | 168 (73) | 176 (78) |
| Non-myeloablative/Reduced-intensity | 62 (27) | 50 (22) |
| Missing              | 1 (<1)  | 1 (<1)          |
| **TBI as part of conditioning regimen; N (%)** |         |                 |
| Yes                  | 49 (21) | 46 (20)         |
| No                   | 182 (79)| 181 (80)        |
| **History of acute GVHD; N (%)** |         |                 |
| Yes                  | 70 (63) | 67 (67)         |
| No                   | 41 (37) | 33 (33)         |
| **History of chronic GVHD; N (%)** |         |                 |
| Yes                  | 67 (60) | 66 (66)         |
| No                   | 44 (40) | 34 (34)         |
| **Health Literacy; N (%)** |         |                 |
| Adequate literacy    | 154 (74)| 172 (83)        |
| Possibility of limited literacy | 36 (17) | 27 (13) |
| High likelihood of limited literacy | 18 (9)  | 9 (4)           |

SCP – survivorship care plan; HCT – hematopoietic cell transplantation; TBI – total body irradiation; GVHD – graft-versus-host disease

* Allogeneic HCT only
† Assessed by Newest Vital Sign instrument; N=208 for SCP arm and N=208 for routine care arm
| Endpoint* | SCP (N=199) | Routine care (N=199) | SCP (N=199) | Routine care (N=198) | SCP (N=200) | Routine care (N=198) | SCP (N=200) | Routine care (N=198) | SCP (N=200) | Routine care (N=198) |
|-----------|-------------|----------------------|-------------|----------------------|-------------|----------------------|-------------|----------------------|-------------|----------------------|
| **Confidence in Survivorship Information†** | 1.44 (0.34) | 1.50 (0.34) | -0.034 (0.028) | 0.223 | 1.40 (0.38) | 1.44 (0.39) | 0.123 (0.042) | 0.004 |
| **Cancer and Treatment Distress‡** | 0.91 (0.61) | 0.78 (0.59) | 0.123 (0.042) | 0.004 | 0.91 (0.64) | 0.91 (0.69) | 0.86 (0.18) | 0.87 (0.16) | -0.018 (0.013) | 0.182 |
| **Knowledge of Transplant Exposures†** | 0.86 (0.18) | 0.87 (0.16) | -0.018 (0.013) | 0.182 | 0.88 (0.15) | 0.86 (0.16) | 0.80 (0.14) | 0.80 (0.15) | 0.014 (0.010) | 0.149 |
| **Health Care Utilization†** | 0.80 (0.14) | 0.82 (0.13) | 0.014 (0.010) | 0.149 | 0.80 (0.14) | 0.82 (0.13) | 0.80 (0.14) | 0.82 (0.13) | 0.014 (0.010) | 0.149 |
| **SF12: Physical Component Summary†** | 46.1 (10.3) | 46.2 (10.6) | -0.368 (0.638) | 0.565 | 46.0 (9.8) | 45.8 (10.1) | 53.9 (7.6) | 54.7 (7.0) | -8.907 (3.009) | 0.003 |
| **SF12: Mental Component Summary†** | 53.9 (7.6) | 54.7 (7.0) | -8.907 (3.009) | 0.003 | 53.9 (7.9) | 53.4 (8.8) |

* N represents number who completed both baseline and 6-month assessments
# Estimate and P-value based on analysis of covariance model with center-level random effects where any differences between the treatment groups were measured after adjustment for patients’ baseline measurement; where applicable, estimates were adjusted for demographic variables and/or interactions (see Methods section)
† Higher score better
‡ Lower score better
FIGURE LEGENDS

**Figure 1:** Study schema

**Figure 2:** CONSORT diagram

**Figure 3:** Patient reported assessment of usefulness of SCP intervention (N=201 respondents on SCP arm who completed 6-month end-of-study assessments)
CIBMTR identifies potentially eligible patients for transplant center

Center verifies eligibility and verifies data to be used for generating SCP

Center consents and enrolls patients

CIBMTR receives subject enrollment form from center

For potentially eligible patients, center provides verified data to CIBMTR for generating SCP

Baseline assessments by phone

CIBMTR generates SCP

Copy of SCP provided to center for their records

RANDOMIZE

SCP

Subjects receive SCP from CIBMTR

Followup phone call: health literacy and SCP utilization assessment

End of study assessments by phone at 6 months

No SCP

Followup phone call: health literacy assessment

Subjects on control arm (no SCP) receive SCP from CIBMTR on completing followup assessments
Patients enrolled by study sites (N=495)

Excluded: Did not complete baseline survey (N=37)

Completed baseline survey (N=458)

Randomized 1:1 to SCP or control arm

SCP arm (N=231)
- Completed 6 month survey (N=200)
- Excluded:
  - Lost to followup (N=21)
  - Declined/withdrawn (N=4)
  - Death (N=1)
  - Deemed ineligible (N=5)

Control arm (N=227)
- Completed 6 month survey (N=199)
- Excluded:
  - Lost to followup (N=8)
  - Declined/withdrawn (N=7)
  - Death (N=3)
  - Deemed ineligible (N=10)
Better understand your transplant and related treatments

- Did not respond: 2
- I have not done this: 19
- Not at all useful: 10
- Somewhat useful: 50
- Very useful: 20

Better understand side effects of your transplant

- Did not respond: 3
- I have not done this: 17
- Not at all useful: 15
- Somewhat useful: 43
- Very useful: 22

Better understand how to manage your health

- Did not respond: 4
- I have not done this: 14
- Not at all useful: 14
- Somewhat useful: 43
- Very useful: 26

Communicate about your transplant and related treatments with medical providers

- Did not respond: 4
- I have not done this: 17
- Not at all useful: 18
- Somewhat useful: 35
- Very useful: 27

Communicate side effects of your transplant with medical providers

- Did not respond: 4
- I have not done this: 20
- Not at all useful: 21
- Somewhat useful: 35
- Very useful: 22

Schedule appointments with medical providers

- Did not respond: 3
- I have not done this: 22
- Not at all useful: 27
- Somewhat useful: 21
- Very useful: 28
SUPPLEMENTAL MATERIALS

Randomized Trial of Individualized Treatment Summary and Survivorship Care Plan for Hematopoietic Cell Transplantation Survivors
DETAILED METHODS

Patients

Seventeen US transplant centers that report autologous and allogeneic HCT to the CIBMTR and representing diverse location and size participated in the study. Potentially eligible patients from participating centers were identified from the CIBMTR. The CIBMTR is a research collaboration between the National Marrow Donor Program (NMDP)/Be The Match in Minneapolis, Minnesota and the Medical College of Wisconsin in Milwaukee, Wisconsin. By law in the US, transplant centers are required to submit data on all allogeneic HCTs to the CIBMTR. Additionally, approximately 80% of the national autologous HCT activity is captured by the registry. Computerized checks for discrepancies, physicians’ review of submitted data and on-site audits of participating centers ensure data quality. Centers submit Transplant Essential Data (TED) on all recipients before transplant, at 100 days and six months after transplant, annually until 6 years, and every other year thereafter, or until death. These data were used to generate the treatment summary including information on patient diagnosis and stage, donor and graft source, and transplantation procedure (e.g., conditioning regimen). HCT specific exposures that determine follow-up and preventive evaluations (age, sex, transplant type, exposure to total body irradiation [TBI], exposure to corticosteroids, and graft-versus-host disease [GVHD]) were abstracted from TED and were used to develop the personalized care plan for each patient.

To maximize generalizability, patient eligibility criteria were intentionally kept broad (≥18 years at the time of HCT, recipients of autologous or allogeneic transplantation, with no evidence of relapse, disease progression or secondary cancers, any diagnosis, donor or graft source, and any conditioning regimen). Patients had to be 1-5 years from their transplant, in order to focus on a group of survivors who are frequently no longer under the direct care of transplant centers and are most vulnerable to receive inadequate HCT specific-survivorship and preventive care. Participants could have received more than one HCT. Participants had to be fluent in English so that they could complete study assessments.

Only centers without an existing mechanism for routinely providing SCPs to their patients were invited to participate in our study. Information on prevalent practices for caring for autologous and allogeneic HCT long-term survivors, including templates for discharge summaries and any routine communications with patients and their local providers, was requested form centers and was reviewed by study investigators to confirm their eligibility to participate and enroll patients. Participating centers also committed to not providing patients a SCP during routine post-transplant care and outside the context of this study during the enrollment and follow up period.

SCP Template

We have previously reported on the development of an individualized SCP instrument generated using CIBMTR registry data and specifically targeted for use by HCT survivors.1 Briefly, a draft paper-based template for the SCP was generated by the investigators and consisted of three elements: an introductory page with information on appropriate use of the SCP, a treatment summary with diagnosis and transplantation procedure electronically abstracted from CIBMTR data, and a care plan that listed recommended preventive evaluations based on published guidelines and patient specific exposures (age, sex, transplant type, exposure to TBI or steroids, or occurrence of GVHD). To obtain qualitative feedback on content and formatting of the SCP,
phone focus groups were conducted with HCT survivors/caregivers (3 focus groups, N=22 participants), HCT physicians and advanced practice providers (2 focus groups, N=14 participants), hematology-oncology and primary care physicians and advanced practice providers (3 focus groups, N=24 participants), and HCT nurses and social workers (4 focus groups, N=17 participants). Qualitative analyses identified patient-centered elements that informed the generation of the final SCP templates used as the intervention in the RCT.\(^1\) A sample SCP template is available as part of Supplemental Materials.

**Study Procedures**

The RCT used a multi-center design with patient-level randomization to treatment (Figure 1). The RCT was reviewed and approved by Institutional Review Boards (IRBs) at the NMDP and each participating site and was registered on clinicaltrials.gov (NCT02200133). To minimize bias in patient enrollment, a random order list of potentially eligible 1-5 year survivors for each center was generated using the CIBMTR database and released in blocks of 10-20 patients. Center coordinators then reviewed medical records to confirm patient survival, disease status, and accuracy of SCP related research data that had been submitted by the center to the CIBMTR. Centers contacted patients by phone and presented the study, and then mailed an information packet to patients who agreed to consider participation; some center IRBs required a mailed letter/post-card with an opt in/opt out option, followed by mailing of the information packet to patients who opted in or with follow-up phone calls if no response to the mailing was received. On receiving the signed informed consent form from patients, transplant centers informed the CIBMTR, who then proceeded with the rest of the study procedures.

The CIBMTR Survey Research Group (SRG) conducted a baseline assessment by phone within 30 days of receiving a completed participant enrollment form and contact information from the transplant center. CIBMTR data were then used to generate personalized SCPs for all consenting patients. Patients were randomized 1:1 to either the SCP arm or standard care with delayed SCP (control) arm. Since centers may preferentially follow long-term allogeneic HCT survivors, patient enrollment was weighted such that at least one-third of the cohort consisted of autologous HCT recipients. Patients randomized to the SCP arm were express mailed an information letter and their printed SCP from the CIBMTR, while patients on the control arm received only an information letter. All patients received a phone call from the CIBMTR SRG between 7-28 days of mailing study materials to conduct a health literacy assessment using the Newest Vital Sign.\(^2\) During this phone contact, patients on the SCP arm were also given the opportunity to ask and address any questions about the content or use of their SCP. No further contact was made with patients till their 6-month outcomes phone survey conducted by the CIBMTR SRG. After completing their end-of-study assessments, printed SCPs were provided to patients in the control arm. Study accrual began in April 2015 and the last patient was enrolled in June 2016. Patients were not offered any compensation for participating on the study.

**Assessments**

Supplemental Table 1 describes our study instruments, including their psychometric properties. The Confidence in Survivorship Information (CSI) was the primary endpoint. The CSI is a 13-item questionnaire that uses a 3-point Likert scale of “not at all” to "very confident".\(^3\) The instrument has two subscales, one that tests confidence in knowledge of past cancer diagnostic and treatment details (3 items, Cronbach’s \(\alpha=0.77\)) and second that evaluates confidence in
knowledge about prevention and treatment of long-term and late-effects of disease and treatment, prevention of disease recurrence, access to resources, and familial risk of cancer (10 items, Cronbach’s α=0.95). Internal consistency reliability for the CSI in our HCT sample at baseline was α=0.87. Secondary endpoints focused on Cancer and Treatment Distress (CTXD), a 23 item instrument validated in HCT recipients that assesses distress and worry specific to HCT and associated complications, as well as measures of Knowledge of Transplant Exposures (developed by study investigators), Health Care Utilization, and HRQOL using the SF-12. The phone-administered assessments required 30-45 minutes to complete. Patients on the intervention arm also received an investigator developed 12-item assessment that obtained qualitative feedback on patient utilization of the SCP at the 6-month assessment.

Statistical Analysis
Sample size and power calculations were performed using a standard error formula that allowed for possible variability in treatment effect across centers and considered dropouts from baseline to 6 months. Our targeted enrollment goal was 495 patients, which yielded adequate power to detect standardized effect sizes of ≥0.3, which are considered to be clinically meaningful, and anticipated a 10% drop-off from baseline to 6-months. An intention-to-treat approach was followed for analysis.

Baseline characteristics between the two groups were compared using Chi-square tests for categorical variables and t-tests for continuous variables. A mixed model with center-level random effects and a fixed treatment effect was used to test whether a change in baseline and 6-month existed between the treatment and control groups for the primary and secondary endpoints. The model, in addition to accounting for center-to-center variation (center effect), allowed for patient responses to be correlated within centers. The 6-month assessment was used as a response variable and the baseline assessment was used as an explanatory variable in the regression models. If a treatment effect existed, we further evaluated whether the effect was modified by demographic variables (including age, sex, transplant type, acute and/or chronic GVHD, diagnosis, and health literacy), or any interactions between variables. Given the short time period projected for accrual and the low risk of adverse events, no interim analyses were planned. Analyses were performed using SAS software (Version 9.4). All P-values reported are two-sided and P<0.05 was considered significant.

Data Sharing Statement
The study was funded by Patient Centered Outcomes Research Institute (PCORI), and their data sharing policy applies (www.pcori.org).

References for Methods
1. Denzen EM, Preussler JM, Murphy EA, et al. Tailoring a survivorship care plan: Patient and provider preferences for recipients of hematopoietic cell transplantation Biol Blood Marrow Transplant. 2018;(In press).
2. Weiss BD, Mays MZ, Martz W, et al. Quick assessment of literacy in primary care: the newest vital sign. Ann Fam Med. 2005;3(6):514-522.
3. Palmer SC, Jacobs LA, Mao J, Stricker CT. Are cancer survivors confident in their knowledge about their disease and care. *Cancer Survivorship Research: Translating Science to Care*. 2012:A32.

4. Syrjala KL, Chapko ME. Evidence for a biopsychosocial model of cancer treatment-related pain. *Pain*. 1995;61(1):69-79.

5. Syrjala KL, Langer SL, Abrams JR, et al. Recovery and long-term function after hematopoietic cell transplantation for leukemia or lymphoma. *JAMA*. 2004;291(19):2335-2343.

6. Khera N, Chow EJ, Leisenring WM, et al. Factors associated with adherence to preventive care practices among hematopoietic cell transplantation survivors. *Biol Blood Marrow Transplant*. 2011;17(7):995-1003.

7. Ware J, Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care*. 1996;34(3):220-233.
**Supplemental Table 1:** Study assessments and patient reported outcome measures

| Instrument                                | Description                                                                                                                                                                                                                                                                                                                                 | Items | Time point | Estimated Time to complete |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|------------|-----------------------------|
| Confidence in Survivorship Information (CSI)\(^1\) | Assesses confidence in knowledge of past cancer diagnostic/treatment details and confidence in knowledge about prevention/treatment of late complications, prevention of future disease, access to resources and familial risk of cancer. This 13-item patient self-reported tool assesses confidence in knowledge of past cancer diagnostic and treatment details (3 items; Cronbach's alpha = 0.77) and confidence in knowledge about prevention and treatment of long term and late-effects of disease and treatment, prevention of future disease, access to resources, and familial risk of cancer (10 items; Cronbach's alpha = 0.95). The scale uses a 3-point scale ranging from "not at all" to "very confident" in each knowledge item. Sample items include "I am confident in the stage of cancer I have/had" and "I am confident in strategies for treating long term physical effects of cancer". Higher score indicates greater confidence in knowledge of treatment details and preventive recommendations. | 13    | Baseline 6 mos | 2 mts |
| Cancer and Treatment Distress (CTXD)\(^2,5\) | Assesses distress or worry specific to HCT and associated complications using items such as “costs of healthcare”, “possibility of relapse” and “being a burden to other people”; subscales include uncertainty, family strain, medical system demands, health burden, finances and impact on function. Response options can range from 0 (“none”) to 3 (“severe”), and the scores represent the mean response across the scale/subscale item. In an analysis of 701 HCT recipients, Syrjala et al reported strong internal consistency reliability at pre-transplant, and at day 100 and day 180 post-transplant (Cronbach α 0.94, 0.95 and 0.95, respectively). The mean scores (standard deviation) at the three time points were 1.12 (0.60), 0.93 (0.60), and 0.85 (0.59), respectively. Subscale reliability was high across time (α >0.70), and there was strong correlation of pre-transplantation CTXD with post-transplant CTXD. A higher score indicates higher level of distress among HCT recipients. Testing supports its value as a predictor of health outcomes and it has been in several randomized clinical trials. | 27    | Baseline 6 mos | 3 mts |
| Knowledge of transplant exposures | Investigator developed measure to assess knowledge of HCT exposures (conditioning type, TBI use, transplant type, donor type, GVHD). Higher score indicates greater knowledge of transplant exposures. | 5     | Baseline 6 mos | 2 mts |
| Health Behaviors | Standardized measures to assess health behaviors: Godin Leisure Time Exercise Q as a measure of minutes/week in moderate/vigorous activity (<150 as cutoff);\(^6\) Tobacco use (any as cutoff);\(^7,8\) Alcohol use (≥ 1 drinks/day for women, ≥ 2 drinks/day for men as cutoff);\(^7,8\) Sunscreen use (daily use of >SPF 30 sunscreen as cutoff);\(^7,8\) Diet (>2 fast food meals/week and <5 fruits and vegetables/day as cutoff);\(^7,8\) Body Mass Index (>30 as cutoff)\(^7,8\) Health behaviors are | 31    | Baseline 6 mos | 8 mts |
Scored as a sum from 0-7, with one point for each behavior: non-smoking, alcohol less than one glass a day for women or two glasses a day for men, moderate to vigorous physical activity ≥ 150 minutes a week, regular use of sunscreen of SPF ≥ 30, food intake of 5 servings of fruit and vegetables a day, body mass index ≤ 25, sleep averaging ≥ 7 hours a night. Item content is matched to NHANES or BRFSS for normative comparisons. Higher scores indicate positive health care behaviors.

| Health Care Utilization\(^9\) | Widely pretested measure of SCP recommended screening and preventive evaluations; scores range from 0-15 with 2 gender specific items each. Scores are transformed to the proportion preventive care recommendations met as indicated on the SCP. Higher scores indicate greater and appropriate health care utilization for preventive care. | 26 | Baseline 6 mos | 4 mts |
| SF-12\(^{10,11}\) | Validated health quality of life 12-item sub-set of the MOS SF-36 which accurately reproduces the two summary component scores: Physical Component Summary Score (PCS) and Mental Health Component Summary Score (MCS). In the general population, the test-retest reliability has been reported to be 0.89 and 0.76 for the two scores, respectively. Studies have shown that the relative validity of SF-12 is comparable to the more comprehensive SF-36 quality of life instrument. The mean PCS scores for chronic health conditions are in the range of 40-45, while that for MCS range from 50-55; in comparison, the mean general population PCS and MCS scores are ~50 and ~50, respectively. Higher scores correspond to better health-related quality of life. | 12 | Baseline 6 mos | 3 mts |
| Generalized Self-Efficacy scale\(^{12,13}\) | Assesses optimistic self-beliefs used to cope with a variety of demands in life known as self-efficacy, i.e., the belief that one’s actions are responsible for successful outcomes. The scaled score for each question ranges from 1 to 4. Higher scores indicate stronger patient’s belief in self-efficacy. | 10 | Baseline 6 mos | 2 mts |
| Newest Vital Sign\(^{14}\) | Measures health literacy level using 1 scenario of an ice cream container nutrition label; 1 score (6 items) includes assessment of two main constructs, numeracy and reading comprehension. Higher score indicates greater health literacy. | 6 | 1-4 wks | 2 mts |
| Survivorship Care Plan Utilization Assessment | Treatment-group participants will be asked whether they if they have any questions about the SCP and how they plan to use it. At the 6 month follow-up assessment, treatment-group participants will be asked how they did use their SCP and what they liked or did not like about it. | 5 | 1-4 wks 6 mos | 3 mts |

HCT – hematopoietic cell transplantation; TBI – total body irradiation; GVHD – graft-versus-host disease; SCP – treatment summary and survivorship care plan; mos – months; mts – minutes

**References for study assessments:**

1. Palmer SC, Jacobs LA, Mao J, Stricker CT. Are cancer survivors confident in their knowledge about their disease and care. *Cancer Survivorship Research: Translating Science to Care*. 2012:A32.
2. Syrjala KL, Langer SL, Abrams JR, et al. Recovery and long-term function after hematopoietic cell transplantation for leukemia or lymphoma. *JAMA*. 2004;291(19):2335-2343.

3. Syrjala KL, Chapko ME. Evidence for a biopsychosocial model of cancer treatment-related pain. *Pain*. 1995;61(1):69-79.

4. McGregor BA, Syrjala KL, Dolan ED, Langer SL, Redman M. The effect of pre-transplant distress on immune reconstitution among adult autologous hematopoietic cell transplantation patients. *Brain Behav Immun*. 2013;30 Suppl:S142-148.

5. Jacobsen PB, Le-Rademacher J, Jim H, et al. Exercise and stress management training prior to hematopoietic cell transplantation: Blood and Marrow Transplant Clinical Trials Network (BMT CTN) 0902. *Biol Blood Marrow Transplant*. 2014;20(10):1530-1536.

6. Godin G, Jobin J, Bouillon J. Assessment of leisure time exercise behavior by self-report: a concurrent validity study. *Can J Public Health*. 1986;77(5):359-362.

7. Centers for Disease Control (CDC). Behavioral Risk Factor Surveillance System Survey Questionnaire. 2010. Atlanta, GA.

8. Centers for Disease Control (CDC) and National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey Questionnaire. 2005-06. Hyattsville, MD.

9. Khera N, Chow EJ, Leisenring WM, et al. Factors associated with adherence to preventive care practices among hematopoietic cell transplantation survivors. *Biol Blood Marrow Transplant*. 2011;17(7):995-1003.

10. Ware J, Jr., Kosinski M, Keller SD. SF-12: How to score SF-12 physical and mental health summary scores. Lincoln, RI: Qualitymetric Incorporated. 1995.

11. Ware J, Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care*. 1996;34(3):220-233.

12. Bandura A. Self-efficacy: The exercise of control. New York: W.H. Freeman and Company. 1997.

13. Schwarzer R, Jerusalem M. Generalized self-efficacy scale. In: Weinman J, Wright S, Johnston M, eds. Measures in health psychology: A user's portfolio. Causal and control beliefs. Windsor, UK: NFER-NELSON. 1995.

14. Weiss BD, Mays MZ, Martz W, et al. Quick assessment of literacy in primary care: the newest vital sign. *Ann Fam Med*. 2005;3(6):514-522.
**Supplemental Table 2.** Baseline characteristics of patients who completed the baseline assessments, and then either completed the study or dropped out/were excluded from the analysis

| Characteristic                                           | Completed study (N=399) | Drop out/excluded (N=59) | P-value |
|----------------------------------------------------------|-------------------------|--------------------------|---------|
| Age at HCT, years; Median (range)                        | 58.8 (19.4-81.1)        | 54.5 (20.2-77.2)         | 0.6760  |
| Time from HCT to enrollment (months); Median (range)     | 42.6 (15.7-66.3)        | 45.3 (17.3-63.8)         | 0.6760  |
| Age group at baseline survey, years; N (%)               |                         |                          |         |
| 18-29                                                    | 12 (3.0)                | 4 (6.8)                  | 0.1755  |
| 30-39                                                    | 19 (4.8)                | 5 (8.5)                  |         |
| 40-49                                                    | 41 (10.3)               | 5 (8.5)                  |         |
| 50-59                                                    | 99 (24.8)               | 14 (23.7)                |         |
| 60-69                                                    | 159 (39.9)              | 16 (27.1)                |         |
| ≥70                                                      | 69 (17.3)               | 15 (25.4)                |         |
| Sex; N (%)                                               |                         |                          |         |
| Male                                                     | 212 (53.1)              | 36 (61.0)                | 0.2667  |
| Female                                                   | 187 (46.9)              | 23 (39.0)                |         |
| Ethnicity; N (%)                                         |                         |                          |         |
| Hispanic/Latino                                          | 13 (3.3)                | 2 (3.4)                  | 0.4346  |
| Non-Hispanic/Latino                                      | 375 (94.0)              | 57 (96.6)                |         |
| Declined                                                 | 11 (2.8)                | -                        |         |
| Race; N (%)                                              |                         |                          |         |
| White                                                    | 380 (95.2)              | 50 (84.8)                | 0.0062  |
| African-American                                         | 12 (3.0)                | 8 (13.6)                 |         |
| Asian                                                    | 4 (1.0)                 | 1 (1.7)                  |         |
| Pacific Islander                                         | 1 (0.3)                 | -                        |         |
| Declined                                                 | 2 (0.5)                 | -                        |         |
| Diagnosis; N (%)                                         |                         |                          |         |
| Acute myeloid leukemia                                   | 90 (22.6)               | 8 (13.6)                 | 0.0801  |
| Acute lymphoblastic leukemia                             | 15 (3.8)                | 3 (5.1)                  |         |
| Myelodysplastic/myeloproliferative disorders             | 40 (10.0)               | 2 (4.8)                  |         |
| Chronic myeloid leukemia                                 | 5 (1.3)                 | -                        |         |
| Hodgkin lymphoma                                         | 16 (4.0)                | 7 (11.9)                 |         |
| Non-Hodgkin lymphoma                                     | 84 (21.1)               | 12 (20.3)                |         |
| Plasma cell disorder/multiple myeloma                   | 134 (33.6)              | 24 (40.7)                |         |
| Other                                                    | 15 (3.8)                | 3 (5.1)                  |         |
| Time from diagnosis to HCT, months; Median (range)       |                         |                          |         |
| Year of transplant; N (%)                                |                         |                          |         |
| 2010                                                     | 28 (7.0)                | 5 (8.5)                  | 0.5831  |
| 2011                                                     | 112 (28.1)              | 16 (27.1)                |         |
| 2012                                                     | 86 (21.6)               | 15 (25.4)                |         |
| 2013                                                     | 125 (31.3)              | 20 (33.9)                |         |
| 2014                                                     | 48 (12.0)               | 3 (5.1)                  |         |
| Category                              | N (%)                  | p-value |
|---------------------------------------|------------------------|---------|
| **Transplant type**                   |                        |         |
| Allogeneic                           | 191 (47.9)             | 0.0503  |
| Autologous                           | 208 (52.1)             |         |
| **Donor type**                        |                        |         |
| Allogeneic, related                  | 77 (19.3)              | 0.0975  |
| Allogeneic, unrelated/umbilical cord blood | 114 (28.6) |         |
| Autologous                           | 208 (52.1)             |         |
| **Graft type**                        |                        |         |
| Bone marrow                          | 29 (7.3)               | 0.4685  |
| Peripheral blood                     | 356 (89.2)             |         |
| Umbilical cord blood                 | 14 (3.5)               |         |
| **Number of transplants**            |                        |         |
| 1                                     | 347 (87.0)             | 0.6809  |
| ≥2                                    | 52 (13.0)              |         |
| **Conditioning regimen intensity**    |                        |         |
| Myeloablative (including autologous regimens) | 296 (74.2) | 0.4533  |
| Non-myeloablative/Reduced-intensity  | 101 (25.3)             |         |
| Missing                               | 2 (0.5)                |         |
| **TBI as part of conditioning regimen** |                      |         |
| Yes                                   | 87 (21.8)              | 0.1449  |
| No                                    | 312 (78.2)             |         |
| **History of acute GVHD**            |                        |         |
| Yes                                   | 123 (64.4)             | 0.8062  |
| No                                    | 68 (35.6)              |         |
| **History of chronic GVHD**          |                        |         |
| Yes                                   | 119 (62.3)             | 0.6288  |
| No                                    | 72 (37.7)              |         |
| **Health Literacy**                  |                        |         |
| Adequate literacy                     | 309 (80.1)             | 0.0112  |
| Possibility of limited literacy      | 54 (14.0)              |         |
| High likelihood of limited literacy   | 23 (6.0)               |         |

SCP – survivorship care plan; HCT – hematopoietic cell transplantation; TBI – total body irradiation; GVHD – graft-versus-host disease

* Allogeneic HCT only
† Assessed by Newest Vital Sign instrument; N=386 for those retained and N=30 for those who dropped out/were excluded from the analysis
Supplemental Appendix: Sample template for treatment summary and survivorship care plan used in the study.
Blood and Marrow Transplant Survivor Treatment Summary

For: [First name_Last name]

Date Your Treatment Summary was Created: [Month DD, YYYY]

The information presented on this Treatment Summary comes from transplant-related data provided to the CIBMTR by your transplant center. There may be additional medical history that is relevant to you and important to share with your doctors and other medical care providers.

| Your Medical Information                  |
|-------------------------------------------|
| Date of birth: (text date)                |
| Sex:                                      |
| Diagnosis:                                |
| Date of Diagnosis: (date)                 |

| Your Transplant Information               |
|-------------------------------------------|
| Transplant center name:                   |
| Address: (hospital)                       |
| Phone number: (BMT program number)        |
| Date of transplant: (date)                |
| Age at transplant: (yrs)                  |
| Transplant type: (autologous/allogeneic unrelated/allogeneic related) |
| Cell source type: (bone marrow, peripheral stem cell, cord blood unit(s)) |
| Prior transplant: (yes/no)                |
| Date of most recent previous transplant:  (date or not applicable) |
| Type of most recent previous transplant:  (autologous / allogeneic / syngeneic(twin) or not applicable) |

Patient CIBMTR research ID (CRID): [CRID]
Your Transplant Treatment

Chemotherapy drugs received as part of the preparative regimen: (list or not applicable)

Steroid drugs received as part of the preparative regimen (for example, prednisone): (list or not applicable)

Total Body Irradiation (TBI): (list dose and dose unit (cGy, Gy)/Yes/No)

Graft versus Host Disease (GVHD)

Drugs to prevent GVHD: (yes/no/not applicable)

GVHD prevention drugs: (list or not applicable)

Acute GVHD: (yes/no/ not applicable)

Chronic GVHD: (yes/no/ not applicable)

Date of chronic GVHD diagnosis: (text date or not applicable)

Your Blood and Marrow Transplant Survivorship Care Plan

Your survivorship care plan is based on research¹ and was developed by doctors and researchers from around the world. This information is not intended as medical advice and does not replace your transplant doctor’s recommendations. Your doctor may recommend or order other tests or evaluations on a different schedule based on your specific situation. Follow his or her recommendations carefully.

In the table below, you’ll find information on the tests and evaluations that physicians commonly recommend for transplant recipients after transplant. Items in bold are found in the Glossary.

The information below will help you:

Patient CIBMTR research ID (CRID):
• Understand what to expect at your checkup appointments, and
• Discuss your questions or concerns with your doctor.

There are questions you can ask your doctor to help you prepare for these tests and exams. Also, these questions will help you understand what the test results mean for you.

**Some questions to ask your doctors**

• Which tests and evaluations do I need to have more often? How often?
• How should I prepare for my exam? How long will the tests take?
• How long does it take to learn my test results?
• Are my test results within an acceptable range for my age and situation?
• How do I know when to call the clinic about symptoms I’m having?

Your care plan is organized by parts of the body (for example, eyes, mouth, and heart). Each section includes more questions to ask your doctor that are specific to a body part. There is space for you to take notes in each section and at the end of the care plan.

You should share this care plan with your doctors. Also, if you need to go to urgent care or the emergency room, it is helpful to take the care plan with you.

---

1 Majhail NS, Rizzo JD, Lee SJ, et al. Recommended screening and preventive practices for long-term survivors after hematopoietic cell transplantation; Center for International Blood and Marrow Transplant Research (CIBMTR), American Society for Blood and Marrow Transplantation (ASBMT), European Group for Blood and Marrow Transplantation (EBMT), Asia-Pacific Blood and Marrow Transplantation Group (APBMT), Bone Marrow Transplant Society of Australia and New Zealand (BMTSANZ), East Mediterranean Blood and Marrow Transplantation Group (EMBMT) and Sociedade Brasileira de Transplante de Medula Ossea (SBTMO). Co-published in Biol Blood Marrow Transplant. 2012; 18(3): 348-371; Bone Marrow Transplant (2012) 47, 337–341; and Hematol Oncol Stem Cel Ther 2012;5(1):1-30.
# Summary of Recommendations for Your Preventive Care

## IMMUNE SYSTEM
- Vaccines to prevent infection
- Because you have a history of GVHD and if you are on immunosuppressant drugs, you might need to take antibiotics to prevent infections like pneumonia and meningitis, for as long as you are on immunosuppressant drugs, and before dental work.
- If you are on immunosuppressant drugs, you may need a test for Cytomegalovirus (CMV).

## EYES
- Wear sunglasses every time you go outside.
- Vision screening by your eye doctor 1 time every year to check how well you can see
- Because you have a history of GVHD, you may need to have eye exams more often

## MOUTH
- Because you have a history of GVHD and/or have received total body irradiation, you need to have mouth, teeth, tongue, and throat exam at least 2 times every year. Talk to your doctor and dentist about when you should have these check-ups.
- Dental exam and tooth cleaning by a dentist at least 1 time every year. Ask your doctor if you should take antibiotics before dental exams.

## LUNGS
- Lung exam at least 1 time every year
- Because you have a history of GVHD, you might need to have lung exams and pulmonary function tests more often. Talk to your doctor about when you should have these check-ups.
- Don’t smoke or use tobacco. Stay away from places where people usually smoke.

## HEART AND BLOOD VESSELS
- Blood pressure checked every time you visit the clinic
- Blood tests to check your cholesterol level at least 1 time every year. This includes triglycerides, LDL, and HDL

## LIVER
- Liver function blood tests (to see if your liver is working well) at least 1 time every year

---

This information is not intended as medical advice and does not replace your transplant doctor’s recommendations. Your doctor may recommend or order other tests or evaluations based on your specific situation. Follow his or her recommendations carefully.
- If you had red blood cell transfusions, have a blood ferritin test to check the level of iron in your blood.

### KIDNEYS AND BLADDER
- Blood pressure checked every time you visit the clinic
- Kidney test at least 1 time every year which includes testing: protein levels in your urine and nitrogen levels in your blood (BUN) and creatinine test
- Because you have a history of GVHD, you might need to have your kidneys checked more often.

### MUSCLES AND JOINTS
- If you have myopathy (weak muscles), muscle pain, or joint pain, schedule an appointment with your doctor right away. Your doctor will check your muscles to find out if you need treatment.
- Because you have a history of GVHD and have taken steroids (such as prednisone), you may need clinical tests of muscle strength and range of motion in your joints.

### BONES
- **Bone density scan** (test) every year.

### SKIN
- Do a self-exam of your skin every month to check for any changes (for example, rash, unusual growth, or patch).
- Use sunscreen with SPF 15 or higher every time you go outside. Reapply at least every 2 hours, or more often if you’re sweating or in and out of the water.
- Avoid direct sunlight. Wear a broad-brimmed hat or use a large umbrella to protect your skin.

### NERVOUS SYSTEM
- Clinical exam by your doctor at least 1 time every year to check for changes or problems.

### ENDOCRINE ORGANS (THYROID, GROWTH AND SEX HORMONES)
- Blood test to check how well your **thyroid** is working
- Blood tests to assess your sex hormone levels
- Fasting glucose (sugar) test to check for Diabetes

### GENITALS AND SEXUAL HEALTH

This information is not intended as medical advice and does not replace your transplant doctor’s recommendations. Your doctor may recommend or order other tests or evaluations based on your specific situation. Follow his or her recommendations carefully.
Discuss with your physician if you are experiencing sexual side effects such as vaginal dryness, pain with sex, or difficulty having an erection.

- Gynecology exam at least 1 time every year

**FERTILITY AND FAMILY PLANNING**

- If you want to have children in the future, ask your doctor to refer you to a fertility doctor.

**EMOTIONAL HEALTH**

- Going through transplant is a very emotional experience. Your feelings and needs will change a lot, maybe even every day. It’s important that you talk openly and regularly with your doctor, family and friends.

**DIET AND NUTRITION**

- Eat a healthy diet
- Keep yourself well hydrated
- Avoid foods with lots of processed (fake) sugar or saturated (bad) fat like candy or soda

**GENERAL HEALTH**

- Use alcohol in moderation (less than 2 drinks a day)
- Stay physically active (2.5 hours each week of moderate exercise)
- Don’t smoke, stay away from second hand smoke, don’t use chewing tobacco

**NEW CANCER SCREENING**

Talk to your doctor about:

- Breast cancer screening (mammography every 1 to 2 years starting at age 25)
- Cervical cancer screening
- Colorectal cancer screening (starting at age 50 or earlier if you have a family history of colorectal cancer)
- Skin cancer screening

---

This information is not intended as medical advice and does not replace your transplant doctor’s recommendations. Your doctor may recommend or order other tests or evaluations based on your specific situation. Follow his or her recommendations carefully.
Your Blood and Marrow Transplant Survivorship Care Plan
For: [First name_Last name]

| RECOMMENDATIONS FOR YOUR ROUTINE SCREENING AND PREVENTIVE CARE | QUESTIONS TO ASK YOUR DOCTOR AND YOUR NOTES |
|---------------------------------------------------------------|--------------------------------------------|
| **IMMUNE SYSTEM**                                             | • What things can I do to lower the risk of getting an infection? Ask your doctor about things like water, food, safe sex, travel, and avoiding second hand smoke. |
| Even 5 years or more after transplant, you are at risk to get infections. This is because it takes time for your immune system to recover from transplant. You might also take medications that lower your body’s ability to fight disease. | • Are my vaccines up-to-date? |
| □ Vaccines to prevent infection                                |                                            |
| □ Because you have a history of GVHD, you might need to take antibiotics: |                                            |
| • To prevent infections like pneumonia and meningitis, for as long as you are on immunosuppressant drugs |                                            |
| • Before dental work                                           |                                            |
| □ If you are on immunosuppressant drugs, you may need a blood test for Cytomegalovirus (CMV) screening. |                                            |
| **EYES**                                                      |                                            |
| □ Wear sunglasses every time you go outside.                  | • Do I need to see an eye specialist? |
| □ Vision screening by your eye doctor 1 time every year to check how well you can see | • How often should I have eye tests? |
| □ Because you have a history of GVHD, you may need to have eye exams more often. |                                            |

This information is not intended as medical advice and does not replace your transplant doctor’s recommendations. Your doctor may recommend or order other tests or evaluations based on your specific situation. Follow his or her recommendations carefully.
**RECOMMENDATIONS FOR YOUR ROUTINE SCREENING AND PREVENTIVE CARE**

- If you have eye pain, dryness, change in vision, sensitivity to light, or watery eyes, you need to have an eye exam. Your doctor will tell you if you need treatment.

| MOUTH | QUESTIONS TO ASK YOUR DOCTOR AND YOUR NOTES |
|-------|---------------------------------------------|
| It’s important that you brush and floss everyday to prevent infections. Also, your doctor needs to check your mouth to make sure your teeth, tongue and throat are healthy and there are no signs of oral cancer. | • Other than not smoking, and brushing and flossing every day, are there other things I can do to keep my mouth healthy? |
| - General mouth, teeth, tongue, and throat exam at least 1 time every year | • Do I need to take medicine before I have any dental procedures? |
| - Because you have a history of GVHD, you need to have mouth, teeth, tongue, and throat exams at least 2 times every year. Talk to your doctor and dentist about when you should have these check-ups. | |
| - Because you had total body irradiation (TBI), you need to have mouth, teeth, tongue, and throat exams at least 2 times every year. Talk to your doctor about when you should have these check-ups. | |
| - Dental exam and tooth cleaning by a dentist at least 1 time every year | |
| - Tell your doctor and dentist if you have dry mouth. This could be a side effect of medications you are taking or a sign of GVHD. | |

| LUNGS | QUESTIONS TO ASK YOUR DOCTOR AND YOUR NOTES |
|-------|---------------------------------------------|

This information is not intended as medical advice and does not replace your transplant doctor’s recommendations. Your doctor may recommend or order other tests or evaluations based on your specific situation. Follow his or her recommendations carefully.
RECOMMENDATIONS FOR YOUR ROUTINE SCREENING AND PREVENTIVE CARE

- Lung exam at least 1 time every year

If you have problems breathing or have had breathing problems in the past, you may need more tests such as:

- Pulmonary function tests
- Chest x-ray
- CT scan

Because you have a history of GVHD, you might need to have lung exams and pulmonary function tests more often. Talk to your doctor about when you should have these check-ups.

- Don’t smoke or use tobacco. Stay away from places where people usually smoke.

HEART AND BLOOD VESSELS

- Blood pressure checked every time you visit the clinic (also see Kidneys and Bladder section)

- Blood tests to check your cholesterol level at least 1 time every year. This includes triglycerides, LDL, and HDL

You may need these tests more often if you had heart or blood vessel problems before or after transplant.

- How can I minimize my risk of heart disease?
- My goals:
  - Blood pressure: ________
  - Cholesterol: ________
  - Weight: ________

This information is not intended as medical advice and does not replace your transplant doctor’s recommendations. Your doctor may recommend or order other tests or evaluations based on your specific situation. Follow his or her recommendations carefully.
**Recommendations for Your Routine Screening and Preventive Care**

| Liver | Questions to Ask Your Doctor and Your Notes |
|-------|---------------------------------------------|
| □ Liver function blood tests (to see if your liver is working well) at least 1 time every year | • Do I need any other tests to make sure my liver is working well? |
| □ If you had red blood cell transfusions, you may need to have a blood ferritin test to check the level of iron in your blood. | • Do I need to see a liver specialist? |
| • If you have too much iron in your blood or your test results are abnormal, your doctor might do more tests. | |
| • If you have a hepatitis B or C infection, your doctor will watch it closely. | |

| Kidneys and Bladder | Questions to Ask Your Doctor and Your Notes |
|---------------------|---------------------------------------------|
| □ Blood pressure checked every time you visit the clinic. High blood pressure (hypertension) can damage your kidneys. | • What are things I can do now to keep my blood pressure in check? |
| □ Kidney test at least 1 time every year which includes testing: | • If my blood pressure is high, what can I do to get it under control? |
| • Protein levels in your urine | • Do I need to see a kidney specialist? How often? |
| • Nitrogen levels in your blood (BUN) and creatinine test | |
| If your test results show that your kidneys are not working properly, you might need further tests such as: | |
| □ Kidney ultrasound | |
| □ Kidney biopsy | |
| If you have kidney disease, you should: | |

This information is not intended as medical advice and does not replace your transplant doctor’s recommendations. Your doctor may recommend or order other tests or evaluations based on your specific situation. Follow his or her recommendations carefully.
### Recommendations for Your Routine Screening and Preventive Care

- Avoid medicines and substances (foods, herbs, vitamin supplements) that can hurt your kidneys
- See a kidney doctor
- Because you have a history of GVHD, you might need to have your kidneys checked more often. Also, you can get urinary tract infections (UTI) more often.

### Muscles and Joints

- If you have **myopathy** (weak muscles), muscle pain, or joint pain, schedule an appointment with your doctor right away. Your doctor will check your muscles to find out if you need treatment.

Because you have a history of GVHD and have taken steroids (such as prednisone), talk to your doctor about clinical exam for:

- **Muscle strength**
- **Range of motion** in your joints

### Bones

Transplant can cause low levels of bone density. You can develop bone diseases if your density levels get too low (such as osteopenia and osteoporosis). As a woman and because you’ve had an allogeneic transplant and taken steroids, you’re more likely to have low levels of bone density. To help keep your bones healthy, you need to have:

- **Bone density scan** (test) every year. If your scan is abnormal, you might need more scans.

### Questions to Ask Your Doctor and Your Notes

**Muscles and Joints**

- Do I need to see a physical therapist?
- How can I build my muscle strength?

**Bones**

- Do I need a bone density scan at all? If so, how often?
- What are the ways to help me prevent bone density loss?

This information is not intended as medical advice and does not replace your transplant doctor’s recommendations. Your doctor may recommend or order other tests or evaluations based on your specific situation. Follow his or her recommendations carefully.
# Recommendations for Your Routine Screening and Preventive Care

## Skin

- Do a self-exam of your skin every month to check for any changes (for example, rash, unusual growth, or patch).
  - If you see unusual growth or patch on your skin, tell your doctor as soon as possible. Your doctor will refer you to a skin specialist.
- Use sunscreen with SPF 15 or higher every time you go outside. Reapply at least every 2 hours, or more often if you’re sweating or in and out of the water.
- Avoid direct sunlight. Wear a broad-brimmed hat or use a large umbrella to protect your skin from the sun.

## Questions to Ask Your Doctor and Your Notes

- How do I do a self-exam of my skin?
- Should I use any special soaps or lotions?
- Do I have **scleroderma**? **Fasciitis**?

## Nervous System

- The nervous system includes your brain, spinal cord and nerves. Sometimes after transplant, patients have changes or problems with how their nervous system works.
- Clinical exam by your doctor at least 1 time every year to check for changes or problems
- Tell your doctor right away if you have trouble with things like your memory, concentration, or making decisions. Your doctor will tell you if you need more tests and/or treatment.

## Endocrine Organs (Thyroid, Growth and Sex Hormones)

**This information is not intended as medical advice and does not replace your transplant doctor’s recommendations. Your doctor may recommend or order other tests or evaluations based on your specific situation. Follow his or her recommendations carefully.**
**Recommendations for Your Routine Screening and Preventive Care**

To make sure your endocrine system is working well, you should have these tests at least 1 time every year:

- Blood test to check how well your **thyroid** is working
- Blood tests to assess your sex hormone levels
- Fasting glucose (sugar) test to check for Diabetes (where you do not eat or drink anything before the test)

You might need to see an OB/GYN (women’s health doctor) to talk about hormone replacement therapy.

**Genitals and Sexual Health**

- To stay healthy you should have a gynecology exam at least 1 time every year

Tell your doctor if you have any of these symptoms:

- Low sex drive
- Erectile dysfunction or impotence
- Hot flashes
- Vaginal dryness
- Vaginal pain or bleeding after sexual intercourse

These could be signs of low sex hormone levels, menopause or GVHD. You might go into early menopause after transplant, even if you’re young. Your doctor will tell you if you need more tests and/or treatment.

**Questions to Ask Your Doctor and Your Notes**

- **Do I need to see an OB/GYN specialist?**
- **Should I do a breast/testicular self exam? How often? What should I be looking for?**
- **Do I need to be tested for sexually transmitted diseases?**
- **How can I stay sexually healthy after transplant?**

This information is not intended as medical advice and does not replace your transplant doctor’s recommendations. Your doctor may recommend or order other tests or evaluations based on your specific situation. Follow his or her recommendations carefully.
### Fertility and Family Planning

Transplant can lower your ability to have children.

- Ask your doctor about your chances of being able to have children after transplant.
- If you want to have children in the future, ask your doctor to refer you to a fertility doctor.
- Talking about fertility can be very emotional. See the Emotional Health section for ways to help you sort out your feelings.

| Questions to Ask Your Doctor and Your Notes |
|---------------------------------------------|
| - Should my partner or I be using birth control? |
| - What type of birth control is best for my partner or me? |

### Emotional Health

Going through transplant is a very emotional experience. Your feelings and needs will change a lot, maybe even every day. It’s important that you talk openly and regularly with your doctor, family and friends.

Here are some questions to help you sort out your feelings and talk about them with people you trust:

- How do you feel overall? Better or worse than expected? How do you feel today? How is it different from how you felt yesterday?
- Are you worried or angry about anything?
- Are you eating well?
- How is your energy level? Are you tired more often or do you easily become tired? Are you sleeping well?

| Questions to Ask Your Doctor and Your Notes |
|---------------------------------------------|
| - What can I do to make sure I’m taking care of myself emotionally? |
| - Should I see another doctor, therapist, or counselor about my emotional health? |
| - Are there any counseling or support groups in my area that I could join? |

---

This information is not intended as medical advice and does not replace your transplant doctor’s recommendations. Your doctor may recommend or order other tests or evaluations based on your specific situation. Follow his or her recommendations carefully.
### Recommendations for Your Routine Screening and Preventive Care

|   |   |
|---|---|
| • Have you noticed if anything makes you feel better or worse? |   |
| • How are your relationships with your loved one/partner/spouse? Family? Close friends? Are you talking with them about any relationship problems? |   |
| • Are you asking for help when you need it? |   |

### Diet and Nutrition

To stay healthy and help your immune system fight disease, eat a healthy diet that includes many different foods. General guidelines for a balanced diet include:

- **Vegetables, fruits and whole grains** - 2-3 cups every day
- **Protein** - 3-6 ounces every day of cooked lean meats like fish and chicken (or 46-56 grams of protein)
- **Dairy** 3 cups every day (low-fat or fat-free)
- **Drink** at least eight 8-ounce glasses of fluid every day to stay hydrated. You need to drink more water when:
  - It’s hot outside
  - You exercise or are more physically active
  - You have a fever or diarrhea or vomit (throw up)
- **Avoid foods** with lots of processed (fake) sugar or saturated (bad) fat like candy or soda

After transplant, you might experience changes in taste, loss of appetite, nausea or other symptoms that make it hard to keep a healthy diet. Talk to your doctor about your symptoms.

### Questions to Ask Your Doctor and Your Notes

- **Should I see a dietician (diet and nutrition expert)?**
- **Should I be concerned about any new allergies?**
- **If I have trouble with GVHD of my GI tract, can you help me make a plan to maintain a healthy diet?**
- **How can I keep a healthy diet and weight?**

This information is not intended as medical advice and does not replace your transplant doctor’s recommendations. Your doctor may recommend or order other tests or evaluations based on your specific situation. Follow his or her recommendations carefully.
## General Health

It’s important to take care of yourself and follow your doctor’s orders to stay healthy and well. To make sure you are staying healthy overall, follow these general lifestyle practices:

- Use alcohol in moderation (less than 2 drinks a day)
- Stay physically active (2.5 hours each week of moderate exercise)
- Don’t smoke or use chewing tobacco
- Stay away from places where people usually smoke
- Don’t let people smoke in your house or car

Smoking cigarettes or using tobacco hurts nearly every organ in the body, especially your lungs and heart. It can also cause new cancers.

## Questions to Ask Your Doctor and Your Notes

- What are some exercises I can do to stay physically active?
- Are medications to help me quit smoking an option? If so, which ones? How long will I be on them? What are the side effects of the medications?
- Where can I go for counseling or a support group to quit smoking?

## New Cancers

New cancers can develop because you’ve had chemotherapy and/or radiation, TBI and have a history of GVHD. You need to have screenings at least 1 time every year for:

- Breast cancer **(mammography every 1 to 2 years starting at age 25)**
- Cervical cancer
- Colorectal cancer (starting at age 50 or earlier if you have a family history of colorectal cancer)
- Skin cancer

## Questions to Ask Your Doctor and Your Notes

- What is my risk for getting new cancers?
- How can I lower my risk of getting new cancers?
- How do I do a self-exam of my skin? How often? What should I be looking for?
- Would I benefit from annual skin exams?

---

This information is not intended as medical advice and does not replace your transplant doctor’s recommendations. Your doctor may recommend or order other tests or evaluations based on your specific situation. Follow his or her recommendations carefully.
| **YOUR CARE TEAM INFORMATION** |
|--------------------------------|
| **Transplant doctor:**        |
| Phone:                         |
| **Primary care doctor:**       |
| **Clinic name:**               | **Phone:** |
| **Oncology (cancer) doctor:**  |
| **Clinic name:**               | **Phone:** |
| **Ophthalmologist (eye specialist):** |
| **Clinic name:**               | **Phone:** |
| **OB/GYN (women’s health specialist):** |
| **Clinic name:**               | **Phone:** |
| **Physical Therapist:**        |
| **Clinic name:**               | **Phone:** |
| **Dentist:**                   |
| **Clinic name:**               | **Phone:** |
| **Other doctor:**              |
| **Clinic name:**               | **Phone:** |
| **Other doctor:**              |
| **Clinic name:**               | **Phone:** |
| **Other doctor:**              |
| **Clinic name:**               | **Phone:** |
| **Other doctor:**              |
| **Clinic name:**               | **Phone:** |

This information is not intended as medical advice and does not replace your transplant doctor’s recommendations. Your doctor may recommend or order other tests or evaluations based on your specific situation. Follow his or her recommendations carefully.
This information is not intended as medical advice and does not replace your transplant doctor’s recommendations. Your doctor may recommend or order other tests or evaluations based on your specific situation. Follow his or her recommendations carefully.
Folder Cover

Individualized Care Plans for HCT Survivors

Study funding provided by the Patient Centered Outcomes Research Institute (PCORI) and sponsored by Be the Match®. This study is conducted by the Center for International Blood and Marrow Transplant Research (CIBMTR) Resource for Clinical Investigation in Blood and Marrow Transplant (RCI BMT).

Your study materials

Inside Left Panel

Congratulations on the one-year anniversary of your blood and marrow transplant (transplant), also known as HCT. Thank you for joining the Individualized Care Plans for HCT Survivors study. This folder contains your study materials:

- Your personalized care plan
- Glossary of terms
- Actions you can take to get the most out of your care plan
- How to get answers to your questions

A survivorship care plan includes a summary of your transplant treatment and plan for follow-up care. You and your doctors can use this information to make decisions together about your care. Transplant follow-up care is important to protecting your health, even many years after transplant.

Your transplant center reviewed the information in this care plan. For this study, treatments or issues that you might have had before transplant are not included in the care plan. Please contact your transplant center or hematologist/oncologist (cancer doctor) for your questions about treatment before transplant.

We will use your feedback to improve HCT survivorship care plans in the future.

Sincerely,

Elizabeth A. Murphy
Principal Investigator

K. Scott Baker
Co-Principal Investigator

Navneet S. Majhail
Co-Principal Investigator
Inside Right Panel

Glossary

**Bone density scan** — An imaging (picture) test that looks for abnormal (or unhealthy) areas in your bones. For this test, you are given a small amount of a fluid in your arm. The fluid is a radioactive contrast material (like a dye) that settles in abnormal areas of the bones. The dye can then be seen in pictures. When bone density is low, your bones become more porous (full of holes) and brittle. When this happens, you have a higher risk of breaking them.

**Cytomegalovirus (CMV)** — A type of herpes virus that can cause infections (for example, pneumonia).

**Endocrine organs** — Endocrine organs release hormones into your blood to manage body functions like your mood and growth. Endocrine organs include the thyroid, pituitary, and pancreas glands.

**Fasciitis** — Inflammation (redness and swelling) of the connective tissue that surrounds muscles, blood vessels, and nerves. Often patients get fasciitis and hardening of the skin (see **Scleroderma**) at the same time.

**Fertility** — A person’s ability to have children

**Gastrointestinal (GI) tract** — Also called the digestive tract. It is made up of body organs that process the food you eat. The GI tract includes the throat, stomach, and intestines.

**Graft-Versus-Host Disease (GVHD)** — A post-transplant condition where the donor cells attack the patient’s tissues or organs.

**HDL cholesterol** — High-density lipoprotein or HDL is known as “good” cholesterol because it helps to remove “bad” cholesterol (LDL) and keep your blood vessels healthy (see **LDL**).

**Immunosuppressant drugs** — Immunosuppressant drugs work to lower the strength of your immune system. The main use of these drugs is to lower the body’s ability to reject the transplanted bone marrow, cord blood or peripheral blood stem cells. Immunosuppressant drugs are usually given to treat GVHD.

**Kidney disease** — When your kidneys don’t properly filter toxins (or poisons) and waste products from your blood.

**Kidney filtration levels test** — Measures how much liquid flows through your kidneys. This test is used to see if you have chronic kidney disease.
**LDL cholesterol** — Low-density lipoprotein or LDL is known as “bad” cholesterol. When you have too much LDL in your blood, it can form a thick, hard deposit. If a clot forms and blocks an artery, you might have a heart attack or stroke.

**Mammography** — An imaging (picture) test to see if you have breast cancer.

**Meningitis** — Inflammation of the membranes covering your brain and spinal cord. This is caused by viruses, fungi or bacteria.

**Myopathy** — Muscle disease and weakness. Steroids are used to treat chronic GVHD, but might result in muscle weakness, especially in your lower body (for example, your legs and feet).

**Osteopenia** — Thinning of your bone tissue. Bones are weak with Osteopenia, but not as weak as with Osteoporosis. Patients develop Osteopenia before Osteoporosis.

**Osteoporosis** — A lot of thinning of your bone tissue, causing very weak bones. Osteoporosis can cause pain and lead to broken bones.

**Oral cancer** — Cancer of the mouth.

**Pneumonia** — Inflammation of the lungs caused by viruses, fungi, or bacteria.

**Pulmonary function tests** — A group of tests to measure how well the lungs are working.

**Range of motion** — A test to find out if a joint (such as elbow, hip, wrist) can move properly and in all normal directions.

**Scleroderma** — When your skin becomes hard, thick, and tight. This can lead to weak muscles, stiff joints or pain in your joints.

**Thyroid** — A gland that controls your body’s metabolism. Metabolism is how quickly your body uses energy from the food you eat.

**Fold-in Panel**

**Take action**

- Schedule twelve-month check-up appointments with your transplant doctor or your hematologist/oncologist.

- Review the tests, procedures and questions to ask your doctor listed in the care plan inside.

- Write down questions or issues you’d like to discuss at your appointments.
Ask your doctor if there are other recommendations unique to your situation.

Bring this care plan to all of your appointments.

At your appointment, ask your doctor if you need to schedule appointments with other health care providers (for example, eye doctor, dentist, physical therapist, OB/GYN, counselor or other specialists).

You might have more than 1 doctor. Talk with your doctors and encourage them to speak with each other. This will help you know who to call when you have new symptoms or to schedule checkup appointments.

Share with your doctor

Review this guide with them at your next appointment.

Ask them to make a copy for your medical record.

For questions or more information

You might have questions about your care plan. For answers to these questions, contact your transplant center. The name and phone number for your transplant center are listed on the care plan inside.

You might have questions about this study. For answers to these questions, contact the Investigator at your transplant center. This information is provided in your consent form and the patient information sheet. You can also contact the Center for International Blood and Marrow Transplant Research (CIBMTR) study team by:

Phone: 1-800-526-7809 Ext. 4368 (toll-free)

E-mail: SCP_SRGTeam@nmdp.org