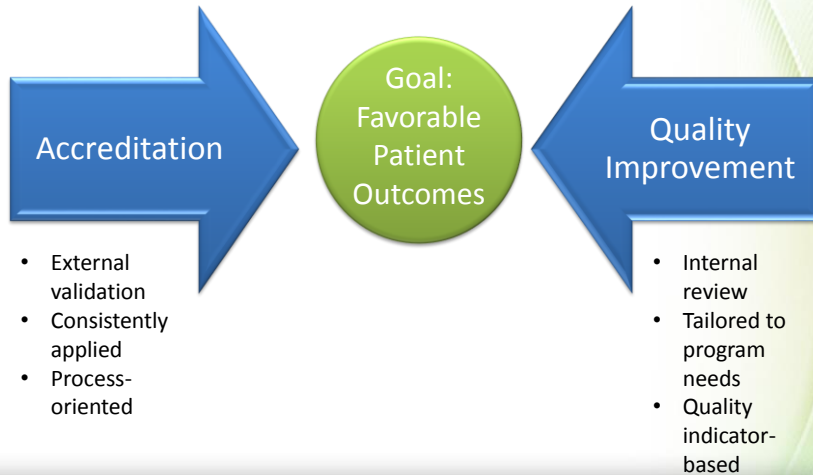
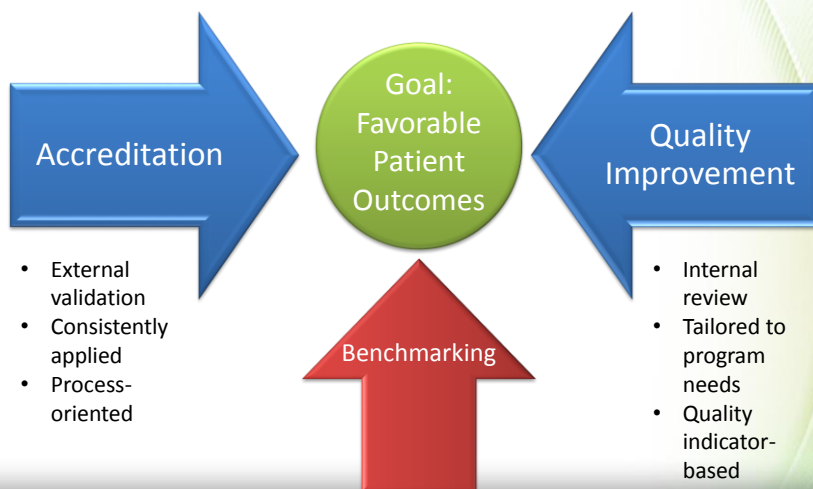


The Relationship Between Accreditation and Quality Improvement



The Relationship Between Accreditation and Quality Improvement



A Review of FACT's 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

Challenges

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

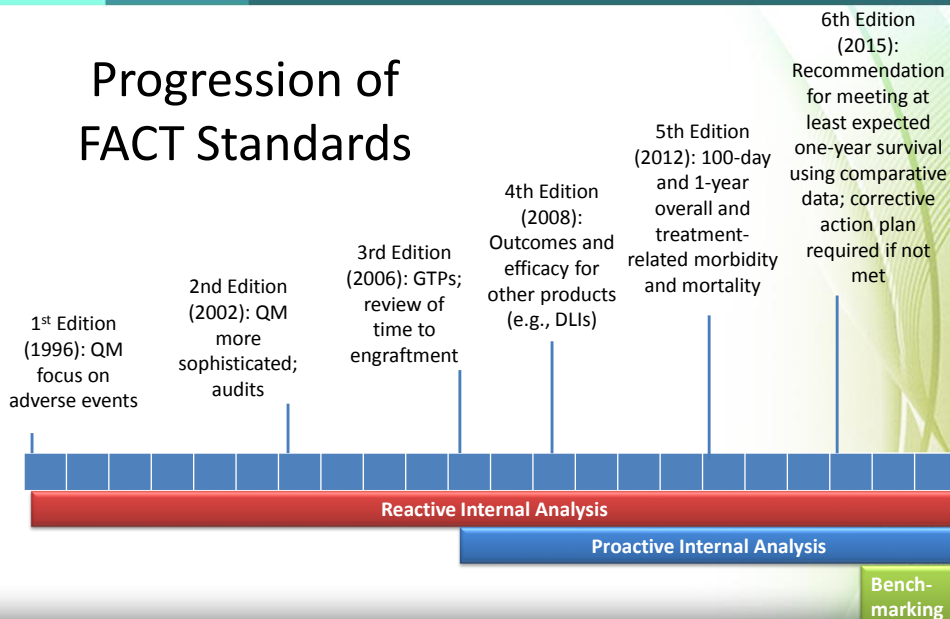
Maintain benefits and credibility of FACT accreditation

Allow FACT and programs to gain solid footing

Goals of the FACT Clinical Outcomes Task Force

- Incorporate validated and objective outcome data into FACT Standards and accreditation process ✓
 - Use CIBMTR data and other surrogate metrics ✓
 - Require formal action plans when performance does not meet expectations ✓
- Establish ongoing Clinical Outcomes Improvement Committee ✓
 - Educate transplant centers on how outcomes can be improved
 - Facilitate specific improvements in clinical outcomes and patient safety

Progression of FACT Standards



New Internal Analyses Required in 6th Edition

- Acute GVHD grade within one hundred (100) days after transplantation.
- Chronic GVHD grade within one (1) year after transplantation.
- Central venous catheter infection.

6th Edition Benchmarking Requirement

- The Clinical Program *should* achieve one-year survival outcome within or above the expected range when compared to national or international outcome data.
 - U.S. allo programs: SCTOD report
- If expected one-year survival outcome is not met, the Clinical Program shall submit a corrective action plan.

Special Public Comment Request: General Responses

- Weaknesses in data
- Consequences to high-risk patients and research
- Detriments to small programs
- Decrease in number of transplant centers
- Need for clarification (most common comment)
- Need for education
- Burden of corrective action plans
- Overreach of FACT purview

Expectations of Transplant Centers

Choose Data

U.S. allo: CIBMTR
Transplant Center-
Specific Report
Other regions: CIBMTR,
regional comparative
data, published
literature, etc. (inform
FACT)

Evaluate and Report Data

Was expected one-year
survival met or
exceeded?
Provide information to
FACT on Compliance
Application and Annual
Reports

Corrective Action Plan

Identify root causes
Create an action plan
(submit to FACT on
Compliance Application
and Annual Reports)
Implement, and then
evaluate, the plan

Implementation

- Centers begin reporting one-year survival via pre-inspection documentation for inspection under 6th edition
- If lower than expected range, program required to submit a corrective action plan prior to being awarded FACT accreditation
 - Will be reviewed by Clinical Outcomes Improvement Committee
- After achieving accreditation, reporting of one-year survival (and submission of corrective action plan if applicable) required on annual reports

Failure to Meet Expected Outcomes

- Consistent underperformance (three consecutive years beginning with 6th edition inspection year) would have consequences, up to loss of FACT accreditation
- *Predict* 7th edition Standards would *require* programs to meet or exceed expected one-year survival
 - Programs not meeting at least expected outcomes suspended
 - If expected outcomes not met in next year, accreditation terminated
 - Terminated programs must reapply for accreditation to regain accredited status. To be eligible, one-year survival must be at expected or better than expected levels.
 - Potential for mitigating factors similar to CMS

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 promoting good outcomes and safety
 - Best practices
- New FACT committee charged with providing resources
 - Identify examples of comparative data for autologous and international programs (immediate need)
 - Determine review criteria for corrective action plans
 - Create tools for gap assessments and root cause analysis
- FACT Consulting Services a separate option
 - More in-depth assistance with reviewing outcomes and root causes of poor outcomes
 - Consulting does not guarantee expected outcomes or FACT accreditation

THANK YOU