



Clinical Safety & Effectiveness Cohort # 11

**Compliance in the Documentation of
Verbal Disclosure of Relevant Financial Relationships with
Commercial Interests from Presenters**



Educating for Quality Improvement & Patient Safety

SAN ANTONIO

UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER
Making Cancer History®

The Team

UT Health Science Center San Antonio School of Medicine

- Quality and Lifelong Learning/Continuing Medical Education
 - Cynthia Garza
- Department of Pediatrics
 - Dennis A. Conrad, MD
- Center for Patient Safety & Health Policy
 - Leticia Z. Bresnahan
 - Hope Nora
- Sponsor Department
 - Quality and Lifelong Learning, Continuing Medical Education – Associate Dean, Jan E. Patterson, MD, MS

Disclosure

Cynthia Garza has no relevant financial relationships with commercial interests to disclose.

Dennis Conrad, MD has disclosed that he has received consulting fees from Merck Pediatric Vaccine Advisory Board.

Leticia Z. Bresnahan has no relevant financial relationships with commercial interests to disclose.

Hope Nora has no relevant financial relationships with commercial interests to disclose.

AIM Statement

To perform at 100% compliance by documenting the verbal disclosure of relevant financial relationships with commercial interests from the presenters in the top three (3) non-compliant Regularly Scheduled Series (RSS) from the 40+ RSS under the purview of the UT Health Science Center San Antonio School of Medicine's Office of Continuing Medical Education by September 14, 2012.

Project Milestones

- Team Created March 2012
- AIM statement created April 2012
- Team Meetings June - September
- Background Data, Brainstorm Sessions, Flowchart and Fishbone Analyses May – September
- Interventions Implemented July – ongoing
- Data Analysis July – September
- CS&E Presentation Sep. 14, 2012

Background

The Accreditation Council for Continuing Medical Education (ACCME) granted the UTHSCSA Office of CME ***Accreditation with Commendation*** status upon the successful completion of its most recent self-study report, evidence of performance-in-practice, and an accreditation interview.

Accreditation with Commendation is awarded to providers that demonstrate compliance with all Accreditation Policies.

- UTHSCSA is an accredited CME Provider through ACCME
- 8 CME Providers in San Antonio, Texas
 - 5 State-accredited providers
 - 3 ACCME-accredited providers
 - UTHSCSA – health institution
 - Dannemiller – specialty society
 - Pan American Allergy Society – specialty society

Background

The UT Health Science Center San Antonio School of Medicine's Office of Continuing Medical Education currently sponsors 41 Regularly Scheduled Series (RSS) and 225 Directly Sponsored and Joint Sponsored CME activities with approximately 24,000 physicians attending per year. During the 2011 re-accreditation period, ACCME audited 15 CME activities; 5 of which were RSS.

Regularly Scheduled Series (RSS)

A course that is planned to have

- a series with multiple sessions that
- occur on an ongoing basis (offered weekly, monthly, or quarterly) and
- are primarily planned by and presented to the accredited organization's professional staff. Examples of activities that are planned and presented as a Regularly Scheduled Series are Grand Rounds, Journal Clubs, Case Conferences, Tumor Boards, and M&M Conferences.

*This CS&E project entails a Grand Rounds, Journal Club and Case Conference.

Background

Per the Accreditation Council for Continuing Medical Education (ACCME):

ACCME Standards for Commercial Support, Standard 6: Disclosures Relevant to Potential Commercial Bias

This policy provides guidance about how to document that disclosure to learners of the financial relationships of those who control CME activity content, such as planners, committee members, teachers, editors, and authors has taken place when that disclosure is made verbally.

Background

Context

Disclosure of information about relevant financial relationships can be disclosed verbally to participants at a CME activity. When such information is disclosed verbally at a CME activity, providers (CME Office) must be able to supply the (ACCME) with written verification that appropriate verbal disclosure occurred at the activity.

Rationale

With respect to this written verification: A designated representative of the provider in attendance at the time of the verbal disclosure must attest, in writing:

- that verbal disclosure did occur; and
- itemize the content of the disclosed information (SCS 6.1); or that there was nothing to disclose (SCS 6.2).

* *The Standards for Commercial Support: Standards to Ensure Independence in CME Activities*

Verbal Disclosure Form



Verbal Disclosure Confirmation Form

Instructions: Please use this form to document that verbal financial disclosure was made for each speaker. The form should be completed by the course director, moderator, or an assigned attendee and returned to the CME Office with your post-activity documentation. Financial disclosure must be made even if a speaker has no relevant financial relationships with commercial interests to disclose and prior to the speaker's presentation.

Speaker's Name:

Please place a check in the box that identifies the verbal disclosure that was given at the conference.

- The speaker disclosed that he/she has no relevant financial relationship with commercial interest to disclose.
 The speaker disclosed the following financial relationship with commercial interests.

Nature of financial relationship	Company Name of Commercial Interest (commercial interests include manufacturers of pharmaceutical product or medical devices)
Employee	<input type="text"/>
Grant/Research Support	<input type="text"/>
Speaker's Bureau	<input type="text"/>
Consultant	<input type="text"/>
Major Stock Shareholder	<input type="text"/>
Other financial or material support	<input type="text"/>

Print Name:

Date:

Signature: _____

Please complete all applicable fields (including Print Name and Date fields), and click the 'Print Form' button. Return completed, signed form via fax to (210) 567-6964.

Print Form

Current Status of Disclosure

40+ Regularly Scheduled Series (RSS) in place; each activity is required to disclose their speaker's relevant financial relationships with commercial interests at the beginning of the activity.

Each RSS can disclose in one of three different ways:

- Slide disclosure
- Print disclosure
- Verbal disclosure (focus of CS&E project)

Currently verbal disclosure is taking place without written documentation.

How Will We Know That a Change is an Improvement?

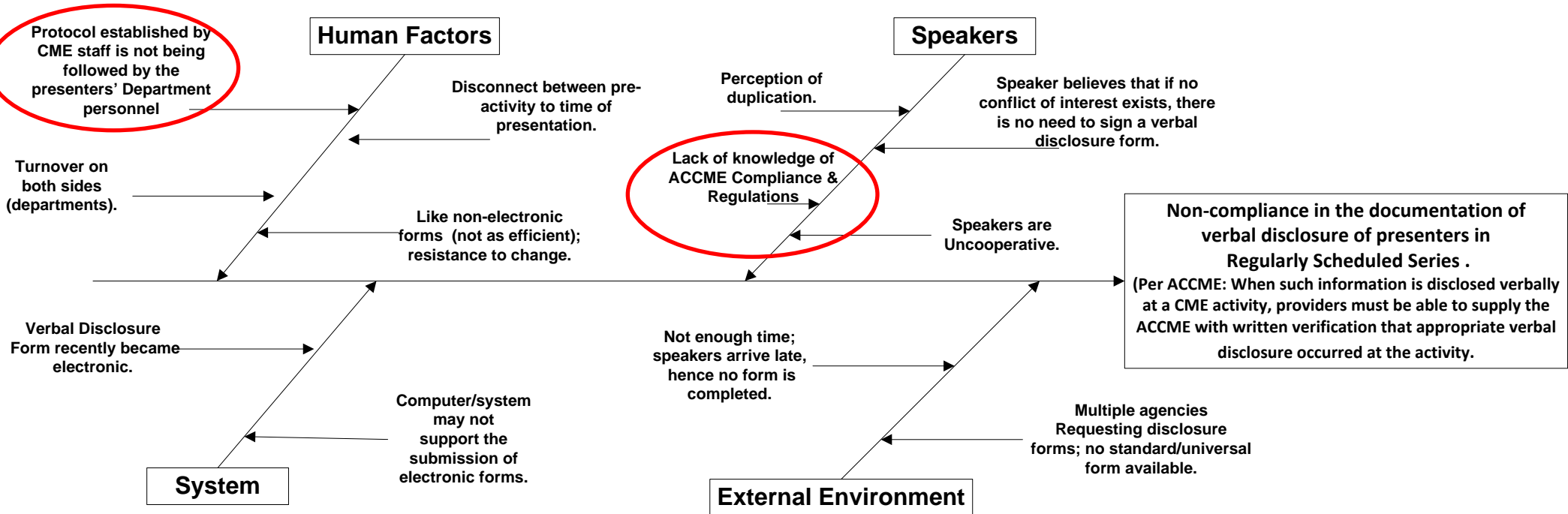
- Type of measure:
 - Retrospective audits for documentation of disclosure
- How you will measure?
 - Surveyed to identify non compliant RSS activities
- Specific targets for change?
 - Top 3 non-compliant RSS activities

What Changes Can We Make That Will Result in an Improvement?

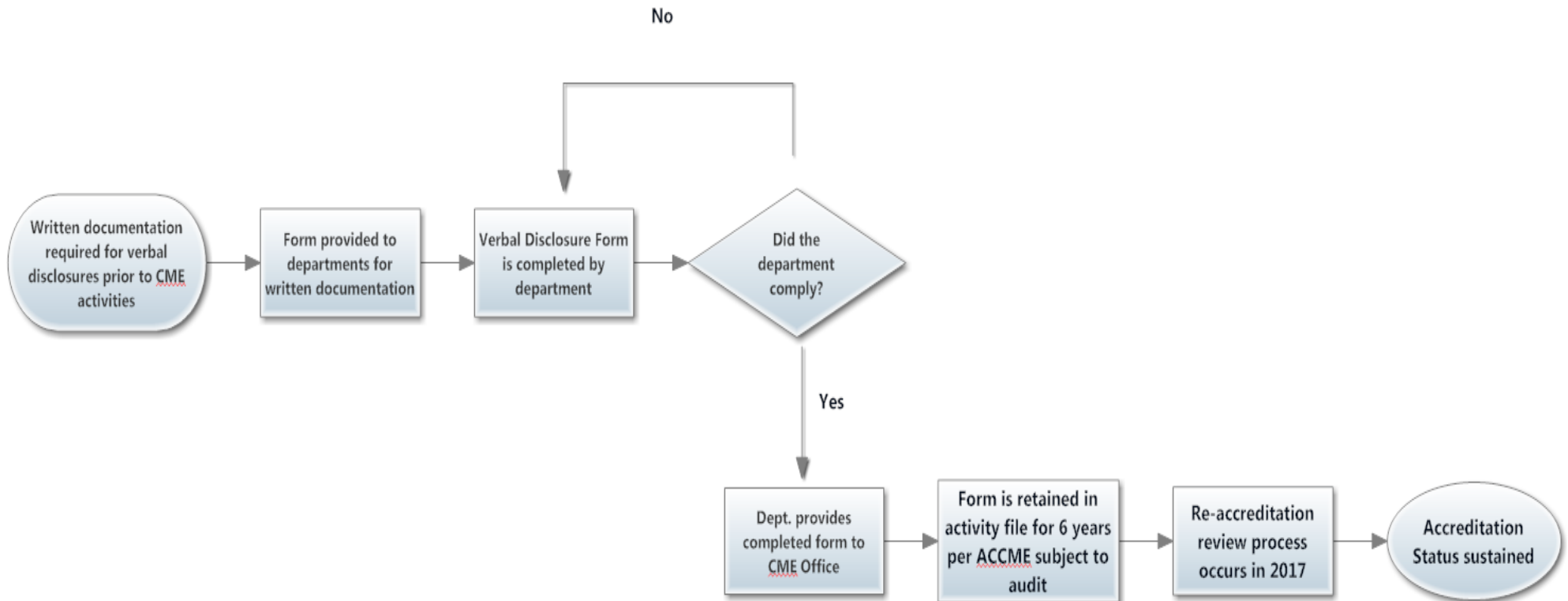
- Communicate to RSS planners the importance of written documentation of verbal disclosure.
- Incorporate the verbal disclosure form as part of their pre-conference routine.

Cause and Effect Diagram

Non-compliance in verbal disclosure documentation for Regularly Scheduled Series



Process Flow Chart: Verbal Disclosure Compliance



Plan

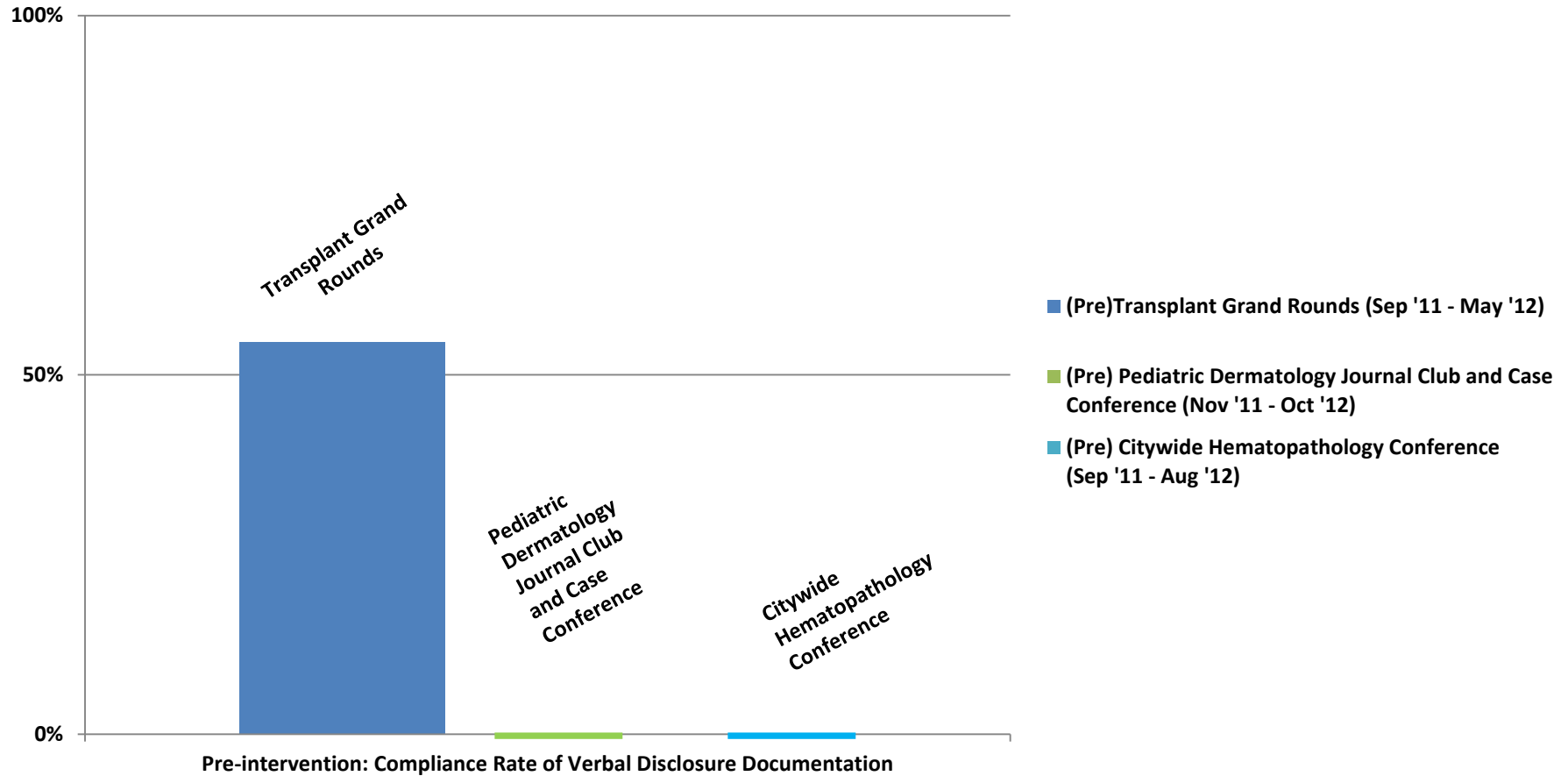
- Verified and documented the history of verbal disclosure documentation for each speaker of the 3 non-compliant RSS activities
- Determined the non-compliance percentage by dividing the total number of verbal disclosures documented in writing by the total number of speakers for each of the 3 non-compliant RSS activities.
- Monitored the 3 non-compliant RSS activities (June 2012 – September 14, 2012) – Transplant Grand Rounds, Pediatric Dermatology Journal Club, and Citywide Hematopathology Conference.

Compliance vs. Non-compliance Rate: Pre-intervention

- The non-compliant percentage rate is higher than the compliant percentage rate, pre-intervention.

Activities (September 2011 - June 2012)	Verbal Disclosure made at beginning of CME Activity		TOTAL	Documentation of Verbal Disclosure
	Yes	No		
(Pre)Transplant Grand Rounds (Sep '11 - May '12)				
Speaker 1	1			1
Speaker 2		1		
Speaker 3	1			1
Speaker 4		1		
Speaker 5		1		
Speaker 6	1			1
Speaker 7	1			1
Speaker 8		1		
Speaker 9		1		
Speaker 10	1			1
Speaker 11		1		
Speaker 12	1			1
Speaker 13	1			1
Speaker 14	1			1
Speaker 15		1		
Speaker 16	1			1
Speaker 17		1		
Speaker 18		1		
Speaker 19	1			1
Speaker 20		1		
Speaker 21	1			1
Speaker 22	1			1
TOTAL	12	10	22	12
Non-Compliant Rate			45.45%	
Compliant Rate			54.55%	

Compliance Rate: Pre-intervention



Do

- Prior to the next scheduled presentation, RSS contacts and course directors received
 - information explaining the importance of being in compliance with ACCME standards and the repercussions to the institution if found delinquent
 - clarification on commonly held misconceptions about what constituted appropriate disclosure
 - written instructions on the protocol for properly documenting verbal disclosures and
 - a sample Verbal Disclosure Form that could be used for all activities
- Planned follow-up intervention consisting of one-on-one meetings which was not necessary (protocol was implemented immediately)
- Continued to monitor compliance of appropriate verbal disclosure documentation

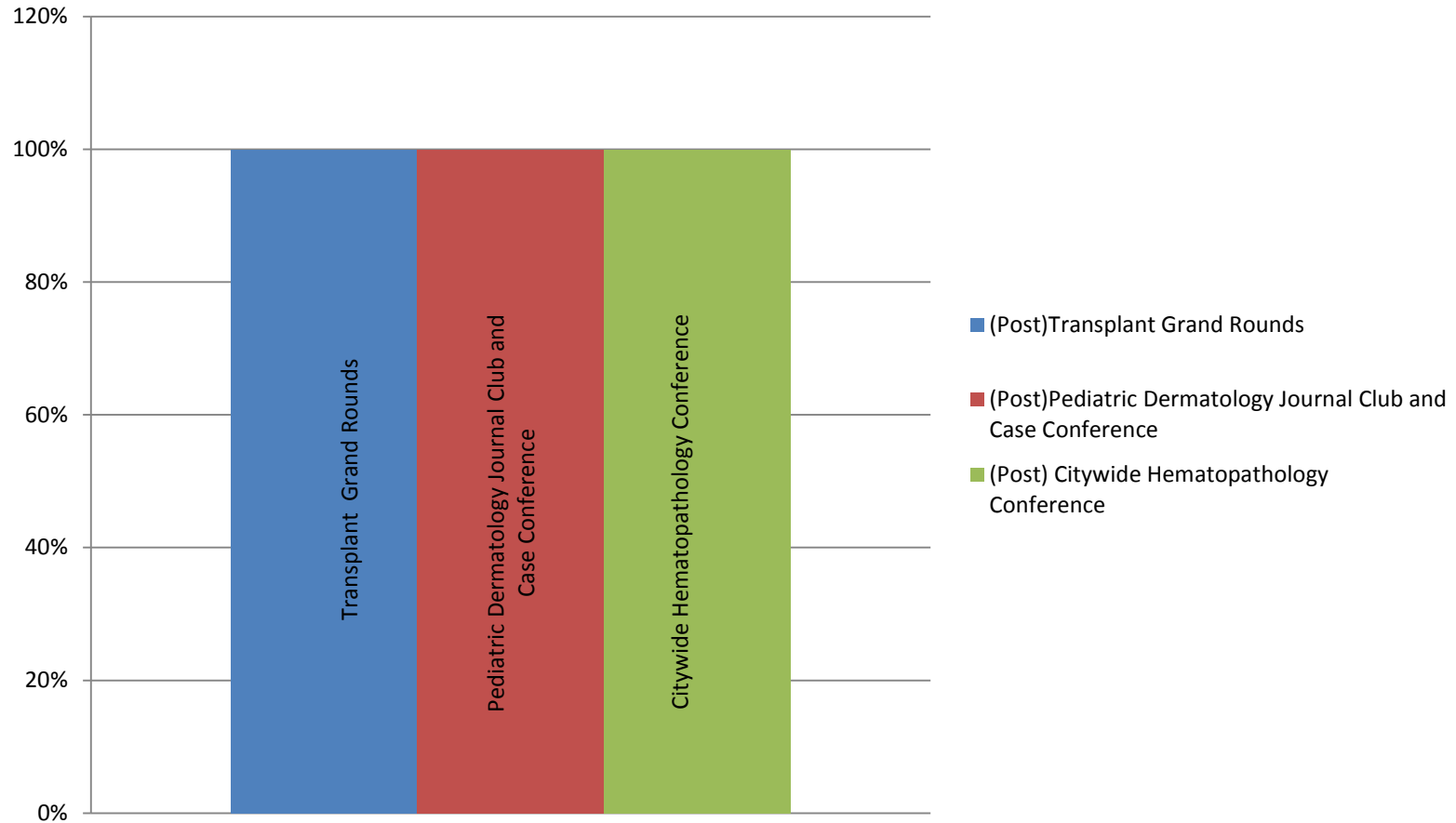
Check

Post-Intervention Results

- The compliance percentage rate is at 100%, post-intervention!

Activities (June 2012 - present)	Verbal Disclosure made at beginning of CME Activity		TOTAL	Documentation of Verbal Disclosure
	Yes	No		
(Post)Transplant Grand Rounds (Sep '11 - May '12)				
Speaker 1	1			1
Speaker 2	1			1
TOTAL	2	0	2	2
Non-Compliant Rate			0.00%	
Compliant Rate			100.00%	

Compliance Rate: Post-intervention



Act

- Focus to create method of improvement and continue to advocate 100% compliance of appropriate verbal disclosure documentation.
- Incorporate audit system for all CME activities.

Return on Investment

- CME Dept. remains an accredited provider where we collect more than \$410K in registration fees annually.
- FY 12 – 5 CME activities collected registration fees totaling \$410K and a net profit of \$60K was returned to the UTHSCSA depts.
- Lack of compliance leads to loss of accreditation status and integrity of the UTHSCSA School of Medicine. Loss of accreditation=no AMA PRA Category 1 Credit. No AMA PRA Category 1 Credit=low attendance. Low attendance=poor health outcomes.
- CME-approved educational activities provide the opportunity to keep physicians and other healthcare professionals current with best clinical practices.

Conclusion

Final conclusions/knowledge gained

- Compliance is critical
- Non-compliance will lead to loss of accreditation status

Next steps

- Moving forward, establish this QI project as a pilot program for all CME activities
- Continuous un-announced audits for documentation of disclosure
- Re-evaluate the CME activities process regarding verbal disclosure and written documentation
- Schedule in-services, if needed, on the importance of written documentation for verbal disclosures and compliance.

What's Next?

Future benefits

- Sustain the “Accreditation with Commendation” status and remain compliant for the next re-accreditation period
- Maintain the integrity and reputation of the UTHSCSA School of Medicine

Thank you!



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