## **Abstract Session D2: Joint SMDM Session**

Measuring Blood Pressure for Decision Making and Quality Reporting: Where and How Many Measures? Benjamin Powers <sup>1</sup>; Maren Olsen <sup>2</sup>; Valerie Smith <sup>2</sup>; Robert Woolson <sup>2</sup>; Hayden Bosworth <sup>2</sup>; Eugene Oddone<sup>2</sup>. <sup>1</sup>Duke University and Durham VAMC, Durham, North Carolina; <sup>2</sup>Duke University Medical Center and Durham VAMC, Durham, North Carolina. (Proposal ID # 8756)

**BACKGROUND:** There is uncertainty about the optimal setting and number of blood pressure (BP) measurements that should be used for clinical decision making and quality reporting. We sought to compare different strategies using home or clinic BP on the certainty with which patients could be classified as in or out of control.

METHODS: We analyzed 444 veterans with hypertension receiving primary care through the Durham Veterans Affairs Medical Center and enrolled in a telephone self-management trial over 18 months. Blood pressure was measured repeatedly by three methods: standardized research BP measurements at 6 month intervals; clinic BP measurements obtained during outpatient visits; and home BP using a monitor that transmitted values electronically. Separate random effects models were fit to all available SBP measurements during the study period for research, home, and clinic values. The models included an overall mean (i.e., no change in SBP over time), an individual-level random effect which yielded an estimated between-person variance, and a measurement error which yielded an estimated within-individual variance. Assuming a bivariate normal distributions, we calculated the probability that an individual's "true" SBP was out of control according to guideline recommendations (SBP >140 mmHg for clinic or study measurements, SBP >135 for home measurements) given a range of observed mean SBP. We estimated these probabilities separately based on one SBP measurements or the average of 2, 5, or 10 measurements.

**RESULTS:** Patients provided 111,181 SBP measurements (3218 research; 7121 clinic; and 100,842 home) over 18 months. SBP control rates at baseline (mean SBP Short-term variability was large and similar across all three modes of measurement with a mean within-individual coefficient of variation of 10% (range: 1%-24%). No single clinic SBP between 120mmHg and 160mmHg allowed correct classification of a patient as in or out of control with >80% certainty (Figure 1). The impact of within-individual variability could be reduced significantly by averaging multiple measurements, with most benefit accrued at 5-6 measurements (Figure 2).

**CONCLUSION:** Physicians who want to be >80% certain they are correctly classifying patients' blood pressure control should use the average of multiple measurements. Hypertension quality metrics based on a single clinic measurement misclassify a large proportion of patients and could be significantly improved with the incorporation of home blood pressure.

Validation Study of Hemoglobin A1C Threshold for Diagnosing Diabetes: The Association between Hemoglobin A1C Levels and 3-year Incidence of Retinopathy Yusuke Tsugawa <sup>1</sup>; Osamu Takahashi <sup>2</sup>; William Taylor <sup>1</sup>; Tsuguya Fukui <sup>2</sup>; Christina Wee<sup>1</sup>. <sup>1</sup>Beth Israel Deaconess Medical Center, Boston, Massachusetts; <sup>2</sup>St. Luke's International Hospital, Tokyo, N/A. (Proposal ID # 10814)

BACKGROUND: In 2010, the American Diabetes Association for the first time incorporated hemoglobin A1C (Hgb A1C) level of 6.5% as the diagnostic threshold for diabetes. Experts have historically used the outcomes of retinopathy as the benchmark for defining the diagnosis of diabetes. Due to scarce data on the relationship between Hgb A1C and the incidence of retinopathy, the expert panel relied primarily on several cross-sectional studies examining the association between Hgb A1C levels and the prevalence of retinopathy. In addition, these previous studies were methodologically limited by the lack of adjustment for participants who were pharmacologically treated for diabetes, and by residual confounding from other independent risk factors of retinopathy such as hypertension. To test the validity of the current Hgb A1C thresholds for the diagnosis of diabetes, we conducted the largest longitudinal study to date, and examined the association between Hgb A1C levels and 3-year incidence of retinopathy.

**METHODS:** We analyzed data from a cohort of 21,137 unselected Japanese adults aged 21 and older who underwent a preventive health check-up between January 1st and December 31st 2006, and returned for follow-up health check-up 3 years later at a medical center in Tokyo, Japan. Fundoscopic digital photos were systematically taken for both eyes for all participants at these check-ups and evaluated by clinical ophthalmologists. Retinopathy was defined as the presence of hard exudates, soft exudates, or retinal hemorrhages. We excluded those with retinopathy at baseline (n=237), with missing information on baseline Hgb A1C (n=24), baseline fundoscopic exams (n=523), or follow-up fundoscopic data (n=371). We conducted a series of logistic regression models to examine the relationship between baseline Hgb A1C levels and the incidence of retinopathy at 3 years adjusting for baseline demographic factors, those with diabetes receiving treatment, and confounding risk factors for retinopathy.

**RESULTS:** Of the 19,982 participants in our analytic sample, approximately 49% were male. The mean age (SD) was 50.8 (11.5) years old, the mean body-mass index was 22.5 (3.3) kg/m2, the mean Hgb A1C was 5.6 (0.6) %, and the mean fasting blood glucose was 100.3 (14.6) mg/dL; 4.5% had diabetes at baseline using Hgb A1C threshold of 6.5%. At 3 years, the cumulative incidence of retinopathy was 0.86% (172/19,982). Compared to those with a Hgb A1C level of 5.0-5.4 % (the reference category), adults with Hgb A1C of 6.5-6.9% were associated with a significantly higher risk of developing retinopathy [odds ratio (OR): 3.83, 95% confidence interval (CI): 1.88-7.81, p < 0.001] (see Table). This risk remained statistically different after the adjustment for blood pressure, hypertension treatment, low-density lipoprotein, high-density lipoprotein, and diabetes treatment [OR: 2.19, 95% CI: 1.03-4.66, p=0.041]. Those with Hgb A1C between 5.5 and 6.4% did not exhibit higher risk of retinopathy relative to the reference group.

**CONCLUSION:** Our results support current American Diabetes Association guidelines recommending using Hgb A1Clevel of 6.5% or higher as the threshold for the diagnosis of diabetes.

Medicare Post-Hospitalization Skilled Nursing Benefit in the Last Six Months of Life Katherine N Aragon <sup>1</sup>; Kenneth Covinsky <sup>1</sup>; Yinghui Miao <sup>1</sup>; W John Boscardin <sup>1</sup>; Alexander Smith <sup>1</sup>. <sup>1</sup>University of California San Francisco, San Francisco, California . (Proposal ID # 11101)

**BACKGROUND:** Older adults often transition to skilled nursing facilities (SNFs) following acute hospitalization in the last months of life under the Medicare SNF benefit. However, current Medicare policy prohibits concomitant payment for both SNF and Hospice services. We sought to examine patterns of SNF use following hospitalization in the last 6 months of life.

**METHODS:** We used the Health and Retirement Study (HRS), a nationally represented study of older adults, linked to Medicare claims data. From Medicare claims, we determined the number of individuals age 65+ who used the SNF benefit in the last 6 months of life following hospitalization, and their admitting diagnosis to SNF. Using linked data from the HRS, we examined demographic, social, and clinical correlates of SNF use.

**RESULTS:** Our sample included 4,516 patients who died between 1994 and 2006 (mean age 83 [sd 8], 54% female, 87% white). Age-adjusted use of the SNF benefit in the last 6 months of life increased from 17% in 1994 to 36% in 2006. The most common admitting diagnoses were heart failure (9%), hip fracture (6%), and rehabilitation (5%). Use of the SNF benefit was greater among patients who were: older (>85 36%, <85 26%), poorer (lowest quartile of net worth 34%, highest quartile 28%), and did not have cancer (no cancer 32%, cancer 26%) (all p<.001). These differences persisted after adjustment for age, sex, race/ethnicity, marital status, educational attainment, region, chronic conditions, and year of death. After using the SNF benefit 18% of patients enrolled in hospice and 27% died in a hospital. Among patients who died in 2006, 14% used the post-hospitalization SNF benefit 2 or more times in the last 6 months of life.

**CONCLUSION:** Over one-third of older adults now receive care in a SNF at the end of life under the Medicare SNF benefit. Many older adults shuffle between the hospital and SNF at the end of life. Although Medicare policy prohibits payment for hospice when patients are using the SNF benefit, many patients use the benefit near the end of life, suggesting a need to incorporate palliative services into the Medicare SNF benefit.

Estimating the Health Effects of Different Delays in Achieving Systolic Blood Pressure Control in Adults with Diabetes Neda Laiteerapong 1; Priya M. John 1; David O. Meltzer 1; Elbert S. Huang 1. University of Chicago, Chicago, Illinois . (Proposal ID # 11348)

**BACKGROUND:** In major clinical trials, blood pressure control that lowers systolic blood pressure (SBP) from 155 to 145 mmHg has been shown to decrease complication rates which improves quality of life in adults with type 2 diabetes. However, in real world clinical practice, patients with elevated blood pressure levels may routinely experience prolonged delays in achieving optimal blood pressure control due to a combination of patient and physician factors (clinical inertia). While delays in achieving control are commonplace, the health effects associated with different delays are not well known. We used decision analytic modeling to estimate the effects on health outcomes of different delays in achieving SBP control.

**METHODS:** We used the diabetes complication model from the United Kingdom Prospective Diabetes Study, which is a Monte Carlo simulation model that is framed by simultaneous progression through diabetes complications (heart disease, myocardial infarction, heart failure, stroke, amputation, renal failure, and blindness) and mortality. We studied adults aged 50 to 59 years old with new onset Type 2 Diabetes. To estimate the health effects of delays in achieving SBP control, we compared hypothetical populations who experience initial suboptimal SBP (150 mmHg) for different durations of delay (from 1 to 45 years after diagnosis) followed by optimal SBP, to a baseline population who has a lifetime of optimal SBP (130 mmHg). We present rates of non-fatal complications and the decrease in life expectancy and quality of life as a result of delays in SBP control for different durations.

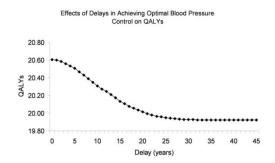
**RESULTS:** Compared to a lifetime of optimal SBP, we found that increasing delays in achieving optimal SBP led to an increased risk of complications, decreased life expectancy, and decreased QALY. Notably, a 5-year delay results in a lifetime 1% relative risk increase of any diabetes-related complication, a 27-day decrease in life expectancy, and a 37-day decrease in quality of life.

Table 1:

with suboptimal		Relative risk increase of any lifetime non-fatal complication	Decrease in life expectancy (days)	Decrease in quality of life (quality- adjusted days)
0	5046	1.000	0	0
1	5056	1.002	0.3	2.2
5	5110	1.013	26.8	37.1
10	5214	1.033	85.7	109.5
20	5487	1.087	170.0	216.2
45	5653	1.120	195.5	249.8

Health effects of delays in achieving optimal SBP control.

Delays ranging between 5 and 20 years had the steepest decline in quality of life. (Figure 1. below)



**CONCLUSION:** Notable clinical effects begin to appear at 5 years of delay in achieving optimal systolic blood pressure in patients with type 2 diabetes. Quantifying the health effects of delays in achieving optimal blood pressure may be useful in medical decision-making regarding the frequency of visits and rate of treatment intensification, especially for patients with historically poor blood pressure control over five years.

Risk of fractures with inhaled corticosteroids in COPD: systematic review and meta-analysis of Randomized Controlled Trials and Observational Studies Sonal Singh <sup>1</sup>; Rodrigo Cavallazi <sup>2</sup>; Yoon Loke <sup>3</sup>. <sup>1</sup>Johns Hopkins University, Baltimore, Maryland; <sup>2</sup>University of Louisville School of Medicine, Louisville, Kentucky; <sup>3</sup>University of East Anglia, Norwich, N/A. (Proposal ID # 12014)

**BACKGROUND:** The effect of inhaled corticosteroids (ICS) on fracture risk in patients with chronic obstructive pulmonary disease (COPD remains uncertain. We aimed to evaluate the association between ICS and fractures in COPD

**METHODS:** We searched MEDLINE, EMBASE, regulatory documents and company registries up to September 2010. Randomized controlled trials (RCTs) of budesonide or fluticasone vs control treatment for COPD (24 weeks duration and controlled observational studies reporting on fracture risk with ICS exposure vs no exposure in COPD were included. Peto Odds Ratio meta-analysis was used for fracture risk from RCTs. odds ratios (OR) from observational studies were pooled using the fixed effect inverse variance method. We conducted dose-response analysis using variance weighted least squares regression in the observational studies.

**RESULTS:** Sixteen RCTs (14 fluticasone, 2 budesonide) with 17, 513 participants, and 7 observational studies (n=69 000 participants) were included after screening 853 citations. ICSs were associated with a significantly increased odds of fractures (Peto OR 1.26; 95% CI, 1.01 - 1.57; P = 0.04;  $I^2 = 0\%$ ) in the RCTs. (Figure 1) Exposure to ICS was associated with a significantly increased odds of fractures (OR 1.21; 95% CI 1.12-1.32, P < 0.001;  $I^2 = 37\%$ ) in the observational studies, (Figure 2) with each 500 mcg increase in beclometasone dose equivalents associated with 9% increased odds of fractures, OR: 1.09 (95% CI 1.06 to 1.12; p < 0.001).

**CONCLUSION:** Among patients with COPD, long term exposure to fluticasone and budesonide is consistently associated with a small but statistically significant dose-dependant increased odds of fracture.

Does compliance with the heart failure inpatient quality measures prevent hospital readmission? <u>Sarah Bou Malham</u><sup>1</sup>; Mario Njeim <sup>1</sup>; Nikhil Ambulgekar <sup>1</sup>; Alaali Yathreb <sup>1</sup>; Mahmoud Assaad <sup>1</sup>; Mustafa Abas<sup>2</sup>. 

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**BACKGROUND:** Congestive heart failure national inpatient quality measures were developed by the Joint Commission in conjunction with the Center of Medicare and Medicaid Services and the American Heart Association. Although most of these measures have evidence-based foundation, data supporting their effect on patient outcomes are sparse and controversial. There is currently an urgent need to assess compliance rates, and most importantly to further analyze the efficacy of the core measures for prevention of re-hospitalization.

**METHODS:** We conducted a retrospective cohort study on patients discharged from a major urban hospital between June 2009 and October 2009 with a primary diagnosis of heart failure. We reviewed compliance with each of the 4 mandatory core measures: assessment of left ventricular function (LVF), use of angiotensin-converting enzyme inhibitor (ACE) or angiotensin-receptor blockers (ARB), smoking cessation education and heart failure discharge instructions. A univariable cox-regression analysis was conducted with each factor for prediction of hospital readmission. In addition, a compliance score (ranging from 0 to 4) defined as the number of measures in compliance was generated for each patient. This score was tested using a cox-regression model for prediction of all-cause hospital readmission.

**RESULTS:** 285 patients were included in the study. Mean follow-up was 5 months. Readmission rate at 30 days was 23.3%. Compliance rates with individual measures were the following: assessment of LVF 84.7%, use of ACE or ARB 72.8%, smoking cessation education 100% and heart failure discharge instructions 74.6%. Each one of the 4 quality measures was independently a poor and statistically non-significant predictor of readmission. Results of the univariable cox-regression analysis were the following: assessment of LVF (HR 0.95; 95% CI 0.65-1.38; P = 0.78), use of ACE or ARB (HR 0.91; 95% CI 0.67-1.24; P = 0.57) and heart failure discharge instructions (HR 1.04; 95% CI 0.75-1.44; P = 0.79). The sample size breakdown according to the compliance score was as follows: 4 patients had a score of 1, 39 had a score of 2, 104 had a score of 3 and 138 had a score of 4. The compliance score showed to be a poor and statistically non-significant predictor of readmission based on the cox-regression results (HR 0.98; 95% CI 0.78-1.22; P = 0.86).

**CONCLUSION:** Compliance with the four mandatory heart failure quality measures did not translate into a significant increase in the time free of readmission. While adherence to these measures is currently a major quality marker that is reported to the public and tied to reimbursement, healthcare providers should reassess the way these measures are being implemented as well as their cost effectiveness. There is also an obvious need to generate new evidence-based and personalized performance measures that have a more significant impact on readmission rates and the overall outcome of heart failure patients.