2015 PITTSBURGH CONFERENCE ON

The Science of Medication Adherence

Moving Adherence Measurement Forward

CONFERENCE PROGRAM

Pittsburgh PA | June 2, 2015

WELCOME

Friends and colleagues,

We are happy to welcome you to Pittsburgh for the inaugural Pittsburgh Conference on the Science of Medication Adherence. The conference is a unique opportunity to bring together individuals from academia, industry, and government from across disciplines, whether HIV, cardiovascular disease, diabetes, cancer, mental health, or other conditions, to focus on the science of how adherence is and should be measured.

We have a full agenda of abstracts and plenary presentations, followed by a reception that we hope you will all join. The conference will introduce you to new topics and ideas in adherence measurement and to new colleagues from across the country and from overseas, and our hope is that these interactions will help us improve the way that adherence is measured.

On behalf of the planning committee and the University, we thank you for joining us and look forward to invigorating conversations throughout the day.

Best regards,

Walid Gellad, MD, MPH

Conference Chair
Co-Director, Center for Pharmaceutical Policy and Prescribing
University of Pittsburgh Health Policy Institute

GENERAL INFORMATION

Themes

This inaugural conference mainly focuses on two issues central to adherence measurement:

- Measuring adherence in patients taking multiple medications for multiple chronic conditions,
- Measuring adherence longitudinally.

The following topics are also of key importance:

- Identifying and synthesizing the gaps in current measurement methods;
- Measuring adherence within a delivery system, rather than in specific patients;
- Implications of setting adherence thresholds as clinical and policy targets (i.e. is 80% PDC right for everyone?);
- Identifying how technology/electronic medical records can change the measurement of adherence;
- Implications of adherence measurement in clinical trial design; and
- Implementation of adherence measures in real-world health systems and practices.

Committee

We would like to thank the members of our planning committee for their dedication to this conference and the field of medication adherence.

Conference Chair: Walid Gellad, MD, MPH

Planning Committee:

- Hayden Bosworth, PhD
- Jacqueline Dunbar-Jacob, PhD, RN
- Everette James, JD, MBA
- Newell McElwee, PharmD, MSPH
- Andrew Peterson, PharmD, PhD
- Janice Pringle, PhD
- John F. Steiner, MD, MPH
- Carolyn Thorpe, PhD, MPH
- Ira Wilson, MD, MSc

Resources

Registration/information desk: open from 7:00am to 6:00pm in the William Pitt Union first floor lobby

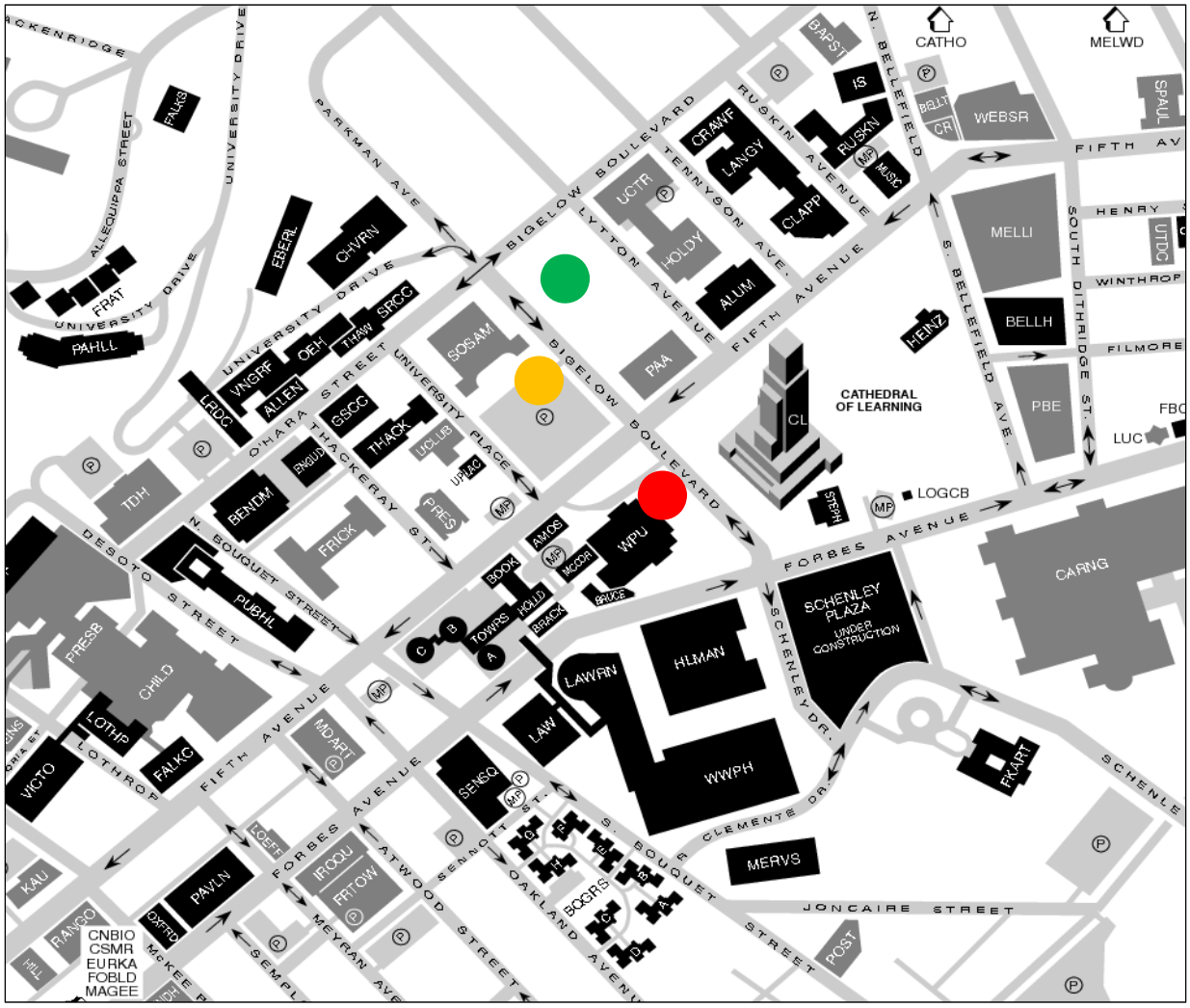
Badges: badges must be worn at all times to enter the sessions, events, and exhibits

Wi-fi: to access wireless internet, please use the network "GUEST-WIRELESS-PITTNET." All registrants will receive an e-mail for signing into the network. If you have trouble, please visit the information desk

Recording devices: recording devices are prohibited without prior authorization

Lost and found: attendees can report stolen items or inquire about found items at the information desk

MAP



Main conference building: William Pitt Union 3959 Fifth Ave. Pittsburgh, PA 15213

Parking (paid): Soldiers and Sailors Parking Garage 4390 Bigelow Blvd. Pittsburgh, PA 15213

Conference hotel: Wyndham Pittsburgh University Center 100 Lytton Ave, Pittsburgh, PA 15213

AT-A-GLANCE AGENDA

University of Pittsburgh William Pitt Union

7:30 a.m. – 8:30 a.m.	Registration and continental breakfast	*Atrium*

8:30 a.m. – 10:00 a.m.	Morning plenary session	*Assembly Room*
	Welcome	**Walid Gellad, MD, MPH** University of Pittsburgh, School of Medicine
	Opening plenary: Adherence measurement for population and delivery system-based interventions	**John F. Steiner, MD, MPH** Kaiser Permanente Colorado, Institute for Health Research
	Abstract Presentations	
	Medication non-adherence: what can be measured can be managed	**Bernard Vrijens, PhD** MWV Healthcare
	Using machine learning to examine medication adherence thresholds and risk of hospitalization	**Wei-Hsuan Lo-Ciganic, PhD, MS, MSPharm** University of Arizona, College of Pharmacy

10:15 a.m. – 11:45 a.m.	Concurrent oral session 1	
A	**Measuring adherence longitudinally** *Assembly Room*	Discussant: **Walid Gellad, MD, MPH** University of Pittsburgh
	Association between trajectories of statin adherence and subsequent cardiovascular events	**Jessica M. Franklin, PhD** Brigham and Women's Hospital and Harvard Medical School
	Trajectories of Buprenorphine treatment and associated emergency department and inpatient use in a large Medicaid program	**Wei-Hsuan Lo-Ciganic, PhD, MS, MSPharm** University of Arizona, College of Pharmacy
	A longitudinal examination of the predictors of changes in medication adherence in hypertensive blacks	**Antoinette Schoenthaler, EdD** New York University, School of Medicine
	Medical cost savings from medication adherence and implications for targeting behavioral interventions	**Steven Kymes, PhD** CVS Health
B	**Adherence measurement in RCTs** *Kurtzman Room*	Discussant: **Michael J. Stirratt, PhD** NIMH Division of AIDS Research
	Assessing the association of four measures of adherence to Tacrolimus for organ transplant recipients	**John D. Peipert, MA** UCLA, David Geffen School of Medicine, Division of Nephrology
	Design and methods of the Telemonitoring Adherence to Medications in Heart Failure Patients (TEAM-HF) trial	**Benjamin D. Gallagher, BS** Columbia University Medical Center
	The impact of packaging and messaging on adherence to malaria treatment: evidence from a randomized controlled trial in Uganda	**Indrani Saran, MA** Harvard University, School of Public Health
	Web based directly observed therapy: a novel method for longitudinal measurement of adherence	**Lakshmanan Krishnamurti, MD** Childrens Healthcare of Atlanta

12:00 p.m. – 1:30 p.m.	Lunch and afternoon plenary session		*Assembly Room*
	Afternoon plenary: Engaging the healthcare system in efforts to enhance medication adherence	**Niteesh K. Choudhry, MD, PhD** Brigham and Women's Hospital and Harvard Medical School	
	Abstract Presentations		
	ISPOR Multiple Medication Adherence Measurement Working Group	**Andrew Peterson, PharmD, PhD** University of the Sciences	
	Heterogeneous patient response to screening and brief intervention	**Janice L. Pringle, PhD** University of Pittsburgh, School of Pharmacy	
1:45 p.m. – 2:45 p.m.	Poster and exhibition session		*Ballroom*
3:00 p.m. – 4:30 p.m.	Concurrent oral session 2		
C	**Self-report – what's new?** *Assembly Room*	Discussant: **Corrine Voils, PhD** Duke University	
	An examination of the reliability and the validity of a 9-item medication adherence scale modified for patients with HIV/AIDS	**Karen E. Wickersham, PhD, RN** University of Maryland, Baltimore, School of Nursing	
	Validation of new self-report adherence measures for HIV and non-HIV medications	**Ira B. Wilson, MD** Brown University	
	Evaluation of a Medication Access and Adherence Tool (MAAT) to identify patients at risk for medication non-adherence after hospital discharge	**Kim C. Coley, PharmD** University of Pittsburgh, School of Pharmacy	
	Self-report measures of medication adherence: evidence-based recommendations on optimal use	**Michael J. Stirratt, PhD** NIMH Division of AIDS Research	
D	**Novel ways to measure adherence** *Kurtzman Room*	Discussant: **Newell McElwee, PharmD, MSPH** Merck & Co.	
	Profiles of medication non-adherence behaviors in older adults	**Carolyn T. Thorpe, PhD, MPH** University of Pittsburgh, School of Pharmacy	
	The Balanced Adherence Metric (BAM): a new spin on current methods for calculating adherence with pharmacy claims data	**Bill Simpson, BSc, PhD(c)** MemoText Corp.	
	Observing versus predicting: Initial patterns of filling predict long-term adherence more accurately than high-dimensional	**Jessica M. Franklin, PhD** Brigham and Women's Hospital and Harvard Medical School	
	Variations on a theme: the 50% adherer	**Jacqueline Dunbar-Jacob, PhD, RN** University of Pittsburgh, School of Nursing	
4:45 p.m. – 5:45 p.m.	Closing plenary session		*Assembly Room*
	Closing panel discussion	**Ira B. Wilson, MD** Brown University **Hayden Bosworth, PhD** Duke University Medical Center **Sabina M. De Geest, PhD, RN** KU Leuven & University of Basel	
6:00 p.m. – 8:00 p.m.	Dinner reception		*Lower Lounge*

PLENARY SPEAKERS

Opening plenary

Adherence measurement for population and delivery system-based interventions

John F. Steiner, MD, MPH

Dr. John Steiner has been the senior director of the Institute for Health Research at Kaiser Permanente Colorado since 2008. He currently serves as chair of the Kaiser Permanente National Research Council, and chaired the Governing Board of the national HMO Research Network in 2013-14. Dr. Steiner graduated from Yale College and the University of Pennsylvania School of Medicine. He trained in primary care internal medicine at the University of Colorado, and received an MPH degree from the University of Washington, where he was a Robert Wood Johnson Clinical Scholar. Prior to 2008 he was a professor in the Department of Medicine and the Director of the Colorado Health Outcomes Program at the University of Colorado School of Medicine. From 2007-11 he chaired the Health Systems Research scientific review group for the Agency for Healthcare Research and Quality. He is the PI of the SUPREME-DM Network, a consortium of 11 integrated delivery systems that conduct surveillance, comparative effectiveness, and patient-centered outcomes research in diabetes. Dr. Steiner is the author or co-author of over 200 publications that reflect his research interests in medication adherence, access to care, health disparities, and prevention and treatment of cardiovascular disease and diabetes.

Afternoon plenary

Engaging the healthcare system in efforts to enhance medication adherence

Niteesh K. Choudhry, MD, PhD

Dr. Niteesh Choudhry is an internist and health services researcher whose work focuses on the design and evaluation of novel strategies to improve health care quality and reduce spending for patients with heart disease and other common chronic conditions. Dr. Choudhry is an Associate Professor at Harvard Medical School. He is also the Executive Director of the Center for Healthcare Delivery Sciences (www.c4hds.org) at Brigham and Women's Hospital, where he is also an Associate Physician in the Division of Pharmacoepidemiology and Pharmacoeconomics and the Hospitalist Program.

Dr. Choudhry has published over 175 scientific papers in leading medical and policy journals and has won awards from AcademyHealth, the Society of General Internal Medicine, the International Society of Pharmacoeconomics and Outcomes Research, and the National Institute of Health Care Management for his research. His work is supported by both public and private funders including the National Heart, Lung, and Blood Institute, the Agency for Healthcare Quality and Research, CVS Caremark, Aetna, the Robert Wood Johnson Foundation, the Commonwealth Fund, the Arnold Foundation, Merck, Sanofi, AstraZeneca and the Pharmaceutical Research and Manufacturers of America.

Dr. Choudhry received his M.D. and completed his residency training in Internal Medicine at the University of Toronto and earned his Ph.D. in Health Policy from Harvard University. He practices inpatient general internal/hospital medicine and has won numerous awards for teaching excellence and clinical mentorship.

ORAL PRESENTATION ABSTRACTS

Using machine learning to examine medication adherence thresholds and risk of hospitalization

Wei-Hsuan Lo-Ciganic, PhD, MS, MSPharm
University of Arizona, College of Pharmacy

Julie M. Donohue, PhD
University of Pittsburgh, Graduate School of Public Health

Bobby Jones, PhD
University of Pittsburgh Medical Center

Joshua M. Thorpe, PhD, MPH
University of Pittsburgh, School of Pharmacy; VA Pittsburgh Healthcare System

Subashan Perera, PhD
University of Pittsburgh, School of Medicine

Carolyn T. Thorpe, PhD, MPH
University of Pittsburgh, School of Pharmacy; VA Pittsburgh Healthcare System

Zachary A. Marcum, PharmD, MS, PhD
University of Washington, School of Pharmacy

Walid F. Gellad, MD, MPH
University of Pittsburgh, School of Medicine; VA Pittsburgh Healthcare System

Background: Quality improvement efforts for chronic diseases, and associated financial incentives, are frequently tied to patients achieving ≥80% annual medication refill adherence. However, little empirical evidence exists that this threshold optimally predicts important health outcomes overall or within different patient sub-groups. We applied machine learning to examine how adherence to oral hypoglycemic medications is associated with avoidance of hospitalizations in diabetes patients, and identified adherence thresholds for optimal discrimination of hospitalization risk.

Methods: A retrospective cohort study of 33,130 Pennsylvania Medicaid non-dual eligible enrollees aged 18-64 with type 2 diabetes and ≥ 2 oral hypoglycemic prescriptions between 2007-2009. We randomly selected 90% of the cohort (training sample) to develop the prediction algorithm and used the remaining (testing sample) for algorithm validation. Refill adherence was calculated using proportion of days covered (PDC) for oral hypoglycemics over one year. We applied random survival forests to identify predictors for time to first all-cause hospitalization in the subsequent year, and fit survival trees to empirically derive adherence thresholds that best discriminate hospitalization risk.

Results: The training and testing samples had similar characteristics (mean age, 48 years; 67% female; 51% whites, mean PDC, 0.65, 24% hospitalization rate). We identified eight important predictors of all-cause hospitalizations (ranked in order): prior hospitalizations or emergency department visits, number of monthly prescriptions, diabetes complications, insulin use ≥90 days, PDC, number of prescribers, Elixhauser index, and Medicaid eligibility category. The adherence thresholds most discriminating for risk of all-cause hospitalization varied from 46% to 94% according to patient health and medication complexity. For example, among individuals who had no prior hospitalizations or ED visits, had insulin prescriptions ≥90 days, and did not have more than 13 prescriptions per month, the tree identified 59% as the PDC threshold that most differentiates two groups with hospitalization risk. PDC was not predictive of subsequent hospitalizations in the healthiest or most complex patient subgroups (46% of the training sample).

Conclusion: Adherence thresholds most discriminating of hospitalization risk were not uniformly 80%. Rather than applying this threshold uniformly across patients, machine-learning approaches may be valuable for identifying appropriate disease- and patient-specific thresholds for measuring quality of care.

A Measuring adherence longitudinally

Assembly Room

Discussant: Walid Gellad, MD, MPH University of Pittsburgh, School of Medicine

1a Association between trajectories of statin adherence and subsequent cardiovascular events

Jessica M. Franklin, PhD
Brigham and Women's Hospital and Harvard Medical School

Alexis K. Krumme, MS
Brigham and Women's Hospital

Angela Y. Tong, MS
Brigham and Women's Hospital

William H. Shrank, MD, MSHS
CVS Caremark

Olga S. Matlin, PhD
CVS Caremark

Troyen A. Brennan, MD, JD
CVS Caremark

Niteesh K. Choudhry, MD, PhD
Brigham and Women's Hospital and Harvard Medical School

Background: Group-based trajectory models identify groups of patients with similar patterns of adherence and model adherence in each group over time. Medication adherence trajectories have been found to accurately summarize longitudinal adherence patterns and classify patients into clinically-meaningful groups, but the association between adherence trajectories and clinical outcomes remains unclear. We investigated the association between 12-month statin trajectories and subsequent cardiovascular events.

Methods: We identified patients who received insurance coverage from a large national insurer and initiated a statin during January 1, 2007 to December 31, 2010. We assessed medication adherence during the 360 days following initiation and classified patients as adherent or not based on the proportion of days covered (PDC) during each 30-day period (PDC ≥/< 0.8). We used these 12 monthly indicators of statin adherence to estimate trajectory models and create multiple groupings of adherence. We then measured cardiovascular events, including hospitalization for acute coronary syndrome, myocardial infarction, stroke, or heart failure, during the year after adherence assessment. Cox proportional hazards models were used to evaluate the association between adherence measures and cardiovascular outcomes; strength of association was quantified by the hazard ratio (HR), the increase in model C-statistic, and the net reclassification index (NRI). Strength of association was compared between trajectory groupings and simple groupings based on 360-day PDC.

Results: Among 519,842 statin initiators, 8,777 (1.7%) had a cardiovascular event during follow-up. More consistent medication use was associated with a lower likelihood of clinical events, whether adherence was measured through trajectory groups or PDC. For example, when using 3 trajectory groups, the moderate adherence trajectory was associated with a 18% reduction in risk compared with the worst adherence trajectory (HR: 0.82, 95% confidence interval: 0.78-0.86), while the best adherence trajectory was associated with a 36% reduction in risk (HR: 0.64, 0.60-0.67). When evaluating the prediction of future cardiovascular events by including a measure of adherence in the model, the best model reclassification was observed when adherence was measured using 3 trajectory groups (NRI=0.199 [95% confidence interval: 0.181, 0.217]).

Conclusions: Statin adherence trajectory predicted future cardiovascular events better than measures categorizing PDC. Thus, adherence trajectories may be useful for targeting adherence interventions or adjusting for adherence behavior in comparative effectiveness studies.

2a Trajectories of Buprenorphine treatment and associated emergency department and inpatient use in a large Medicaid program

Wei-Hsuan Lo-Ciganic, PhD, MS, MSPharm
University of Arizona, College of Pharmacy

Walid F. Gellad, MD, MPH
University of Pittsburgh, School of Medicine; VA Pittsburgh Healthcare System

Adam J. Gordon, MD, MPH
University of Pittsburgh, School of Medicine; VA Pittsburgh Healthcare System

Gerald Cochran, PhD
University of Pittsburgh, School of Social Work

Julie M. Donohue, PhD
University of Pittsburgh, Graduate School of Public Health

Background: Buprenorphine is an effective treatment for opioid use disorders, which affect 2 million individuals in the US. However, uncertainty about optimal duration of buprenorphine treatment may lead to substantial variation in provider decision-making, and patient outcomes. In response to the high cost of treatment, some payers have placed limits on treatment duration although little is known about the impact of these limits. Understanding the relationship between differential patterns of buprenorphine use over time and patient outcomes would inform payers like state Medicaid programs, which finance a large share of health care for individuals with opioid use disorders. We used group-based trajectory models to identify distinct trajectories of buprenorphine use based on prescription refill patterns, and examined emergency department (ED) and inpatient use associated with these trajectories in a large state Medicaid program.

Methods: We analyzed data from a retrospective cohort study of 10,945 adults (18-64 years) Pennsylvania Medicaid enrollees, not dually eligible for Medicare, initiating a new episode of buprenorphine treatment between 7/2007-12/2011. We obtained data from all of Pennsylvania Medicaid's managed care organizations, which varied with respect to limits placed on buprenorphine, as well as its fee-for-service program. We used group-based trajectory models to identify trajectories of buprenorphine use based on proportion of days covered in the 12 months following buprenorphine initiation. Multivariate Cox proportional hazard models were used to examine the association between trajectories and time to first all-cause hospitalization and first emergency department (ED) visit in the following year.

Results: Six distinct buprenorphine treatment trajectories were identified: 24.9% discontinued buprenorphine <3 months, 18.7% discontinued between 3-5 months, 12.4% discontinued between 5-8 months, 13.3% discontinued >8 months, 9.5% refilled buprenorphine intermittently over the 12 months, and 21.2% refilled buprenorphine persistently for 12 months. Factors associated with treatment discontinuation were minority race, history of frequent ED visits and hospitalizations, and comorbid psychoses. In addition, buprenorphine trajectories varied significantly between the managed care and fee-for-service programs. After adjusting for sociodemographics, health status, and provider-level covariates, patients who refilled persistently had a 20% lower risk of all-cause hospitalizations (hazard ratio [HR]= 0.80, 95% CI, 0.68-0.94) and 15% lower risk of an ED visit (HR=0.85, 95% CI, 0.77-0.94) in the subsequent year, compared to those discontinuing between 3-5 months.

Conclusion: Buprenorphine treatment trajectories were highly variable in this large Medicaid cohort. Patients who used buprenorphine persistently for 12 months had lower risk of all-cause hospitalizations and ED visits than those experiencing early discontinuation. Wide-spread variation in treatment duration of buprenorphine may arise from a combination of factors including provider and patient decisions. In addition, payer restrictions such as prior authorization of prescribing may contribute to the observed variations in discontinuation of buprenorphine treatment and outcomes. Trajectory models are valuable tools for providers and health systems to identify patients with distinct patterns of buprenorphine fills and target those at the highest risk of premature discontinuation.

3a A longitudinal examination of the predictors of changes in medication adherence in hypertensive blacks

Antoinette Schoenthaler, EdD
New York University, School of Medicine

Mark Butler, PhD
New York University, School of Medicine

William Chaplin, PhD
St. Johns University

Gbenga Ogedegbe, MD
New York University, School of Medicine

Background: Poor adherence to prescribed antihypertensive medications has been indicated as a major contributor to poor blood pressure control in Blacks. While many studies have examined the multiple correlates of non-adherence in Blacks, they have been limited to cross-sectional designs and thus, unable to examine the complex interactions between various factors and their subsequent impact on changes in medication adherence over time. The aim of the present study was to confirm and extend previous research by assessing the predictive role of key psychosocial and interpersonal factors on changes in medication adherence over a one-year period.

Methods: This study was conducted as part of a group randomized clinical trial, which was designed to evaluate the effectiveness of a multi-level intervention in improving blood pressure control among Black patients with uncontrolled hypertension (HTN) receiving care in community health centers in the New York metropolitan area from 2004-2008. A total of 815 patients had complete data and were included in the analysis for this study. Medication adherence was assessed with the 4-item Morisky self-report measure. The psychosocial predictor variables of medication adherence self-efficacy (MASES), and depressive symptomology (PHQ-9) were assessed with well-validated self-report measures at the baseline, 3-month, and 6-month study visits. Social support (MOS) and quality of patient-provider communication on medication-taking behaviors were assessed at baseline. A linear growth model was used to examine changes in medication adherence over a year with assessments at baseline, 6 months, and 12 months. The model regressed the slope and intercept of the measures of both depression and self-efficacy onto the slope and intercept of continuously measured medication adherence. Baseline social support and patient-provider communication were entered as additional predictors of change in medication adherence, depression, and self-efficacy. Treatment group, age, gender, income and number of antihypertensive medications were covariates.

Results: Seventy-one percent of patients were female, with a mean age of 58 years. Approximately half had Medicaid (46%), one-third had less than a high school education (35%), two-thirds were unemployed (69%), and most reported a household income of less than $20,000. At baseline, higher levels of self-efficacy was associated with lower levels of depression and better medication adherence. Higher levels of social support at baseline was associated with more collaborative patient-provider communication, which were both associated with lower levels of baseline depression. Examining the data longitudinally, only increasing levels of medication adherence self-efficacy predicted improvements in medication adherence over the one-year period (CFI= 0.954; RMSEA=0.042; SRMR=0.038; p<.001).

Conclusion: By using longitudinal analysis, this study provides some clarification into the role of key psychosocial and interpersonal factors on medication adherence in hypertensive Blacks. Our findings showed that only self-efficacy was a significant predictor of improvements in medication adherence over time. However, in contrast to observational findings, there were no longitudinal associations between depression, social support or patient-provider communication and adherence. Future studies should utilize a more robust measure of medication adherence to corroborate these findings.

4a Medical cost savings from medication adherence and implications for targeting behavioral interventions

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CVS Health

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Background: Behavioral interventions intended to support patients in maintaining or achieving medication adherence must be implemented in an efficient manner if providers and payors are to meet the goal of improving population health on a limited budget. We investigated the question of whether differences in the direction of change in adherence behavior (i.e., moving from adherent to non-adherent or from non-adherent to adherent) modifies the magnitude of changes medical spending in patients with diabetes, hypertension and hypercholesterolemia. We also considered how this impact varies by the burden of comorbid conditions.

Methods: We identified patients who had at least one of three conditions – diabetes, hypertension or hypercholesterolemia – from ICD-9 code or medication profile using a nationally representative medical and pharmacy claims data set of 10 million commercially insured members from Optum (Minneapolis, MN), The baseline period was April 1, 2011 to March 31, 2012; and the follow-up period was April 1, 2012 to March 31, 2013. We assembled two cohorts based upon prescription filling behavior: 1) members adherent (MPR>0.80) in the baseline period; and 2) members not adherent (MPR<0.80) at baseline. Medical spending in patients who maintained adherence at baseline and follow-up (reference) were compared with those who became non-adherent at follow-up (i.e., A2N). Members who newly achieved adherence at follow-up (i.e, N2A) were compared with those who were non-adherent at baseline and follow-up (reference).Estimation of spending during the follow-up period was made using generalized linear modeling methods adjusting for baseline medical spending, preventive health service utilization, age, gender, comorbidity (Charlson Index), initiator/continuer medication use status, and census region. In addition, models were stratified by high comorbidity (Charlson score >3) versus low (<3) to gain insight into as to whether members' comorbidity burden further modified the association

Results: See table below for results showing changes in medical spending between baseline and follow-up. A negative number indicates a decrease in spending between years. Overall, patients with diabetes experienced a similar magnitude of change in spending regardless of whether non-adherence was prevented or members achieved adherence. In patients with hypertension and hypercholesterolemia, those who became non-adherent had a larger change in spending than those who became adherent. In stratified analyses, we found that the largest changes are seen in patients who have a Charlson score of 3 or more in the baseline year. Among these sicker patients, there was at least a $2,000 change in spending when adherence status changed.

Conclusion: The association between adherence behavior and medical spending differs significantly between patients who maintain or achieve adherence; as well as across levels of comorbidity. Understanding these differences has important implications when implementing programs to help patients struggling with medication adherence and can assist providers and payers in prioritizing intervention efforts.

	All		Charlson 3+		Charlson < 2	
	A2N	N2A	A2N	N2A	A2N	N2A
Diabetes	$2,763	($2,495)	$4,653	($5,341)	$1,654	($757)
Hypertension	$2,663	($766)	$7,946	($4,423)	$1,706	($124)
Hypercholes	$1,526	($26)	$4,008	($2,081)	$1,045	$365

B

Adherence measurement in RCTs

Kurtzman Room

Discussant: Michael J. Stirratt, PhD NIMH Division of AIDS Research

1b

Assessing the association of four measures of adherence to Tacrolimus for organ transplant recipients

John D. Peipert, MA
UCLA, David Geffen School of Medicine, Division of Nephrology

Amy D. Waterman, PhD
UCLA, David Geffen School of Medicine, Division of Nephrology

Eileen W. Tsai, MD
UCLA, Mattel Children's Hospital, Division of Pediatric Nephrology

Donald E. Morisky, ScD
UCLA, Field School of Public Health, Department of Community Health Sciences

Moses A. Zonana, MBA
Compliance Meds Technologies

Suphamai Bunnapradist, MD, MS
UCLA, David Geffen School of Medicine, Division of Nephrology

Background: For end-stage solid organ disease patients, transplantation offers increased life span and quality of life. However, recipients must adhere to a complex regimen of immunosuppressant medications, particularly tacrolimus, to prevent rejection of the transplanted organ. There is not a standardized method of detecting medication adherence (MA) in solid organ transplantation. Assessments range from patient surveys and dosing diaries, electronic pill bottle caps, and biological measures of the levels of medication in a patient's blood. Each approach has advantages and disadvantages, thus a reasonable assessment strategy is to employ multiple validated measures. Understanding the comparability of multiple measures is critical for interpreting the results of studies involving adherence measure comparisons. As part of a FDA-sponsored, multicenter trial we will compare 300 adult and pediatric organ recipients' experiences receiving heart, liver, and kidney transplants with branded and generic tacrolimus in which MA is a secondary outcome. Furthermore, we will examine the comparability of four validated and non-validated measures of adherence over 36 months.

Methods: Assessments of adherence will be made at several timepoints over three years of follow-up post-transplantation. A validated, patient-reported MA scale, the Morisky Medication Adherence Scale (MMAS-8), will be assessed at 9-, 18-, and 36-months post-transplantation; scale scores range between 0-8 (higher = better adherence). The coefficient of variation (CV), a validated measure of the level of tacrolimus in patient's blood, defines adherence as the standard deviation of patients' trough blood levels divided by the mean level across 11 points over 36 months, generating scores between 0%-100% (higher = better adherence). Daily measurement of MA will be conducted with a pill-by-pill utilization measurement cap device that appends to a pill vial called CleverCap®, and daily dosage diaries; these assessments will utilize the CleverScore™, a novel adherence metric formulated for the CleverCap® reporting and analytics platform and defined as the difference between the number of actual doses taken and non-prescribed doses taken divided by the number of prescribed doses taken, ranging between 0%-100% (higher = better adherence). Correlations between each of these measures will first be tested at 9-, 18-, and 36-months post-transplant, and each will be assessed for sensitivity to change in adherence levels over time. On the MMAS-8, categories of low (score of <6), medium (6-<8), and high adherence (8) will be tested for association with the CV (dichotomized at established cut-off of >40% = adherent, < 40% = non-adherent), as well as data from the CleverCap® and diaries using chi-square and Wilcoxon rank-sum tests. Finally, receiver-operator curves will be used to establish a meaningful cut-off point to distinguish adherent patients for the CleverScore™. These analyses will help identify the most efficient and cost-effective measure of medication taking behavior.

Conclusions: The results of these analyses will establish and quantify the degree to which multiple measures of adherence are related in a novel study setting with adult and pediatric patients assessed over multiple timepoints, and create a basis for comparing their individual results in a single clinical trial across solid organ transplantation.

2b Design and methods of the Telemonitoring Adherence to Medications in Heart Failure Patients (TEAM-HF) trial

Benjamin D. Gallagher, BS
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Nathalie Moise, MD
Columbia University Medical Center

Vivian Medina, MSW
Columbia University Medical Center

Brian Wayda, MD, MPH
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Siqin Ye, MD, MPH
Columbia University Medical Center

Ian M. Kronish, MD, MPH
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Background: Approximately 1 in 4 patients hospitalized with heart failure (HF) is readmitted within 30 days of discharge, and more than 50% are readmitted within 6 months. Poor medication adherence is a major contributor to unnecessary HF readmissions. Telemonitoring—the use of telecommunication tools to monitor clinical status as a chronic disease management strategy—can improve outcomes through early, targeted interventions. While telemonitoring traditionally has been used to monitor clinical signs or symptoms, we aimed to test the feasibility of extending the concept of telemonitoring to medication adherence in HF patients.

Methods: We are conducting a pilot randomized clinical trial comparing telemonitoring of adherence to loop diuretics versus usual care. We aim to enroll 50 English- or Spanish-speaking patients admitted to New York-Presbyterian Hospital with HF who are discharged home on a loop diuretic. All participants are given an electronic pill bottle that wirelessly transmits adherence data (GlowCap, Vitality, Inc.). Participants are instructed to fill the GlowCap with their loop diuretic medication when they return home. The device records the date and time when the cap is opened and syncs with a secure website in real time. Participants are randomized to the intervention group or usual care in a 1:1 ratio. In the intervention group, the study team reviews adherence data remotely and proactively contacts participants by telephone if a pattern of missed doses is observed. The study team also inquires about HF symptoms and assesses and responds to reasons for missed doses in the non-adherent patients. In the usual care group, cap-opening data are not viewed by the study team during the monitoring period. All participants complete a phone questionnaire 30 days after discharge to assess acceptability of using the GlowCap, attendance at outpatient visits, emergency department visits, and hospital readmissions.

Results: Thus far, 17 of 22 patients screened have been enrolled and randomized (3 ineligible, 2 declined to participate). Median age is 67 years (interquartile range [IQR] 53-82 years); 39% are women, 17% are black, 50% are Hispanic, and 17% are Spanish-speaking. One participant received a malfunctioning GlowCap that was replaced, and 1 participant declined to use the GlowCap after randomization. Nine participants have completed the 30-day follow-up. As the study is ongoing, we do not yet compare results between intervention and control groups. Irrespective of group assignment, median adherence during the 30-day post-discharge study period, defined as the percentage of days on which the correct number of doses was taken, was 80% (IQR 40-100%), and 56% of participants were non-adherent (adherence <88%). All participants rated the GlowCap as very or somewhat easy to use on a 5-point Likert scale, and all would agree to use it again if asked by their provider.

Conclusions: Our preliminary results suggest that adherence telemonitoring is acceptable to most HF patients, non-adherence is common even when patients know they are being monitored, and it is feasible to remotely track adherence. Thus, adherence telemonitoring is a promising approach to improving adherence and decreasing readmissions in HF patients.

3b The impact of packaging and messaging on adherence to malaria treatment: evidence from a randomized controlled trial in Uganda

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Background: Artemisinin-combination therapies (ACTs) are currently the only effective treatment for malaria, and this class of drugs has contributed to large declines in the morbidity and mortality burden of malaria over the past decade. However, over 35 percent of patients do not complete the full course of ACTs, despite it being a short, 3-day treatment for malaria. Non-adherent patients are less likely to be cured of malaria and may face recurrent infections. In addition, patients taking sub-therapeutic doses of ACTs increases the risk of widespread parasite resistance to the drugs.

Methods: We conducted a randomized controlled trial in Central Uganda, with 2,500 households, in order to understand the reasons for poor adherence to the ACT treatment regimen. Each household was given a voucher that enabled them to purchase subsidized ACTs at their local drug shop. During the study period, nine participating drug shops were randomly assigned each day to stock either the control ACT package or one of four treatment packages that were designed to increase adherence to the medication. A random subset of patients who purchased ACTs at these drug shops were visited at their household three days later to assess adherence to the medication by counting the number of pills remaining in their ACT blister pack.

Results: We find that patients who felt much better on the second day of the 3-day treatment were less likely to finish their medication, perhaps because they believed they were cured of malaria. Consistent with this hypothesis, patients who received the standard ACT package with a sticker that said “malaria is not gone until all tablets are finished” were approximately five percentage points more likely to finish the treatment (an 8 percent increase on the baseline adherence rate of 65 percent). Moreover, this simple message increased adherence primarily among patients who were feeling better mid-treatment, who may otherwise have stopped taking the pills. A second simple message that discouraged saving pills for future malaria episodes had no significant effect on adherence. We also tested two versions of specialized packaging that included pictorial instructions for illiterate patients, and a colorful, glossy design intended to increase consumer confidence in the quality of the drugs. Although this special packaging increases the production cost of ACTs by 10 to 50 percent, it had no significant effect on medication-taking behavior or on comprehension of instructions.

Conclusion: We show that the standard approach to increasing adherence to ACTs in Africa, using costly specialized packaging, did not significantly increase adherence rates. Instead, a simple message emphasizing the importance of finishing the medication, in order to be cured of malaria, modestly increased adherence rates at a very low cost. Rather than relying on self-reports, we measured adherence by directly counting the pills remaining in the medication blister packs. Blister packs were available in 86% of cases, even though patients were not aware that they would potentially be visited to check for adherence.

4b Web based directly observed therapy: a novel method for longitudinal measurement of adherence

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Background: Surrogate measures of adherence such as medication possession ratio are limited by the fact that they do not directly measure adherence. Further, such measures represent substantial burden of data collection that limits their use for longitudinal measurement of adherence. We have previously described the feasibility of using a web based directly observed therapy as a novel method for the longitudinal measurement of adherence (Creary et al Pediatric Blood and Cancer 2014). We adapted this approach to develop a web based approach to longitudinal collection of adherence in the context of a randomized clinical trial.

Methods: Brief videos recorded by patients using a smartphone documenting medication administration are emailed to a secure website (tookmymed.com). The web site also served to send automated reminders to patients at prearranged time intervals to take their medication. It also served as a means for messages from the adherence coordinator to communicate with the patient. The website also was used to administer surveys of patient barriers to adherence, document pharmacy records of medication refills and disease related healthcare utilization at baseline and following the intervention.

Results: This web based adherence measurement is being used in randomized controlled trial to assess the comparative effectiveness of this approach to improve adherence with hydroxyurea in patients with sickle cell disease. One hundred and ten patients have completed randomization and follow up for 1-12 months to date. Study is ongoing with targeted enrollment of 80 pediatric and adult patients randomized to receive the intervention vs standard of care. After one year follow up patients in the control arm will also cross over to the intervention arm for the second year of follow up.

Conclusions: A web based application for longitudinal direct measurement of adherence through brief videos taken by patients using their smartphone is feasible for use in randomized clinical trial to measure the effectiveness of this approach for longitudinal measurement of adherence.

Heterogeneous patient response to screening and brief intervention

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Background: Costs associated with medication non-adherence are upwards of $100 billion annually, largely because medication non-adherence increases risk of disease progression, hospitalization, and premature death in chronically ill patients. The objective of this trial was to test the efficacy of Screening and Brief Intervention (SBI) on medication adherence in a pharmacy setting. SBI has demonstrated improved medication adherence and reduced healthcare costs across large patient populations, and suggests that community pharmacists are an untapped resource for improving population health. Despite studies showing population-level effectiveness, little research exists examining heterogeneous treatment effects among differing patients (e.g., adherence history). Moreover, such variation has direct implications for optimal strategies and protocols for SBI that can be tailored to target patients more likely to respond to BIs, yielding clinically meaningful improvements.

Methods: Four-arm Randomized Controlled Trial (RCT) to test the efficacy of SBI on medication adherence in adult patients in Tennessee. All patients were screened for non-adherence risk, and received one of four treatments: (a) Brief Intervention (BI), (b) Pillbox (PB), (c) BI and Pillbox (BI+PB), or (d) Standard Care (SC). Adherence is presented as proportion of days covered (PDC) for five classes of chronic disease medications: beta blockers (BB), calcium channel blockers (CCB), diabetes, renin angiotensin system antagonists (RASA), and statins. Claims and other administrative data will be used to assess patient risk levels to characterize screening results and measure population effects (e.g., adherence) based on screening and BI delivery rates.

Results: In the initial study, the two BI-involved study arms had large and statistically significant effects on adherence when assessing the above noted combination of medications and especially among statins, BB and diabetes medications. The BI arm demonstrated significantly improved adherence across the combination of medication classes and diabetes medications, with marginal significantly improved adherence for BB medications. The BI + PB arm demonstrated significantly improved adherence across the combination of medication classes, statins and BB medications, with increased but not statistically significantly improved diabetes medication adherence. PB provision significantly improved diabetes medication adherence only, similar in magnitude to the BI arm. Changes in PDC as a function of Baseline PDCs show lower Baseline PDCs do improve over time (following intervention). However, such improvement is not strictly in response to the interventions. Much of the improvement is due to adherence history, patterns of cycling and the way PDCs are measured, particularly among patients with lower initial PDCs (i.e., <25%). After accounting for this, patients receiving the BI and BI+PB who have higher yet still at-risk baseline PDCs of 25% to 50% are the prominent group of patients driving the intervention effectiveness results.

Conclusion: The analytic methods used in this study advance the science of adherence measurement, especially for patients taking multiple medications for multiple chronic conditions. The application of BI or BI+PB significantly improved medication adherence across the combination of medication classes examined and the primary medications targeted in the trial (diabetes or statins). This finding suggests that with limited resources, interventions for poor adherence can be more efficiently targeted.

C Self-report – what's new?

Assembly Room

Discussant: Corrine Voils, PhD Duke University

1c An examination of the reliability and the validity of a 9-item medication adherence scale modified for patients with HIV/AIDS

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Background: Adherence to antiretroviral therapy is critical for viral suppression, avoidance of drug resistance and disease progression, and extending life for persons infected with the human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS). Self-report measures, such as a multi-item medication adherence scale (MAS), have been and continue to be used to assess adherence for patients with HIV/AIDS in both research and clinical practice. However, little information exists concerning the reliability and the validity of a 9-item MAS in patients with HIV/AIDS taking antiretroviral therapy.

Methods: Our aim was to examine the reliability and the validity of a 9-item MAS modified for patients with HIV/AIDS. This was a secondary analysis of two independent randomized controlled trials (Study 1; Study 2) examining telephone-delivered interventions for improving adherence to antiretroviral therapy. Data were collected from 1999 to 2008. Descriptive analyses were conducted to characterize and compare each study sample. Reliability was assessed by examining the internal consistency of the modified 9-item medication adherence scale via Cronbach's alpha and Pearson's product-moment correlations to assess test-retest reliability. Convergent validity was assessed through correlations of social support, depressive symptoms, self-efficacy, HIV stigma, and the impact of the medication regimen and side effects with the 9-item medication adherence score. Concurrent validity was evaluated through correlations with adherence measured by electronic event monitoring (EEM) in terms of the percentage of prescribed doses taken ("dose adherence") and percentage of days with correct intake ("days adherence"). Confirmatory factor analysis was used to test whether the dimensionality of our modified 9-item version of the MAS was consistent with the unidimensional structure reported in the literature.

Results: The reliability of the 9-item MAS was .66 (Study 1) and .69 (Study 2) for internal consistency and.50 to .74. for temporal stability over 3-months. Estimates of convergent validity between the 9-item MAS total score and scores from measures of social support, self-efficacy, depressive symptoms, stigma, and the impact of the medication regimen and side effects showed statistically significant correlations for both studies ($r = -.30$ to $.68$). When examining concurrent validity, the correlations between EEM dose adherence and the MAS total score were $r = .12$, $p = .005$ (Study 1) and $r = .33$, $p < .001$ (Study 2). Confirmatory factor analyses to examine the factor structure of the 9-item medication adherence as a unidimensional scale suggested a good fit for both Study 1, $\chi^2(1,213)=34.52$, $p=.151$, RMSEA=.04, CFI=.98, WRMR =.70, and Study 2, $\chi^2(1,315)=40.89$, $p=.042$, RMSEA=.04, CFI=.98, WRMR=.74.

Conclusion: When compared to other self-report measures of adherence, our 9-item MAS demonstrated similar reliability and convergent and concurrent validity. The 9-item MAS allows one to know specific areas of nonadherence to target for intervention as it is targeted to a specific patient population. Therefore, the 9-item MAS may be a better tool than the original 4-item MAS measure when counseling persons regarding their medication adherence. Although longer, a 9-item MAS includes more areas and thus can identify focal areas for intervention by clinicians.

2c Validation of new self-report adherence measures for HIV and non-HIV medications

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Background: A wide variety of self-report (SR) items for medication adherence have been used in the clinical and research literature. Few have been developed using rigorous cognitive testing and validated using electronic drug monitoring (EDM) as an objective gold standard. We previously reported the rigorous development and field testing of three (SR) items (a rating item, a frequency item, and an item that asked about days missing doses). Here we report the results of a study to assess the validity of these three -report items by comparing them with EDM. In addition, we report results for both HIV antiretroviral medications, and also for other, non-HIV related medications.

Methods: Participants were patients with HIV cared for at a large HIV specialty care practice based at an academic teaching hospital. Enrollment criteria included being HIV-positive, currently being treated with an HIV antiretroviral medication and at least one other non-HIV related chronic medication, being over the age of 18 years, and having had a detectable viral load at one of the two most recent viral load assessments. Each participant had an initial visit at which baseline information was collection and participants were given a MedSignals device and taught how to use it. This device has 4 medication bays which can be used to monitor individual medications using wireless technology. At 3 subsequent visits participants responded to the 3 SR items for each of the (up to) 4 medications that were being monitored. Primary analyses compared the EDM measures to the self-report measures for the previous 30 days, which was the reference period for the self-report items, using models that accounted for clustering. EDM summary adherence measures used a “covered time” approach previously reported on which combines data about frequency and timing of bin openings.

Results: The mean age of patients was 46 years, 37% were female, 49% had some education beyond high school, 24% were black, and 22% were Hispanic. Eighty-one participants completed the enrollment visit, and 71, 63, and 59 completed 1, 2, and 3 follow-up visits, respectively. The numbers of HIV antiretroviral medications monitored at the three follow-up visits were 157, 138, and 136 respectively. The numbers of non-HIV medicines at the three follow-up visits were 74, 62, and 59, respectively. Of the non-HIV medications, 58 were mental health medications, 50 were antihypertensives, 16 were for elevated lipids, and 10 were for diabetes. For the 3-item scale the Crohnbach’s alphas for HIV and non-HIV medications were 0.83 and 0.87, and Pearson correlation coefficients between the self-reports and the EDM for HIV and non-HIV medications were 0.41 and 0.54. The mean difference (self-report minus EDM) for the EDM for HIV and non-HIV medications were 7.5 and 5.2 points on a 100 point scale ($p<0.0001$ for both).

Conclusions: This 3-item scale overestimated the EDM measure by amounts that were statistically significant, but clinically small compared with other such comparisons of self-reports and objective measures. Performance was similar for HIV and non-HIV medications. These data support the construct validity of this 3-item SR scale for both HIV and non-HIV medications.

3c Evaluation of a Medication Access and Adherence Tool (MAAT) to identify patients at risk for medication non-adherence after hospital discharge

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Background: Medication nonadherence after hospital discharge is a major cause of morbidity and mortality. Although there are many factors that influence medication-taking behaviors, few tools include an assessment of medication affordability as a domain component. Additionally, many hospitals utilize the total number of medications or comorbidities as the signal to identify patients at risk for medication nonadherence. The goal of this study was to test a new tool that includes an assessment of medication affordability to determine its effectiveness at identifying patients with medication affordability and other adherence problems.

Methods: A 5-item Medication Access and Adherence Tool (MAAT) was developed and included one question each on beliefs about treatment, unintentional factors for nonadherence, intentional factors for nonadherence, medication affordability, and adverse drug events. Item responses were scored on a 0-2 Likert scale. Inpatients on a medicine unit were administered the tool and then interviewed by a pharmacist to assess for medication affordability and other adherence problems they experienced at home. Pearson correlations between the MAAT score and medication adherence problems were assessed.

Results: There were 206 inpatients that completed the MAAT: median age 57 years; 53% female. MAAT items: 23% were not always certain they needed medications to treat their health problems (medication beliefs); 11% were not always sure they could take their medications as prescribed (unintentional nonadherence); 13% sometimes stopped taking or skipped doses of their medications (intentional nonadherence); 28% found it difficult to pay for their medications (affordability); and 18% experienced adverse effects from their medications that could impact their medication taking behavior (side effects). During the inpatient stay, pharmacists identified 71 (34%) patients with medication affordability or other adherence problems. There was a moderate correlation ($r=0.46$, $p<0.001$) between the MAAT score and the total number of medication adherence problems patients experienced at home. There were no correlations between the number of identified medication adherence problems and age, number of discharge medications, or number of comorbidities.

Conclusions: Difficulty in affording medications accounted for the largest percentage of medication adherence problems in this patient population. This underscores the importance for evaluating medication affordability as part of any comprehensive assessment of medication adherence. When administered in the hospital setting, the 5-item MAAT was an effective tool for identifying patients at risk for medication adherence problems at home. Use of this tool before hospital discharge can help determine which patients would benefit most from a pharmacist assessment and intervention.

4c Self-report measures of medication adherence: evidence-based recommendations on optimal use

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Background: Medication adherence plays an important role in optimizing the outcomes of many treatment and preventive regimens in chronic illness. Self-report is the most common method for assessing adherence behavior in research and clinical care, but there are questions about its validity and precision. Few studies have examined research on self-report medication adherence measures across multiple areas of chronic illness. This presentation reviews research on self-report medication adherence measures from all areas of chronic illness and makes best practice recommendations for their optimal use.

Methods: The NIH Adherence Network assembled a panel of adherence research experts working across various chronic illnesses to review self-report medication adherence measures and research on their validity, with the goal of producing evidence-based recommendations on methods to enhance their validity.

Results: Self-report medication adherence measures vary substantially in their question phrasing, recall periods, and response items. They tend to overestimate adherence behavior compared to other assessment methods and generally have high specificity but low sensitivity. Most evidence indicates that self-report adherence measures show moderate correspondence to other adherence measures, and they can significantly predict clinical outcomes. The quality of self-report adherence measures may be enhanced through efforts to use scales that are validated and that assess the proper construct. There is evidence to support question response formats that ask respondents to estimate their overall adherence behavior rather that count a specific number of missed doses. Longer recall periods (up to 30 days) have also been shown to reduce ceiling effects (reports of perfect adherence). The validity of self-report measures can be further strengthened through efforts to address social desirability bias and employ technologic delivery.

Conclusion: Self-report medication adherence measures can provide actionable information despite their limitations. They are preferred when speed, efficiency, and low-cost measures are required, as is often the case in clinical care. A number of evidence-based steps can be used to improve the validity of self-report adherence measures. Research is needed to further strengthen self-report adherence measures used in healthcare delivery and health research.

D Novel ways to measure adherence

Kurtzman Room

Discussant: Newell McElwee, PharmD, MSPH Merck & Co.

1d Profiles of medication non-adherence behaviors in older adults

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Background: Although the accepted definition of medication non-adherence consists of failing to take medications in accordance with agreed-upon recommendations from providers, measurement of non-adherence has almost exclusively focused on underuse of medications to the exclusion of other types of non-adherence behavior. We sought to 1) determine the prevalence of a range of medication non-adherence behaviors in addition to underuse; 2) identify distinct clusters of older adults with similar profiles of non-adherence behaviors; and 3) determine the impact of predisposing, enabling, and medical need factors on likelihood of exhibiting each profile of non-adherence behaviors.

Methods: We used self-administered survey data from the most recent wave (2011) of the Wisconsin Longitudinal Study, a longitudinal study of 10,000 graduates of Wisconsin high schools in 1957. Our analysis included respondents who reported taking at least one prescription medication. Eight medication non-adherence behaviors were assessed: forgetting to take medications, being careless about using medications, stopping medications due to feeling better, taking less medication than prescribed due to feeling better, taking extra doses of medication, frequently obtaining refills more than a few days early (i.e., stockpiling), storing expired medications in the home, and sharing prescription medication with others. We used latent class analysis (LCA) on these items to identify clusters of respondents with similar profiles of non-adherence behaviors, and examined the association of predisposing, enabling, and medical need factors to likelihood of exhibiting different profiles of non-adherence behaviors via multinomial logistic regression.

Results: The final sample consisted of 2,991 adults (56% female) aged 71-74 years, taking a mean of 5.9 (SD=3.7) prescription medications and reporting a mean of 2.5 (SD=1.9) diagnosed conditions. The most common non-adherence behaviors included storing expired medications in the home (28.1%) and frequently obtaining refills more than a few days early (23.3%), followed by being careless about using medications (17.8%), taking less than prescribed due to feeling better (12.5%), stopping medications due to feeling better (9.4%), and forgetting to take medications (9.0%). Sharing (2.2%) and taking extra doses (4.0%) were reported infrequently. The LCA revealed four distinct clusters of individuals with similar non-adherence profiles: 1) Adherers (75.6% of respondents), characterized by a low likelihood of all non-adherence behaviors; 2) Unintentional Under-users (11.1%), characterized by a higher likelihood of forgetting and being careless with taking medications; 3) Intentional Under-users (8.7%) characterized by a higher likelihood of taking less or stopping medications due to feeling better; and 4) Medication “Vigilantes” (4.6%), characterized by a higher likelihood of all non-adherence behaviors, except for frequent early refilling. Unintentional Under-users, Intentional Under-users, and Vigilantes also demonstrated a higher likelihood of storing expired medications in their homes compared to Adherers. Several significant predictors of exhibiting different non-adherence profiles were identified.

Conclusions: Our results suggest that medication non-adherence behaviors other than underuse are common, and may or may not co-occur with underuse, thereby supporting the conceptualization of medication non-adherence as a multidimensional construct. Measurement and intervention strategies focused solely on underuse may miss capturing other important non-adherence behaviors that place patients and others at risk for medication-related adverse events.

2d The Balanced Adherence Metric (BAM): a new spin on current methods for calculating adherence with pharmacy claims data

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Background: The use of prescription claims data to calculate adherence is ubiquitous within the adherence literature. Compared to pill counters and self-reported assessments, claims data is significantly more pragmatic, while offering greater levels of validity and objectivity. Among the adherence measures derived from this data, Proportion of Days Covered (PDC) is considered by many to be the most accurate. While PDC solves the problem of calculating adherence in patients with complex regimens, if fails to accurately quantify other important adherence factors. Claims-data adherence measures can be classified into four main groups: large/study interval (PDC, Medication Possession Ratio (MPR)), single interval (Compliance Rate (CR), adjusted MPR), refill timing (Delay to Refill) and persistence (Survival analysis). Together these factors give a more complete picture of patient adherence behaviour. However, there is currently no one metric which incorporates each of these dimensions. Our objective was to develop one, with an emphasis on simplicity, ease of calculation and ease of interpretation.

Method: Nine months of pharmacy claims data from 4780 patients with hypertension, high cholesterol or both was used. All patients were newly diagnosed and had never been treated previously for these conditions. Patients with abnormally short refill cycles (<30 days) or who did not persist after their first prescription were excluded. PDC, CR, Delay to Refill and persistence were calculated using the statistical package R. Delay to Refill was expressed as the proportion of time patients refilled their prescriptions early/on time. Persistence was expressed as the percentage of the study interval that a patient was actively refilling their prescriptions.

Results: The mean PDC and CR were near or within the optimal range (PDC = 73.9%, CR= 90.6%). Patient refills were early/on time an average of 37.0% of the time. By the end of the 9-month study interval, 84.4% of patients were still taking their medication. Together these metrics suggested that patients were adherent over the study interval, but we often refilling their prescriptions late. This poor adherence behaviour was not evident from inspection of the PDC and CR distributions. In an effort to unify these metrics, we computed the weighted geometric mean of all four metrics (termed the Balanced Adherence Metric). Equal weighting was given to PDC and persistence, while CR and Delay to Refill were weighted less. The resulting metric showed a bimodal distribution of adherence, with a mean of 68.0%.

Conclusions: Our study has shown that a mathematical combination of currently available adherence metrics may be more beneficial than either metric alone in objectively assessing adherence. The mean of the BAM was similar to that of PDC (68.0% vs. 73.9%), but was bimodal, incorporating the poor refill behaviour observed in large subset of patients. Interpretation of the BAM is identical to that of PDC and it is simple to calculate with modern statistical software. The BAM and other similar weighted metrics may provide a more accurate and complete picture of adherence derived from claims data.

3d Observing versus predicting: Initial patterns of filling predict long-term adherence more accurately than high-dimensional

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Background: Despite the proliferation of databases with increasingly rich patient data, prediction of medication adherence remains poor. Traditional approaches use a small number of clinical and demographic characteristics available at the time of treatment initiation to create a simple logistic prediction model. Because adherence is a complex behavior, other approaches may provide a better alternative. We sought to evaluate the performance of 4 potential improvements for predicting medication adherence: 1) including area sociodemographic variables from linked census data, 2) mining all available claims information with the high-dimensional propensity score algorithm, 3) using generalized boosted regression, a non-parametric machine learning method, to create a more complex prediction model, and 4) including patterns of refills after medication initiation.

Methods: We identified Medicare beneficiaries who received prescription drug coverage through CVS Caremark and initiated a statin. At baseline, we extracted 35 investigator-specified clinical and demographic characteristics, 208 variables from linked census data and 400 variables from claims during the year prior to medication initiation using the high-dimensional propensity score algorithm. In addition, we identified 3 post-baseline predictors, consisting of indicators of full adherence (PDC $\geq$ 0.8) to statins during each of the first 3 months of follow-up. Using varying subsets of these predictors, we estimated 10 models predicting the binary indicator of PDC $\geq$ 0.8 during 360 days of follow-up, using logistic regression and boosted regression. Models were also estimated within strata defined by the index days supply.

Results: In 77,703 statin initiators, prediction using baseline variables only was poor with maximum cross-validated C-statistics of 0.606 and 0.577 among patients with index supply $\leq$30 days and >30 days, respectively. Using only indicators of adherence during the first 3 months of follow-up improved prediction accuracy substantially among patients with shorter initial dispensings (C=0.827/0.518), and when combined with a small subset of investigator-specified variables, prediction accuracy was further improved (C=0.842/0.596).

Conclusions: Observed adherence immediately after initiation provided substantial information on future adherence behaviors for patients whose initial dispensings were relatively short. This approach may provide a simple algorithm for quickly identifying patients most likely to benefit from interventions to improve adherence.

4d Variations on a theme: the 50% adherer

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Background: Nearly 40 years of intervention research on adherence has not succeeded in improving the ability of individuals to take their medication consistently and persistently. Numerous systematic reviews have noted the low effect sizes of adherence interventions and the suggestion that multi-component interventions yield better outcomes than single focus ones. These findings suggest that the lack of potency of interventions may be due to underlying variability in the behavior identified as non-adherence, which does not get addressed in the majority of the research on adherence. Consequently, we examined the patterns of adherence, using electronic monitoring, among individuals on a diabetes or hypertension medication regimen whose percent adherence was 50% + 10%.

Method: We examined the level of medication adherence over a 21-day period using electronic event monitoring (EEM) for 251 subjects with diabetes and other chronic comorbidities participating in a medication adherence intervention study. The period of study reflected the pre-randomization period. The sample was predominantly white (81%), married (60%), well educated (M=14yr of education), female (59%) and late middle aged (M=64yr). All subjects were taking oral medication for type 2 diabetes which had been prescribed by their provider. Medication had been taken over a period of at least one year. To examine variability in patterns of medication taking within a similar average amount of medication taken, we searched for individuals with 50% adherence, that is, had taken one-half of their medication doses during the 21 day period. Six such subjects were identified with adherence ranging between 43% and 57%. Each line graph was examined to identify patterns of adherence.

Results: Four clear patterns of adherence emerged. First was high day to day variability ranging from 0 to 25% to 50% to 100% taken on any given day. A second pattern indicated a stable but low consumption of one-half of the doses each day ending in a 0 to 50% pattern of variability. The third reflected a variable but high pattern of adherence (50% to 100%), dropping to complete non-adherence and ultimately resulting in a stable 50% dosing pattern. The fourth pattern showed a variation between 0% and 100%. The patterns were different enough to suggest that different factors may be affecting the ability to adhere, and thus, might benefit from different interventions.

Conclusions: Our data suggest that there is substantial variability in medication taking patterns. Consideration should be given to these patterns in testing intervention strategies in the hopes of identifying more robust methods for improving adherence.

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1 Predictors of Allopurinol adherence in patients with gout

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2 How people test whether a medicine is working: implications for adherence

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3 Variability in medication adherence influences self-report

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6 Predictors of medication adherence: fact or artifact

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7 Analyzing times between dose administrations in the ACT study

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9 Implementation of an asthma treatment program to improve asthma inhaler adherence and self-management in a remote community of Honduras

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10 Initial medication adherence in the elderly – a pilot study using claims reversal

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11 The architecture of physician choices: A randomized experiment evaluating the impact of providing non-adherence information and pharmacist assistance to physicians

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12 Feasibility and preliminary efficacy of a culturally informed, health promotion program to improve glaucoma medication adherence among African Americans: "Glaucoma Management Optimism for African Americans Living with Glaucoma" (GOAL)©

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13 Trajectories of oral hypoglycemic treatment and associated inpatient use in a large Medicaid program

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14 Methods of longitudinal adherence quantification in the treatment of bipolar disorder

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15 Development and field testing of a mobile health application to improve adherence in adolescent solid organ recipients: Teen Pocket Path®

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16 Teen Pocket PATH: A randomized pilot of an mHealth intervention to improve adherence in adolescents

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17 The impact of out-of-stock medications on adherence in a community pharmacy setting

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18 Why Are Patients Late to Refill their Maintenance Medications?

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19 A meta-analysis of determinants and outcomes of medication adherence in adult solid organ transplantation

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20 Overcoming measurement challenges in a pooled analysis of longitudinal data of symptoms and adherence to cancer therapy

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22 Impact of brief interventions on patient medication adherence and customer loyalty in a grocery store chain pharmacy

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23 Impact of clinical pharmacy services on medication adherence at a psychiatric primary care clinic

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24 A comparison of objectively- and subjectively-measured adherence in glaucoma patients of African descent

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