Incorporating Clinical Outcomes into Accreditation Requirements

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FACT’s Beginnings

• A perceived need existed for Professional Standards across the fields of Hematology/Oncology and cellular therapy
• Physicians (ASBMT) and laboratory scientists (ISCT) merged their respective Standards in 1996.
• Formed FACT to establish voluntary accreditation program to:
  • Improve patient care and laboratory practice
  • Minimize burden of regulatory oversight
  • Advance the field of cellular therapy
Current FACT Requirements

• Process oriented
  – Surrogate measures of quality believed to lead to better outcomes

• Internal outcome analysis
  – Transplant centers required to review overall and treatment-related morbidity and mortality at 100 days and 1 year
  – Risk adjusted methodology is not required
  – Focus is on internal monitoring; no formal reporting of outcomes to FACT is required

FACT Clinical Outcomes Task Force

Michael Lill, MD - Chair
- ASBMT Committee on Reimbursement, Chair
- NMDP Payor Policy Advisory Group & AGFBT
- CIBMTR Scientific Oversight Committee

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- ASBMT Quality Outcomes
- CIBMTR/SCTOD, Associate Scientific Director
- FACT Data Management Task Force
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- ASBMT Committee on Reimbursement
- FACT Quality Committee, Chair

Richard Champlin, MD
- FACT Grievance Committee, Chair
- FACT, Founding Board Member
- DKMS Bone Marrow Donor Center, Board Member

Phyllis Warkentin, MD
- FACT, Chief Medical Officer
- FACT Data Management Task Force

Jean Sanders, MD
- FACT, Board Member and Treasurer
Goals of the Clinical Outcomes Task Force

• Incorporate validated and objective outcome data into FACT Standards and accreditation process
  – Use SCTOD data and other surrogate metrics
  – Require formal action plans when performance does not meet expectations
• Educate transplant centers on how outcomes can be improved
• Facilitate specific improvements in clinical outcomes and patient safety

Premises

• Patients and caregivers could benefit from a valid, reliable system for assessing clinical outcomes and patient safety
• A voluntary organization of practicing health professionals is best positioned to develop such a system
• A valid, reliable system is scientifically and statistically more difficult than most would expect
How Could Evaluation of Clinical Outcome Impact Patients?

Balancing the Needs of Transplant Recipients

Reimbursement

Access

Quality

Additional Considerations

Many risk factors in clinical outcome

Comparative assessments of outcomes is new territory

Some factors beyond direct control of a program

Loss or suspension of accreditation can have devastating impacts

Minimize unintended consequences to current system

Efforts should advance in calibrated, incremental steps

Avoid incentives for cherry picking patients

Program reimbursements and personnel retention

Patient access to transplants

Maintain benefits and credibility of FACT accreditation

Allow FACT and programs to gain solid footing
Selecting Outcome and Safety Metrics

• Assessment of outcomes and patient safety are difficult and complex
  – Many variables to consider
• FACT’s goal is to help transplant centers evaluate outcome data and make improvements when necessary for three main reasons:
  – Support centers’ efforts to improve
  – Improve patient outcomes
  – Maintain payer and public confidence
• Feedback during roundtable discussions will be greatly appreciated

One-Year Survival

• Based on data collected and analyzed for the Stem Cell Therapeutic Outcomes Database (SCTOD)
  – Only generally accepted risk-adjusted metric that exists
• If expected outcomes not met, a plan for improvement would be required for accreditation
  – Three consecutive years of underperforming would result in a consequence
100-Day Survival

- Determined to be an unsatisfactory index for reasons extensively studied by the CIBMTR
  - However, is an important measure for transplant center review, evaluation, and improvement
- Centers would be required to report 100-day survival annually
- If expected outcomes not met, a plan for improvement and evidence of implementation would be required

Infections

- Important patient safety measure
- Limitations in risk-adjusting and indexing infection rates
- Programs would be required to have an infection rate surveillance and evaluation program and a procedure for necessary corrective action
Chronic Graft Versus Host Disease

• GVHD requirements a larger focus in the draft 6th edition Cellular Therapy Standards
  – Regular assessments for acute and chronic GVHD using established grading systems
  – Outcome analysis of acute GVHD after 100 days
• Programs would be required to have a chronic GVHD surveillance and evaluation program and a procedure for necessary corrective action

Other Metrics to Consider

• Quality of life
• Submission of autologous transplant data to CIBMTR
• Minimum Critical Field Error Rates found during CIBMTR audits
• Others?
Implementation Plan

• 6th edition (2015): Outcome analysis required for additional metrics
• 7th edition (2018): Internal benchmarking and improvement
• Future editions: May consider center-to-center benchmarking should metrics become more sophisticated and accepted

Failure to Meet Expected Outcomes

• 7th Edition Standards would require:
  – Internal benchmarking
  – Performance at or above benchmark
  – Improvement when benchmark is not reached
• If expected outcomes not met:
  – Plan for improvement must be submitted before accreditation is awarded
  – Updates must be submitted at time of annual reporting
  – Consistent underperformance would have consequences, up to loss of FACT accreditation
Assistance to Transplant Centers

• Ultimate goal is to improve clinical outcomes and patient safety
  – Additional standards are only means to an end

• Education will be key
  – Workshops and webinars related to ways to promote good outcomes and safety
  – Best practices
  – Templates for improvement plans

Evaluation and Outlook

• Structurally, evaluation of outcomes easy to implement
  – Challenges lie in selecting metrics to include

• Process will evolve over time based on:
  – Suggestions for implementation
  – Review of inspection results and program submissions
  – Ongoing feedback from physicians, payers, and others

• FACT will continue to be a leader and supporter of setting expectations for clinical outcomes and patient safety