

Scientific Abstract

The Prevalence of Conflicts of Interest among Guideline Panel Members Jennifer Neuman¹; Deborah Korenstein¹; Joseph S Ross²; Salomeh Keyhani¹. ¹Mount Sinai School of Medicine, New York, New York ; ²Yale University School of Medicine, New Haven, Connecticut . (Proposal ID # 10767)

BACKGROUND: Conflict of interest (COI) among authors of clinical practice guidelines may adversely impact the objectivity of the recommendations issued. Over the past decade, scant research has examined this topic in the field of Internal Medicine. We sought to determine the frequency of COI among authors of clinical practice guidelines between the years 2000-2010.

METHODS: We conducted a retrospective study of authors of hyperlipidemia and diabetes guidelines, published between the years 2000 and 2010 in the U.S. and Canada. We chose hyperlipidemia and diabetes as representative disease categories because of the high prevalence of both diseases in the population. Guidelines were identified through The National Guideline Clearinghouse, MDConsult, UpToDate, and the websites of organizations with a potential interest in these diseases. COI were defined in two ways: 1) as the direct compensation of a guideline author by a pharmaceutical company in the form of grants (including research), speakers fees, honoraria, etc., or 2) primary authorship (1st author) of a clinical trial funded by the manufacturer of a drug used to treat the disease of interest in the guideline, in the two years prior to and the year of guideline publication. Direct compensation was determined by examining declarations of COI that were published within the guideline. Authors that declared no COI were further investigated through examination of publications via MEDLINE and through an internet search. Guidelines were categorized as government-sponsored versus other, year developed (before and after 2007), disease (hyperlipidemia versus diabetes) and country of origin (U.S. and Canada). We used descriptive statistics to characterize the prevalence of COI among authors and panel Chairs and used two-sampled tests of proportion to examine differences by guideline characteristics.

RESULTS: We identified 14 guidelines meeting our search criteria. These guidelines included 288 authors, representing 246 separate individuals. All guideline panels had at least one author with a COI. Overall, 55% (158/288) of authors were found to have COI. Among authors not reporting COI, 13% (20/150) had undeclared COI. Among Chaired guidelines, 60% (6/10) of Chairs had COI. Government-sponsored guideline panels had significantly fewer authors with COI than non-government-sponsored panels (71% vs. 20% P less than 0.001), and COI was more prevalent among Canadian specialty organizations than U.S. specialty organizations (84% vs. 62%, p less than 0.01). We found an increased presence of COI in guidelines published after 2007 compared to those published prior (66% vs. 28%, p less than 0.001).

CONCLUSION: We found a high prevalence of COI, under-reporting of COI by guideline authors, and significant differences in the prevalence of COI between government and non-government-sponsored guidelines. Our finding that the majority of guideline authors and Chairs have COI, and that one out of eight authors did not report their COI raises concerns about the objectivity of these guidelines and the effectiveness of current disclosure practices. The guideline development process must be reformed to minimize conflicts of interest among authors to ensure the credibility and evidence-based nature of the clinical practice guidelines issued in the U.S. and Canada.

Scientific Abstract

Randomized Controlled Trial of Medical Home Features to Reduce Cardiovascular Risk Barbara J Turner¹; Christopher Hollenbeak²; Pandit Kavita³; Shelly Joseph³; Mark Weiner⁴. ¹University of Texas Health Science Center San Antonio, San Antonio, Texas; ²Penn State College of Medicine, Hershey, Pennsylvania; ³University of Pennsylvania, Philadelphia, Pennsylvania; ⁴University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania. (Proposal ID # 10673)

BACKGROUND: The patient-centered medical home offers services and tools that may reduce coronary heart disease (CHD) risk and blood pressure in vulnerable populations. We conducted a randomized, controlled trial in African-American primary care patients with uncontrolled hypertension to evaluate the impact of an intervention using practice-based registry, staff support and community-based peer coaches on predicted CHD risk and systolic blood pressure after 6 months.

METHODS: A single-blind, randomized, controlled trial of behavioral support to reduce CHD risk was conducted in two level 3 NCQA certified, academic general medicine practices in the University of Pennsylvania Health System. A practice-based electronic medical record (EMR) registry was used to identify African-American patients aged 40-75 with uncontrolled hypertension, defined as a mean blood pressure above goal over a two-year period with at least one reading >10 mmHg above goal. Peer coaches were recruited and trained from among African-American patients with well controlled hypertension according to the same practices' EMR registry or from local community volunteers. Eligible subjects were recruited from July 2007 to November 2009. The intervention group received telephone-based lifestyle counseling by peer coaches to reduce CHD risk every other month for six months and educational visits to primary care staff on alternate months (two visits). All subjects received brochures about healthy foods and lifestyle. The primary outcome was 6 month change in predicted 4-year risk of a CHD event, based on a model developed by D'Agostino, for intervention versus control groups, and the secondary outcome was change in systolic blood pressure. Multiple imputation was used to estimate missing values for intent-to-treat analysis. Sensitivity analyses were conducted to evaluate comparability of completers versus non-completers.

RESULTS: Of 566 eligible patients, the 280 (49%) randomized subjects were characterized by: mean age 62 (SD 8.8); 65% women, 53% diabetes mellitus, and 18% had prior CHD or equivalent. Baseline 4-yr CHD risk did not differ significantly for the 136 intervention and 144 control subjects (5.8% and 6.4%, respectively). In both groups, mean baseline systolic blood pressure was 140.5 mmHg. Follow-up for 4-year CHD risk was completed in 76% of subjects and for systolic blood pressure in 88% of subjects. In an intent-to-treat analyses, the intervention group had greater reductions in both CHD risk (difference 0.8%, $P=0.023$) and systolic blood pressure (difference 7.1 mmHg, $P=0.001$). After adjustment, these significant differences persisted as well as for a reduction in diastolic blood pressure ($P=0.023$). Reduction in systolic blood pressure was similar for completers versus non-completers for the CHD risk analysis. One patient died in each study arm.

CONCLUSION: In this randomized, controlled trial, components of the medical home that included using a registry to identify at-risk hypertensive African-American patients and an intervention combining community- and office-based behavioral support produced clinically significant reductions in predicted 4-yr CHD risk and blood pressure. This trial supports the potential for the medical home to produce improved clinical outcomes in vulnerable populations.

Innovations in Practice Management

The JC-ICU: Close Follow up for Ambulatory Patients Rose Kakoza¹; Joy Lewis²; Andrew Ellner²; Lori Wiviott Tishler². ¹Brigham and Women's Hospital, Roxbury Crossing, Massachusetts ; ²Brigham and Women's Hospital, Boston, Massachusetts . (Proposal ID # 7272)

STATEMENT OF PROBLEM OR QUESTION: Resident clinics create a challenging practice environment that can result in fragmented patient care and leave residents with a discouraging impression of primary care.

DESCRIPTION OF PROGRAM/INTERVENTION: The Phyllis Jen Center for Primary care is a faculty/resident clinic at the Brigham & Women's Hospital that serves 40,000 patients/year and provides 800 urgent care visits/month. Urgent care doctors include residents and faculty. Many patients seen in the Jen Center are medically and psychosocially complex, often from disadvantaged communities. The JC-ICU is a virtual ICU into which residents and faculty refer patients at risk for hospitalization, inappropriate ED use or exacerbation of an acute or chronic condition. The JC-ICU team includes 3 nurses, the referring physician and the primary care physician. After referral, a care plan is determined and graduation criteria defined. The JC-ICU nurse learns about the patient via the medical record and implements the care plan via phone encounters with the patient and emails with the provider. Once the patient achieves the goal, they graduate from the ICU. Patients may re-enroll.

OBJECTIVES OF PROGRAM/INTERVENTION: Using a team-based model, the JC-ICU will: 1. Provide short-term case management for at risk patients 2. Provide continuity and flow of information between patient and provider and 3. Improve the primary care experience of residents

FINDINGS TO DATE: Patient Outcomes: Preliminary data have shown: 1. 90% of patients (90/100) have been able to meet their goal. ED visits have been significantly reduced in key patients with a history of frequent ED visits. 2. Patient Experience: a. Some patients have stated that they appreciate the follow up calls and reminders. b. Patients have formed a relationship with the JC-ICU nurse and feel comfortable reaching out with questions or concerns c. Patients receive a timely report of test results if their referring physician is away from the clinic 3. Team Member Experience: a. Residents and faculty feel comfortable delegating titration of medications within certain parameters to the JC-ICU nurse. b. Residents feel more supported in their delivery of primary care to complex patients c. Nurses feel more engaged with patient care d. Nurses feel they are using more of their skill set than was required of them prior to the start of the program

KEY LESSONS LEARNED: \We have successfully implemented an ambulatory ICU that uses a team-based approach to address the significant issue of fragmented care that often plagues resident clinics.

1. Preliminary data support that the Jen Center ambulatory ICU may significantly improve service utilization, and patient and provider experience
2. This model may also be successful in other residency clinics nationwide
3. In a predominantly revenue neutral way, we can successfully build capacity among existing nursing staff in order to transition to team-based patient care interventions