Project Summary/Abstract

*This application addresses **Dissemination and Implementation Research in Health (R21)**; Exploratory/Developmental Research (PAR-10-040)*

Health systems want to know which implementation strategies will have the greatest population impact so they can make wise use of limited funds. This application proposes to identify the key bottlenecks that are barriers to the implementation of recommended diabetes and dyslipidemia screening for adults with mental disorders in order to identify the best intervention strategies. Among the most economically-disadvantaged with serious mental illness, excess cardiovascular risk contributes to decades of reduced life expectancy. Physicians prescribing second-generation antipsychotics (SGA) will be studied to focus the analysis because SGAs are commonly taken by adults with mental disorders, they increase metabolic risk themselves, specific monitoring is recommended and data show severe under-screening in clinical practice. The study tests four physician-practice domains hypothesized to affect screening rates: knowledge; attitudes; physical-behavioral health care coordination; and practice recall and reminder systems. We aim to identify implementation target groups (i.e. segments) based on the patient-mix, provider and practice factors most strongly associated with screening (Aim 2). This project focuses on the upstream issue of screening because it is where there is a big initial barrier to care, and screening is the gateway to treatment. However, downstream treatment barriers are also critical. We aim to estimate how often no follow-up care occurs among patients with abnormal lab values and if barriers affecting screening also affect the likelihood of follow-up (Aim 3). To reach these aims, a unique and comprehensive dataset of Medicaid providers and patient claims data from the State of Missouri will be analyzed. These data will be combined with a survey of physician knowledge, attitudes and practice characteristics and with electronic medical record data from community mental health centers. For Aims 1 and 2, the primary outcome is baseline and annual glucose and lipid testing using laboratory claims. Analysis for Aim 1 uses multivariate models designed to measure the extent that the factors describe variation in screening tests. Results of Aim 1 will inform the selection of segmentation factors used in the Aim 2 cluster analysis. Split-sample validation will be used to assess the stability of the segments. For Aim 3, the analytic approach for Aim 1 will be used for the outcome of follow-up care (defined as a repeat lab test, primary care office visit, or initiation of a cholesterol-lowering or oral diabetes drug). An Advisory Board of public health stakeholders and academic experts in mental health and implementation sciences will advise the research team in interpreting the findings and selecting the implementation strategies to move forward into testing. Missouri Medicaid is a unique research environment to achieve this objective because a disproportionate number of adults with mental disorders receive care through Medicaid, the research team has an active collaboration with Missouri stakeholders, and significant interest exists within Missouri to apply the research learning to conduct a randomized intervention trial to test implementation strategies.

Project Narrative

Cardiovascular disease is the leading cause of reduced life expectancy for adults with mental disorders, and importantly, use of some antipsychotic medications contributes to increased cardiovascular risk. Diabetes and dyslipidemia screening in high-risk populations is clinically recommended and cost effective. The goal of this study is to identify the key physician and practice barriers affecting current low rates of glucose and lipid testing in mental health patients taking antipsychotics. We will determine how many patients receive appropriate follow-up care following screening and whether the screening barriers are also related to poor follow-up. Findings will be used to prioritize and target implementation strategies for improving screening and subsequent patient care.

SPECIFIC AIMS

Implementation strategies should be targeted to the specific needs of real-world provider-practice settings. Health system decision makers, policy makers, and accountable care organizations want to know which strategies will give them the "biggest bang for the buck" so that they may make wise use of limited funds. ***This application proposes to identify the most appropriate implementation strategies for improving diabetes and dyslipidemia screening for adults with mental disorders.*** 11 million adults suffer from serious mental illness (SMI) in the United States. Life expectancy can be two decades shorter in adults with SMI because of excess cardiovascular risk.[1] Medical guidance recommends heightened physical health monitoring for this at-risk population.[2] Moreover, an adverse drug effect of second-generation antipsychotics (SGA) – commonly prescribed to persons with SMI – is increased cardiovascular risk[3]. The American Diabetes Association recommends glucose and lipid testing at SGA drug initiation and regularly throughout treatment.[4] Despite this, research has shown severe under-screening in clinical practice. For example, baseline glucose and lipid testing rates averaged 20-30% and 10%.[5-8]

Research on barriers to metabolic screening in persons with mental disorders, particularly those taking SGA drugs, has primarily studied patient factors[7-9]. Research on provider-practice barriers has been qualitative[10] or small in scale[11, 12]. To address this gap and inform the selection of implementation strategies, we aim to:

Aim1: Determine the key provider and practice barriers to diabetes and dyslipidemia screening of adults with mental disorders initiating SGA drug therapy.

In order to strategically select the best implementation strategy(ies) (that is, interventions targeted and tailored to physician-practice populations of the greatest size), we also aim to:

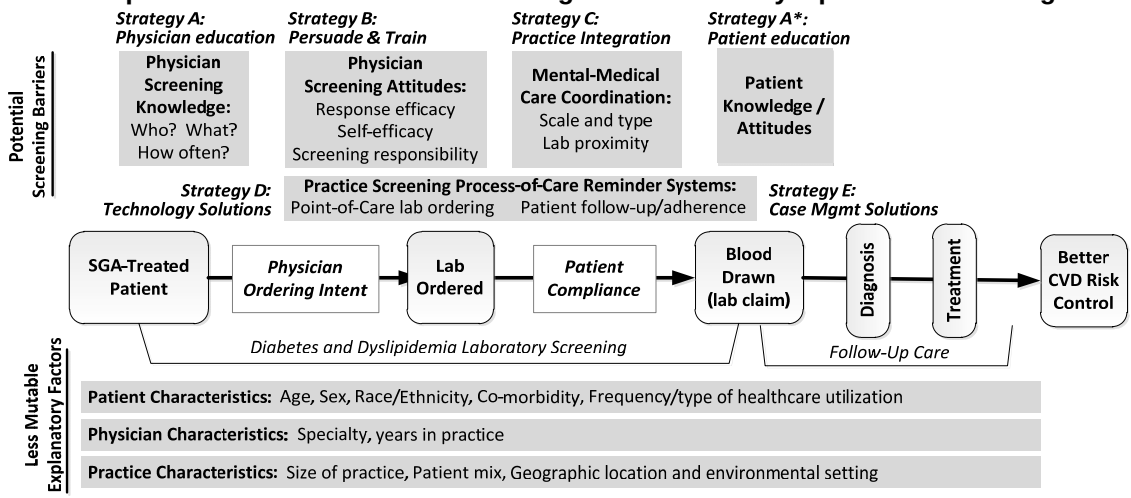
Aim 2: Identify implementation target groups (or 'market segments') based on the patient-mix, practice, and provider factors studied.

When trying to reduce CVD risk, it is important to first screen and then to treat. This project focuses on the upstream issue of screening because it is where there is a big initial barrier to care, and screening is the gateway to treatment. However, downstream treatment barriers are also critical. Importantly, interventions to improve screening may also help to improve systems affecting follow-up care. Therefore, we aim to:

Aim 3: Estimate how often no follow-up care occurs among patients with abnormal lab values and if barriers affecting screening are also associated with the likelihood of follow-up.

To reach these aims, we propose analyzing a unique and comprehensive dataset of Medicaid providers and patients from the State of Missouri. The majority of patients with SMI receive care in the Medicaid system[13]. Electronic claims and laboratory data will be combined with physician survey data on knowledge, attitudes, and clinical practice factors and Electronic Medical Record data from community mental health centers. Physician, practice, and patient factors affecting screening (with related implementation strategies) are shown in Figure 1.

Figure 1. Conceptual Framework: Factors Affecting Diabetes and Dyslipidemia Screening and Follow-Up Care



Our goal is to identify the best implementation strategy to test in a future R01 trial to improve diabetes and dyslipidemia risk management in adults with mental disorders. Our proposal is responsive to PAR-10-040 because it (1) is a theory-driven study of implementation barriers; (2) occurs within a relevant real-world practice setting; (3) involves interdisciplinary cooperation (public health, clinical, and social sciences); and (4) uses transdisciplinary methods from the field of marketing . We hope that our approach may provide a generalizable model to identify and prioritize target groups for other implementation efforts.

3. RESEARCH STRATEGY *Several elements of the diffusion of diabetes and dyslipidemia screening guidelines for taking second-generation antipsychotics (SGAs) make it an excellent case study of the need to target and prioritize screening interventions*. Metabolic risk information has been broadly disseminated over the last decade in the medical literature[3, 14-19], through warnings[20-22], recommendations[2, 4, 23, 24], newsletters[25-27], and continuing medical education[28-30]. Thus, a strong consensus about the need for screening exists. Psychiatrists have been the primary audience of the risk communication, yet non-psychiatrists prescribe >50% of new SGA prescriptions[8]. Their knowledge and attitudes about metabolic risks and screening are unknown. Continuity of care is also important because screening follow-up occurs in a physical health care setting. Several implementation solutions have been proposed[31], e.g., co-locating medical-behavioral health care delivery[32], audit-feedback systems[33], and screening fairs[34]. However, it is not known which barriers are the key drivers affecting low rates of screening and thereby which implementation strategies should be prioritized over others.

3.1 INNOVATION

We will apply market segmentation analytics to identify and prioritize intervention target groups for implementation research and practice[35, 36]. Market segmentation is the "process of partitioning markets into groups of potential customers with similar needs and/or characteristics who are likely to exhibit similar purchase behavior"[35]. In our case, our "customers" are health care providers and our "products" are metabolic screening interventions. Marketers know that it is impossible to pursue every product opportunity so strategic choices are made for maximum efficiency. Significant potential exists to apply this analytic framework to how we identify and prioritize provider-practice target groups (i.e., "segments) for implementation interventions.

Although segmentation methods are not new (i.e., cluster analysis), we believe this application of the marketing discipline to implementation sciences is innovative. The value of segmentation is two-fold. First, dividing the total provider-practice population into individual segments can offer insight into which segments may be successfully targeted based on ease of identification, feasibility to affect the barriers, and current resources. One particular segment may be so lucrative that policy makers may target that segment first even though there are others they could effectively affect, too. Second, related provider-practice attributes and barriers are grouped together so that we can be more synergistic in how we communicate and tailor the intervention – for example, what messages will more likely resonate with that particular segment[37-40].

We propose using a novel dataset of provider demographics, knowledge, attitudes and practice-setting factors for the segmentation analysis. Previous studies on barriers to screening in persons with mental disorders were either limited to patient factors[7-9] and clinical characteristics or psychiatrist self-reports of screening behavior[41, 42]. Data on physician-practice barriers have been qualitative[10] or small in scale[11, 12]. To our knowledge, the proposed study will be the first population-based dataset which integrates:

- Objective measures of metabolic lab testing, including lab values (source: Medicaid Claims)
- Physician knowledge and beliefs about screening (Source: Physician Survey)
- Practice data on care coordination and use of screening reminder systems (Source: Physician Survey)
- Office-based metabolic risk assessments and dates (Source: Community Mental Health Center EMR)
- Urbanicity and sociodemographic characteristics of the practice environment (Source: U.S. Census)
- Physician/practice (Source: AMI physician file) and patient–mix (Source: Medicaid Claims) characteristics

3.1 SIGNIFICANCE

Cardiovascular disease (CVD) is a leading cause of reduced life expectancy for adults with mental disorders, and importantly[43, 44] use of SGAs contributes to increased cardiovascular risk[3]. The U.S. prevalence of serious mental illness (SMI) is 4.8% (or ~11.0 million adults)[45]. Adults with mental disorders die 8 years sooner than the general population[46]. Among the most economically-disadvantaged, life expectancy is reduced by over two decades, primarily due to excess cardiovascular risk[1]. Obesity, hypertension, type 2 diabetes, and dyslipidemia prevalence rates are 1.5 to 2 times higher in adults with SMI[3, 47, 48], yet are under-diagnosed[48, 49] and under-treated[50]. SGAs (used for schizophrenia, bipolar disorder, depression, anxiety)[51-53] are among the Top 100 drugs prescribed[54]; their use increased from 6.2 million to 14.3 million treatment visits between 1995 and 2008[55]. However, SGAs carry FDA warnings for weight gain and risk for diabetes and dyslipidemia[56-58]. Better approaches for reducing CVD risk in patients with serious mental disorders, specifically SGA-treated patients, are priorities for NIMH (PA-08-029) and NIDDK (PA-08-160).

Diabetes and dyslipidemia screening in high-risk populations is cost effective Medical guidelines recommend increased physical health monitoring for adults with SMI[2]. The American Diabetes Association and American Psychiatric Association recommend fasting glucose and lipid testing at SGA drug initiation and

regularly throughout treatment[4]. Early and more frequent diabetes and dyslipidemia screening of high risk individuals is cost effective, and early intervention promotes better long-term outcomes [59-62].

Identification of the most efficient implementation strategy to improve diabetes and dyslipidemia screening in adults with mental disorders is urgently needed. Before policy decision makers and payers can determine how to allocate limited health care resources, we must know which provider groups will be amenable to which implementation strategies and which will affect the health of the most patients. The proposed segmentation analysis will provide strategic guidance for selecting the best implementation strategies for the population of providers and practices treating patients with SMI.

3.3 APPROACH

3.3.1 Preliminary studies. We have an established research collaboration with Missouri Medicaid (MO HealthNet) regarding metabolic screening[6, 9, 63]. The PI and co-investigators have published a series of studies examining glucose and lipid testing in SGA-treated patients using patient claims data from Medicaid[6, 9, 63, 64] and commercially-insured populations[5, 8]. Testing rates did not improve following FDA warnings and the ADA-APA recommendations[5, 6, 8]. Baseline glucose and lipid testing rates averaged 20-30% and 10%, respectively. In a multi-state Medicaid study, glucose and lipid testing among SGA-users varied significantly between states, counties, and by patient factors[9]. In this study, ***only 22% of glucose and 19% of lipid testing variation could be explained by patient factors alone.*** The proposed research assesses provider and practice factors and is a logical next step in this line of research to identify the most effective implementation strategies.

MOHealthNet is a unique public health-academic research laboratory for studying barriers to metabolic screening in adults with mental disorders. First, Medicaid is a highly relevant population. More adults with SMI receive their care in the public versus private health care sector[13]. MOHealthNet has a similar Medicaid demographic and health utilization profile as national Medicaid[65]. Moreover, up to 70% of antipsychotic prescriptions are written within the Medicaid system[66]. Lastly, there is significant public health interest within Missouri to improve metabolic risk management and willingness to conduct a randomize intervention trial to compare implementation strategies (see Letters of Support). Importantly, Missouri also meets scientific requirements for studying and prioritizing implementation strategies. There is both heterogeneity in testing rates across the state[9] and in clinical efforts affecting screening (e.g., co-location of medical and mental health services[67]; use of feedback and audit mechanisms[33], additional CME). Thus, we will have a range of screening rates and explanatory measures for our modeling.

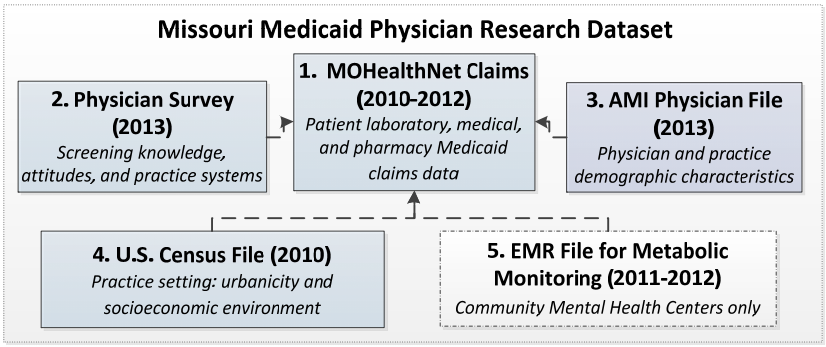
3.3.2 Key Personnel. The PI (Dr. Morrato) is an epidemiologist with expertise in mental health research and quality of diabetes and dyslipidemia screening and care [5, 6, 63, 68-72]. She is also a former product development manager in the consumer products industry with experience in market segmentation analysis and application. The team includes a biostatistician (Dr. Dickinson[73-75]) and health economist (Dr. Lindrooth[76-78]) with expertise in mental health research, physician survey analysis, and causal inference using secondary data; and a GIS expert to guide selection and harmonization of geospatial measures used in the analysis (Dr. Thomas[9, 79, 80]).

We will also institute an **Implementation Advisory Board** comprised of public health partners (Missouri and FDA's Safe Drug Use Initiative) and academic content experts. The Board will guide the research team at key milestones (see **Timeline**). It will help bridge findings from the proposed study to a future R01 intervention trial to compare the effectiveness of the proposed implementation strategy(ies) identified in this R21 project.

Public Health Partners	Academic Content Experts
Rhonda Driver, RPh (MOHealthNet)	James Dearing, PhD (dissemination/implementation sciences)[81-83]
Joe Parks, MD[84] (Dept. Mental Health)	Benjamin Druss, MD MPH (mental health policy and public health)[85-87]
Salma Lemtouni, MD MPH[88] (FDA)	Benjamin Miller, PhD (integrating mental health and primary care)[89, 90]
	John Newcomer, MD (antipsychotics and metabolic risk)[3, 41, 43]

3.3.3 Study Population. A cohort of physicians who wrote at least 6 SGA "new starts" for continuously enrolled Missouri Medicaid patients (21-64 yrs) will be selected. A "new start" is defined as a patient who had a first prescription claim (Rx) for an SGA drug (aripiprazole, iloperidone, olanzapine, paliperidone, quetiapine, risperidone, ziprasidone) but had no SGA Rx's in the previous year. The Index date is the date the first "new start" prescription was filled and serves as the anchor point for calculating "baseline" and "annual" rates[6]. We use 'new starts' because the ADA recommends ***all*** SGA-treated patients, regardless of the date of their mental health diagnosis, receive screening when starting SGAs[4]. A 'new user' design is recommended in the field of pharmacoepidemiology[91] because it ensures we have patients at a similar course of treatment. In Q1 2011, 3,831 providers prescribed SGAs to 41,902 patients.

3.3.4 Research Dataset and Data Collection. The Missouri Medicaid Physician Dataset will be comprised of 5 linked data files. One involves primary data collection (Physician Survey) and the other four are from secondary data sources.



1. MOHealthNet (Medicaid) claims data. The backbone of the dataset is the MOHealthNet Medicaid claims from which we will identify the physician cohort, primary outcome measures, and patient characteristics. The file includes all claims for outpatient and emergency department visits; inpatient discharges; drug prescriptions; and lab tests. Patient demographic characteristics (age, sex, race/ethnicity) and ICD-9 primary and secondary diagnosis codes to define comorbidities (including diabetes and cardiovascular disease) are available to use as patient-level controls (denoted X_i). Lab results are electronically available for about 60% of the lab claims (EMR file + lab vendors). The zipcode centroid of the patient's residence will be used to characterize the patient's socioeconomic environment and to calculate drive time to the street address of physician practices and lab sites. Three years of claims will be used (2010 – 2012). SGA new starts will accrue in 2011. "Looking back" 12 months, we will calculate baseline patient characteristics. "Looking forward" 12 months we will calculate testing rates after drug initiation. Claims will be merged with the provider survey using the provider information (name, address).

2. Physician survey data. The survey instrument (see **Appendix**) was developed using the conceptual model (Fig 1) and piloted with physicians. We will administer paper surveys via the U.S. Mail (a complete e-mail roster is lacking) to 3,500 SGA-prescribing physicians randomly selected from the pool of eligible Medicaid providers. We have completed another survey among providers in Missouri Community Mental Health Centers and achieved an 84% response rate. We followed a modified Dillman survey protocol[92] used by our research center[74]. We propose replicating the protocol to try to attain a similarly high response, i.e., cleaning the mailing list so it is current; sending a pre-notification letter with sponsorship from State leaders attesting to the value of the study, providing a $2 pre-incentive. Non-respondents are sent reminders every 3 days (up to 6 reminders total), then 2 final reminders at 1-week intervals, for a total span of 6 weeks.

3. American Medical Information (AMI) Physician data. The AMI file is a national database of physician listings from a variety of public sources including Internet/Yellow Page Directories, State Licensing information, and medical education directories. Physician and practice demographics (see 3.3.5) will be obtained from this file and linked to the MOHealthNet data using physician name, address, and licensure ID. InfoUSA, who sells the data, reports an 87% match rate from a similar administrative data linkage study. ***4. U.S. Census data (2010).*** Census-track data on urbanicity and employment/income and education levels will be linked with the Medicaid records using physical addresses to provide geographic context for the clinical setting. ***5. Electronic Medical Record (EMR) File for Metabolic Monitoring.*** The Missouri Dept. of Mental Health (DMH) requires all contracted Community Mental Health Centers (N=31) report quarterly on metabolic risk assessments. Dates and results for clinical vitals (e.g., BMI) and monitoring are available. These data will be used in a sub-analysis to determine rates and variation in patient compliance with provider screening orders.

3.3.5 Outcome Measures. LABORATORY TESTING (AIMS 1 AND 2): The PRIMARY outcome variable will be the occurrence of laboratory testing among "new SGA starts". Using medical claims data, we will assess baseline rates of testing (+/- 30 days from the Index date) in patients with >2 Rx's and annual follow-up (31-395 days from the Index date) in continuously enrolled patients[6]. CPT procedure codes will be used to identify glucose-specific or general health panel (in which serum glucose is a measure) testing and lipid-specific or lipid panel testing[5, 9]. Two SECONDARY measures of glucose and lipid screening will be evaluated: physician lab ordering intent(93) (source: Physician Survey) and patient adherence with laboratory orders (source: CMHC EMR file).

FOLLOW-UP CARE (AIM 3): Patients with abnormal lab values will be identified using thresholds from the National Heart, Lung, and Blood Institute[94] and American Diabetes Association[95]. Follow-up care will be defined as the occurrence of a medical claim for a repeat lab test and/or primary care office visit (defined by CPT codes) occurring within 90 days of the qualifying lab claim; or a pharmacy drug claim occurring in that same time window for a cholesterol-lowering or oral diabetes drug.

3.3.6 Explanatory Measures. Based on the conceptual framework (Fig 1), we will study four physician-practice domains hypothesized to affect screening rates. Table 1 describes the measures and related inter-

vention strategies. With the exception of the lab proximity measure (which will be derived from the geocoded Medicaid data), these primary explanatory measures will be drawn from the physician survey. (See the Survey Appendix for specific questions corresponding to each domain.)

Table 1. Explanatory variable domains and related implementation strategies

Domain		Parameter	Available Implementation Strategies
Knowledge(96, 97)	$Know_j$	Who should receive testing. How often should testing be performed?	Continuing Medication Education[98] Academic detailing[99, 100]
Attitudes(96, 97, 101-106)	$Attitude_j$	Self-efficacy Response efficacy Screening responsibility Perceived screening barriers	Physician training[107-109] Screening health fairs[34] Policy (e.g., Pay-for-Performance)[110]
Coordination of Care(111)	$Coord_j$	Structure of care Lab proximity	Physical-behavioral health co-location[112] Health Information Exchanges[113]
Practice Systems(114)	$Pract_k$	Point-of-care screening reminders Patient adherence/follow-up systems	EHR adoption/meaningful use[115] Feedback/audit mechanisms[33, 116, 117] Patient navigator[118, 119]

The analysis will be adjusted for other less-mutable **DEMOGRAPHIC CHARACTERISTICS** associated with metabolic screening in adults with mental disorders and/or with diffusion of physician behaviors: Patient [29,45] (age, sex, race/ethnicity, co-morbidity, healthcare utilization[9, 64]; source: Medicaid claims); Physician[97] (specialty, years in practice; source AMI File and physician survey); and Practice[9, 97] (size of practice, patient mix, geographic location and environment; source: AMI and Census Files).

3.3.7 Analysis Plan. The analysis for Aim 1 is based on multivariate models designed to measure the extent that the hypothesized domains describe variation in screening tests. The selection of physician and practice barriers that guide the Aim 2 market segmentation analysis will be informed by the results of the Aim 1 with input from our Advisory Board. The Aim 2 segmentation analysis will define clusters of related provider and practice attributes associated with low rates of testing. We will assess the validity of the Aim 2 results by testing how well the market segments predict screening rates using a sample of physicians who did not respond to the survey. The analysis for Aim 3 will determine the magnitude of the gap in follow-up care for patients with clinically high lab values and the degree to which the screening barriers are also associated with the gap in follow-up care. From there, we will identify the optimal intervention strategy.

***Specific Aim 1 (Provider and Practice Factors)*:** Multivariable regression models, employing primary and secondary screening outcome measures, will be used to test the following hypotheses:

Hypothesis 1:	*Physician knowledge ($know_j$) of screening recommendations…*	*… is/are positively associated with glucose and lipid testing.*
Hypothesis 2:	*Physician attitudes ($attitude_j$) about the benefits of screening (response efficacy), ability to screen (self-efficacy), and screening responsibility.…*	
Hypothesis 3:	*Type of mental-medical care coordination present in the practice and geographic proximity between the practice and the lab ($coord_j$) …*	
Hypothesis 4:	*Use of practice-level process-of-care systems for metabolic screening reminders and patient follow-up ($pract_j$)…*	

PRIMARY OUTCOMES: The primary outcomes will be modeled separately as the probability of the lab claim using a logistic regression model. The general model specification for each i^{th} patient being prescribed SGA medication by each j^{th} physician in practice *p* is shown in Equation 1:

$$Pr\ (test_{ijp}=1) = f(know_j, attitude_j, coord_{ij}, pract_j, X_{ijp}, Y_{ip}, Z_p, \alpha_j, \gamma_p) \quad (1)$$

where $know_j$, $attitude_j$, $coord_{ij}$, $pract_j$ are the domains described in Table 1; the control variables include the patient (X), physician (*Y*), and practice (Z) characteristics described in Section 3.3.4. We allow for unobserved physician, and practice characteristics denoted α_j, *and* γ_r, respectively. Note that $know_j$, $attitude_j$, and $pract_j$ are measured using the physician survey and thus there is no physician-level variation. Elements of $coord_{ij}$ will vary by practice (e.g. proximity of a lab to a physician's office). We expect physicians to be largely nested within a practice, although we do not know this *a priori*. We describe our methods below as though physicians are nested within practices and specify α_{jp} to represent physician *j* in practice *p*. If physicians practice at many sites to a large enough extent we could use physician fixed effects in our identification of the effect $coord_{ij}$.

According to the guidelines all patients should be directed to be tested and if we had access to the EMR of all patients we would not need to control for patient characteristics given our focus on the recommendations. However, as is common in studies using claims data we only observe whether a test was performed. The first

stage of a mixed effects model will control for patient characteristics in order to adjust for patient compliance and other patient-level variation (e.g. comorbidities) in the probability of a test: $Pr\ (test_{ijp}=1) = X_{ijp}\beta + \alpha_{jp},$ (1a)

The parameters in the vector β will be informative in that we can tell how patient characteristics affect the joint probability of being prescribed a test and getting it filled. X also contains a dummy variable that measures the quarter of the SGA start to control for contemporaneous trends. We will also create a dummy variable that identifies the counties affected by the Spring 2011 weather disasters and interact it with the quarter dummy variables. The physician fixed effect, $\alpha_{jp,}$, is the physician's rate of testing adjusted for patient mix. This fixed effect is modeled as a function of physician and practice characteristics:

$$\hat{\alpha}_{jp} = \beta_1 know_{jp} + \beta_2 attitude_{jp} + \beta_3 coord_{jp} + \beta_4 pract_{jp} + \beta_5 Y_{jp} + \beta_6 Z_p + \gamma_p + \varepsilon_{jp} \quad (2)$$

The above hypotheses can be tested using tests of the significance of the parameter estimates, β_1- β_4. The specification of γ_r will depend upon the extent physicians are nested within practices and the number of physicians per practice. We will be guided by a Bruesch-Pagan Lagrange multiplier test of the significance of γ_r modeled as a random effect[120]. The specification of fixed vs. random effects will be chosen using a Hausman test[121]. Robust standard errors will be used for hypothesis tests controlling for heteroskedasticity[122, 123].

SECONDARY OUTCOMES: The secondary outcomes are *Prescribing Intent* from the physician survey, and *Patient Compliance* from the CMHC sub sample. The former is a physician level variable and will not require patient-level controls. Thus a specification based Equation 2 that replaces α_{jp} with *Prescribing Intent* will be estimated. Prescribing Intent will be modeled using an ordered logistic regression consistent with the levels of response in the survey. Patient Compliance will be modeled at the patient level using the specification in Equation 1a. We will compare the coefficients from the *Patient Compliance* regression with the coefficients from the Stage 1 regression with the primary outcome to better understand the role of patient compliance in explaining the variation in test rates. Due to the smaller sample of CMHCs, this sub-analysis should be considered exploratory. However, it will give us an indication of what factors affect patient compliance and the extent that patient compliance is an issue warranting a patient-focused intervention.

METHODOLOGICAL CONSIDERATIONS: First, it is possible that there are cases where either 100% or 0% of a physician's patients completed a test. Thus the physician fixed effect in Equation 1 would be a perfect predictor of failure or success. If we find perfect predictors we will calculate the fixed effects using a linear probability model. Alternatively, we can estimate Equation 1 directly and specify $\alpha_{jp,}$ as a random effect and test whether it is endogenous using a Hausman test[121]. Second, Equations 1 and 2 can be estimated jointly though with the logistic first stage there may be convergence problems. Consistent, though less efficient, parameter estimates can be obtained by estimating the stages separately. Third, there may be sample selection bias related to survey response. Equation 2 can be estimated using a Heckman (1979) sample selection model[124]. We propose using the indicator variable of whether the doctor responded to other survey questions compiled by AMI as an IV (propensity to respond to any survey) to identify the selection model.

Specific Aim 2: Identification and Prioritization of Target Groups: We will perform a market segmentation analysis to identify which clusters of physician and practice characteristics are associated with low rates of testing. We can then identify target groups that are suitable for a specific implementation strategy based on the relationships in Table 1. The analysis will be conducted to ensure out-of-sample validity such that physicians and practices can be appropriately targeted without the need of a survey. Because segmentation is sensitive to multicollinearity, we want to eliminate excessive redundancy in the survey responses (basis variables) used in the analysis. We also want to use variables that are strongly correlated with testing behavior. To accomplish this, we will estimate a version of Equation 2 that excludes Y_{ip}, Z_p *and* γ_r to inform the selection of a parsimonious set of survey responses within $know_j$, $attitude_j$, $coord_{ij}$, and $pract_j$ as the starting point of the segmentation analysis. **TWO-STAGE PARTITION CLUSTERING**[36]. In stage 1, hierarchical clustering will be performed to identify good starting seeds (cluster centroid) for the stage 2 k-means iterative partition clustering[36]. Hierarchical clustering identifies pairs, and then clusters, of physicians who are most similar in their responses to all basis variables. This approach identifies locations of highest density of respondents in the spatial matrix of all possible responses. Designating the hierarchical cluster each respondent belongs to will in effect provide the initial partitioning of the sample. In stage 2, successive iterations comparing individual respondent distance to each cluster centroid will be performed to move physicians back and forth between the clusters until maximum homogeneity within clusters is obtained. We will compare solutions for model specification using 2-8 clusters, a typical market segmentation range[36, 125]. **VALIDATION**. The robustness and validity of the clusters will be assessed using (1) statistical testing between clusters for all basis variables; and (2) visual inspection of the clustering plots and basis variable profiles[36]. To assess the stability of the segmentation results, the sample will be split in half randomly, and identical

clustering performed on each half. If the composition of clusters in the two solutions is similar, there is greater confidence in the results. Glucose and lipid testing will be modeled independently to compare effects on clustering. To assess out of sample validity when survey responses are unavailable, we will construct receiver-operating-characteristic curves using commonly observable demographics to predict segment membership; the incremental value of using added factors will be measured by the C statistic[126, 127]. To validate the power of the clusters to predict screening behavior, we will use the best set of demographic factors from the out of sample validation to segment physicians who did not respond to the survey. Then we will compare summary statistics of glucose and lipid testing rates between these segments. Lastly, the Advisory Board will review all results to assess the face-validity of the findings[35] and to discuss which implementation strategy(ies) are most appropriate for which segments and whether the target groups are large enough to practically pursue.

Specific Aim 3: Follow-Up Care Factors. We will employ the same analytic approach as in Aim 1. First, we will estimate the proportion of patients with lab testing and high glucose or lipid lab values. Then we will identify the proportion that has follow-up care (defined in Section 3.3.5). Outcomes will be modeled as the probability of follow-up care using a sequential nested multivariate logistic regression model (See Eqn 1)[128].

Sample Size and Power Calculations. **PHYSICIAN SAMPLE.** Missouri Medicaid data indicate >3500 physicians prescribe SGAs (~700 psychiatrists; ~2800 non-psychiatrists). We estimate 700 psychiatrists (100%) and 2100 non-psychiatrists (75%) write new starts and are study eligible. Using previous SGA claims data and if we assume a 70% survey response rate, then we estimate a sample size of 490 psychiatrists and 1470 non-psychiatrist physicians (total 1960) will yield 23,520 new starts (average:12 patients/physician). **ESTIMATED POWER: AIM 1: PATIENT-LEVEL OUTCOME (E.G., HYPOTHESIS 1.1)**. Based on prior work[9], we assume a relatively higher intraclass correlation (ICC=50%). Assuming half of the physicians are knowledgeable about screening guidelines, this sample size will provide 85% power (α=.05) to detect a 5% difference between physicians who do and don't know about screening guidelines, conservatively assuming the testing rate in one group is 50% (maximum variability). Power will be similar for other hypotheses with patient-level outcomes. **AIM 1: PHYSICIAN-LEVEL OUTCOME**. For the physician lab ordering intent outcomes from the physician survey and assuming half are positive on the explanatory variable of interest, a sample size of 1960 physicians will provide 87% power to detect a 6% difference between groups. **AIM 2: SEGMENTATION ANALYSIS***:* Post-hoc segmentation studies should have at least 1000 respondents for confidence in the results[36]. Conservatively, we should exceed that threshold. **AIM 3: FOLLOW-UP***:* Assuming 30% of patients are tested (n=7056 based on a 70% initial response rate from physicians), we estimate that 60% of those tested will have electronic lab results (n=4233). Of those with a test result, if 20% have an abnormal outcome this will provide a sample size of 846 to test this hypothesis. This sample size will provide >80% power (α=.05) to detect a 10% difference between follow-up rates between two equal-sized patient groups defined by a characteristic of interest, conservatively assuming the follow-up rate in one group is 50% (maximum variability).

3.3.8 Research Limitations. Glucose and lipid screening of high-risk patients is a necessary (but not sufficient) step to improve cardiovascular outcomes. In this study, we also explore the degree to which screening barriers are associated with a lack of follow-up care and treatment. Barriers to life-style changes (e.g. diet/exercise) are also important, but beyond the scope of this R21. We focused on physicians in this study given data availability, but future research may involve other health providers and patients (if adherence is a key barrier).

	Tasks	Year 1 Q1	Year 1 Q2	Year 1 Q3	Year 1 Q4	Year 2 Q1	Year 2 Q2	Year 2 Q3	Year 2 Q4
Data Collection	Physician survey	Field							
	MOHealthNet		Receive	Link					
	Secondary data: AMI &Census		Receive						
Data Analysis	Descriptive analysis								
	Aim 1: physician-practice factors								
	Aim 2: segmentation- target groups								
	Aim 3: follow-up care								
Trans-lation	Advisory Board Meetings	Phone		Person			Phone		Person
	Manuscript submission				Survey			Aims 1&2	Aim 3
	Target groups prioritized								

3.3.9 Project Timeline

Semi-annual meetings with the Advisory Board will occur at key points: (1) Kick-off and review of survey before administration; (2) Review of the survey results and variable selection for Aims 1 and 2; (3) Review of results for Aims 1 and 2 and modeling considerations for Aim 3; and (4) Review of results for Aim 3. At the last meeting, recommendations will be made for selecting the implementation intervention based on the totality of the findings from Aims 1, 2, and 3.

Protection of Human Subjects

Risks to Human Subjects

This research will be undertaken with the strictest procedures in place to assure the safety, anonymity, and confidentiality of the human subjects involved. The research protocol will be reviewed by the Colorado Multiple Institutional Review Board (COMIRB), the body that governs human subjects research at the University of Colorado Denver. The study team has previously obtained expedited COMIRB approval for multiple administrative dataset and health outcomes research projects. The study methods for the current proposal (including analysis of Medicaid claims data and physician survey responses and the integration of the data with other publicly-available secondary databases to investigate U.S. census and practice characterisitcs) are similar to methods used in the prior IRB-approved protocols directed by Dr. Morrato and her study team.

A. Human Subjects Involvement, Characteristics, and Design

Design: The research project uses a mixed methods study design.

- Survey methods will be used to ascertain practice factors and physician attitudes and behaviors regarding metabolic screening practices for patients with mental illness receiving antipsychotic medication.
- A retrospective cohort study will be used to the determine the average diabetes and dyslipidemia screening rates for each surveyed physician using Medicaid claims data and electronic medical record data.

Using the collected data, multivariate models will be performed to measure the extent that physician and practice factors describe variation in screening tests. A market segmentation analysis will be performed to identify which clusters of physician and practice characteristics are associated with low rates of testing.

Human Subject Involvement: There are two groups of human subjects involved.

- ***Antipsychotic-prescribing physicians*** who prescribe antipsychotic medications to Medicaid beneficiaries in the state of Missouri. 3,500 physicians will be given information on the study and asked to provide consent to their participation. Study information will include how their survey responses will be linked to the other datasets for analysis and that only aggregate, de-identified data will be reported.
- ***Missouri Medicaid patients*** with a new start of second-generation antipsychotic (SGA) medication and whose Medicaid claims data will be used to calculate average diabetes and dyslipidemia screening rates for each participating physician. Patient records from a limited medical record dataset of metabolic screening in Community Mental Health Centers will also be studied. We estimate 13,440 patients will meet the new start definition and be linked to the practices of the physician survey respondents. Because the data are de-identified, it is not feasible to obtain informed consent from patients for whom we are analyzing their prescription and metabolic testing claims. Only anonymous aggregate patient data will be reported.

Human Subject Characteristics:

- The ***physicians*** are licensed to practice medicine in the State of Missouri and are Missouri Medicaid providers. As such, they have agreed that their medical and pharmacy claims data may be reviewed by the Missouri drug utilization review board to monitor drug usage and prescribing practices in the Medicaid program. The drug utilization review board is established by national mandate. It provides for educational outreach programs to educate practitioners on common drug therapy problems with the aim of improving prescribing and dispensing practices. The drug utilization review board may provide advice on guidelines, policies, and procedures necessary to maintain the safe and effective use of prescription medicines that the Missouri Rx plan covers.

- While ***Missouri Medicaid patients*** may be considered a vulnerable population, it is a highly relevant study population for the proposed research. A disproportionate number of adults with mental disorders receive their care in the public versus private health care sector. Up to 70% of antipsychotic prescriptions are written in the Medicaid system. MOHealthNet is similar to national Medicaid norms in terms of demographics and health care utilization. As described above, we are collecting only existing de-identified patient-level. There is no increased risk to study participation for individuals institutionalized or incarcerated. Identification of which individuals are institutionalized or incarcerated will also be not possible in the data set we will receive.

B. Sources of Materials

The proposed human subject dataset for this study will be comprised of ***5 linked data files***. One involves primary data collection, and four involve existing secondary data. These datasets will be linked together using identification data on the prescriber (name, practice address). Only key research team personnel, monitored by Dr. Morrato (PI), will have access to physician identifiers for linking purposes. Once the process of linking the data with the publicly available data sources is complete, the physician identifiers will be destroyed.

1. Physician survey data on attitudes and behaviors regarding metabolic screening for adult patients with mental illness receiving antipsychotic medication – Primary data collection.

   Paper surveys mailed through the U.S. Postal Service will be used to collect the data.

2. De-identified patient-level Missouri Medicaid claims data (MOHealthNet) – Existing data

   Claims data from Missouri Medicaid (MOHealthNet) will be provided by Care Management Technologies (CMT), Missouri's data vendor, and will include patient data, *without* direct identifiers such as names, for persons enrolled in the Medicaid program, including medical and pharmacy claims and eligibility files. Data files will also include physician data *with* direct identifiers, such as name, address and prescribing DEA code for linking purposes.

   The Medicaid claims file will provide the following data: physician identification/address; patient Medicaid enrollment, demographic characteristics (age, sex, race, ethnicity); geographic location (county, zipcode); medical claims, including office and emergency department visits (diagnosis and procedure codes, date of service); pharmacy claims (drug name, prescription fill date); and hospitalization claims (admission date, diagnosis related groups). Claims will be geocoded using the zipcode centroid for patients and street address for physician practices and laboratory sites.

   Laboratory results are also electronically available from one lab vendor (estimated to represent 7% of lab claims).

   The state Medicaid enrollment and claims data may be shipped to the CMT data team as either (a) SAS data sets, (b) raw fixed field or delimited text or (c) Access database tables via a carrier that provides tracking numbers. Hard disk drives are the preferred shipping medium, but DVDs may be appropriate in some circumstances. Alternatively, CMT may ship data to the University of Colorado Denver using a similar protocol as above, or through a secure electronic transfer. In an electronic transfer, the data will be deposited directly into the research server in the University of Colorado Denver from the Missouri site through a secure transfer so that the digital files. The Colorado research server can be securely accessed remotely utilizing Citrix client; the server is HIPAA compliant, is backed up daily, and connects to the university Internet backbone with a fiber optic connection.

   The University of Colorado Denver will operate under a data use agreement with the State of Missouri while it stores and analyzes the MOHealthNet data.

3. De-identified patient-level metabolic monitoring data from the Missouri Department of Mental Health's electronic medical record (EMR-Lite) file collected quarterly from its Community Mental Health Centers – Existing data

Data include dates of clinic visits, vitals taken (height, weight, BMI) and cardiometabolic monitoring for blood pressure, glucose, and lipids. Lab results are also available in this dataset. Approximately, 55% of Medicaid clients starting an antipsychotic medication receive care through a Community Mental Health Center.

4. Physician and practice characteristics from the national database, American Medical Information (AMI) Physician File - Existing data

   Data from this public physician file include: physician gender, primary/secondary specialty, type of practice, group practice size, and age and year of medical school graduation (to derive years in practice).

5. U.S. Census data on urbanicity and socioeconomic characteristics of the physician's practice environment – Existing data

Data Management and Protection:

The study dataset will be stored on the server at the University of Colorado Outcomes Research (COHO) Program. Data uploads will be on the secure production servers, which are accessible only to key personnel, who are under the direction of Dr. Morrato and will be monitored regularly. The database management is built with multiple layers of security and follows best practices and University of Colorado School of Medicine requirements for securing sensitive data. The main levels of security include:

- Project computers are all password protected, are protected by the University of Colorado firewall, and are in locked offices within a building having limited, electronic passkey access. Data will not be accessible to the Internet or contained on laptop computers.
- Password protection will be used in additional places at the server and web portal levels for all transactions that allow entry and editing of data, provide access to sensitive subject data or administrative privileges. Passwords will be managed to require all users to change their password within 90 days and strict rules will be implemented to require strong passwords.
- All data hosted on the server will be limited to PIs and key members of the research team. Prior to receiving server access, researchers must demonstrate completion of HIPAA training and abide by security procedures developed by the IT staff at the University of Colorado School of Medicine.
- The production servers at the University of Colorado Children's Outcomes Research Program facility will be housed in a dedicated computer machine room containing emergency backup power, a UPS, a non-liquid fire suppression system and authorization-based limited access. The computer and corresponding disk storage will be locked in a computer cabinet within the computer room with keys to the server and rack only distributed to key personnel under the supervision of Dr. Morrato.
- According to industry best practices, all software services and corresponding ports on the servers that are known to be substantial security risks and which are not used by the project data management resources will be disabled, including telnet, ftp, r* commands and sendmail. Furthermore, all databases will reside behind industry-strength Firewalls.
- Individually identifiable or deducible data will not be transmitted by unsecured telecommunications, which include the Internet, email, and electronic File Transfer Protocol (FTP).

C. Potential Risks

Anticipated Risks. Data confidentiality and loss of privacy are the primary risks to subjects in this study.

For patients, the potential harm is social or psychological harm resulting from public release of individual protected health information.

For physicians, the potential harm is social and possibly financial harm resulting from public release of information about medical provider opinions and their clinical practices (from the medical claims and

patient record data). It is necessary to obtain identifying physician information in order to link survey responses, provider characteristic data and to derive variables such as patient travel time. We have described the fact that we will be combining survey results with MO HealthNet claims and other publicly available data from the U.S. Census and AMA records to help us identify the most important barriers to screening in the setting in which they practice. We explain that all identifying information will be stripped from the data when they are presented. However, participation is voluntary and if a physician is uncomfortable with how we plan to combine the datasets, they have the right to opt out from the survey in total or in part for specific questions.

Moreover, Rhonda Drive (Director of Pharmacy, MO HealthNet Division) is on the Implementation Advisory Board for this study. She is also on the Missouri drug utilization review board, which is responsible for reviewing physician prescribing and drug-related monitoring practices. She will help us ensure that the risks to physicians in this study (resulting from analyzing linked survey data with medical claims and record data) will be no different than current risks posed through the normal drug utilization review process.

Plan to Minimize Risk.

For patients, the study team will receive de-identified patient data for analysis; therefore, the likelihood of loss of data confidentiality and privacy is uncommon.

For physicians, the prescriber identified information will be destroyed after linking the data files and the working data set will be converted to de-identified physician information. Therefore, the likelihood of the release of private and confidential information about the provider is also uncommon.

To further ensure the privacy and confidentiality of data for this project we will store and use the identifiable data on the server at the University of Colorado Outcomes Research (COHO) Program. Data uploads will be on the secure production servers, which are accessible only to key personnel, who are under the direction of Dr. Morrato and will be monitored regularly. The database management is built with multiple layers of security and follows best practices and University of Colorado School of Medicine requirements for securing sensitive data. See section Data Management and Protection (above) for a description of the main levels of security.

The electronic data files for this study will be processed on this dedicated, layered-security system, which can be accessed only by the PI, Dr. Morrato, and designated project staff that are under the direct supervision of the PI. Since the system is behind multiple firewalls, is monitored regularly, and is accessible only to key personnel, the risk of unlawful penetration is not a significant data safeguard concern. In the event of any real or suspected breach of confidentiality or security (e.g., loss of data disk, violation of password-protection, etc.), the party discovering such breach will immediately (within 48 hours) notify the PI.

D. Potential Benefits of the Proposed Research to Human Subjects and Others

The study is likely to yield generalizable knowledge to further society's understanding of the barriers that are the key bottlenecks influencing the implementation of recommended diabetes and dyslipidemia screening for adults with mental disorders taking second-generation antipsychotic (SGA) medication.

There is no direct benefit to the patient subjects and minimal risk of loss of privacy for the patient subjects in this research project. Therefore, the risks are reasonable in relation to the anticipated benefits to society and the importance of the knowledge that may reasonably be expected to result from the data analysis.

There is no direct benefit to the physician subjects and minimal risk of loss of privacy for the physician subjects in this research project. Therefore, the risks are reasonable in relation to the anticipated benefits to society and the importance of the knowledge that may reasonably be expected to result from the data analysis.

Importance of the Knowledge to be Gained. The main outcome from this study will be general scientific, non-clinical knowledge in which there is no direct benefit to the patients or the physicians. The primary findings will inform clinicians, policy makers and payers about cardiometabolic screening barriers and potential implementation strategies for improvement within a state Medicaid system.

Cardiovascular disease is the major cause of shorter life expectancy for people with mental illness. Diabetes and dyslipidemia significantly increase a person's risk for cardiovascular disease. Second-generation antipsychotic medication, commonly taken by persons with mental illness, also independently increases the risk for diabetes and dyslipidemia. Medical guidelines recommend that persons with mental illness (especially those receiving antipsychotic medication) should have blood glucose and lipids measured regularly. Several studies have shown that actual rates of screening are significantly lower than recommended.

To our knowledge, our study will be the first in the United States to systematically assess provider and practice barriers for why mental health patients are not getting tested as often as they should. Different screening barriers dictate different intervention strategies. In a resource-constrained environment, it is vital that implementation strategies be targeted to the specific needs of a given provider-practice setting and target groups are strategically prioritized. The knowledge gained from this study will help identify key bottlenecks against which to select the most efficient and effective implementation strategies.

E. Data and Safety Monitoring Plan

Per NIH guidelines, we do not need to create a data and safety monitoring plan for this study since it is not a clinical trial design. We will, however, be governed by our local Institutional Review Board policies and procedures for the method and frequency of data and safety monitoring for all research conducted by UCD faculty and staff. Breach of confidentiality is a reportable Unanticipated Problem (UAP). The PI, Dr. Morrato, will be responsible for monitoring this study. All UAPs will be reported in accordance with current COMIRB policy using the electronic forms available within their online protocol manager system.

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