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Integration of Publicly Reported Center Outcomes into Standards and Accreditation: The FACT Model

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A B S T R A C T

The rapid evolution of blood and marrow transplantation (BMT), coupled with diverse outcomes associated with heterogeneous groups of patients, led to the formation of 2 important organizations early in the development of the field: the Center for International Blood and Marrow Transplant Research (CIBMTR) and the Foundation for the Accreditation of Cellular Therapy (FACT). These organizations have addressed 2 of the 9 elements identified by the National Quality Strategy (NQS) for achieving better health care, more affordable care, and healthy people and communities: a registry that promotes improvement of care and accreditation based on quality standards. More recently, a federally mandated database in the United States addresses the third element of the NQS: public reporting of treatment results. Here we describe the current process by which FACT incorporates patient outcomes reported by the CIBMTR into standards for accreditation, the requirements for accredited programs with performance below expected outcomes to maintain accreditation, and preliminary findings of an assessment of corrective action plans intended to improve outcomes.

INTRODUCTION

Quality in Blood and Marrow Transplantation

The blood and marrow transplantation (BMT) field was an early adopter of quality management principles in health care to improve patient outcomes. In 1995, 2 leading societies in cellular therapy, the American Society for Transplantation and Cellular Therapy (ASTCT) and the International Society for Cell and Gene Therapy (ISCT), founded the Foundation for the Accreditation of Cellular Therapy (FACT) as an independent, nonprofit organization to develop consensus standards and voluntary accreditation for BMT programs. In 1999, ISCT and the European Society for Blood and Marrow Transplantation (EBMT) formed the Joint Accreditation Committee–ISCT and EBMT (JACIE) to perform similar services in Europe. These initiatives predate most laws and regulations, as well as standards and voluntary accreditation, in BMT and other health care fields involving human cells and tissues.

In the same spirit of collaboration and quality, the BMT leaders developed a shared data registry in the 1970s, which ultimately became the Center for International Blood and Marrow Transplant Research (CIBMTR). The CIBMTR collects data from BMT programs around the world to advance the field through research and data analysis [1]. Reporting clinical outcomes data has been found to positively affect patient outcomes in a variety of health care fields [2]. FACT recognizes the

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importance of data to advancements and health care decision making. Since its first edition of standards, published in 1996, FACT has required accredited BMT programs to collect and evaluate outcome data and participate in relevant outcomes registries.

Stem Cell Therapeutic Outcomes Database

In the United States, the Stem Cell Therapeutic and Research Act of 2005 [3] began requiring annual public reporting of patient outcomes for all allogeneic BMT programs. To facilitate this, CIBMTR administers a Stem Cell Therapeutic Outcomes Database (SCTOD) under contract for the U.S. Health Resources and Services Administration. Using this database, CIBMTR annually publishes reports of risk-adjusted 1-year survival for participating BMT programs [4]. FACT standards recommend that clinical programs achieve expected outcomes for 1-year survival; for allogeneic programs in the United States, this is determined by risk-adjusted SCTOD data. Programs that do not meet this standard are required to submit a corrective action plan (CAP) for outcomes improvement [5].

The CIBMTR methodology for calculating expected 1-year survival is complex and based on a rolling 3 years of data reported by the clinical programs. Factored into the analyses are variables known to significantly influence transplantation outcomes, such as type of disease and severity, comorbidities, and patient demographics. The CIBMTR continues to identify and evaluate the impact of additional factors on risk-adjusted outcomes; for example, factors new to the outcomes assessment in 2018 included additional comorbidity conditions, numerous disease risk characteristics, and recipients' socioeconomic status. Factors included in the 2018 Center-Specific Survival Report are listed in Table 1 [6]. The 1-year survival of allogeneic transplant recipients in each BMT program is then compared with that in a similar group of patients drawn from all reporting programs.

BMT programs participating in the outcomes registry can extract their own data using an online data portal [7]. The portal offers a suite of applications that allow a program to perform self-analyses and outcomes monitoring.

Patients and referring physicians can use the published survival reports when choosing a clinical program for patient treatment. Some payers use the data in reimbursement decisions and for selecting and contracting with "centers of excellence." Patients, referring physicians, and payers can also rely on FACT accreditation, knowing that the accreditation takes these survival reports into consideration.

FACT-JACIE Standards

The FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration [5] encompass the entire process of stem cell transplantation: patient evaluation, donor selection, informed consent, cell collection and processing, cell product storage and distribution, clinical administration and evaluation, and reporting of treatment outcomes.

The standards historically have been process-oriented and have served as a measure of quality believed to lead to desirable outcomes. Within the quality management requirements are standards for outcome analysis. These include the use of aggregate data to identify trends in several metrics, such as engraftment rates, morbidity and mortality, graft-versus-host disease (GVHD), and infections. Gratwohl et al [8] reported improvements in patient survival by implementing compliance with the standards. Although internal monitoring of outcomes has always been a requirement of the standards, there were no standards requiring specific patient outcomes, given their dependence on patient and disease variables.

Benchmarking 1-year survival against national or international target ranges was first required by FACT in 2015 in the sixth edition of its standards. Although outcomes measures may seem to be an optimal indicator for measuring quality, an outcome is often the result of numerous factors, some beyond the providers' control. At least 1 study of survival outcomes in BMT programs indicated that a structural metric of quality, participation in the Blood and Marrow Transplant Clinical Trials Network, led to improved outcomes in FACT-accredited centers [9]. Recognizing that almost all BMT programs in the United States have adopted FACT standards and are accredited, a task force was established to evaluate how to include a standard for clinical outcome reporting in FACT accreditation. After extensive study and a public comment period, the task force determined that program-specific survival data, as collected, processed, and published by the CIBMTR, provided the most reliable and least ambiguous risk-adjusted measure of outcomes. Programs that do not report to the CIBMTR, because they either perform only autologous transplantations or are outside of the United States, still must compare their outcomes using comparative data that are applicable to their programs and patient populations. JACIE, aware of similar efforts in Europe, supported this concept and concurred with the recommendation in the standards that programs meet expected 1-year survival, and requiring CAP plans if this is not met [10].

When a BMT program does not meet expected 1-year survival, it must submit a CAP to identify the possible causes and propose remedies [5]. Plans must meet FACT guidelines and be submitted for review by the FACT Clinical Outcomes Improvement Committee.

THE FACT ACCREDITATION PROCESS

FACT accreditation is voluntary and based on documented compliance with the current edition of the standards [11]. Compliance is determined by an evaluation of written documents submitted by the applicant program and an onsite inspection by a team of inspectors who are active practitioners in the area of cellular therapy that they are inspecting. The inspectors are qualified by education, specific training, and experience. Their findings and recommendations are reviewed by an Accreditation Committee composed of experienced inspectors and Board members to ensure consistency of reviews and accreditation decisions.

Accreditation renewal, which occurs on a 3-year cycle, requires document submission and an onsite inspection to verify continued compliance with the current edition of the standards. The renewal exercise is necessary at defined intervals for at least 2 reasons. First, the standards represent the minimum requirements; however, the intent is to raise the bar of quality with each new edition. Practices that were sufficient in one edition of the standards might not be adequate to meet the next edition. Second, deficiencies are still cited at renewal inspections. Various factors at programs account for this observation, including new personnel, failure to sustain quality initiatives, and lack of compliance with new standards. As shown in Figure 1, the average number of deficiencies cited during a program's initial onsite inspection is similar to the average number of citations at later renewal inspections.

Each accredited program must submit an annual report that includes new or discontinued services or providers and, when applicable, document continued implementation of any long-term corrective actions. Included in the annual report is documentation of whether the program's 1-year survival

Table 1
Risk Factors Included in Final 2018 Center-Specific Outcomes Multivariate Model [6]

Factors considered in prior years analyses	Recipient age
	Recipient race
	Karnofsky / Lansky score at transplant
	Prior autologous transplant
	Recipient CMV status
	Coexisting disease (Sorror HCT-CI)
	Disease and disease status/stage
	Time from diagnosis to transplant for AML and ALL in CR2 (used as surrogate for length of CR)
	T-cell lineage in ALL patients
	Philadelphia chromosome in ALL patients
	CLL and other chronic leukemia stage
	Sensitivity to chemotherapy in NHL and HL
	NHL subtype
	Year of transplant
	HLA matching by donor and graft type
	Donor/Recipient sex match (bone marrow or peripheral blood stem cell (PBSC) only)
	Donor age (unrelated bone marrow or PBSC donors only)
New factors in 2018 analysis	History of mechanical ventilation
	History of invasive fungal infection
	AML transformed from Myelodysplastic (MDS) / myeloproliferative (MPN) diseases
	AML ELN risk group
	ALL cytogenetic risk group
	MDS with predisposing condition
	MDS IPSS-R risk score at HCT
	Plasma cell disorder disease status at HCT
	Socioeconomic status (median household income) based on zip code of residence of recipient

Risk factors included in the final 2018 center-specific outcomes multivariate model used by the CIBMTR to generate the 2018 CIBMTR Transplant Center-Specific Survival Report. See https://www.cibmtr.org/ReferenceCenter/SlidesReports/USStats/Documents/CIBMTR_HCT_Center_Survival_Report_Methodology.pdf for all factors considered in development of the model.

meets or exceeds the risk-adjusted range for programs with similar patients, as determined by risk-adjusted SCTOD data published by CIBMTR. Autologous-only or non-U.S. programs that are not required to report outcomes to the SCTOD must compare their 1-year survival with alternative comparative data.

FACT accreditation staff also monitor SCTOD published reports of risk-adjusted outcomes. Accredited programs that fail to meet their expected ranges for 1-year survival are notified within 2 weeks of publication that a CAP is required and must be submitted within the next 3 months to maintain FACT accreditation. The process and limits for assessment of clinical outcomes is illustrated in Figure 2.

Clinical Outcomes Assessment Process

Each BMT program has the responsibility for assessing patient survival, investigating the causes for lower-than-expected patient outcomes, and implementing quality measures to improve outcomes. FACT has created guidelines to assist programs with a logical approach to outcome review and development of CAPs (Table 2).

When a clinical program is not meeting a predicted survival range, the typical reflexive action by its staff is to investigate the accuracy of the reported data. If there are indeed deficiencies in the collection, analysis, and reporting of treatment outcomes, better data management can be part of the CAP.

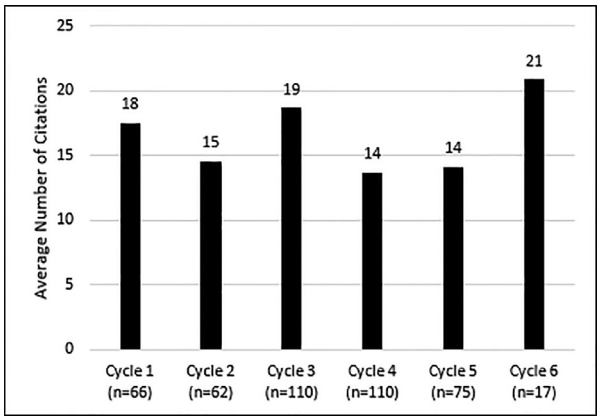

Figure 1. Average number of citations per program by FACT accreditation cycle. Results are based on 440 inspections covering 3 consecutive editions of the FACT-JACIE standards, editions 3–5. Programs are grouped according to accreditation cycle, with cycle 1 being the first accreditation for that program (n, number of inspections at programs in that cycle).

However, this single factor is seldom sufficient. FACT requires that this initial assessment be followed by a broader and more in-depth investigation of the causes of lower-than-expected survival. Identification of specific cause(s) of death is the first step in evaluating survival. Data on patient, disease, and transplantation characteristics must be reviewed and quantified. Wherever possible, trends among patients should be identified. The CAP then outlines actions to correct problems. Actions must address the identified causes, and a plan to monitor patient survival and measure outcome improvement must be implemented.

CAPs are reviewed by the FACT Clinical Outcomes Improvement Committee, whose members are leaders in the field of clinical transplantation, with extensive experience in quality management and statistics. Many committee members are also Clinical Program Directors of their transplantation programs, members of FACT's Board of Directors, and experienced FACT inspectors. The chair of the FACT Accreditation Committee serves as a member and a liaison between the 2 committees. Centralizing the review of CAPs in this Committee helps

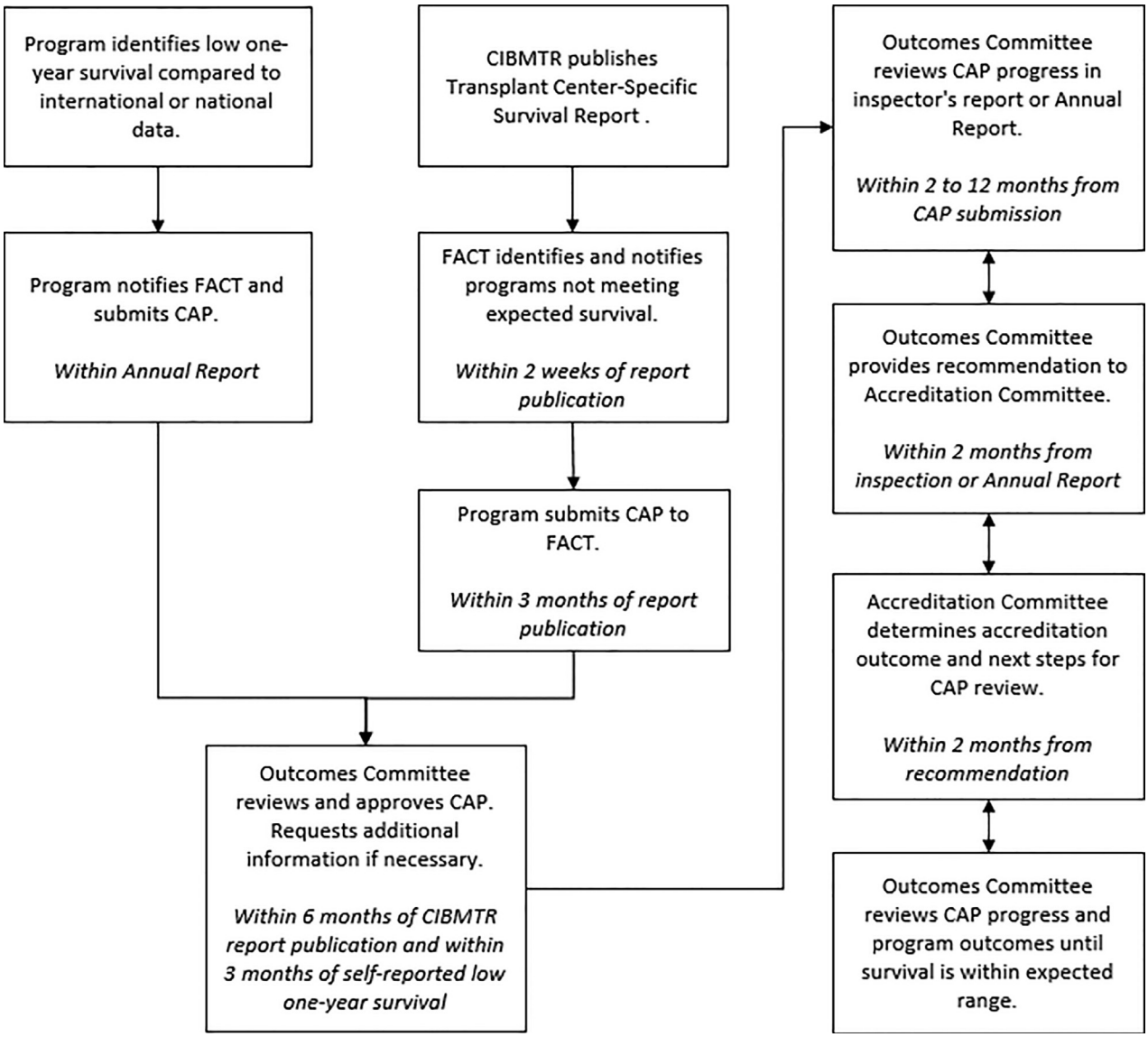

Figure 2. FACT process for reviewing Corrective Action Plans. Interaction between FACT and FACT-accredited programs when lower than expected 1-year patient survival is identified through either the program's internal processes (upper left) or notification via publication of the SCTOD Report by CIBMTR (top center). The figure illustrates the steps in the process and the expected timeline until the program has achieved 1 expected 1-year patient survival (lower right).

Table 2
Guidelines for Corrective Action Plans

CAPS must:

1. Identify specific causes of death.
2. State current 100-day and 1-year overall and treatment-related mortality based on internal outcome analyses.
3. Provide quantitative data.
4. Identify reasonable causes of low one-year survival rate.
5. Address the identified causes.

Subsequent submissions must:

1. Update quanitative data provided in the initial CAP.
2. Provide any additional information requested by the Committee.
3. Outline a timeline of implementation of corrective actions and their effectiveness.
4. Demonstrate a measurable outcome improvement, or, if outcomes do not improve, a reassessment and appropriate corrective actions based on that reassessment.

Minimum components of a Corrective Action Plan to be submitted to the FACT Clinical Outcomes Improvement Committee. Inclusion of all factors allows the committee reviewers to understand the plan and ensure that the program has undertaken a comprehensive review of its own data, assessed its practices, and developed a reasonable improvement approach. Plans meeting these criteria are considered to be initially satisfactory.

achieve consistency in evaluations and allows FACT to analyze and disseminate information about factors and processes that improve outcomes. The Committee provides input by carefully reviewing submitted CAPs, identifying weaknesses, requesting additional information, and offering high-level advice and guidance. Intensive support is provided to programs with consistently insufficient CAPs. The committee then monitors the programs' progress, requesting audits of compliance with corrective actions and assessing their effectiveness. The Committee considers the trends in both expected survival and actual survival to determine whether survival rates are improving. More frequent monitoring is provided for programs in which trend lines clearly are not improving. A case study, Evolution of a Corrective Action Plan to Improve One-Year Survival in Hematopoietic Progenitor Cell (HPC) Transplantation, is provided as supplemental material.

When the Committee observes issues that are affecting multiple programs, webinars and educational bulletins are used to inform all accredited programs. With program permission, commendable CAPs are redacted and posted on the FACT website as examples.

After approval of the CAP and its implementation, the clinical program provides annual updates to FACT and to the onsite inspector at the time of accreditation renewal. The FACT Accreditation Committee uses the recommendations of the Clinical Outcomes Improvement Committee and inspectors to make accreditation decisions, as outlined in Table 3. For accreditation renewal, programs implementing a CAP must

Table 3
Program Accreditation Status Based on Outcomes Review

Adequacy of Corrective Action Plan	Accreditation Status and Next Steps
The CAP is satisfactory. No additional information is required at this time. Corrective actions have been implemented and internal audit data show improvement in survival.	The program is accredited. The program will continue to update FACT of its 1-year survival compared with the CIBMTR report or other data, as applicable, on an annual basis.
The CAP is satisfactory and has been implemented recently. No further information is required at this time. No follow-up data are yet available.	The program is accredited. Internal audit data must be submitted to FACT with annual reports or sooner as directed by the Committee.
The CAP is satisfactory as determined by the Clinical Outcomes Committee. Owing to the date of approval of the CAP, the CAP has not been implemented. No follow- up data are available.	The program will submit updates on implementation of corrective actions and internal data to demonstrate continued improvement in 1-year survival at least annually throughout the accreditation process. If 1-year survival does not improve, the program must submit a reassessment and revised corrective action plan based on that assessment. The program is accredited contingent on continued timely submissions at the direction of the Committee.
The CAP has been submitted, but it is not completely satisfactory. The Committee requires additional information before approving the CAP.	The program must submit this information within timelines requested by the Committee. The program maintains accreditation throughout the process, contingent on timely and appropriate responses.
The CAP does not meet required guidelines.	The program must submit a revised CAP that meets the guidelines within the timeframes required of the accreditation process. The program is at risk of accreditation lapse if appropriate responses are not submitted in a timely manner.
The program has not demonstrated sufficient ability or effort to evaluate 1-year survival and potential corrective actions.	The program must undergo a focused reinspection. The program's FACT accreditation may be suspended until the focused reinspection has demonstrated satisfactory correction of this deficiency.

Program accreditation status based on outcomes review. Accreditation is contingent on submission of CAPs that meet FACT guidelines, complete and timely responses to requests for additional information, and demonstration of effectiveness.
CAP indicates corrective action plan; FACT, Foundation for the Accreditation of Cellular Therapy; CIBMTR, Center for International Blood and Marrow Transplant Research.

demonstrate satisfactory progress. FACT provides each clinical program with documentation of its status related to clinical outcomes, approved CAPs, and internally documented clinical improvement during its accreditation cycle.

CLINICAL OUTCOMES IMPROVEMENT COMMITTEE FINDINGS

From March 2016 through October 2018, the Clinical Outcomes Improvement Committee reviewed 47 clinical programs that had either failed to meet expected 1-year survival as determined by the CIBMTR or that had self-reported lower-than-expected patient survival. For initial CAPs submitted by those 47 programs, the Committee requested additional or clarifying information for 20 (43%). The Committee reviewed an additional 61 revised or updated submissions in the 19-month period and asked for additional or clarifying information for 14 (23%).

COMMON THEMES

Causes of Death

BMT programs typically reported multiple reasons for a lower-than-expected 1-year survival rate. The 3 causes of death that are most often the focus of CAPs are disease progression or relapse, infection, and GVHD, as shown in Figure 3.

Corrective Actions

Programs typically proposed several corrective actions, ranging from simple and direct solutions to complex and systematic changes. Figure 4 illustrates the wide variety of corrective actions.

Refusing transplantation to high-risk patients is rarely an adequate or useful solution. It may improve a program's 1-year survival rate, but the comparable range of expected outcomes in the annual CIBMTR survival reports will also be higher, because it is risk-adjusted. Furthermore, turning away high-risk patients denies them participation in clinical trials of advanced therapies that they may need and does little to help advance the BMT field. When CAPs propose stricter eligibility criteria for transplantation, the Committee usually requests follow-up information to understand the rationale for and expected effect of the strategy.

Reported Improvement

Given the duration of the reporting cycle for center-specific analysis, it is too early to assess whether the FACT evaluation process has a measurable and durable impact on 1-year survival as published in the CIBMTR report. However, there are signs of improvement in the programs reviewed. Thirty-three (70%) reported improved survival, as illustrated in Figure 5.

DISCUSSION

Role of Accreditation in Outcomes Improvement

Accreditation is one of the 9 elements, referred to as levers, identified by the NQS to meet the objectives of better health care, affordable care, and healthy people and communities [12]. Adoption of principles of quality management can help achieve those objectives. Data registries are another, and a third is the use of publicly reported treatment outcomes data which can help educate clinicians and assist payers wishing to incentivize high-quality care.

Programs that do not meet expected outcomes have strong incentives to submit, implement, and monitor a CAP to maintain FACT accreditation. Although the primary goal is to help programs develop systems to proactively monitor and improve outcomes, the FACT process also mitigates the limitations of depending solely on public outcomes reporting. Although the CIBMTR survival reports are risk-adjusted, it is impossible to truly capture all real-world influences that may affect clinical outcomes.

Because FACT identifies common themes within CAPs, it collaborates with related organizations, such as ASBMT and CIBMTR, to convey collective experiences to BMT programs. These themes also may apply to other cellular therapies, such as immune effector cell therapy, and could be used to improve clinical outcomes on a broader scale. Furthermore, if methods to objectively and unambiguously evaluate clinical outcomes for other cellular therapies are designed and validated, FACT's

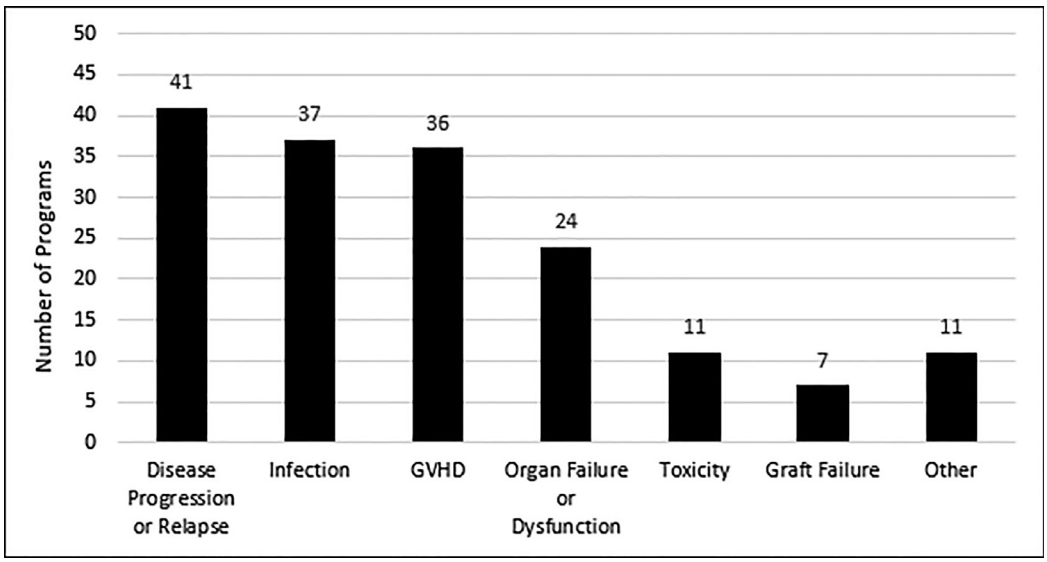

Figure 3. Center-reported causes of death. The graph shows results of in-depth analysis performed by each individual center of the multiple causes of death associated with less-than-expected outcomes. Programs are free to identify all contributing factors to facilitate the development of corrective action plans (n = 47 programs).

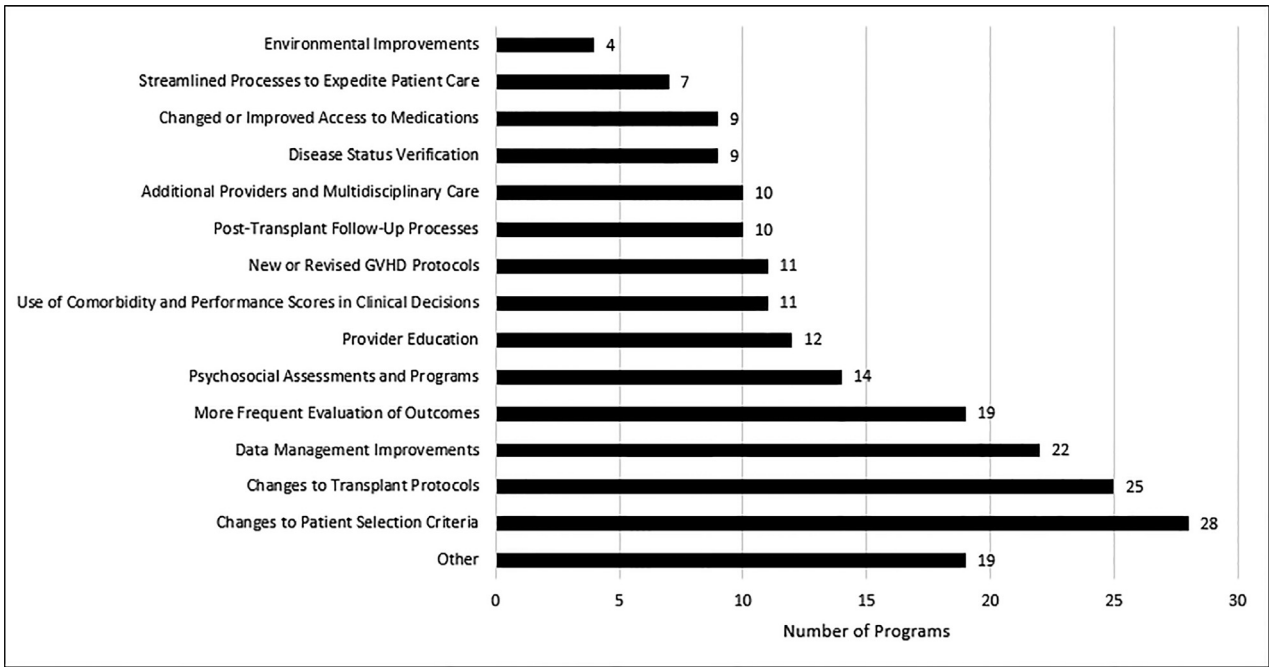

Figure 4. Corrective actions. Depicted are the specific corrective actions included in Corrective Action Plans (CAPs) submitted to FACT as a result of lower-than-expected 1-year patient survival. Numbers indicate the number of programs that identified that corrective action. All CAPs included more than 1 specific action (n = 47 programs).

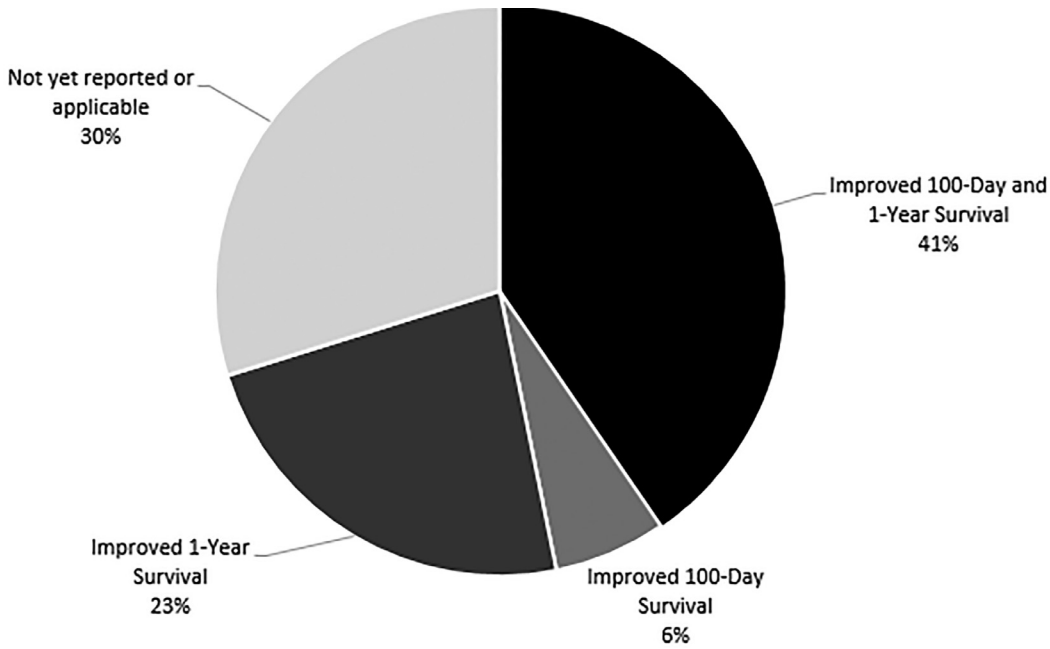

Figure 5. Program-reported improvement in survival (n = 47). Following implementation of a Corrective Action Plan, each program must develop an internal auditing plan to assess the effectiveness of the corrective action. Following implementation of corrective action, typical times to monitor survival are 100 days after transplantation, 1 year after transplantation, or both. As shown, 70% of the 47 programs reported improvement in survival.

clinical outcome review process could be formally applied accordingly.

CONCLUSION

The availability of CIBMTR's risk-adjusted 1-year survival metric has allowed more in-depth evaluation of outcomes. The incorporation of outcome analysis as a requirement for accreditation has resulted in more specific guidance from FACT and more comprehensive quality improvement programs, providing assurance to patients, referring physicians, and payers while potentially improving survival.

The culture of quality in BMT and current systems in place for continuous improvement may serve as a model for other healthcare fields. Specifically, FACT's use of risk-based outcome data within a process designed to help programs improve incorporates the findings of previous evaluations of healthcare quality improvement initiatives. Ongoing peer review in the context of voluntary FACT accreditation shows

promise in improving outcomes and provides an opportunity to reduce interruptions in care or reimbursement that occur when publicly reported, center-specific analysis is used for reimbursement by payers.

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SUPPLEMENTARY MATERIALS

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