

## The Medication Metronome Project Final Progress Report

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**Abstract** (max 250 words)

**Purpose:** To develop and examine the clinical impact of a novel health information technology (IT) tool designed to facilitate between-visit ordering and tracking of future laboratory testing.

**Scope:** Lack of timely medication intensification and inadequate medication safety monitoring are prevalent and potentially modifiable barriers to effective and safe chronic care. Innovative health IT applications may better support chronic disease management.

**Methods:** Clinical trial randomized at the provider level (n = 44 primary care physicians); patient-level outcomes among 3655 patients prescribed 5454 oral medicines for hyperlipidemia, diabetes, and/or hypertension management over a 12-month period. Main outcome measures included: time from prescription to corresponding follow-up laboratory test; proportion of follow-up time that patients achieved corresponding risk factor control (A1c, LDL); adverse event laboratory monitoring 4 weeks after medication prescription.

**Results:** Patients whose physicians were allocated to the intervention (n = 1143) had earlier LDL laboratory assessment compared to similar patients (n = 703) of control physicians (adjusted Hazard Ratio (aHR): 1.15 [1.01-1.32], p 0.04). Among patients with elevated baseline LDL levels (486 intervention, 324 control), there was decreased time to LDL goal among those in the intervention group (aHR 1.26 [0.99-1.62]). However, for the overall study period there were no significant differences between study arms in time spent at LDL or HbA1c goal. Follow-up laboratory safety monitoring was infrequently performed (7-29% at 4 weeks) and not statistically different between study arms.

Intervention physician surveys indicated that lack of reimbursement for non-visit based care was a barrier to use of the tool.

**Key Words:** primary care, health information technology, diabetes, hypertension, hyperlipidemia, randomized controlled trial

## **PURPOSE:**

The original grant application had the following specific aims:

Specific Aim 1: To develop the Medication Metronome system. This work will involve both health IT development and qualitative evaluation of design prototypes with both providers and patients to create a system that supports timely medication intensification, improves safety, and meets both patient and provider needs.

Specific Aim 2: To conduct a randomized controlled trial of the Medication Metronome system. We will use three target chronic conditions (diabetes, hypertension, hyperlipidemia) to test different elements of the system.

Specific Aim 3: To evaluate the impact of the Medication Metronome visit-independent care model on both the frequency and content of office-based visits. Time spent addressing different clinical care domains will be assessed using audiotape-based content analysis in a subset of selected office visits.

In summary, we proposed to develop, implement, and rigorously evaluate a health IT-supported model of visit-independent medication management designed to enable safer and more effective chronic disease care. We also sought to carefully investigate the impact of this system on primary care visits. The broader goal of this work was to support health delivery redesign that fosters patient-centered primary care by combining visit-independent medication management with more productive visit-based patient-provider interactions.

## **SCOPE:**

### **Background:**

A major goal of primary care is to prevent the morbidity and mortality associated with common chronic diseases such as hypertension, type 2 diabetes, and hyperlipidemia. However, national and local data indicate that we are falling well short of treatment goals for these three conditions, both in terms of risk factor control and of monitoring for associated adverse drug events (ADEs). Although there are many contributors to sub-optimal care, lack of timely medication intensification and inadequate safety monitoring among patients taking prescription medications have been identified as two prevalent and potentially modifiable barriers to effective and safe chronic care.

The U.S. primary care system was initially designed to manage acute complaints via episodic, visit-based care and is currently not well-suited to longitudinal chronic disease management, particularly for conditions that require medication initiation, monitoring, and iterative dose titration to achieve risk factor control. As our health care system begins the transition to electronic health records (EHRs), advances in health information technology (IT) now offer the opportunity to develop and rigorously evaluate new models of primary care.

### **Context:**

In this project, we implemented a visit-independent medication management system to augment visit-based clinical work. This model required that primary care providers (PCPs) were willing to: 1) make medication changes without the patient physically present, and 2) review lists of their

own patients and make clinical decisions based on available electronic data. Prior work done by our group demonstrated that PCPs were willing to start or change statin therapy between office visits after receiving content-rich email that allowed one-click order writing (Lester et al, J Gen Intern Med, 2006, 21(1): 22-9). This one-time intervention reduced the median interval to first hyperlipidemia regimen adjustment by more than a half year among intervention patients. Additionally, among patients with poorly controlled LDL, the first post-intervention LDL levels were substantially lower in the intervention group. In the Medication Metronome project, we expanded this proof-of-concept study to make the process iterative, embed the actionable component within the electronic medication management section of the electronic health record, expand medication management to include safety monitoring, and apply the concept to a wider range of chronic conditions.

Local clinical data prior to this project indicated that the current model of relying on office visits to trigger medication management changes is inefficient, and that providers have independently established range of imperfect strategies to address the perceived need for systematic monitoring of chronic medications. We reviewed all scheduled appointments in 2008 among all patients over 50 years of age and for patients with diabetes in our network's largest primary care practice. For both groups, fewer than two-thirds of planned visits actually occurred. One-quarter of all visits were cancelled by the patient, while the remaining visits were either cancelled by the provider (6%) or the patient "no-showed." These data provide strong empiric evidence from our health system that: 1) relying solely on planned visits as the primary method for organizing sequential changes in care is likely to be inefficient since more than one-third of these visits are delayed or cancelled, and 2) there is substantial opportunity for a visit-independent system to optimize the cycle time for iterative medication dose adjustment.

In this study, we tested a model of chronic disease medication management in which the decision to initiate or adjust medical therapy was directly linked to a sequence of subsequent clinical actions (e.g., monitoring for ADEs, assessing response to therapy, changing medication dose) performed independently of the office visit. We hypothesized that establishing a visit-independent, health IT-supported cycle of laboratory monitoring and iterative medication dose adjustment would result in more effective and safe chronic disease care.

### **Setting:**

Two primary care practices within the Massachusetts General Primary Care Practice-Based Research Network (MGPC-PBRN) participated. Each practice utilized an electronic health record with an electronic medication management interface. The larger participating practice was Internal Medicine Associates (IMA), which is located on the main Massachusetts General Hospital campus in Boston. The IMA practice has 46 PCPs and cares for over 30,000 patients, of which 34% are >65 years of age, 82% are Caucasian, 65% have commercial insurance and 26% have Medicare insurance. The smaller participating practice was North End Waterfront Health, which is located on Hanover Street in Boston's North End neighborhood. This community health center had 6 PCPs and cares for over 8000 patients, of which 10% are >6 years of age, 86% are Caucasian, 82% have commercial health insurance and 8% have Medicare insurance.

### **Participants:**

**Specific Aim 1:** Focus groups involved primary care providers and practice leaders from the Massachusetts General Hospital (MGH) Primary Care Operations Improvement (PCOI) Advisory Board. The PCOI program has a goal of improving the quality of care for common primary care problems and to enhance cost-effective health promotion and evidence-based disease prevention activities in MGH practices. The PCOI Advisory Board was created in 2000 to provide a mechanism for feedback from MGH primary care practices (especially community-based ones). The PCOI Advisory Board consists of providers and practice leaders (PCPs, registered nurses, and nurse practitioners) and is an important mechanism for obtaining research-related advice from community providers and for implementing and sustaining research innovations.

**Specific Aim 2:** The two practices in the study included 5 PCPs practicing either full or part time. Of the 5 PCPs invited, 4 agreed to participate (85%). The analytic cohort of patients consisted of those individuals who were prescribed medications used to treat LDL-cholesterol levels (statins), type 2 diabetes (oral hypoglycemic agents), and hypertension (angiotensin converting enzyme [ACE]-inhibitors, angiotensin receptor blockers [ARBs], thiazide diuretics).

**Specific Aim 3:** PCPs participating in the Metronome randomized trial whose practice was located on the main MGH campus were invited to participate in audiotaped visits with their patients before and after the trial to assess the impact of Metronome on how time is spent during routine office visits. We were unable to enroll patients located at the North End Waterfront Health site due to logistical reasons around office-based visits since it is not on the MGH main campus where the research personnel were located. Twelve of the 4 PCPs from the Internal Medicine Associates practice and enrolled in Specific Aim 2 (27%), agreed to participate. Patients of the participating PCPs were eligible to participate if they were age 50--65, had greater than 2 years of visit history with that PCP, and had a routine office visit scheduled during the enrollment period. We focused preferentially on patients with a diagnosis of hypertension, type 2 diabetes, or hyperlipidemia, and limited enrollment to English speakers.

## **METHODS:**

### **Study Design:**

**Specific Aim 1:** Development of the Medication Metronome health IT system involved making changes to an existing electronic health record (EHR) user interface. We established an underlying system architecture, the Medication Metronome Enterprise Server Bus (ESB) which drove the rules engine to enable the Medication Metronome to accomplish the planned tasks of monitoring for laboratory test results and initiating patient letters and EHR updates. A key component was establishing an output table architecture to establish the necessary variable columns for the Medication Prescription User Interface output to be read by the Metronome ESB. These included date, medication, name, medication class, laboratory class, specific lab ordered, and due date. Business logic also needed to be created to accommodate a wide range of use cases, including multiple medication prescriptions, discontinuation of study medicines, prescription by non-study providers, and aggregating multiple lab testing due dates. Key outputs from the Metronome ESB were initial laboratory request letters and subsequent laboratory reminder/overdue letters. A mechanism for automated letter writing and mailing was developed.

Additionally, we established a mechanism to feed missing laboratory results into an existing "Watchlist" section of the EHR to alert PCPs. Additional work involved categorizing study medications into larger medication classes that corresponded to non-overlapping laboratory test classes. To conduct a randomized trial of the system, we developed sign-in keys to designate which consented PCPs were allocated to control vs. intervention arms. Intervention PCPs received automatic access to the

medication prescription user interface when going into the EHR, while control PCPs continued to see the standard prescription interface.

Development and testing of the Metronome health IT system required collaboration with practices and leadership within our network as well as getting feedback from potential users. Focus groups to discuss the initial conceptual framework and to present user interface mock-ups were conducted using our PCOI Advisory Board at MGH. We received comments and feedback from the Advisory Group on three separate occasions and incorporated this feedback when development of the health IT tool began. Once design of the health IT was underway, additional one-on-one meetings were done with clinicians to establish work-flow for the Metronome user interface use and identify additional use cases. Crucial feedback from these sessions was integrated into system redesign efforts.

Though our original protocol including conducting patient focus groups to facilitate patient acceptance of a non-visit based medication management system, as the study began to take shape, it became clear that the patient-facing aspect was actually not that different from what was already being done in practice. Patients in Metronome encountered reminder letters and laboratory letters that were basically the same as what was already being sent out. We realized that patient focus groups would not add much to the development process. Given the short timeline and limited resources devoted to Specific Aim 1, we decided to focus on PCP focus groups within our PCOI Advisory Board, IT development, implementing the rigorous randomized controlled trial, and conducting high level analyses of our results.

With input from our PCOI Advisory Board we developed a novel health IT tool that was integrated into the electronic health record used by our two study practices. Two key decisions were influenced by input from our PCP focus groups:

- 1) We limited the health IT functionality to oral medications used to treat LDL-cholesterol levels (statins), type 2 diabetes (oral hypoglycemic agents), and hypertension (ACE inhibitors, angiotensin receptor blockers [ARBs], thiazide diuretics).
- 2) Efficacy laboratory tests were defaulted to order, while safety laboratory tests required the PCP to actively initiate the order. A default time was set based on PCP input when the future efficacy and safety tests should be completed (e.g. within 3-months for HbA1c), but the PCP could also customize the follow-up time interval. Based on feedback from our focus groups, ordering of safety follow-up labs was not set as a default option but rather required an additional step to order, reflecting the clinical impression that these tests were frequently not necessary. Reasons given by the focus group participants for not making this safety testing the default option included the fact that many patients have had prior monitoring that did not require repeating.

**Specific Aim 2:** The 1-year randomized trial was from May 25, 2012 – May 24, 2013. PCPs in the two practices were randomized to intervention or control groups. To minimize imbalance between study arms, PCP randomization within each practice was stratified by PCP panel size, years since medical school graduation, and physician gender.

Intervention arm: The new feature was added to the existing medication ordering screen that allowed study PCPs to order a follow-up laboratory test when initially prescribing a study-specific medication or when changing the dose (**Figure 1**) For this study, we limited this functionality to oral medications used to treat LDL-cholesterol levels (statins), type 2 diabetes (oral hypoglycemic agents), and hypertension (ACE-inhibitors, angiotensin receptor blockers [ARBs], thiazide diuretics). When one of these study medications was prescribed, the intervention physician had the opportunity to order a corresponding future laboratory test to evaluate the

efficacy (e.g., HbA1c after metformin) or safety (e.g., serum potassium after a thiazide diuretic) of the prescribed drug. Laboratory testing options were to monitor **treatment efficacy** (LDL, HbA1c) and/or **treatment safety** (potassium, renal function, liver function).

Efficacy laboratory tests were defaulted to order, while safety laboratory tests required the PCP to actively initiate the order. A default time was set for when the future efficacy and safety tests should be completed (e.g., within 3 months for HbA1c), but the PCP could also customize the follow-up time interval.

The Medication Metronome system tracked the future laboratory tests ordered by an intervention physician prescribing a study medicine. The week before a scheduled laboratory test became due, the system automatically mailed the patient an explanatory letter signed by the ordering physician that included a laboratory test requisition form. If there was no result noted 2 weeks after the first letter was mailed, a second reminder letter and laboratory requisition was automatically mailed to the patient. If after an additional weeks the requested test result was still not registered, a "missing" result was posted to the PCP's "Result List" page. Thus, this system was designed to support between-visit laboratory ordering and monitoring both by reaching out to patients when a scheduled test became due and by alerting PCPs when future scheduled test was not completed.

**Figure 1:** Electronic health record prescription user interface with additional Medication Metronome user interface added

**lovastatin**

Add Rx **10 mg Tab...**

Strength / Form  
10 mg Tab

Dose+ Route+ Frequency+  
po qpm

Directions+ Quant+ Qualifier+ Refills+  
90 tablet 3

Start Date  
09/26/2011

Comments

Drug-allergy and drug-drug interactions reviewed.

**Efficacy and Safety Monitoring**  
Last AST (SGOT): 25 on 01/19/2011  
Last ALT (SGPT): 30 on 01/19/2011

Order lipid panel for efficacy monitoring to be done on 09/26/2011  
No new SGOT/SGPT order is necessary at this time.  
No new CPK order is necessary at this time.

Other pending lab existing - For Hepatic Panel due on 07/08/2011

**Cholesterol Lowering Agents**

- colestipol
- fenofibrate
- gemfibrozil
- Lofibra NS
- lovastatin
- Niacin OTC
- pravastatin
- simvastatin
- Crestor
- Tricor
- Advicor
- Altoprev
- Antara
- cholestyramine
- Colestid
- Fenoglide
- Fibricor

low-dose PA - Requires Prioritization  
 mid-dose DL - Dispensing Limitation  
 high-dose NS - No Generic Substitution

**Allergies**  
Aspirin  
Chocolate  
TRIMETHOPRIM/SULFAMETHOXAZOLE DOUBLE STRENGTH  
Diarrhea  
Unknown Sweeten

Update Cancel

Additionally, we surveyed study physicians after implementation of the Medication Metronome. Participants completed brief online or paper surveys that asked about time spent managing laboratory testing results and follow-up. Among intervention PCPs at follow-up, we also specifically asked about facilitators and barriers to use of the tool.

**Specific Aim 3:** Patients eligible to participate in the audiotaped office visits were sent a letter describing the study and inviting them to participate. Those who did not respond to the invitation letter were contacted by phone and asked to participate. Participating patients provided written consent for an initial (baseline) audiotaped visit and for a follow up audiotaped visit approximately one year later. In addition, patients were asked to complete brief written surveys at the time of both baseline and follow up visits. The surveys included Consumer Assessment of Healthcare Providers and Systems (CAHPS) questions on patient--provider communication. Baseline visits were recorded between January and June 2011 and follow--up visits were recorded between January and October 2013.

Transcription of baseline and follow--up recordings was done by a HIPAA compliant transcription services company. In accordance with IRB protocol, audiotapes and transcripts were de--identified prior to being sent to study collaborators at Palo Alto Medical Foundation Research Institute for coding and analysis.

We first coded audio--recordings and transcripts of the visits to capture "topics" within seven major areas: biomedical (e.g., high blood pressure, diabetes), health behaviors (e.g., smoking, alcohol), mental health (e.g., depression, anxiety), psychosocial (e.g., work, family and friends), physician--patient relationship (e.g., physician availability), visit flow management (e.g., agenda setting, mid--visit check--in of understanding, and concluding visit), and other (e.g., small talk about weather or clothing). "Topics" were defined as an issue that had at least two complete exchanges between patient and physician. The time spent on each topic, defined as the amount of time between the start and end of all instances of the topic, was also recorded. This analytical approach has been described and applied in previous research (Tai--Seale, M., et al, 2013; *Health Affairs* 32(2), 259--267).

Next, we coded each of these topics for variables related to how well physicians discussed medication management, the purpose of lab tests, and how well they informed the patient and practiced shared decision making. We then placed time stamps into the transcripts to calculate how much time the patient and physician each spent talking about a specific topic. Data from these three steps of coding work were combined to form the analytical data file for Aim 3.

#### **Data Sources:**

**Specific Aim 2:** Patient characteristics and laboratory data were obtained from an electronic central data repository at Partners Healthcare. Prescribed study medications by participating PCPs were obtained from the EHR. Dates of laboratory tests and results were obtained over 2--year period beginning 6-- months before the 12--month study start date through 6--months after the study completion date.

Physician characteristics were obtained from the hospital registrar.

**Specific Aim 3:** For each consented PCP, we merged his/her eligible patient list with scheduling data to identify patients with upcoming visits. Updated scheduling data was obtained at regular intervals throughout the study enrollment period. Additional clinical data on enrolled patients was obtained from Partners electronic data sources.

#### **Measures:**

**Specific Aim 2:** We evaluated the following study outcomes and compared results between patients in intervention vs. control arms: 1) Time from prescription of LDL or HbA1c--related medicine to subsequent LDL or HbA1c test result, 2) Time from medication prescription to corresponding LDL or HbA1c control (defined as LDL < 130 mg/dl or <100 mg/dL for patients



with cardiovascular disease or diabetes; and HbA1c  $\leq$  7.0%), 3) Proportion of time after medication prescription that the patient was at or below LDL or HbA1c goal. In addition to the efficacy of chronic disease management, we also evaluated whether the Medication Metronome system would increase safety-related laboratory monitoring. For this question, we compared the proportion of patients who had a corresponding test result 4 weeks after prescription (e.g., potassium after prescription of a thiazide diuretic). In a sensitivity analysis, we also compared safety test result proportions between study arms after 1 weeks.

**Specific Aim 3:** We evaluated the content of office-based visits by examining the time spent addressing clinical care related to treatment of diabetes, hypertension, and hyperlipidemia and the quality of decision making and discussions occurring around those topics during office visits. Time was measured in minutes spent on biomedical topics related to diabetes, hypertension, and hyperlipidemia, at both the visit and conversation topic level. The quality of all decisions discussed during the appointment was assessed through a decision making quality index consisting of 9 items, each coded on a 0 to 2 scale, for a total possible 18 points. We also used two additional indices to assess decision making quality specific to laboratory tests and medications, based on The Four Habits Coding Scheme. The laboratory tests decision quality index included 9 items rated on a scale of 1-5, for total possible of 4 points, and the medications quality index included 8 items rated on a scale of 1-5, for total possible of 4 points.

#### **Statistical Analyses:**

**Specific Aim 1:** This aim focused user input for system design. Findings were of qualitative nature and were incorporated directly into the design of the tool. We describe design choices influenced by PCP focus groups in the Methods- Study Design section for Specific Aim 1.

**Specific Aim 2:** We compared patient characteristics between intervention and control groups using two-sample t-tests or chi-square tests, as appropriate. Comparisons between study arms were at the patient level and controlled for small but statistically significant patient baseline differences (age, gender, race, language, insurance, and baseline laboratory values) while accounting for clustering by PCP in multivariable models. We used Cox Proportional Hazards models with robust sandwich covariance matrix estimates (PROC PHREG, SAS version 9.3, SAS Institute, Cary, NC) for time-to-event analyses to account for clustering. We used linear regression for proportion of time spent at or below goal analyses, and logistic regression (PROC GENMOD) for our safety monitoring outcomes with general estimating equation techniques to account for clustering. All primary analyses were "Intention-to-Treat". In exploratory analyses, we also examined characteristics among eligible intervention patients comparing those who did vs. did not receive the Medication Metronome intervention ("as-treated" analyses).

#### **Specific Aim 3:**

Three types of data coding: 1) topic, 2) additional variables, and 3) time-stamping, occurred for all 49 pre-intervention visits. Coding for all three stages of the post-intervention visits was halted when the results from the randomized clinical trial (Aim 2) did not show significant differences pre and post the intervention. The original purpose of our analysis was to examine whether there were any differences in how patient-physician pairs discussed topics pre- and post-intervention, particularly the three conditions of interest (diabetes, hypertension, and hyperlipidemia). We compared the completely coded pre- and post-intervention visits to determine if there were any more qualitative differences. Two researchers, one who did the topic coding and the other who did the multiple variables for each topic, examined these cases and found no major differences in how the

physicians discussed the 3 key topics, medication adjustment, nor laboratory values. We also examined 3 other pre- and post- intervention visits for physicians who reported using Metronome. Again, there appeared to be no significant qualitative difference in the quality of the conversations surrounding the 3 key conditions, medication management, nor laboratory tests and results. We also conducted text search of all of the post-intervention transcripts and did not find any mention of the word “Metronome” nor of a “tool” that aided in medication and lab management. Based on these explorations, and the finding from the MGH team indicating that the Medication Metronome tool was used in less than 25% of the intervention patients, the study team chose to not finish coding the rest of the post-intervention visits.

## RESULTS:

### Principal Findings:

#### Specific Aim 1

Focus groups with our PCOI Advisory Board influenced several important aspects of the design and implementation of the health IT tool. These included design aspects of the user interface to make using the health IT tool as intuitive as possible, which medications were included in the study, the intervals for recommended follow-up and when patients and providers should be alerted when follow-up testing did not occur, and that safety laboratory ordering should be defaulted to not order and needed to be turned on by the user.

#### Practice, Physician and Patient Characteristics

The 4 primary care physicians participating in the study had a mean of 17.8 years (SD: 11.4) of clinical practice experience and 27 (61%) were women. There were no statistically significant PCP differences between study arms. Over the 12-month study period, 3022 eligible study medications were prescribed for 2049 patients in the intervention arm and 2432 eligible study medications were prescribed for 1606 patients in the control arm. Study patients had a mean age of 65.8 years (SD: 13.0). There were few small, though statistically significant, differences between study arm patients (Table 1).

Table 1: Patient characteristics by intervention and control group (3655 unique patients prescribed 5454 study-eligible medications)

	Intervention Patients	Control Patients (n=1606)	P-Value
Age, mean (SD)	65.9 (13.1)	65.7 (12.8)	0.64
Gender, female	97 (47.8%)	85 (52.9%)	0.002
Ethnicity			0.01
African-American	14 (7.2%)	16 (10.0%)	
Asian	9 (4.7%)	7 (4.7%)	
Hispanic	6 (3.1%)	6 (4.1%)	
Other/unknown	2 (1.0%)	1 (0.9%)	
Non-Hispanic white	171 (84.3%)	129 (80.4%)	
Insurance status			0.69
Commercial	101 (49.4%)	79 (49.3%)	
Medicaid	13 (6.5%)	12 (7.5%)	

	Intervention Patients	Control Patients (n=1606)	P---Value
Medicare	85 (41.7%)	65 (41.0%)	
No insurance, self---pay/free	4 (2.4%)	3 (2.1%)	
Primary language spoken, English	195 (95.3%)	148 (92.4%)	<0.001
Clinic visits over 3 years, mean (SD)	9.2 (5.8)	9.2 (5.9)	0.90
Baseline HbA1c value, mean (SD)	7.9 (1.6)	8.1 (1.9)	0.05
Baseline LDL value, mean (SD)	117.7 (39.8)	121.6 (43.8)	0.07
Diabetes	60 (29.6%)	51 (32.3%)	0.08
Hypertension	156 (76.6%)	123 (76.7%)	0.96
Coronary Artery Disease	37 (18.5%)	29 (18.1%)	0.73

#### Time to LDL Testing and Control

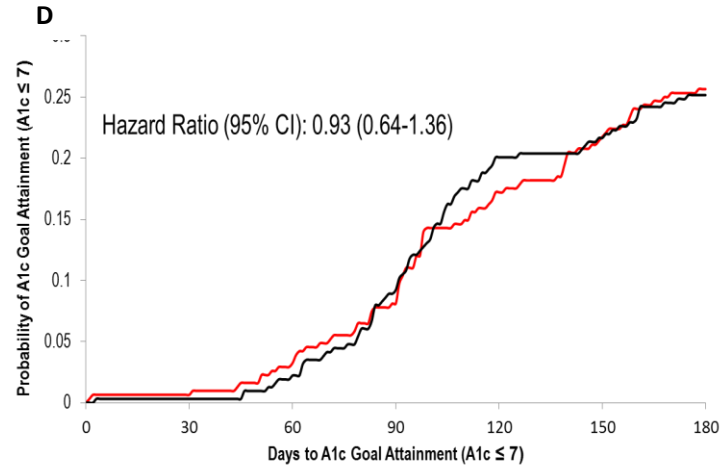
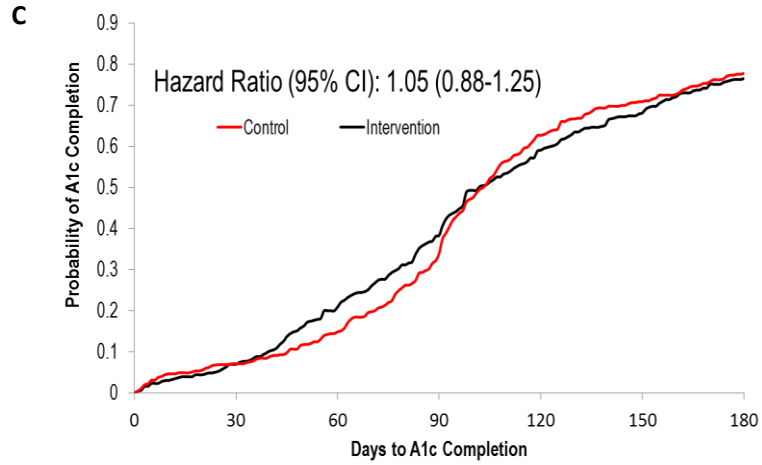
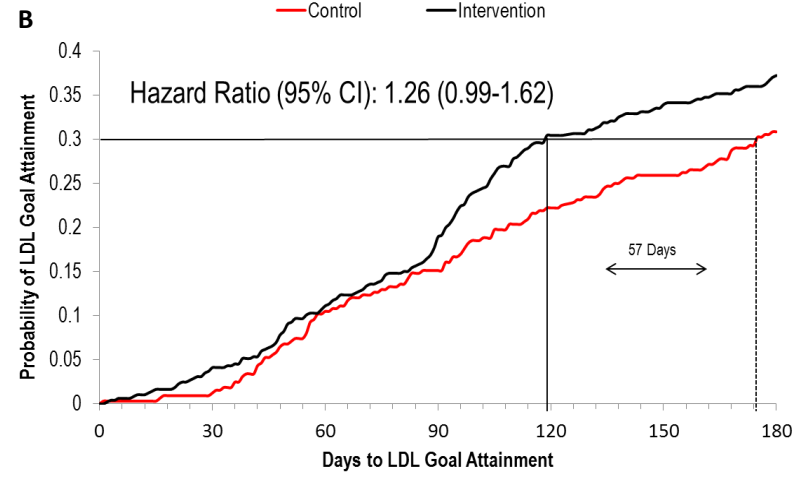
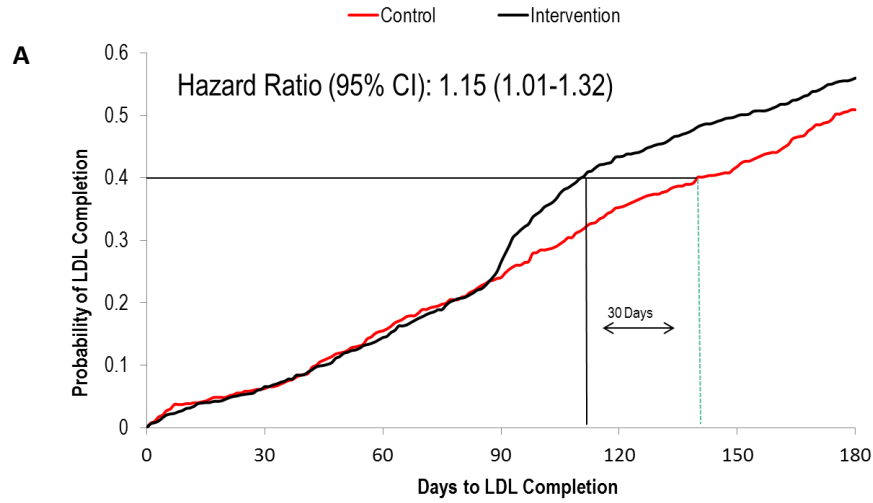
There were 114 statins prescribed for 95 patients in the intervention arm and 70 statins prescribed for 621 patients in the control arm. After adjusting for baseline differences between groups, patients in the intervention arm had a shorter time interval to next LDL test after statin prescription (adjusted HR

1.15 [1.01---1.32, p 0.04]). As shown in **Figure 2A** this corresponded to a 30 day improvement in the time it took for 40% of the patient cohort to have LDL testing after statin prescription. Among the subset of patients above LDL goal at baseline (LDL > 130 mg/dl, or LDL > 100 mg/dl for patients with cardiovascular disease or diabetes; n = 810), intervention patients had shorter time interval to reaching LDL goal (aHR 1.26 [0.99---1.62], **Figure 2B**), although this result did not meet statistical significance (p = 0.07). For the overall study period, the difference in time spent at goal after prescription was not significantly different between arms (57.9% of time for intervention patients vs. 54.8% for control patients, adjusted p---value = 0.30).

#### Time to HbA1c Testing and Control

There were fewer patients prescribed oral medications for diabetes control than LDL control during the 12---month study period (450 prescriptions for 318 intervention patients, 430 prescriptions for 300 control patients). As shown in **Figure 2C & 2D** differences in test result timing and HbA1c control were small and not statistically significant. The time spent at HbA1c goal  $\leq$  7.0% (or  $\leq$  9.0%) for the overall study period was also similar between arms (32.5% vs. 34.3% of time  $\leq$  7.0%, p = 0.6; 83.0% vs. 81.6% of time  $\leq$  9.0%, p = 0.55).

Figure 2



## Medication Safety Monitoring

Rates of follow-up laboratory monitoring within 4 weeks of prescription were highest for renal function testing after prescription of an ACE/ARB and lowest for liver function testing after statin prescription (**Table 2**). There were no differences between study arms based on an intention-to-treat analysis, reflecting the low rate of Medication Metronome use for this purpose by intervention physicians. In a sensitivity analysis, this lack of intervention effect remained evident at 1 weeks

Table 2: Percentage of laboratory tests results within 4 weeks after medication prescription

Laboratory result (prescription)	Intervention (N/total)	Control % (N/total)	Difference I% – C% (95% CI)	P-value*
AST/ALT (statin)	6.7% (76/1134)	8.6% (60/699)	-2.0% (-3.9, -0.1)	0.16
Creatinine (metformin)	13.7% (61/445)	16.2% (69/425)	-2.9% (-7.1, 1.3)	0.29
Creatinine (ACE/ARB, thiazide)	26.9% (380/1411)	24.0% (311/12960)	2.9% (-2.4, 9.0%)	0.30

I = Number of laboratory test results within 4 weeks/number of medications prescribed  
 Difference, I% – C% (95% CI) = Difference between Intervention and Control arms in % patients with laboratory tests within 4 weeks of medication prescription after adjusting for baseline imbalances (95% confidence interval)

\*p-values are adjusted for patient baseline differences between study arms

ALT/AST = aspartate transaminase/alanine transaminase

ACE/ARB = angiotensin converting enzyme inhibitor/ angiotensin receptor

## blocker Eligible Intervention Patients Who Did Vs. Did Not Receive

### Intervention

Among the 2049 patients with eligible prescriptions in the intervention arm, only 442 patients (21.6%) had a future reminder letter scheduled through the Medication Metronome system. In this group of potentially eligible intervention patients, patients who actually received the intervention were substantially more likely to have an established relationship with their PCP (96.8% vs. 80.2% for intervention patients who did not receive a Medication Metronome follow-up order, < 0.001). These “On-Treatment” patients also had fewer annual visits (8.3 vs. 9.5, p<0.001) and higher baseline LDL levels (122.7 vs. 114.3 mg/dL, p<0.001).

### Post-Intervention Provider Surveys

Post-intervention surveys were completed by 91% (20 of 22) of intervention PCPs. Among respondents, 30% indicated that Medication Metronome improved their ability to provide timely medication management, while the remaining 70% reported no change. Most intervention group PCPs (85%) reported barriers to using the Medication Metronome tool (Table 3). Provider responses to an open ended question on barriers to use included: poor alignment with current visit-based reimbursement practices, inability of the Metronome IT system to capture lab results performed at outside facilities, and reminder letters to patients which did not always reflect up to date information and sometimes led to patient confusion.

Surveys were also completed by 86% of control group providers (19/22). There were no significant differences found between providers in control and intervention groups on satisfaction with medication management for the conditions of interest (Table 4) or for time spent on medication management (data not shown).

Table 3: Barriers reported to use of Medication Metronome

Barrier	reporting
Not clear how to use the interface to order and schedule lab tests	(30%)
Did not want to schedule lab testing using this system	(30%)
Using the module required extra time	(25%)
Other, please specify:	(35%)
No barriers to use of the module	(15%)

Table 4: Satisfaction with ability to provide timely medication management and reach patient's treatment goal

	Group	
	Control (N=19)	Intervention (N=20)
<b>Diabetes: n (%)</b>		
Dissatisfied	(11%)	(25%)
Neither satisfied nor dissatisfied	(37%)	(20%)
Satisfied	1 (53%)	1 (55%)
<b>Hypertension: n (%)</b>		
Dissatisfied	(11%)	(15%)
Neither satisfied nor dissatisfied	(5%)	(10%)
Satisfied	1 (84%)	1 (75%)
<b>Hyperlipidemia: n (%)</b>		
Dissatisfied	(11%)	(16%)
Neither satisfied nor dissatisfied	(21%)	(16%)
Satisfied	1 (68%)	1 (68%)
<i>Missing</i>		1

*Differences between intervention and control groups were not significant using Fisher's exact test.*

**Specific Aim 3:** We enrolled 49 patients in the audiotape study of visit content and completed follow-up recordings with 43/49 (88%). For the 6 patient-PCP pairs for whom follow up visits were not recorded, 3 were lost to follow up due to their PCP leaving MGH, 1 patient switched to a new PCP and the remaining patients did not schedule visits with their PCPs during the study follow up window.

Results from patient surveys showed no significant differences in patient satisfaction with provider communication before and after the Metronome intervention based on the CAHPS questions. PCPs consistently received positive scores on the CAHPS questions with each question receiving the highest score on a six point scale from over 75% of patients at both baseline and follow up.

Among 49 visits conducted during the study baseline period, the average visit took 23.9 minutes, with some visits taking as short as 8 minutes and others as long as 46 minutes (Table 5). Not all visits included discussions of the 3 focal conditions, diabetes, hypertension or hyperlipidemia. In the 35 visits that included one of the three focal biomedical topics, visit duration was very similar to all visits. Within these visits, 514 topics were coded, with an average time of 2.2 minutes per topic. Among the 39 topics coded as focused on diabetes, hypertension or hyperlipidemia, those topics tended to be longer, averaging minutes each.

Table 5: Summary statistics for visit and topic length of time for visits conducted in study baseline period

	Total N	Time (minutes)				
		Mean	SD	Min	50 <sup>th</sup> percentile	Max
<b>Visits</b>						
All Visits	49	23.85	7.88	7.99	24.21	45.52
Visits with focal biomedical topics*	35	22.63	8.32	7.99	20.78	45.52
<b>Topics</b>						
All Topics	514	2.23	2.63	0.06	1.27	23.37
Biomedical topics	143	3.03	3.42	0.07	2.09	23.37
Focal biomedical topics*	39	5.09	4.61	0.41	4.14	23.37
Diabetes topics	7	3.87	2.54	0.88	4.14	8.41
Hypertension topics	27	5.87	5.06	1.43	4.63	23.37
Hyperlipidemia topics	16	5.03	3.53	0.41	4.61	11.94

Notes: \*Focal biomedical topics include: topics coded as discussing diabetes, hypertension or hyperlipidemia.

Although the relatively small number of topics where decisions were made limited statistical comparisons, the diabetes, hypertension and hyperlipidemia topics tended to have higher decision quality for each of the three decision---quality indices, in comparison to all other topics (Table 6). The 3 coded post---intervention visits provided by physicians --who had indicated their use of the Medication Metronome tool-- showed similar patterns of communication between patients and physicians, with neither direct nor indirect mention of the Medication Metronome tool.

Table 6: Summary statistics for decision making quality, by topic type for visits conducted in study baseline period

	Diabetes	Hypertensio	Hyperlipidemia	All other
	n=7	n=27	n=16	n=475
Decision quality index (range 0--- 18), mean (SD)	9.0 (4.9)	10.4 (4.1)	10.5 (4.3)	7.0 (4.8)
Laboratory test decision making index (range 9---45),	34.0 (4.2)	23.0 (6.3)	25.7 (5.5)	21.1 (6.2)
Medication decision making index (range 8---40), mean	16.6 (11.0)	17.3 (11.0)	15.5 (11.4)	10.6 (9.1)

Notes: This table includes average decision making index values at the topic level, for diabetes, hypertension and hyperlipidemia topics. Only topics where a relevant decision was made were coded for each of the three indices.

## Discussion:

This study was designed to evaluate the impact of an innovative health IT tool designed to improve the medical management of three common chronic diseases (hyperlipidemia, type 2 diabetes, and hypertension). We hypothesized that improved, non-visit based laboratory monitoring would lead to more timely medication titration and therefore better disease control.

We found that compared to the patients of physicians in the control arm, patients whose physicians had access to the intervention had significantly shorter time interval between statin prescription and subsequent LDL testing result. Although not quite reaching statistical significance, this shortened prescription/testing cycle appeared to also decrease the time to achieving LDL control in the subset of patients with elevated levels at baseline. However, similar results were not seen for HbA1c control among oral medications used to manage type 2 diabetes, and the percentage of time patient was at or below risk factor goal did not differ among treatment groups. Overall, the Medication Metronome was used in less than one-quarter of potentially eligible intervention patients. Thus, while the goal of improving the efficacy of medication prescribing showed promise, the overall intervention impact may have been hampered by underuse of the tool among intervention providers.

Prior interventions designed to improve medication intensification have also had higher success for cholesterol management compared to glycemic management (Lester WT, et al. J Gen Intern Med, Jan 2006; 21(1): 22-29; Selby JV, et al. BMC Health Services Research, Jul 2012; 12(1): 183). This result may reflect differences between the two conditions: there is a strong direct link between statin prescription and LDL lowering, whereas HbA1c control is complex, patient-specific interplay between medications, lifestyle changes, and underlying disease phenotype. Alternatively, the smaller number of prescriptions for diabetic medications may have given us insufficient power to show an HbA1c difference in our intention-to-treat analysis.

We also examined the impact of the health IT tool in supporting safety-related laboratory monitoring after medication prescribing. In our study we found low rates of "safety" lab monitoring after prescription of statins, ACE/ARBs, and metformin among intervention and control group PCPs. One explanation for these results is the relative lack of outcomes evidence to support many of the suggested drug monitoring tests for primary care patients. Indeed, based on feedback from our physician stakeholder group, ordering of safety follow-up labs was not set as a default option but rather required an additional click to order, reflecting the clinical impression that these tests were frequently not necessary. Reasons given by our stakeholder advisory board for not making this safety testing the default option included the fact that many patients have had prior monitoring that did not require repeating.

Analyses of all of the audio-recorded visits in the baseline and select audio-recorded visits in the post-intervention period suggest that discussions of the three focal conditions not only took more time (4 to minutes compared with minutes) but also had higher qualities in decision making than all other topics. While improving the efficiency of time use during post-intervention period office visits was a hypothesized outcome of the intervention, the intervention didn't include a specific workflow for physicians to use in discussing the Metronome program with their patients. Therefore, physicians might not have made an explicit plan to discuss the program with their patients. Furthermore, some physicians may have feared that discussing the program could extend their visit length. The combined influence of this fear and the lack of instruction on how to introduce the Metronome program could have led to the lack of change in physicians'



communication behaviors during the visits. Future considerations would include providing patients with a short fact sheet about the follow-up process (e.g., reminder letter and lab slip mailed before the test due date) at the time of the initial visit to improve expectations and comfort with this non-visit based follow-up model of medication management.

### **Limitations:**

Several important limitations are worth noting. While our physician stakeholders and primary care physicians appeared enthusiastic about the Medication Metronome during the development and initial implementation phases of the study, in practice the tool was not widely used by intervention PCPs.

Study participants did not embrace this method of non-visit based care, with only 660 medication prescriptions using the Medication Metronome ordering option (21% of possible orders). Our survey and exit interviews identified several factors that might have contributed to this underuse. Barriers included:

1) the misalignment of visit-based reimbursement and productivity requirements with a non-visit based model of care, 2) the desire by both patients and PCPs to rely on personal clinical encounters for medication management discussions, and 3) the frustrations some physicians felt at the many concurrent changes and initiatives that were implemented during the study period that focused on optimizing clinical productivity.

Another barrier raised by intervention PCPs after study completion was the need for creating an optimal workflow strategy. Unlike scheduling a follow-up clinic visit, non-visit based clinical work often does not have a clearly established or standardized workflow. As might be expected from experienced clinicians working in a busy practice environment, many study PCPs had already developed their own strategies to coordinate laboratory follow-up and monitoring such as relying on nurses or using personal e-mails.

Given the limited time available for clinical management outside of the visit setting, many physicians may have found it easier to schedule a follow-up visit, even though any future missed appointments would delay medication titration. Another potential impediment for use of the tool may have been the need to take time during the visit to explain the process of a non-visit based follow-up for patients who were not accustomed to this care model. The fear of having to spend more time explaining the Metronome program may have prevented the physicians from having that discussion, thereby missing an opportunity to engage patients in visit-independent management of chronic conditions. Finally, many intervention physicians noted that a substantial minority of tests were completed at laboratory facilities outside of the MGPC-PBRN. These results were not captured by the Medication Metronome system, leading to erroneous "missing test" reminder letters that the PCPs needed to explain to the patients who received them.

### **Conclusions/Significance**

The U.S. health system is undergoing much needed change. The ongoing implementation of the Affordable Care Act (ACA) includes incentives to reorganize health care delivery systems as accountable care organizations that take a population-level view of care quality. Modernizing the current health care system may require fundamental changes to how medicine is currently practiced. Part of this change includes an incentive structure to increase the meaningful use of health IT in clinical care. Health policy and reimbursement changes that support non-visit based care models as a way to deliver high quality, efficient services are needed to encourage greater adoption of innovative tools designed to support visit-independent medication management. Specifically, new payment models and workflow practices that integrate non-visit clinical work may be needed before visit-independent medication management systems will be

more widely adopted. As the organization of primary care systems evolve, we anticipate that tools such as the Medication Metronome to support clinical care outside of the traditional in-person visit may have greater adoption and clinical impact.

## Implications

1. Persisting gaps in goal attainment for managing chronic disease support the role of non-visit based care to supplement and extend face-to-face interactions.
2. Health IT innovations that support between-visit work represent a new model of care delivery that will require more patient and provider input to support standard workflow and educational outreach.
3. New payment models that reimburse for non-visit based medication management may be needed before visit-independent medication management systems will be more widely adopted.

## LIST OF PRESENTATIONS AND PUBLICATIONS:

### Abstracts and Presentations

- 1) Ashburner JM, Grant RW, Jernigan M, Borowsky LH, Atlas SJ. The Medication Metronome: Health IT System to Improve Medication Management and Laboratory Monitoring for Chronic Diseases. 2013 Society of General Internal Medicine Annual Meeting, Denver, CO. April 24--27
- 2) Ashburner JM, Grant RW, Jernigan M, Borowsky LH, Atlas SJ. The Medication Metronome: Health IT System to Improve Medication Management and Laboratory Monitoring for Chronic Diseases. 2013 Harvard Center for Primary Care Innovations Conference, Boston, MA. October 7, 2013.
- 3) Borowsky LH, Grant RW, Ashburner JM, Jernigan MC, Atlas SJ. Primary Care Provider Experience with New Health Information Technology Tool to Facilitate Between Visit Medication Management. 2014 Society of General Internal Medicine Annual Meeting, San Diego, CA. April 2014.
- 4) Atlas SJ, Jernigan MC, Ashburner JM, Chang J, Borowsky LH, Chang Y, Grant RW. health IT system to improve medication management and laboratory monitoring for chronic diseases: The medication metronome trial. 201 Society of General Internal Medicine Annual Meeting, San Diego, CA. April 2014.
- 5) Stone A, Stults C, McClellan S, Grant R, Atlas S, Borowsky L, Ashburner J, Tai Seale M. ObamaCare in the Exam Room: How do Physicians Communicate with Patients about the Affordable Care Act. 2014 Annual Research Meeting of Academy Health, San Diego, CA. June 2014.
- 6) Atlas SJ, Grant RW. National Web Conference on the *Using Health IT to Reduce Medication Errors and Improve Patient Safety*. Agency for Healthcare Research and Quality. August 2014.
- 7) Atlas SJ, Jernigan MC, Ashburner JM, Chang J, Borowsky LH, Chang Y, Grant RW. health IT system to improve medication management and laboratory monitoring for chronic diseases: The medication

metronome trial. 201 Harvard Center for Primary Care Innovations Conference, Boston, MA. October 2014.

Manuscripts:

1) Grant RW, Ashburner JM, Jernigan MC, Chang J, Borowsky LH, Chang Y, Atlas SJ. The Medication Metronome: A Randomized Trial of a Health IT Tool to Support Non-Visit Based Medication and Laboratory Monitoring for Chronic Disease. *J Gen Intern Med* In press.