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Title

Use of evidence-based therapies in a community-based sample of older African-Americans and Latinos with diabetes

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medications. Associations between categorical variables (i.e. race, gender, HIV status) and use of DS or CAM therapies were analyzed using chi-square or Fisher's exact tests and odds ratios (OR) with 95% confidence intervals (CI). Student's

T-test was used to assess differences in means of continuous variables (i.e. age). Multiple logistic regression was used to assess independent correlates of daily DS use.

RESULTS: In November 2004, 123 of 131 (94%) CHAMPS and Ms participants agreed to participate in the CAM substudy. Mean ages were higher for men 55 (+4.5) than women 45 (+5.1) ($p < .01$) due to study design. Substudy participants were 63% male, 53% HIV infected, 57% black, 26% Hispanic and 17% white, 18% were homosexual and 53% reported illicit drug use in the last 5 years. HIV infected individuals were similar to HIV uninfected individuals in age, educational attainment, and illicit drug use but were more likely to be Black (OR=2.9, 95% CI 1.4, 6.2). CAM use in the last 6 months was common, 82% reported use of a CAM therapy, 68% reported using some DS and 50% reported daily DS use. In bivariate analyses daily DS use was associated with being HIV infected ($p=0.03$) and not associated with illicit drug use or adherence to antiretroviral medications. In multivariate analysis, controlling for gender and race, HIV infected individuals were almost 3 times more likely to report daily DS use (OR 2.9; 95% CI 1.4, 6.4). 95% of HIV infected participants reported use of both DS and other prescription medications. The most common reasons given for DS use were to prevent illness or boost immunity (26%), increase energy (22%) and to cleanse/treat toxic effects of medications (7%).

CONCLUSIONS: CAM use among inner city residents with or at risk for HIV is highly prevalent, but is used almost exclusively as an adjunct to and not an alternative to conventional healthcare. Daily use of dietary supplements is especially prevalent among those with HIV infection but not associated with worse antiretroviral adherence. More research is needed to determine how health care providers can best advise patients to integrate dietary supplements and other CAM therapies safely into their health care activities.

USE OF A MODIFIED INFORMED CONSENT PROCESS AMONG VULNERABLE PATIENTS: A DESCRIPTIVE STUDY. R. Sudore¹, C.S. Landefeld¹, B. Williams¹, D. Barnes¹, K. Lindquist¹, D. Schillinger¹. ¹University of California, San Francisco, San Francisco, CA. (Tracking ID # 152044)

BACKGROUND: Many research participants do not understand consent information. However, little is known about patient characteristics associated with poor understanding of consent information or whether modifications to the consent process can promote participant understanding. Therefore, our objective was to describe a modified research consent process, and explore whether literacy and demographic characteristics were associated with understanding consent information.

METHODS: This descriptive study included 204 ethnically diverse patients from an inner city public hospital in San Francisco, aged 50 or older, who were consenting for a randomized trial of advance directives. Participants had to self-report fluency in English or Spanish. We employed a modified, interactive consent process for the trial which included a simplified consent form (written at the 6th grade level) that was read to and discussed with participants. This was then combined with 7 comprehension questions followed by targeted education. Questions and targeted education were repeated until complete comprehension was achieved. Measures included the number of passes through the consent process required to answer all consent comprehension questions correctly. Literacy was assessed in English and Spanish with the short form Test of Functional Health Literacy in Adults (s-TOFHLA, scores 0-36).

RESULTS: Participants had a mean age of 61 years; 53% were female; 26% were White/non-Hispanic, 31% White/Hispanic, 24% Black, 9% Asian-Pacific Islander, and 10% were Multi-ethnic/Other. Forty percent had limited literacy (s-TOFHLA <23). Only 28% of participants answered all comprehension questions correctly on the first pass. After adjusting for age, race/ethnicity, education, gender, primary language, and s-TOFHLA score, only lower literacy and minority status were significantly associated with requiring more passes through the consent process. For example, participants' odds of requiring more passes through the consent process increased with each one-point decrease in s-TOFHLA score (Odds Ratio (OR), 1.04; 95% CI, 1.00 to 1.07) with ORs ranging from 1.00 for those with s-TOFHLA scores of 36 (a perfect score), to 3.76 for those who scored 0 out of 36 (illiterate). After adjustment, being Black was also associated with requiring more passes (OR 2.45; 95% CI 1.08 to 5.56). After the second pass through the consent process, most participants (80%) were able to answer all comprehension questions correctly.

CONCLUSIONS: Despite employing a number of consent modifications, most participants had poor comprehension on the first pass through the consent process. Lower literacy and minority status were important determinants of poor understanding. However, by using an interactive, educational consent method, only modest efforts were required to improve comprehension and obtain informed consent in this diverse, vulnerable population. Employing modifications to the consent process may improve the quality of informed consent for diverse populations and, if confirmed in other settings, should be considered as a standard means to elicit informed consent for research.

USE OF A SCREENING TOOL BY MEDICAL RESIDENTS TO RECOGNIZE AND TREAT MAJOR DEPRESSION IN HOSPITALIZED PATIENTS: A CONTROLLED TRIAL. C.A. Smith¹, E. Chinga-Alayo¹, S. Fung¹, A.T. Evans¹, B.M. Reilly¹, S. Mandelbaum¹. ¹Cook County (Stroger) Hospital/Rush Medical College, Chicago, IL. (Tracking ID # 151647)

BACKGROUND: Major depression in hospitalized patients is common, but often goes unrecognized and thus untreated. We hypothesized that use of a simple

screening tool by medical residents would increase the diagnosis and treatment of depression in medical inpatients.

METHODS: The study was conducted on the medical service at a university-affiliated public teaching hospital. The design was a single-blinded firm-based controlled trial. One firm served as the intervention group (n=16 residents) and were taught to use a simple screening tool (based on DSM-IV criteria). The tool required that two questions be asked initially. If either question was positive then the residents asked seven more (yes/no) questions. The intervention residents received a 1-hour lecture on the diagnosis and treatment of depression. Residents from the two control firms (n=32 residents) received their usual clinical teaching. Eligible patients were consecutive admissions to the medical service, Sunday through Thursday during a 4-week period, and had to be admitted and discharged from the same study group of residents (intervention or control). The primary outcome measure of major depression required a diagnosis of depression in the discharge summary or patient chart and a discharge medication appropriate for treating major depression. We also surveyed residents in both groups at the end of the 4-week study period.

RESULTS: A total of 651 patients were eligible for analysis after 4 weeks (220 intervention, 431 control). Residents in the intervention group screened 202 (92%) of the 220 patients and diagnosed and treated major depression in 23 (10.5%). The control group diagnosed and treated 15 (3.5%) of 431 patients ($P=0.001$). The absolute benefit increase of 7% (95% CI 3%-12%) is equivalent to a number needed to screen of 14 (95% CI 8-33). In the survey at the end of the trial both groups of residents overestimated the prevalence of major depression in their inpatients at 21%. There was no difference between groups in their confidence in diagnosing or treating depression. Intervention residents reported an average time of one minute to ask the screening questions.

CONCLUSIONS: A brief educational intervention and adoption of a rapid simple screening tool for depression produced a clinically important improvement: For every 14 admissions to the medical service 1 extra patient was diagnosed and treated for major depression.

USE OF BETA-BLOCKERS IN COCAINE TOXICITY: IS IT SAFE? P.B. Dattilo¹, K. Fearon¹, D. Sohal¹, C. Nordin¹. ¹Albert Einstein College of Medicine & Jacobi Medical Center, Bronx, NY. (Tracking ID # 154713)

BACKGROUND: Studies done in the mid-late 1980s and early 1990s suggest that beta blockers induce hypertension and coronary artery spasm when given to active cocaine users. This ultimately led to the current practice of avoiding beta blockers in the setting of cocaine use. However, no human studies have demonstrated an increased incidence of myocardial infarction (MI) or mortality in patients who are exposed to both beta blockers and cocaine. Furthermore, studies clearly show that beta blockers decrease mortality in patients with MI or systolic dysfunction heart failure. We hypothesized that beta-blockers do not increase the incidence of MI or mortality in patients admitted to an acute care inpatient setting who have recently used cocaine.

METHODS: We conducted a retrospective study analyzing beta blocker use in 365 consecutive patients over a 5 year period at an urban municipal hospital. Inclusion criteria were 1) documentation of cocaine use by urine toxicology and 2) admission to a high acuity bed (telemetry, intensive care and coronary care units). Hospital records were analyzed for documented beta-blocker administration. Fifteen patients were excluded from the analysis because they had been prescribed beta-blockers as outpatients but had no documented beta-blocker use in-house. One additional patient was excluded from the MI outcome analysis because the temporal relationship of beta-blocker administration to elevated troponin was ambiguous. MI was defined by elevated troponin levels (3 sets taken approximately 6 hours apart with a minimum single value of 0.10) and/or significant ST elevations in 2 contiguous leads by EKG. We secondarily analyzed reasons for use of beta blockers, as well as the temporal relationships between beta blocker administration, toxicologic confirmation of cocaine use and troponin elevation.

RESULTS: Sixty one patients (17%) were prescribed beta blockers during hospitalization. In the analysis of 350 patients, there were 17 deaths, only 1 of which occurred in a patient who had received beta-blockade (RR for death with beta blockade=0.30, CI 0.04-2.19; $p=0.33$). 57 patients had MIs (48 NSTEMI & 9 STEMI). Only one patient was given beta blockade prior to having an MI. Relative risk of MI following administration of beta blocker vs. MI without prior beta blocker was 0.13 (CI 0.02-0.91; $p=0.007$). Reasons for giving beta blockers included rule out MI (n=56), on beta blocker at home (n=21), cirrhosis/variceal prophylaxis with propranolol (n=5), and arrhythmia (n=3). Nine patients were started on beta blockers after positive urine toxicology, all for documented MI: one patient from this group died secondary to pericardial tamponade following thrombolysis given for a STEMI.

CONCLUSIONS: We found no evidence that giving beta blockers to patients with confirmed cocaine ingestion increased the risk of death, but rather a non-significant trend towards benefit. Further, this analysis showed a significantly lower risk of myocardial infarctions in patients receiving beta blockade prior to detection of MI.

USE OF EVIDENCE-BASED THERAPIES IN A COMMUNITY-BASED SAMPLE OF OLDER AFRICAN-AMERICANS AND LATINOS WITH DIABETES. A.F. Brown¹, E. Goodman², W.N. Steers¹, R. Brusuelas-James¹, C. Sarkisian¹, K.C. Norris³, M.B. Davidson³, R.M. Anderson⁴, C.M. Mangione¹. ¹University of California, Los Angeles, Los Angeles, CA; ²Washington University in St. Louis, St. Louis, MO; ³Charles Drew School of Medicine, Los Angeles, CA; ⁴University of Michigan, Ann Arbor, MI. (Tracking ID # 154180)

BACKGROUND: Although older African Americans and Latinos with diabetes have higher mortality and rates of diabetes complications than whites, they are

less likely to use evidence-based therapies. We compared use of evidence-based medications among older African Americans and Spanish-speaking Latinos from community settings. We hypothesized that having insurance would be associated with higher rates of use of evidence-based therapies.

METHODS: We analyzed baseline data from a randomized intervention to enhance diabetes self-management among older African Americans and Latinos recruited from senior centers, churches, and community clinics in Los Angeles County between February 2004 and September 2005. Eligible participants had to be English- or Spanish-speaking, ≥ 55 years, and have HbA1c $\geq 8\%$ on our laboratory examination. Through interviews, medication review, and physical examinations, we assessed: 1) use of insulin or ≥ 2 oral antidiabetic agents among all participants; 2) aspirin use among participants not on anticoagulants or antiplatelet therapy; 3) use of lipid lowering agents among participants with hyperlipidemia; 4) beta-blockers after myocardial infarction (MI); and 5) ACE inhibitor or ARB use among participants with albuminuria. We categorized insurance status as uninsured (reference group), insured without Medicaid, or Medicaid insured. To evaluate the effect of insurance coverage on use of evidence-based therapies, we constructed multivariate models for each therapy that included insurance type, age, sex, ethnicity, income, education, smoking, and medical comorbidities.

RESULTS: We enrolled 312 Latinos and 195 African Americans, 71% female. Mean age was 63.3 years (SD=6.2), 70% had annual household income $< \$15,000$, 54% had less than a high school education, and mean HbA1c was 9.7% (SD=1.7). Uninsured persons were younger, more likely to be Latino, less educated, poorer, and had fewer comorbidities. In adjusted (see table) and unadjusted analyses, uninsured participants had comparable or higher rates of use of evidence based therapies, though no differences were statistically significant.

CONCLUSIONS: In this community-based sample of low-income older African Americans and Latinos with diabetes, we found that regardless of insurance status, there was extremely low use of evidence-based medications known to benefit persons with diabetes. Our findings may be explained by the receipt of free or low-cost medications through community clinics and other safety net institutions by persons without insurance or inadequate coverage for medications among insured low-income adults. We need a better understand of the complex factors driving these low rates, even among those with insurance coverage, so that we can improve care for all older adults.

Adjusted Differences in Use of Evidence Based Therapies Among Older Adults with Diabetes and HbA1c $> 8\%$

	Uninsured (Reference)	Insured (no Medicaid)	Medicaid
N	223	161	115
Insulin or ≥ 2 oral antidiabetic agents (N=499)	66%	68% (P=0.76)	65% (P=0.97)
Aspirin use (N=457)	48%	41% (P=0.30)	47% (P=0.94)
Lipid-lowering agents if hyperlipidemia (N=443)	55%	49% (P=0.37)	63% (P=0.35)
Beta-blockers after MI (N=44)	78%	50% (P=0.24)	41% (P=0.17)
ACE inhibitor or ARB use if albuminuria (N=167)	60%	48% (P=0.24)	62% (P=0.86)

USE OF HOMEOPATHIC REMEDIES FOR PAIN: A SYSTEMATIC REVIEW. S.M. McDonald¹; M.J. Bair²; K. Kroenke³. ¹Indiana University School of Medicine, Indianapolis, IN; ²Richard L. Roudebush VA Medical Center, Indianapolis, IN; ³Regenstrief Institute, Indianapolis, IN. (Tracking ID # 154295)

BACKGROUND: Although a variety of homeopathic remedies have been used by patients and practitioners to treat pain, questions about their efficacy remain. We performed a systematic review of randomized controlled trials evaluating different homeopathic remedies for pain.

METHODS: We searched MEDLINE database from 1966 to October, 2005 using the following search terms: pain, analgesics, analgesia, and homeopathy. Studies were included if they were systematic reviews or randomized controlled trials of homeopathic remedies and measured pain severity as a key outcome. For pragmatic reasons, non-English studies or those involving non-human subjects were excluded. All potentially pertinent studies were reviewed by 2 independent investigators. Data related to target pain condition, homeopathic remedy, comparison group, study length, primary outcomes, co-intervention, blinding, and results was collected. Because of missing variance data in several studies, diverse clinical contexts and varied remedies investigated, meta-analytic techniques were precluded. Instead, mean differences in visual analog scale (0 to 100) pain scores between homeopathic remedy and control groups were calculated for each study. Study quality was assessed by checklist, using methods developed and validated by Jadad.

RESULTS: We retrieved 12 studies meeting our initial search criteria. One study was subsequently excluded because its primary outcome was "immunomodulatory activity," not pain specifically. Of the 11 studies included, 5 investigated chronic pain conditions (headaches, arthritis, and back pain), 4 involved post-operative pain control, and 2 studied muscle soreness after exercise. The homeopathic remedy tested also varied across studies: arnica (n=4 studies), spiroflor or homeopathic gel (n=2), rheus-tox (n=2), and an individualized menu of homeopathic medicines (n=3). Nine studies compared a homeopathic remedy to placebo and 2 compared homeopathy to active treatments (e.g., anti-

inflammatory medication or pain-relieving gel). A total of 1351 patients were evaluated (n=24 to 184). Studies ranged in length from 1 week to 6 months and all included pain severity as an outcome. While 6 studies demonstrated greater mean pain reduction in the homeopathic remedy vs. comparison group, only 2 were statistically significant (p=0.001 and p<0.03) differences. One of the positive studies tested a combination of homeopathic remedy and an unspecified traditional anti-inflammatory treatment. The mean Jadad quality score for the 11 studies was 6.2, and 3 of the 11 studies received the maximum score of 8. **CONCLUSIONS:** There are relatively few randomized controlled trials investigating homeopathic remedies for pain management. Of the existing studies, there is considerable variation in remedies tested, pain conditions, clinical context, and comparison groups. Furthermore these studies are relatively small (i.e. underpowered to show effect), of short duration, and have methodological shortcomings. Most studies found no significant improvement in pain. Thus, evidence for homeopathic remedies in pain conditions is lacking. Future efforts should focus on conducting larger studies of standardized treatments with more rigorous methodology.

USE OF MASSAGE THERAPY IN LOW BACK PAIN IN AN URBAN COMMUNITY HEALTH CARE CENTER. S.L. Schlair¹; C.A. Levine¹. ¹Albert Einstein College of Medicine, Bronx, NY. (Tracking ID # 151944)

BACKGROUND: The high prevalence, public health impact and health care expenditures of chronic low back pain are well known. Massage has been found to be a popular, effective and safe treatment modality for low back pain. Little is known about its use and barriers to its use in inner-city populations. Our goal was to explore the use of, interest in, and potential barriers to the use of massage therapy in our patients with low back pain.

METHODS: We assessed a convenience sample of 240 patients at a South Bronx community health care center via a standardized questionnaire interview administered verbally in English. Chi square analysis was performed on the data with the help of SPSS.

RESULTS: Sixty percent of the subjects were women, 40% were Black, 35% were Hispanic and 20% were mixed race. Age ranged from 18-84 years old with an average age of 26 years old. Seventy-three percent of patients were insured by Medicaid and 6% were insured by Medicare. Thirty-seven percent completed high school. Fifty-six percent of interviewees experienced chronic low back pain (LBP) lasting more than two weeks in the preceding year. Morbidity was high, vis-à-vis work or daily activities: Seventy-four percent of the patients reported cutting down on the amount of time, 80% reported accomplishing less, 81% reported having difficulty performing, and 74% reported limiting work or daily activities due to their low back pain. Forty-nine percent reported using massage to treat their LBP. Females had LBP more frequently (p=0.013). Males felt more uncomfortable about receiving massage (p=0.041) and less frequently had money for massage (p=0.038). Hispanics perceived greater efficacy of massage (p=0.012). Other commonly employed treatment modalities for chronic LBP included: Over-the-counter pain medications (86%), prescribed pain medications (58%) and heat (59%). Patients reported receiving massage from family members and friends (94% and 100% respectively) as well as from professional massage therapists (82%). Massage was viewed as at least somewhat effective, with varied perceived efficacy: Twenty-four percent found massage to be quite or extremely helpful, 20% found it to be moderately helpful, and 46% found it to have little to no effect. Barriers to massage that were most frequently cited were lack of knowledge (56%), not knowing how to find a massage therapist (68%), and financial constraints (77%). Ninety-five percent of respondents with chronic LBP reported interest in receiving massage for their LBP if it was offered at our clinic. Eighteen percent would try it regardless of fee, 36% for a small fee (USD \$25), and 41% only if free.

CONCLUSIONS: LBP is a common and significantly disabling problem in our patient population. Massage has been used by many of our patients with LBP with perceived efficacy. The majority of patients with chronic LBP would be interested in utilizing massage therapy if available at our clinic with 54% willing to pay for massage services regardless of the fee or for a small fee. Our results suggest the provision of massage therapy for LBP would be utilized by a significant portion of our patient population with this common medical problem.

USE OF POLYMER-COATED EXTENDED-RELEASE MORPHINE SULFATE IN THE TREATMENT OF CHRONIC, NON-MALIGNANT BACK PAIN. J. Sasaki¹; A. Wei²; E. Ross³; B. Nicholson⁴. ¹Casa Colina Centers for Rehabilitation, Upland, CA; ²Non-Surgical Orthopaedic & Spine Center, Marietta, GA; ³Brigham and Women's Hospital, Chestnut Hill, MA; ⁴Lehigh Valley Hospital & Health Network, Allentown, PA. (Tracking ID # 153967)

BACKGROUND: Ideal treatment of chronic back pain (CBP) is multimodal and multidisciplinary. Use of pharmacologic agents for pain relief may facilitate the effectiveness of interventions such as exercise and rehabilitative therapies.¹ When other medications have failed or are not acceptable due to side effects, the role of opioids in treating appropriate patients with CBP is gaining recognition.^{1,2} When pain is chronic, long-acting formulations are preferred over short-acting forms to provide continuous analgesia.³ The purpose of this analysis is to determine the efficacy and tolerability of polymer-coated extended-release morphine sulfate (P-ERMS), a long-acting morphine formulation,⁴ in patients with CBP.

METHODS: Data on 662 patients reporting back pain as a primary indication for pain medication were identified from a larger 4-week study (N=1428)⁵ of patients who took P-ERMS to treat chronic, moderate to severe, non-malignant pain that was under-treated (pain score 4 on a 0-10 scale). Dosing with P-ERMS was initiated once daily at doses determined by the investigator based on