Applying Quality Methods to Improve Patient Outcomes

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Disclosures

The following faculty and planning committee staff have no financial disclosures:

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Navneet Majhail, M.D., M.S.	Cleveland Clinic	Anthem, Inc; Honorarium/Consultant

Learning objectives

At the conclusion of this session, attendees will be able to:

- Identify relevant FACT standards that apply to improving patient outcomes
- Evaluate areas of clinical focus for your center to consider in developing a patient outcomes quality improvement strategy
- Assess your role in implementing a quality plan to improve patient outcomes at your center

Operative Principle

- Expressed by most medical institutions in one way or another:

  - **Hold patient interests paramount**

- What does this mean in practice and what does it have to do with "quality"

Best Interest of Patient and Quality

- Quality Management is not quality in and of itself. It is not the goal.

- It is the PROCESS of quality management that CAN bring one to the goal of the best for the patient

FACT Definition of Outcome Analysis

"The process by which the results of a therapeutic procedure are formally assessed"	
Results of Therapy	Formal Assessment
• *Measure the success of therapy using outcome metrics*	• *Thoughtful planning, data collection, evaluation, investigation, and follow-up*

Required Internal Analyses

HPC Transplants
- Time to engraftment
- Overall and treatment-related morbidity and mortality at 100 days and 1 year (interim Standards requires 30 days also)
- Acute GVHD within 100 days and chronic GVHD within 1 year
- Central venous catheter infection

Immune Effector Cells
- An endpoint of clinical function as approved by the Clinical Program Director
- Overall and treatment-related morbidity and mortality at 30 days, 100 days, and 1 year

Cord Blood Units
- Good faith effort to collect the following within specified timeframes:
- Adverse events, time to neutrophil and platelet engraftment, chimerism, which product engrafted in double transplant, survival, GVHD

Others
- An endpoint of clinical function as approved by the Clinical Program Director
- Overall and treatment-related morbidity and mortality at 100 days and 1 year

FACT 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.

- If expected one-year survival outcome is not met, the Clinical Program *shall* submit a corrective action plan.

Rationale for Benchmarking

- Historically, accreditation has focused on quality processes
  - Surrogate measures of quality believed to lead to better outcomes
  - Continuous quality improvement – can we do better?
- A voluntary organization of practicing health professionals is best positioned to develop such a system
- FACT's goal is to help transplant centers evaluate outcome data and make improvements for three main reasons:
  - Improve patient outcomes
  - Support centers' efforts to improve
  - Maintain payer and public confidence

Comparative Data Sources
Allogeneic Programs in U.S.

- Meet or exceed expected one-year survival as reported by CIBMTR using the Stem Cell Therapeutic Outcomes Database (SCTOD)
- Only generally accepted risk-adjusted metric that exists

Getting Past the Myths of the CIBMTR Report

Perceived roadblocks to corrective actions	Needed clarifications
High-risk patients	High risk is not a cause of death; look at the specifics
Small programs	Good-faith effort will provide insight into cause of death
Confidence interval	Each program has its own interval; all can succeed
Delay in reporting	Upward trajectories in survival over time considered
Broad endpoint	Only overall one-year survival is provided, but programs are responsible for drilling down into data
Data errors	Corrective actions related to data management and reporting expected if this is a problem—almost all programs probably under-report KPS, for example

Getting Past the Myths of the CIBMTR Report

- Major claim is of CIBMTR's algorithm not accounting for program's specific challenge such as socioeconomic conditions
- Programs WITH those disadvantages have proposed means to counter-act across the continuum of care
  - Have not said "we won't transplant these candidates"

Comparative Data Sources:
Autologous Programs and Allogeneic Programs Outside of U.S.

- C.W. Bill Young Cell Transplantation Program's U.S. Patient Survival Report
  - *Available at: http://bloodcell.transplant.hrsa.gov/research/transplant_data/us_tx_data/survival_data/survival.aspx*
- *Be the Match/National Marrow Donor Program* Disease-Specific HCT Indications and Outcomes Data
  - *Available at: https://bethematchclinical.org/Transplant-Indications-and-Outcomes/Disease-Specific-Indications-and-Outcomes/*
- Country or region-specific registries
- Peer-reviewed Medical Literature
  - Scholarly articles examining multi-center one-year survival using relevant disease, donor type, and date range

Examples of Corrective Action Plans: Learning Together

- FACT committee wanted to first see programs' current approaches to benchmarking and evaluating outcomes

- First Clinical Programs to submit corrective action plans (CAPs) had little guidance
  - Deserve credit for their role in refining the FACT process
  - FACT committee appreciated their efforts

- FACT and accredited programs learned together
  - Dialogue with questions and answers
  - Development of guidelines for CAPs
  - Examples on following slides are from programs that ultimately submitted adequate CAPs

The First CAPs – What We Learned
Summaries are not enough

- FACT needs specific information to evaluate CAPs and programs need specifics for analysis:
  - How did patients die?—if infection, WHAT infection?
  - Do the corrective actions address the causes of death?

Action Suggested/Recommended:

Practice One Year Survival Status less than National Average on NHL patients whose disease was in the 'Active' Stage Post Transplant and patients who were in 2nd or subsequent remission Post Transplant.

Action Plan: Low numbers in both categories due to being a small autologous center create potential for large variance without clinical significance. Seven of Nine patients survived greater than 1 year in the 2nd or subsequent remission category. One of six patients survived greater than 1 year in the Active Disease category.

Per accepted guidelines, all patients proceedings to transplant with recurrent or refractory lymphoma are required to have chemo responsive disease immediately prior to transplant. For patients with Hodgkin's disease post transplant maintenance therapy with Brentuximab is recommended. At this current time, there is no definitive data for maintenance therapy for patients with NHL post transplant.

Data will continue being tracked quarterly.

The First CAPs – What We Learned
It is easy to jump to conclusions.

- Cause of death is a major data point for effective root cause analysis.

- Corrective actions may not improve outcomes if focus is not on the root cause of low survival.

ANALYZE

After seeing a percentage of 55.4% in the 2014 report, our center compared specific disease outcomes against Health Resources and Services Administration (HRSA) published data and focused review of diseases where   survival was below HRSA published disease-specific percentages. This lead to multiple discussions of the possible cause for reduced survival.

We began brainstorming ways to impact Day 100 survival, perceiving improved/standardized selection criteria to be an immediate source of impact.

IMPROVEMENT

Based on internal review of survival data, we anticipated a 50% survival rating for those years, with the possibility of that percentage falling below the confidence interval. In early 2015, our center initiated multiple changes to improve survival at our center.

The First CAPs – What We Learned
Regular data review by program expedites improvement.

- Programs need to review their data rather than just report it.
- Ongoing data analysis helps program improve and *prevent* low one-year survival.

List the tasks needed to set up the test of change	Person responsible	When to be done
• Obtain data and review all allo patients from 2013-2015 • Assess for trends –looking at primary cause of death, contributing factors and co morbidities • Verify correct data was submitted • Review high risk patients with low psychosocial assessment • Identify potential causes of low 100 day and One year survival rates • Review Process/Structural that we can influence that impact 100 day and 1 year survival rates • Review Patient Care factors that we may not be able to influence that impact 100 day and 1 year survival rates		Goal 30 days: April 17, 2016

The Result of Initial Experiences: FACT Guidelines for Corrective Action Plans

- Must identify *specific* causes of death

- Must provide *quantitative* data

- Must identify *reasonable* causes of the low one-year survival rate

- Must *address* the identified causes.

- Must be a *measurable* outcome improvement.

- Must provide *updates* at time of inspection, annual reporting, and as otherwise directed by committee

Identifying Specific Causes of Death

- Should be first step in evaluating 100-day and one-year survival rates
- Do this in a literal sense; many programs created tables listing for each patient: cause of death, and other factors (age, diagnosis, preparative regimen, disease status, type of transplant, etc.)
- Determine trends in causes of death
- Perform root cause analysis of those causes identified

# Providing Quantitative Data

- Not just to FACT – to yourselves!
- Quantitative data prevents inaccurate assumptions
- Types of data seen in CAPs:
  - Tables and charts of causes of death
  - Trends in survival rates, including Kaplan-Meier survival estimates
  - Survival by disease
  - Changes made to misreported data
  - Improvements in survival after implementation of corrective actions
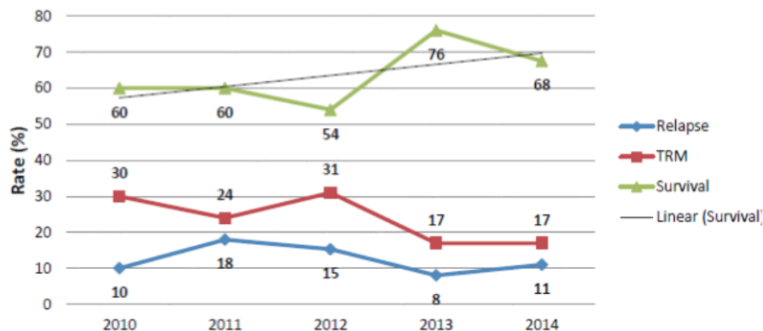
Graphical Displays of Data
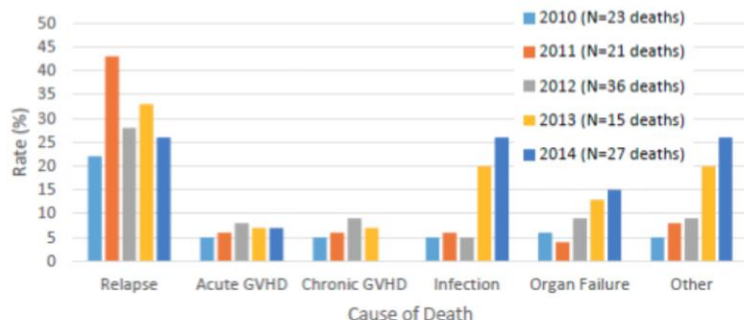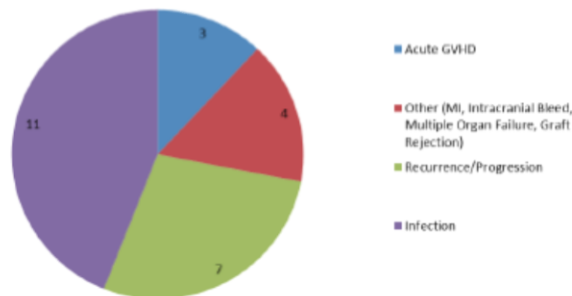
Identifying Reasonable Causes of Low One-Year Survival

1. Identify common causes of death
2. Collect additional data regarding those patients
   1. Patient characteristics
   2. Disease characteristics
   3. Transplant characteristics
3. Look for common themes

Examples of Root Causes Identified by Programs

- Disease relapse
- Infection
- GVHD
- Protocols—Conditioning regimens contributing to TRM
- Over reporting performance status/underreporting comorbidities

Addressing the Identified Causes

- Data already collected assists with brainstorming potential corrective actions
- Think outside of the box, but don't "overthink"
  - Corrective actions have ranged from simple to complex
- Each Clinical Program will have different needs based on their causes of death
  - Example: Some programs will choose to reinstate high-dose chemotherapy to address disease relapse while others will choose to use reduced intensity conditioning (RIC) to better treat frail patients.
- The following examples are not guarantees and are based on programs' own assessments

Examples of Corrective Actions (1 of 2)

Root Cause	Corrective Actions
Disease relapse	Use of ablative regimens instead of RIC for patients with low comorbidities; bone marrow biopsy within two weeks of admission for transplant; review of social barriers to transplant; minimize delay of transplant by improving graft procurement logistics; education of referring physicians regarding early referrals; allogeneic patient scoring by DRI, PAM, and HCT-CI methods
Infection	Early foscarnet prophylaxis for CB transplants; infectious disease group review of supportive care measures; educate referral network about importance of CNS prophylaxis; modified surveillance guidelines for detecting viral infections; chlorhexidine baths for patients continued upon transfer to ICU

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Examples of Corrective Actions (2 of 2)

Root Cause	Corrective Action
GVHD	Allogeneic patient clinic staffed by physician with NP and pharmacist, "Who do I call if I'm sick" program to provide best phone numbers, return to full-dose methotrexate with tacrolimus for prophylaxis, clinical pathway for ECP, use of MSC therapy for steroid resistant GVHD
High comorbidity scores	Psychosocial review to include housing, transportation, caregiver, smoking cessation, and drug addiction
Protocols	Change to fludarabine/busulfan-based treatment regimen, expanded indications for RIC, switch from TBI-based regimen to thiotepa/cyclophosphamide for adult patients under 60 years (except for ALL)
Incorrect data	Additional data management staff, physician review of key data before submission to CIBMTR, pre-transplant physician dictation templates

Importance of Teamwork

Roles in BMT

- Transplant physicians
- APPs and Nurses
- Coordinators
- Pharmacists
- Psychologists
- Social workers
- Referring physicians
- Data managers
- Administrators
- Laboratories
- Environmental services

Multidisciplinary corrective actions submitted to FACT:

- Follow-up clinic
- Outcomes reporting at staff meetings
- Streamlined donor search and selection
- Improved environmental cleaning
- Expedited lab testing
- Psychosocial assessments

Program Updates Submitted to FACT

- Updates provided via:
  - On-site inspection
  - Annual reports
  - Subsequent Compliance Application
- FACT committee wants to see:
  - Evidence of implementation of corrective actions
  - Measurable improvement in one-year survival
  - If no improvement, further analysis and modified CAP
- Generally, programs are submitting such information
  - Programs not demonstrating adequate progress required to submit more detailed, specific information

Assistance to Transplant Centers

- Education has shown to be key
  - Several workshops and webinars are offered
  - Examples of corrective action plans displayed on website at http://www.factwebsite.org/clinicaloutcomes/
  - FACT, ASBMT, NMDP Education Consortium to consolidate resources
- Individualized attention appears to be necessary
  - FACT Outcomes Committee identifies weaknesses in corrective actions, offers advice, monitors progress
  - Staff frequently fields questions directly from programs
- FACT Consulting and ASK-A-PEER are additional, separate options
  - Does not guarantee accreditation or improved outcomes, but can provide more intensive support

CIBMTR Center Specific Survival Report

- **US law (Stem Cell Act) established Stem Cell Therapeutic Outcomes Database → CIBMTR has contract and reports 1-year survival for allogeneic HCT performed at US centers**
  - **Annual report**
  - **Related and unrelated donor HCT**
  - **3 year inclusion period (e.g., 2016 report included allogeneic HCT reported from 2012-2014)**
  - **1-year survival**
- **Rigorous methodology (www.cibmtr.org)**

CIBMTR Center Survival For Cleveland Clinic

Program Performance in CIBMTR Center Specific Survival Report

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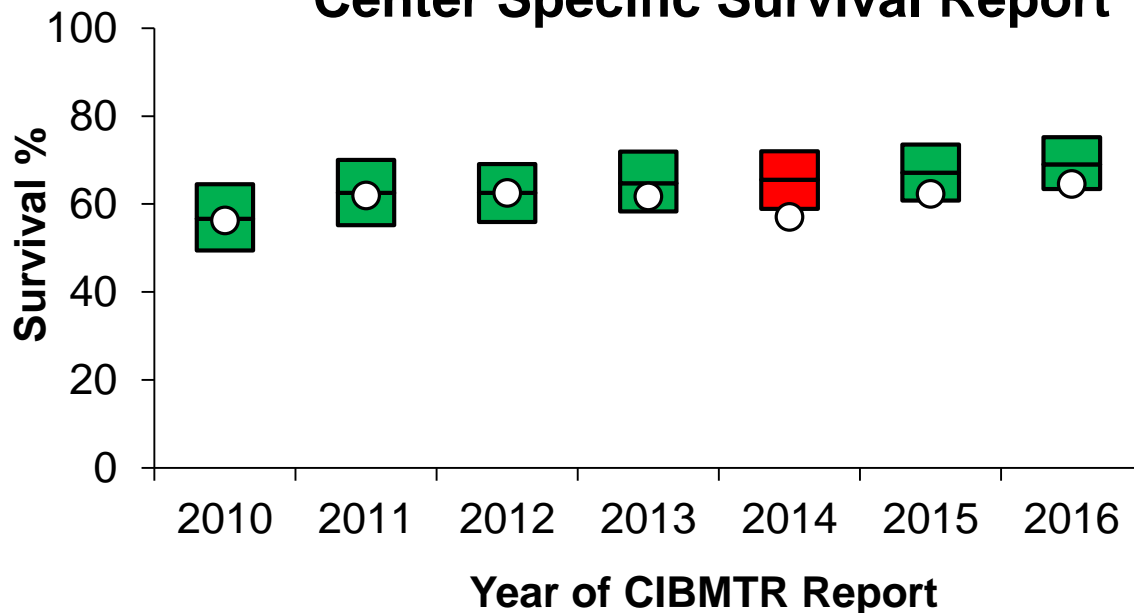
Five Stages Of Grief For Underperforming Center

Process For Review Of Program Outcomes

- **Set up committee of BMT Program staff:**
  - **Director**
  - **Quality Officer**
  - **Administrator**
  - **Clinical Manager**
  - **Quality Manager**
- **Identified three areas of focus:**
  - **Review data submitted to CIBMTR**
  - **Review program processes that may impact survival**
  - **Identify areas for improvement**

Review Of Data Submitted To CIBMTR

- **Reviewed data for accuracy**
- **Performed repeat audit for some critical data fields (e.g., HCT CI score, disease status)**
- **Reviewed outcomes to identify subgroups that may have impacted outcomes**

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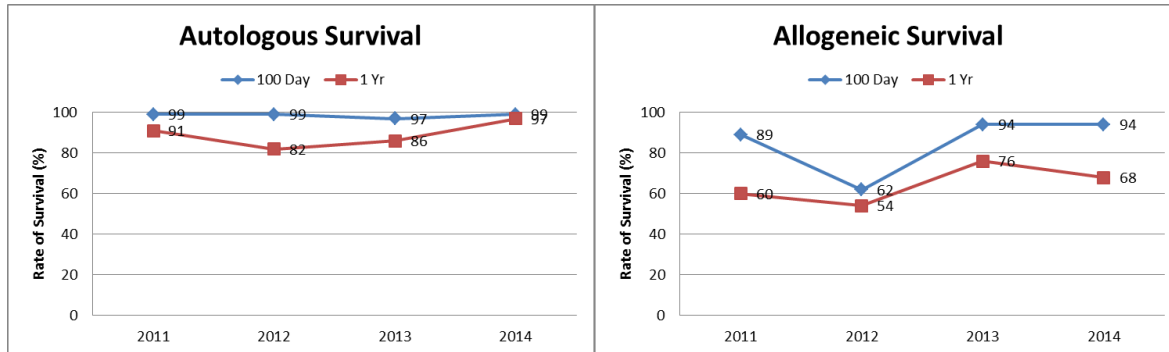
Reviewed Program Processes

- **Reviewed program processes that may impact patient survival or help capture survival information**
  - **Patient selection meetings**
  - **Patient review meetings**
  - **Program quality dashboard/metrics/meetings**
  - **Mortality review meetings**
- **Changes made**
  - **Review of all mortality upto 1-year post-transplant (previously reviewed 100 day mortality)**
  - **Added following fields to weekly patient selection/review meeting: KPS, HCT-CI score, PACT score, estimated survival (CIBMTR calculator)**

Patient Selection Dashboard

HCT CI Score		PACT SCORE		1-YEAR Survival		PAMS Score	
High risk: ≥ 3 Int risk: 1,2 Low risk: 0		High risk: 0,1 Int risk: 2 Low risk: 3,4		High risk: <60% Int risk: 60-75% Low risk:≥75%		High risk: ≥24 Int risk: 17-23 Low risk: <17	
0		3		75		10	
1		1		75		15	
3		0		55		30	
0		4		89		10	
0		4		76		17	
1		4		47		10	

Cleveland Clinic

Identify Areas For Improvement

- **Conducted retreat to engage program and focus on:**
  - **Decrease time to transplant**
  - **Improve care coordination beyond day 100**
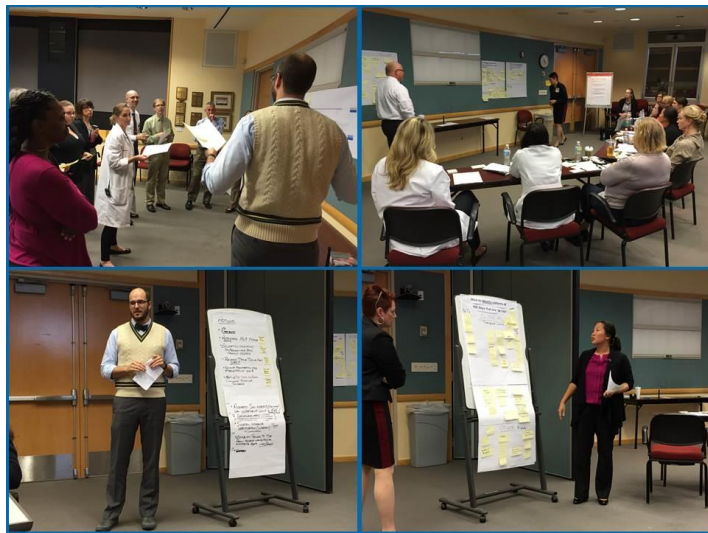
Projects Identified And Prioritized

- **Better patient selection**
  - **Clinical case discussion for high-risk patients**
- **Earlier determination of transplant indication**
  - **Shorter turnaround for cytogenetics at diagnosis**
- **Alternative care models**
  - **Identify patients at high-risk for adverse survival and follow with nurse-patient telemedicine visits**
- **Enhanced metrics**
  - **Individual physician dashboards**

BMT DASHBOARD (January 2016)
Navneet Majhail, MD, MS

CONSULTS
Time period: Jan 2015 to Dec 2015

DIAGNOSIS	Staff	BMT Program
AML	8	33
ALL	2	11
MDS/MPD/MFB	7	35
CML	0	5
Hodgkin ds	0	7
NHL	5	35
Myeloma	10	76
Amyloidosis	5	13
SAA/BM failure	1	6
Solid tumor	3	3
Other	1	5
TOTAL	**42**	**229**

NEW APPT	Staff	BMT Program
Within 14 days	62%	45%
Within 30 days	88%	83%

SURVIVAL
Time period: Jan 2013 to Dec 2014

TYPE	N		100 day survival (%)		1-year survival (%)	
	Staff	Program	Staff	BMT Program*	Staff	BMT Program*
Allo, MAC	1	72	100	96	0	74
Allo, RIC	1	65	100	91	100	68
Auto, NHL	2	88	100	95	100	88
Auto, myeloma	5	97	100	100	100	95

BONE MARROW HARVESTS   (minimum 1/year)
Time period: Jan 2015 to Dec 2015

	Staff	BMT Program	
# Harvests	4	11	
Avg TNC dose	2.93	3.11	x 10^8/kg

CLINICAL TRIAL ACCRUAL
Time period: Jan 2015 to Dec 2015

	Staff	BMT Program
Therapeutic	8	33

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100 Day Allogeneic High Risk Evaluation

Patient Name:				MRN #			
T-0:			Day +:			Date of Report:	2/5/16
Date Reviewed:	2/11/16						

Post-Transplant Assessment	Value	Yes (1) No (0)
Co-morbidity score pre-transplant ≥3		
Distance from CCF >1 hrs		
GVHD/steroids within 100 days		
Poor functional status (unable to perform ADL's)/ECOG PS>2		
Infection requiring home and/or recurrent IV antimicrobial treatment w/in 100 days		
Caregiver support concerns		
Poor coping skills/motivation		
Substance abuse concerns		
Poor health literacy/access		
Medication compliance		
BMT team concerns/"other":		
	TOTAL:	

Comments:

Identify Areas For Improvement

- **Visit to comparable sized high-performing program**
  - **Met leadership**
  - **Reviewed processes**
  - **Shared ideas for improving program survival**

Conclusion

- **Our case study highlights systematic approach to review and improve program outcomes**

- **Engaging program essential to improving patient outcomes**

- **Our focus was survival, but methodology can be translated to assess other program outcomes**

Blood & Marrow Transplant Program

Evaluation Reminder

Please complete the Council Meeting 2017 evaluation in order to receive continuing education credits and to provide suggestions for future topics.

We appreciate your feedback!