Collaborative, Mixed-Methods Outcomes Research Into Primary Care Continuing Education on Pre-Treatment Counseling of Men With Age-Associated Testosterone Deficiency

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ABSTRACT

Modern CEhp maintains a strong focus on improving health care practice through education that promotes quality and patient outcomes. We present educational outcomes data on a CME initiative addressing care gaps for testosterone deficiency (TD). Mixed methods were indicated because primary care for TD requires thorough counseling and shared decision-making. Interviews used in this design promoted reflection among clinicians and were ultimately found to serve as educational interventions, a finding of interest for educational planners.

In-depth interviews with physicians revealed communication styles and PCP counseling strategies for verifying patients' understanding of, and satisfaction with, TD care. Insights into these practices are relevant to partnering with patients for many conditions seen in primary care. The interviews also reinforced the top content messages and encouraged physician reflections, and therefore became educational interventions. Insights into self-assessment research and clinician-patient communication add to the educational literature.

Educators will learn that well-coordinated, qualitative and quantitative methods produce findings that inform the most frequently changing factor in educational design: learners. These effectiveness data from a TD CME initiative illustrate mixed methods using the strengths of collaborative research contributed by CME Outfitters and the newly established Alliance Foundation for Continuing Education in the Health Professions.

INTRODUCTION

Gaps in Primary Care Practices in Managing Testosterone Deficiency

Age-associated testosterone deficiency (TD) affects approximately 38.7% of men ≥ 45 years.[1] Commonly associated signs and symptoms are fatigue, sleep disturbances, weight gain or adiposity, reduced libido, erectile dysfunction, osteoporosis, loss of muscle mass and strength, depressed mood, increased irritability, and difficulty concentrating.[2,3] Caring for an aging population, primary care practitioners (PCPs) will see increasing numbers of patients with TD-related symptoms.[3,4] Standard treatment for TD is testosterone replacement therapy (TRT), which benefits overall health and is designed to relieve symptoms and improve energy and quality of life.[2,3,5,6] Appropriate TRT use requires thorough pre-treatment assessment and ongoing monitoring to mitigate potential risks.[2,7] Shared decision-making and patient counseling to alleviate potential concerns[2,8] and set realistic expectations for therapy[2] are particularly valuable to TD treatment.

Continuing medical education (CME) activities can address primary care gaps in treating TD in men ≥ 45 years: pre-treatment counseling on TD, and guidelines-based practice on treatment-selection and monitoring.[2,4,9]

Study Objectives

This study examines whether PCP participation in CME/CE is associated with improved, patient-focused, pre-treatment counseling on TD-related symptoms and clinical effects, expectations for therapy, safety during TRT, and the individualized selection of TRT formulation.

METHODS

Study Design

The study used a pre-post and comparison-group design for each of two webcast (WC) activities. Both multimedia activities featured expert discussion and scientific content slides of TD and TRT evidence and Endocrine Society guidelines.[1] WC1 included 60 minutes of live, case-based, moderated discussion, plus a 30-minute, interactive, Q&A session, with all 90 minutes available enduring; WC2 was a 30-minute, enduring activity. Both offered *AMA PRA Category I Credit™*.

PCPs could elect to participate in both activities; participating and comparison PCPs were not limited from completing non-initiative CME. WC1 applied a mixed-methods design to investigate PCPs' perspectives on TD care and evaluate educational outcomes for the initiative..

Sampling & Instruments

"PCP" was defined as a practitioner with MD, DO, PA, or NP discipline practicing in Family Medicine or Geriatrics, General Internal Medicine, General Practice, or Preventive Medicine.

The timeline (see Figure 1) shows distribution of groups to outcomes instruments (see Table 1). Brief pre-surveys for each activity probed different measures. Quantitative tools and discussion guides queried TD and TRT knowledge; attitudes toward TRT; rates of delivering core pre-treatment counseling messages on benefits and risks; selection of TRT formulation; monitoring plans; and reflections on practice approaches and patients' experiences.

Mixed-Methods Research Timeline

Figure 1. Timeline (2013 – 2014) for testosterone deficiency CME activities and use of mixed outcomes instruments.

Interview Timing Related Results:

** Interviews, Round 1: Recruitment, 10 physicians at data-saturation. Median interval, first activity participation to Round 1 = 98 days, interquartile range 65 – 106 days, total range 50 – 175 days.*

*** Interviews, Round 2: Median interval, Round 1 to Round 2 = 156 days, interquartile range 130 – 198 days, total range 116 – 210 days.*

METHODS, cont'd

Table 1. Definitions and allocation of study groups to testosterone deficiency CME/CE initiative outcomes instruments.

Study Group	Outcomes Instrument
All PCPs: Pre-activity instruments for each activity: all PCPs in that activity. Post-activity instruments for each activity: PCPs who requested credit for that activity.	*Activity-specific:* Pre Survey + Pre Test Post Test + Post Survey
Physicians in Interim Interviews: U.S.-based, PCPs with MD or DO discipline, currently seeing patients taking TRT that they had prescribed, and participating in WC1 at least 50 days earlier. Recruitment until data reached thematic saturation.	Round 1 Interview *(25 minutes)* Round 2 Interview *(35 minutes)*
PCPs Surveyed at 11-Month Follow-Up: Participants currently seeing patients with TD who participated in one or both activities at least 50 days earlier	Quantitative Survey
PCP Comparison Group: Non-participating PCPs in the educational provider's database (invited 10,000)	

Data Analysis

Quantitative performance rates are self-report within patient percentage ranges, analyzed between groups at the 51% cutpoint by two-tailed Fisher's exact test (2x2 contingency tables at QuickCalcs [graphpad.com]). Survey respondents who participated in both activities were included in analysis of each activity. Interview transcripts were analyzed using constant comparative method and analysis software (*NVivo 10*).

RESULTS & DISCUSSION

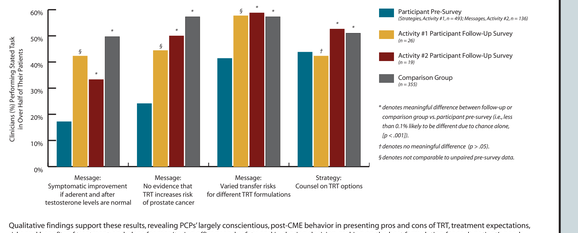
CME Educational Effectiveness

Overall Results

Quantitative findings for both activities show improved knowledge, competence, and performance for measured clinical tasks requiring counseling skills;$p < .001$.

- Before CME, participants had significantly lower rates of performing 4 counseling measures than PCPs in the comparison group had (Figure 2). This suggests that participants self-selected for education after identifying their care gaps.
- For WC2, self-reported performance on communicating 3 core messages to patients significantly improved; for 2 of these, participants' post-educational performance rates closed the gap with the comparison group.

Figure 2. Primary care practitioners' self-assessed performance rates in carrying out the stated clinical strategy or counseling on the specific message in ≥ 51% of patients with testosterone deficiency (TD), since participating or in the previous 3 months—before versus ≤ 11 months after, participating in continuing medical education. "Over half of patients" = self-assessed task performance with 51%–75% or 76%–100% of patients.



** denotes meaningful difference between follow-up or comparison group vs. participant pre-survey (i.e., less than 0.1% likely to be different due to chance alone, [p < .001]).*

† denotes no meaningful difference (p > .05).

§ denotes not comparable to unpaired pre-survey data.

Qualitative findings support these results, revealing PCPs' largely conscientious, post-CME behavior in presenting pros and cons of TRT, treatment expectations, risks and benefits of treatment, and plans for monitoring efficacy and safety, and in sharing decision-making on the best formulation for each patient's needs.

PCP Comments

"Before the webcast, I basically thought, well, if he doesn't want to do it [adhere to treatment], he doesn't want to do it, it's his choice. But now I take a more proactive stance, approaching them about the potential positive health benefits, about the potential health benefits that can come from the TRT.… So I'm more proactive in that regard."

"I guess I worry a lot less about cancer and spend less time dwelling on that conversation. The webcast did give good data to show that was an area where people worry too much."

Taken together, quantitative and qualitative findings on self-reported gaps and barriers provided insight into the reasons behind lack of full implementation. For 3 behaviors that affect rates of delivering the 3 messages—counseling on options, monitoring for efficacy, and monitoring for adherence—surveyed WC1 participants generally claimed that they had ongoing educational needs or confidence issues, while the comparison group claimed barriers to, and disagreement with, these practices. When interviewers discussed PCPs' low pre-activity counseling rates, they appeared to see themselves as diligent in providing quality counseling and more aware of the need for counseling than peers.

Counseling on TRT Benefits & Risks

Interviewees were highly supportive of TRT's efficacy in helping patients "feel better," although a case scenario involving a new TD diagnosis showed that some were more enthusiastic than others; 9 of 10 favored treating TD. They also improved their competence in providing evidence-based counseling on TD health effects, TRT benefits, and TRT risks. Most were familiar with the general and specific health risks related to TD that would continue without treatment and endorsed clinical workups for suspected or confirmed TD. Nine of ten interviewees stated that they believe that TRT promotes "weight loss" and improves "quality of life," "sexual health," and "energy or vitality." Several also mentioned benefits including "cardioprotection," "[lower] cholesterol" levels, "energy" supporting a "healthier lifestyle," and improved "mental clarity," "mental health" or "mood," "sleep," "bone strength," and "muscle mass."

RESULTS & DISCUSSION, cont'd

Supporting this finding, WC1 participants had high rates of telling patients to "expect symptomatic improvement if they adhere to TRT and testosterone levels return to normal." WC2 rates significantly improved on delivering this message, from 17.2% pre-survey to 33.3% follow-up (n = 193 and n = 19, respectively; $p < .0001$). Despite near doubling, follow-up performance did not reach the comparison level of 49.7% (n = 355; $p < .001$).

Interviewees' risk counseling included having patients return for hematocrit monitoring in 3 – 6 months, which applied a 15.6-point, pre/post knowledge improvement for WC1 (74.0% to 89.6% pre-test, n = 493; post-test, n = 452; $p < .0001$). Patients' concerns about cancer risk were addressed in a case vignette in the post-tests, in which 94.0% of WC1 participants (n = 452) and 85.7% of WC2 participants (n = 99) would have told patients, "TRT does not cause the development of prostate cancer." 10 Such results are consistent with high rates of delivering this message for both activities: WC2 performance more than doubled, increasing by 107.5% ($p < .0001$), to match that of the comparison group. WC1 performance was nearly as high. Most interviewed physicians either buffered concerns with safety assurances by evaluating underlying risks or directly refuted cancer contents.

Counseling on Options & Formulations

WC2 participants improved rates of providing counseling on therapeutic options, whereas WC1 participants did not. WC1 participants showed suboptimal follow-up rates of counseling on therapeutic options, i.e., not reaching rates of WC2 participants or the comparison group. WC2 participant follow-up rates were higher than at baseline and matched comparison group rates. Differences between WC1 and WC2 groups (see Table 2) suggest that a greater perception of continuing educational need combined with greater treatment confidence may reduce self-reported performance in counseling on treatment options.

Table 2. Primary care practitioners' top factors behind lack of counseling patients on options for testosterone replacement therapy, by study group, at 11-month follow-up versus comparison group.

Factor	Practitioners (%) Claiming Factor as "Top Reason" Behind Lack of Counseling on Therapeutic Options		
	Webcast 1 Participants (n = 9)	Webcast 2 Participants (n = 12)	Comparison Group (n = 169)
Educational Need	55.6	25.0	43.2
Confidence	11.1	25.0	14.8
Disagreement	0.0	0.0	5.9
Barriers: Practice, System, or Patient	22.2	33.3	33.7
Other	11.1	16.7	2.4

Interviewees recognized that the optimal formulation to support TRT adherence would suit patient preference. Despite acknowledging individualized treatment, several interviewees indicated a strong preference for specific options, and it was clear that these PCPs would likely steer their patients toward the preferred treatments. The most noted reasons for practitioner preferences were cost, titration issues, and lack of efficacy due to adherence problems (situations for which injectable TRT was commonly preferred). Dosing convenience for the patient and potential risk for close contacts' passive reabsorption of topical testosterone minimally affected choice. Topical formulations were preferred for patients with concerns about needles or invasiveness, or who wished to avoid routine or specialty office visits. Skin irritation discouraged some from using a transdermal patch.

PCP Comments

"I spend more time [than before] explaining to patients the difference and the virtues of the different [formulations] … . I'll let them participate in the decision more in terms of which method of treatment, because there are big cost implications."

Counseling on transfer risk was the only measure where both WC participant groups had no gaps versus the comparison group on follow-up. This was also the counseling message that had the highest baseline and follow-up rates, so perhaps implementation was less challenging or education was less needed on transfer risk than on the other core counseling concerns. Yet it seems that more education is needed because a case vignette (issued post and follow-up) showed that all participant and comparison groups continue to have suboptimal competence in selecting TRT formulation per guidelines[7] and several factors. Performance data were more promising for one aspect of selecting a formulation: WC2 participants increased delivery of safety messaging on transfer risk by 42.0%, and WC1 participants also had high rates, matching performance of both WC2 participants and comparison peers at follow-up.

Overall, despite treatment-selection gaps among many PCPs and pre-existing formulation preferences among some, most interviewees counseled on the pros and cons of various TRT formulations.

Focus on PCP Communication

Communication Styles and Patient-Centered Care

While some interviewees led the treatment conversation with patients, most shared decision-making and used a predominantly supportive communication style. In contrast, physicians who led conversations offered one or few choices to patients, rather than shared decision-making, and saw themselves as taking charge of treatment.

PCP Comments

"Usually my decision is based on both the patient and mine as far as preference. It's not really truly my choice …it depends on their medical coverage. Sometimes the preferred choice is not the best choice because it's the most expensive choice, so it depends on both of our decisions. It's a team effort."

Practices to Check Patient Understanding of and Satisfaction With Care

Physician assessment of patient understanding of clinical situations is rare.[11] Few physicians in this study explicitly checked whether a) their patients fully understand the reasons for and implications of treatment, or b) they are satisfied with therapeutic recommendations and explanations. Others merely assumed these, although nearly half acknowledged that patients did not clearly communicate their level of satisfaction. WC1 content encouraged explicit patient-communication strategies about treatment expectations,2 and some interviewed PCPs were using a demonstration kit, asking direct questions, and requesting patient feedback. Most, however, were using implicit strategies for checking patient understanding of, and satisfaction with, TD care: adherence to refills, appointments, and monitoring schedules; and patient nonverbal communication and perceived patient "excitement" or "enthusiasm" about treatment.

PCP Comments

Q: *Can you describe how or whether these interviews themselves—not the Webcast or its resource materials—have actually changed your care practices for men with TD since Summer 2013?*

A: *"Oh, definitely …, reflecting on what I have been doing and if I should do differently or not. It's a learning experience for me also … the thought process and some plan … that I'm not necessarily doing."*

A: *"When you asked me a question, it reminds me what we need to do. It gives me a reinforcement, like 'this is nothing simple, you've got to monitor it and you've got to keep a close eye on it.' Definitely it helps me out to bring up my idea to somebody."*

Findings suggest attitudinal and clinical competence gaps in "counseling." Interviewees' tendency to talk about ***what they tell patients*** suggests that physicians view "counseling" in practice as a one-way provision of information that physicians assume patients (should) receive and act on. TD counseling may also not be a priority for some PCPs.

Interviews as Interventions

Post-activity interviews (see Figure 1) stimulated PCP reflection to support quality improvement[12,13] about TD treatment goals, options, realistic expectations,[7] monitoring plans, and pros/cons of various TRT formulations to suit individual needs. Answering interview questions required PCPs to formulate their counseling ideas into spoken language, which would improve readiness for a patient conversation. Interviewed PCPs told us how interviews reinforced CME content and stimulated reflection on TD practices.

The mixed data suggest performance differences created by interviewing as an educational intervention, if not accounted for by existing subgroup differences. Findings showed a lack of WC1 participants' quantitative performance change in counseling on TRT options. Qualitative data contradict these findings, showing interviewees' increased treatment confidence, particularly in advising on TRT options. One explanation could be that the participant subgroup we interviewed may have been more self-critical of performance than other participants and comparison PCPs because interviews showed that we were truly interested in their practices, countering widespread evidence of clinicians' survey fatigue. In contrast, comparison-group PCPs may have lacked knowledge of available therapeutic options, causing them to overestimate their rates of thorough counseling. They may have also lacked sufficient attitudinal investment in accurate self-reporting because they did not interview.

RESULTS & DISCUSSION, cont'd

Using Mixed Methods for Research Into Counseling

Pearl from the literature: "Patients seek relationships in which they experience trust, the right amount of autonomy, caring, and expertise."[14]

Several findings from mixed-methods research into primary care practices for managing testosterone deficiency can be viewed alongside recommendations and lessons for educational research practice (see Table 4).

Table 4. Conducting CME/CE mixed-methods research on testosterone deficiency (TD) offers continuing professional development opportunities and practice pearls for health care educators.

TD CME/CE Outcomes Finding	Educational or Clinical Best Practice	Practical Tactics for Educational Research
Patient Communication Strategies		
Most interviewees shared TD and TRT decision-making with patients; others led patients to treatment and preferred formulations. PCPs in our study used various, but usually implicit, strategies to assess patient understanding and satisfaction with care. To tailor decision-making approaches to individual patients as per the Institute of Medicine,[7] clinicians providing pre-treatment TD counseling must be able to understand the experience of patients who are considering TRT.	Interpersonal and communication skills are critical components of TD treatment and compose one of six core competencies for desirable physician attributes, per ACGME.[15] Effective patient-communication skills can improve outcomes for patients and PCPs, and the art of communication can be developed throughout the clinical career.[17]	When asking clinicians to describe the patient experience with a condition, phrase your question around "practice patterns" that the clinician uses to determine the patient's experience or response to care When studying treatment-selection patterns, gather evidence of supportive or sharing—versus clinician-led—practices. When studying patient counseling, gather data on clinicians' explicit versus implicit strategies to assessing patients' understanding.
Reflection/Self-Assessment, and Interviews as Interventions		
Interviewed PCPs appreciated opportunities to reflect on the patient's experience with TD and TRT, as well as the application of this information toward improving patient-centered care for TD.	Interviews with practicing clinicians to investigate practice patterns and educational outcomes also reinforce key educational messages, and thereby influence sustained practice improvement Reflection is a complex activity that "draws upon both external and internal data, standards, and resources to inform and make decisions about one's performance."[12]	Use qualitative analysis to study whether interviews with clinicians changed clinical competence, changed attitude, or promoted reflection on patient experiences and empowerment in decision-making.
Insights From Qualitative and Mixed-Methods Research		
Layered explanations exist for variables that influence pre-treatment counseling for TD. Clinicians participating in-depth interviews should not be included in groups that complete later quantitative outcomes instruments. Qualitative analysis revealed PCP preferences for TRT formulation, the "team effort" in which many PCPs engage with patients, and interviewed physicians' improved confidence that encouraged us to consider group-level differences behind quantitative data.	Mixed-methods research improves researchers' understanding of and insights into clinicians' decision-making, communication skills, attitudes, and other competencies that underlie quantitative survey practice data. Consider using mixed methods if your study investigates clinical tasks requiring counseling skills but quantitative tools are not optimal for detecting the expected outcomes of the educational experience.	Multiple interviews with the same clinicians should not repeat past questions but rather take the opportunity to explore quantitative patterns or expand into previously unexplored aspects of clinician practices or decision-making. Investigate patterns and seek clinically relevant explanations for contradicting findings seen in mixed methods.

Limitations of Study

Quantitative study limitations existed. Pre-survey space prevented asking all 4 performance questions in both activities. Subgroup analysis showed that WC2 pre-survey "messages" results could not be used as proxy pre-survey for WC1. Sample sizes were small in follow-up surveys, although significant changes and differences were seen across groups. Some surveyed PCPs were also interviewed, receiving content reinforcement. Performance data were self-report.

CONCLUSIONS

Outcomes Data on Testosterone Deficiency CME/CE

- CME/CE was effective in improving practice. Before CME/CE, participants had significantly lower rates in performing 4 counseling measures than non-participant comparison PCPs had. By follow-up, participants improved performance to nearly match or exceed performance rates of comparison PCPs. Participants appeared to identify and address needs through CME/CE.
- Webcast 1 qualitative and quantitative analyses showed competence and implementation of performance measures into routine practice in all areas, with descriptions of how change was implemented; Webcast 2 showed significant change through quantitative analyses.
- Core counseling messages and therapeutic options offered to men with TD were consistent with the content of the educational activities.
- Data on ongoing gaps and barriers to performance suggest that a greater perception of continuing educational need plus greater treatment confidence may reduce self-reported performance in counseling on treatment options.
- Participants more often cite educational needs or lack of confidence as a challenge to implementing performance change, whereas PCPs who did not participate in the initiative claimed barriers and disagreement.
- Competence findings indicate that PCPs continue to need education on TRT formulations, counseling methods, and managing barriers. PCPs who have not participated would benefit from education on patient-centered care and pre-treatment counseling regarding TD treatment.

Future Directions

Future research should a) investigate patient-reported outcomes and juxtapose patient data with PCP self-assessments; b) study outcomes of CME on sharing decision-making and strategies for effective counseling; and c) compare patient feedback about care with outcomes data on PCPs' strategies for checking patient understanding and satisfaction with care. Researchers are encouraged to investigate whether follow-up interviews in their initiatives show evidence of interviews reinforcing CME/CE content.

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