Grant Final Report

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Veterans Affairs Integrated Medication Manager

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Abstract

Purpose: Veterans Affairs (VA) is modernizing its electronic health record (EHR) systems including the graphical user interface (GUI). Recent attention to usability and meaningful use are welcome but leave an unaddressed gap between low-level ergonomics and high-level work support. Contextual Control Model (COCOM) provides one framework to design information systems that fills the need for an evidence-based approach to EHR GUI design in support of human cognition.

Scope: Aim 1—COCOM was translated to medicine and suitability of the translated framework was tested. Aim 2—The framework guided the development of a new approach to EHR GUI design.

Methods: Aim 1—Qualitative methods such as verbal protocol analyses of observation sessions, formal cognitive task analyses, and semi-structured interviews were used. Aim 2—Simulated cases in a randomized controlled trial were used to test speed and accuracy of the new interface versus a mockup of the VA's current EHR.

Results: Aim 1—COCOM behavioral characteristics singly and in aggregate followed patterns predicted by the theory. The COCOM translation is promising for targeting characteristics that predict higher levels of performance on tasks related to chronic disease management. The specified hypotheses were tested but results were not statistically significant. Aim 2—Despite minimal training on using the new GUI, time to complete assessments and plans was significantly less using the new GUI (p-value = 0.041). Accuracy and appropriateness evaluations of the assessments and plans are ongoing.

Key Words: health IT, innovations, emerging issues, prevention, care management, medication management, EHR, EMR

Final Report

Purpose

In an attempt to address barriers to the access and integration of health information that impede the achievement of treatment goals, the study had the following objectives.

Aim 1. Identify cognitive components of providers' therapeutic decision making in the field.

Aim 2. Refine and evaluate the Integrated Medication Manager using simulation studies.

- Aim 2a. Refine interfaces and logic of the Integrated Medication Manager.
- Aim 2b. Compare the performance of the Integrated Medication Manager and usual Computerized Patient Record System (CPRS, the VA's standard EHR).

Aim 3. Implement and Evaluate the Integrated Medication Manager in a cluster-randomized trial.

- Aim 3a. Assess differences in surrogate clinical endpoints such as blood pressure versus usual CPRS.
- Aim 3b. Evaluate provider satisfaction and adoption.

Aim 3 was not conducted due to forces outside the control of the project.

Scope

Background and Context

National standards for treatment goals remain unmet in a significant proportion of patients. For all affected Americans, non-compliance with quality goals is 49%.[1] Non-compliance with hypertension goals is estimated at over 35%.[1] In the VA, a higher proportion achieves goals due to widely available point-of-care computerized decision support, performance measures for management and physicians, and interdisciplinary teams designed to optimize therapy. Nonetheless, 25% of VA hypertensive patients did not meet performance standards for hypertension (less than 140/90) in fiscal year 2006.[2]

Several barriers related to the access and integration of health information impede the achievement of treatment goals.[3,4] First, physicians often do not clearly express their thoughts in the medical record. The conceptualization of conditions, rationale for therapies, and parameters

of goals are often vague or absent.[5-7] Second, the relationships among various conditions, therapies, and goals can be too implicit or difficult to access.[6-8] As a result, physicians and other health professionals need to read carefully through the chart at each encounter to reestablish an adequate mental model of the patient's status and treatment plan.[9] Third, the history of therapy in relation to goals is frequently buried across different progress notes. Consequently, patterns of over- and under-treatment are difficult to discern, and mistakes can persist or be repeated.[10,11] Finally, individual conditions are often not managed in the larger context of other problems and higher-level patient goals, with potentially negative effects.[12,13]

In an attempt to address some of these issues, the VA is developing a new approach to the electronic medical record. The VA is moving away from the paper-chart metaphor and towards an integrated representation of the patient's status and care process across time. One of the first steps in the development phase has been to explicitly relate patient conditions, therapies, and goals in the domain of pharmacotherapy. This integrated medication management will be achieved through an application, the Integrated Medication Manager (IMM), which draws on a theory from Cognitive Systems Engineering, Hollnagel's Contextual Control Model (COCOM).[14] Providers will be able to plan care and create orders directly in the context of these explicit relationships. This application will be implemented nationwide through a web interface embedded within the existing Computerized Patient Record System (CPRS), the graphical user interface to VA Information Systems (VistA).

COCOM is a phenomenological description of behavior from Cognitive Systems Engineering. It maps characteristics of processing and acting on information to summary modes of control that are hierarchically associated with increasing control: Scrambled, Opportunistic, Tactical, and Strategic. Higher modes of control are typically associated with higher cognitive effort. Engineers have successfully used COCOM to design and analyze technical systems in non-health care domains with the goal of making it easier to achieve higher modes of control. The purpose of this study was to take the translation and examination of how the model performs in the health care context, specifically processing information for chronic disease treatment with the goal of using the findings to inform the development of the IMM.

The clinical focus of this grant is hypertension and the setting is the Veterans Healthcare Administration.

Methods

Aim 1

Study Design. A descriptive, observational design was most appropriate. The simulations were designed to collect information about provider's mental models regarding medication management, goals associated with ordering and information search behavior, and information needs for the generation of hypotheses.

Settings and Participants. Four VA medical center sites with somewhat even size, location and presence or absence of resident training were identified and recruited. Five sites participated: Salt Lake City UT (main site), Asheville NC, West Haven CT, Seattle WA, and American Lake WA. Provider participants were selected based on their staffing in primary care outpatient clinics.

Additional criteria included being a prescribing provider and having at least one year of involvement in the VA. Patient involvement was based on provider participation and the presence of hypertension. Once a provider volunteered and an appropriate patient identified, the patient was approached and asked to participate. Eight to ten primary care providers were recruited at each site; 45 recruited in total (Table 1).

Table 1. Aim 1 participants' clinical role by site

	West Haven	Asheville	Salt Lake City	American Lakes	Seattle	Total
MD	6	6	4	3	5	24
$1^{st}/2^{nd}$ year resident			3			3
PA		1	1	2		4
Pharmacist		1	1	1	1	4
NP	3	1		2	4	10
Total	9	9	9	8	10	45

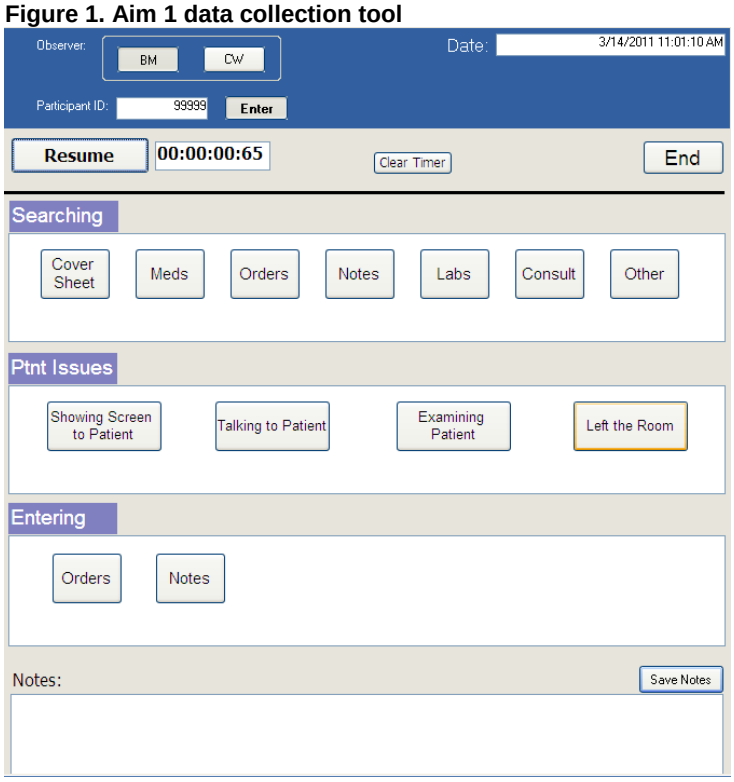
Phase 1. During the pre-visit preparation, providers were observed using the VA's EMR, CPRS, to review a patient participant's record and prepare for the patient visit. Providers were instructed to "Please think aloud what is in your mind while you do this task. Please indicate where you are in CPRS, what tab you are on, what you are doing, and what information you are attending to at each step. Also let us know when you are entering orders or creating notes. Please be as descriptive and explicit as possible. There are no right or wrong things to say." Prompts and follow-up questions were asked when necessary. If the providers prepped for the patient and/or began their note earlier, they were asked to describe what they did and how they did it. This portion lasted 5-15 minutes.

Phase 2. A researcher silently observed and audio recorded the patient visit. The researcher also recorded information-seeking and decision-making strategies of the provider on a portable tablet.

Phase 3. After the visit, based on items of interest identified during any of the phases, the researcher asked questions and prompted the provider to comment on aspects of his/her decision-making and information-gathering (Appendix 1). This discussion lasted about 10-15 minutes. In some cases, up to two of the phases may not have been recorded. In this case, the researcher asked the provider to summarize a recent patient visit while sitting at the computer and to talk about information-gathering and decision-making strategies used.

Microsoft Access was used to build a data entry interface to code provider's behavior and make notes about observations during the patient visit (Figure 1).

Figure 1. Aim 1 data collection tool



Forty-five observations were conducted in total. Observation audio recordings were transcribed and sensitive information removed.

Data Analysis: Qualitative Transcript Coding. The principle and co-investigators used ATLAS.ti, a qualitative software, to review 14 transcripts. At least one transcript from each site and a variety of transcripts of different participant roles were read. Behaviors, thoughts, actions, etc. of the providers during the pre-visit planning and visit were coded according to relation to the COCOM modes. In the end, the team had defined what actions and behavior of providers were scrambled, opportunistic, tactical, or strategic. This information was used for the creation of the quantitative coding workbooks.

Data Analysis: Quantitative Transcript Coding. Thirty-nine of the 45 transcripts were selected for content coding due to having a patient visit and having and addressing one of the five target diseases (hypertension, diabetes, congestive heart failure, coronary heart disease, and depression). Six of these 39 did not have the interview portion coded because of recorder problems or the interview did not address any of the five target diseases.

Definitions and examples of quantitative codes were developed and refined through a series of small group sessions. Pilot transcripts were coded independently by four coders and then discussed as a group. When confusion arose, category definitions were adjusted and examples were added. This process was repeated until coder agreement was high and the quantitative coding dictionary was deemed solid. This process and the coding workbook were the basis for the coding instrument.

The workbook was designed to identify which COCOM mode the provider's actions and reasoning best matched his/her caring and planning for one or two specific target diseases. The workbook was designed so that the coders would mark if specific information or tasks representing high level performance, according to the COCOM theory, were present in the transcripts. The coding instrument was built in Excel. At first the coders read through the pre-visit and visit portions of the transcript to understand the gist of the visit and directly answer non-disease specific questions. These questions incorporated COCOM constructs translated for medicine. The constructs included preparation, familiarity, reaction to new developments, interpretation of what's going on, patient disruptiveness, recovery, action taking, decision making, patterns of behavior, adaptability of patterns of behavior, integration of information, strategies and exchange of information.

Next, coders were to reread the phases 1 and 2 in the transcript and code the two prominent diseases only, or one if there were not two diseases addressed, on disease specific coding sheets. A team member determined which one or two diseases were most prominent. Each disease had its own sheet in the workbook. The coding concepts were the same on each disease's sheet. Lastly, the coders were to decide which COCOM mode most matched the provider's care plan for the specific disease.

The disease specific coding sheets were divided into two parts: a) the prior goals, plans, and actions ("Evaluation of Outcome"), and b) the provider's new goals, plans, actions ("Action Selection (Decision Making) & Goal Complexity"). The workbook incorporated the following COCOM constructs translated to medicine: history, uncertainty, explicitness of deviations, model, expectation, action, goal interaction, goal customization, outcome expectations, addressing uncertainty, and plan specification. (Appendix 2) The coder marked the COCOM areas according to: a) certain status areas used to judge the progress of the care of the disease, e.g. systolic blood pressure and lipids for hypertension; b) adverse drug reactions, e.g. dizziness, lightheadedness, potassium for hypertension; and c) patient issues, e.g. med compliance.

When the coder felt they had captured everything in the pre-visit and visit, and appropriately, they were to code the interview portion of the transcript (phase 3). A copy was made of the most prominent disease's coding sheet with the coder's coding. This allowed coders to change their coding, if needed, while reading the post-visit interview. The purpose for this was to allow comparison of what the provider actually did (the visit) and what they say they did (the interview). Some demographic and structured provider practice questions, such as excitement to deal with the problem and did they have adequate information to deal with the problem, etc., were asked at the end of the interview. These last questions were scaled or binary yes/no questions.

The workbook coding provided the data for the Aim 1 quantitative data analysis.

Seven coders were divided into groups of expert (clinician) and non-expert (non-clinician). Multiple training sessions were conducted for both groups to ensure coder agreement and correct understanding. Each coder was asked to code a pilot transcript first and percent agreement was calculated separately for the two groups. Both groups were brought together again to discuss the coding of the transcript, answer any questions, clear up misunderstandings, and provide further education or training if needed. Next, all coders were assigned a non-pilot, full visit transcript. Percent agreement was computed and another meeting set to discuss coding and more education provided if needed. Percent agreement between all coders was high enough (85%) at this point for coders to begin coding individually.

Transcripts were randomly assigned to each coder. The expert coders were assigned one transcript from each site. All the transcripts were assigned at least one non-expert. Each expert was paired at least once with each non-expert coder. To ensure reliability, the non-clinicians coded in rounds. Each non-clinician was randomly assigned three separate transcripts to code. When these three were coded, all were assigned the same fourth transcript to code, from which percent agreement was computed. If the percent agreement was too low (<80%), the three non-clinicians met to discuss their coding, come to agreement, and provide further education. This cycle was conducted three times. In the end, the three non-clinicians coded between nine to fourteen transcripts each.

Aim 2

Study Design. Simulations were chosen to measure the hypothesized difference between a standard EHR and a more medication integrated EHR designed according to the principles of COCOM.

Settings and Participants. Participants could be physicians, nurse practitioners, physician assistants, pharmacists and nurses who had practiced in primary care for at least two years. Third year residents could participate but only if they completed at least two years of residency in internal medicine or family practice. All could be VA or non-VA employees and did not have to be currently practicing. Due to time constraints, pharmacists and nurses were not recruited. Participants were also compensated for their time with comparative hourly rates respective of their positions and roles. In total, 58 providers were enrolled and all participated in the simulation. (Table 2)

Table 2. Aim 2 participants demographic information by EHR used

	All	IMM	Chart Reader
Gender: Male	25	12	13
Gender: Female	33	18	15
Total participants	58	30	28
Average age	39	40	37
Average number of years practicing	10	10	10
Current role: MD	22	11	11
Current role: DO	2	1	1
Current role: 3rd year resident	13	6	7
Current role: PA	3	1	2
Current role: NP	18	11	7
Currently practicing at: university	5	3	2
Currently practicing at: VA	43	25	18
Currently practicing at: university and VA	7	0	7
Currently practicing at: other	3	2	1

Data Collection Procedures. A prototype of IMM was developed for use in the simulations. (Appendix 3) IMM organizes information around core concepts of interventions, observations, and conditions. IMM presents this information in a manner that reduces the cognitive effort to consider data across time, relationships among concepts, and decision-making strategies. Standard and VA-specific terminologies and knowledge bases are used to relate concepts and

provide the basis for cognitive support and documentation. Coded and semi-coded annotations about these concepts form the basis of communication and documentation. This documentation supports clinical and quality-measurement activity. Breaking up documentation into concept-specific annotations facilitates viewing documentation in a variety of display contexts including: all concepts related to an episode of care, one or more concepts across time, and graphics. Finally, the interface prominently features patient-tailored goals of care that relate to observations, interventions, and conditions. All these features combine to promote enhanced shared cognition about the patient's medical status and care plan.

Participants were asked to review ten patient cases and write assessments and plans (A&Ps) for each patient. The patient's information was presented in either the new IMM EHR or the generic EHR patterned after the VA's EHR, CPRS. Participants were randomly assigned to use only one of the programs for the task. The generic EHR had been used for a previous study and did not need to be pilot tested. The IMM program was pilot tested by six clinicians who met the participant criteria. Eleven patient cases were created by doctors from scratch but based on typical VA patients. One of the cases was used for training purposes only. Throughout the patient cases, the complexity, time horizon, and saliency of the available information differs. The focus disease is more or less evident, important information is located further back in time in the patient's medical history or is more recent, and patients' problems are highly complex or less complex depending on the assigned theme. Two cases were complex and included a planned interruption, and two more were control cases. Patient cases were reviewed by three physicians to check validity, believability, and internal consistency. Each participant had a unique random order of patient cases.

Before beginning the simulation, participants were asked to take a typing test for one minute to reduce any time differences due to participant typing speed. Participants then watched a training video for the assigned EHR. The training videos also suggested a work flow to follow when reviewing each case. They then had up to ten minutes to play around in and become familiar with the program.

The simulation consisted of participants reviewing patient information and writing an A&P for each of the ten patient cases. The participants were given ten minutes to complete the task for each patient. Two and one minute warnings were given, and the participant was told to move onto the next patient when the ten minutes was over. Ten minute breaks were allowed halfway through the patient cases. For the two complex cases with an interruption, the participant was interrupted five minutes into the current respective case. The interruption was either asking the participant to go back to a prior completed patient to check that the A&P was saved or to sign a piece of paper. They were then allowed to continue working on the current case, but no additional time was given. Most interruptions took no longer than a minute.

After the last patient, the participants were asked to answer some demographic and usability questions such as was the program easy to learn, did it perform as expected, etc. If participants had time and were interested, the purpose and hypotheses of the study were explained.

The simulations were recorded several different ways. Participants were asked for permission to video and audio record them during the simulation. A recording program, Camtasia, also took a screen shot video. Both EHRs were programmed to record mouse movements in the program.

Data Analysis. In the end 58 participants were enrolled and participated in the simulation. With 10 patients for each of the 58 simulations, there are 580 A&Ps. Due to the large amount of

data, data analyses for this aim are ongoing. A few physicians will read through the A&Ps and extract the data pertaining to what the participant included therein.

Limitations. One major limitation was the inability to evaluate a system-wide deployment of the resulting GUI in terms of patient outcomes (Aim 3). Forces outside the control of this project resulted in the termination of a majority of the development team that was to support this project. Consequently, the deployment of the product (Aim 3) was prevented.

Sampling of subjects was limited. Aim 1 limited recruitment to one institution (VA only). Aim 2 limited recruitment to Salt Lake City and prescribing providers. Pharmacists and nurses use EHRs as much as physicians and nurse practitioners. Their perspectives should be included in the creation of future EHRs.

Theoretical testing was limited by lack of a validated measurement model. Some variables lacked sufficient variation to allow meaningful differentiation of behaviors corresponding to the theoretical spectrum of control characteristics. The measurement model was susceptible to a missing data problem. In the case of the patient's problems being in control, the provider typically sped through the visit and did not think aloud about many of the variables. To address this problem, in Aim 1 a stratified analysis by whether the patient's condition deviated from control was used. The stratification reduced the power for hypothesis testing and impaired the ability to determine clear clusters.

Results

Aim 1

Principal Findings. Median values for the encounter characteristics were calculated and compared between the sets of encounters with no stated deviations from goal and those with deviations from goal. The Wilcoxon Rank-Sum nonparametric test was used to compare the medians. The attributed modes of control were also compared between the two sets of encounters using Fisher's Exact test for independence. Correlations among encounter characteristics and between them and attributed mode were calculated using Spearman's Rank Correlation.

The K Means clustering procedure was applied to the standardized (division by maximum value) encounter characteristics using the kmeans function in R. The number of clusters between 1 and n (the number of observations) were considered. The number of clusters was chosen to maximize the stability criterion based on the Jaccard similarity value.[15,16] For each specified number of clusters, random seeds for each cluster were chosen ten times to ensure convergence of the algorithm. Results did not change using more than ten clusters. Star diagrams were used to visualize the final cluster descriptions. The clusters were hypothesized to represent emergent modes of control.

A cross-tabulation was used to describe the relationship between the attributed and emergent mode of control. Fisher's Exact test was used to test the hypothesis of independence.

A series of pre-specified hypotheses were tested for the emergent and attributed modes of control.

1. H_A: Increased Time Pressure results in Lower Mode of Control

2. H_A: More Years of Experience results in Higher Mode of Control

3. H_A: Greater Expertise with Problem results in Higher Mode of Control

4. H_A: Greater Familiarity with the Patient results in Different Mode of Control

5. H_A: Greater Motivation results in Different Mode of Control

These hypotheses were tested using Kruskal-Wallis test for attributed and emergent mode (clusters).

Of the 35 encounters observed, 20 had no evidence that there were deviations from hypertension goals. The encounter characteristic values were consistently lower for encounters without stated deviations from goal (Table 3), most statistically significantly so (p-value < 0.05), and the exception being Goal Complexity.

Table 3. Median (IQR) of encounter characteristic values for sets of encounters without and with evidence of deviation from goal and p-values from Wilcoxon Rank-Sum nonparametric tests for equality of medians

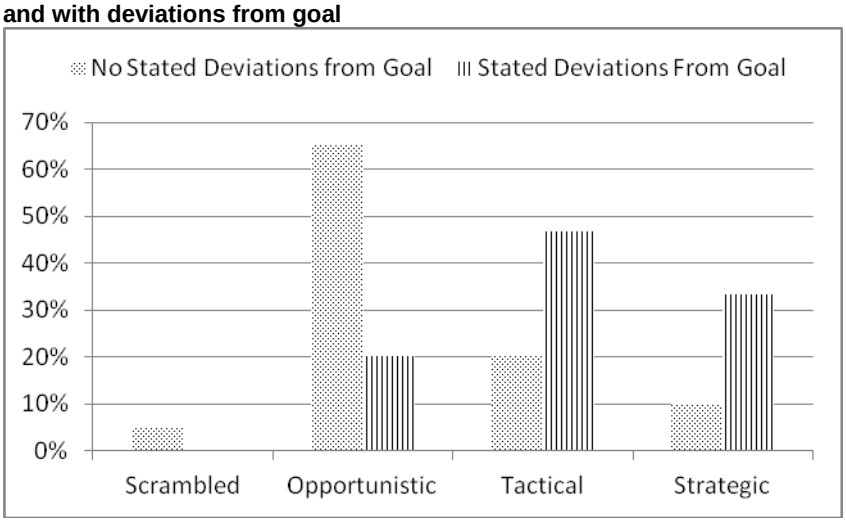
Encounter Characteristics (observed range)	No Deviations (n=20)	Yes Deviations (n=15)	Wilcoxon Rank-Sum Test P-value
Status Time Horizon (0-5)	2.67 (2 - 3)	3.67 (3 – 4)	0.0031
Action Selection (0-3)	0.5 (0.45 – 1)	1.5 (1.25 – 2)	< 0.0001
Goal Complexity (0-4)	0.07 (0 – 1)	1.0 (0 – 1)	0.19
Model Expectations (0-2)	0.0 (0 – 0)	1.0 (0.17 – 1)	< 0.0001
Plan Specifications (0-4)	0.0 (0 – 0)	1.0 (0 – 2)	0.012
Address Uncertainty (0-3)	0.0 (0 – 0)	1.0 (0 – 2)	0.0004

The attributed mode of control for the encounters covered the range of modes, but was mostly within the range of opportunistic and tactical, and with more strategic encounters than scrambled. (Figure 2) The attributed mode of control was not independent of stated deviation (Fisher's Exact test p-value = 0.004); encounters with stated deviations from goal were associated with high levels of attributed mode of control.

The encounter characteristic of Plan Specifications was statistically significantly correlated with Goal Complexity for encounters with stated deviations from goal ($r = 0.71$, $p=0.003$) and for encounters without stated deviations from goal ($r = 0.47$, $p = 0.04$). Plan Specifications was also statistically significantly correlated with Action Selection for encounters without stated deviations from goal ($r = 0.50$, $p = 0.02$). The attributed mode of control was only statistically significantly correlated with Model Expectation for encounters with stated deviations from goal ($r = 0.77$, $p = 0.0007$). The cluster analysis, used to assess the theory that encounter characteristics could be used to define the modes of control, provided evidence of three clusters for each set of encounters, those without and those with deviations from goal. (Figures 3 and 4). The number of clusters to specify and the stability of those clusters were assessed using the Jaccard similarity measure on 100 bootstrap samples. All values were greater than 0.5, which suggests that the clusters indicate patterns in the data but the values were all lower than 0.8,

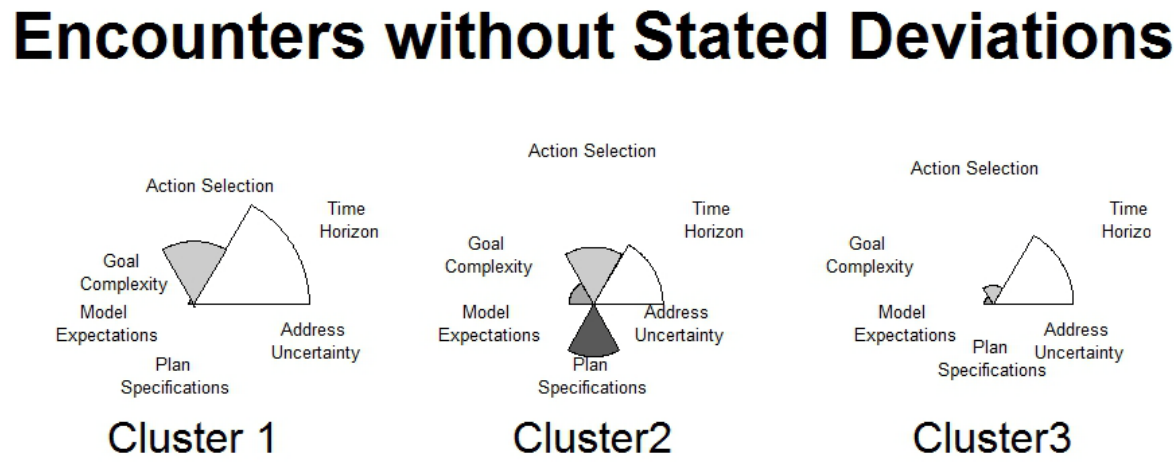
indicating that cluster membership was not stable. The lack of clear stability is not surprising given the sample size but it is promising to see patterns.

Figure 2. Percent frequency of attributed modes of control by encounters without and with deviations from goal



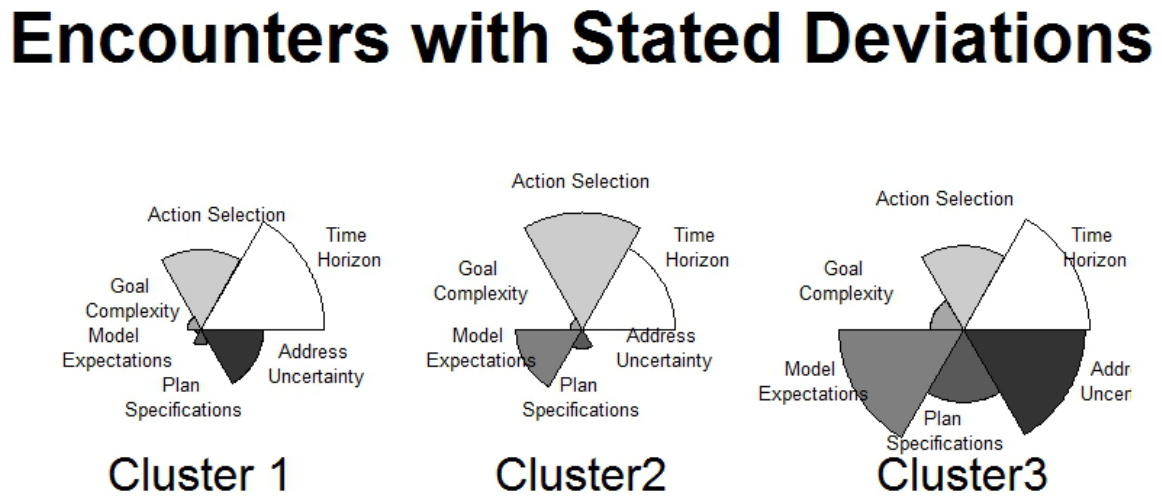
The clusters reflect differences in encounter characteristics within the groups of encounters with and with no stated deviations. The clusters within the set of encounters with no stated deviations from goal (Figure 3) revealed large differences in Action Selection and Plan Specification, with lesser differences in Time Horizon and Goal Complexity. The clusters within the set of encounters with stated deviations from goal (Figure 4) revealed the same large difference in Plan Specification with the addition of large differences in Goal Complexity, Model Expectations and Address Uncertainty. These relationships can also be seen in the mean values within clusters. (Table 4)

Figure 3. Star chart representation of K means clusters for encounters with no stated deviations from goal



Note: The size of section indicates average of the standardized (between 0 and 1) variable for the cluster.

Figure 4. Star chart representation of K means clusters for encounters with stated deviations from goal



Note: The size of section indicates average of the standardized (between 0 and 1) variable for the cluster.

Table 4. Mean values for clusters within sets of encounters without and with stated deviations from goal

Encounter Type & Cluster	Time Horizon	Action Selection	Goal Complexity	Model Expectations	Plan Specifications	Address Uncertainty
No Deviations 1 (5)	3.3	1.1	0.2	0	0.1	0.2
No Deviations 2 (3)	2	1	1	0	1.5	0
No Deviations 3 (12)	2.3	0.3	0.4	0	0	0
Deviations 1 (5)	3.7	1.4	0.6	0.1	0.5	1.1
Deviations 2 (5)	2.8	2.1	0.5	0.8	0.6	0
Deviations 3 (5)	3.8	1.5	1.4	1.5	2.2	2.2

Note: that there is no intended relationship between the cluster numbers across encounter types but they match the start charts. Number of encounters per cluster in parentheses.

The emergent modes of control were compared to the attributed modes of control through a Fisher exact test. (Table 5) For encounters without stated deviations from goal, there is some difference in the distribution of attributed mode of control between the clusters but the pattern is not definitive. For encounters with stated deviations from goal, there appears to be a more definitive difference in distribution of attributed mode of control between the two clusters. No statistically significant associations were found (Fisher's Exact test) for either the no stated deviations from goal set (p-value = 0.37) or the set with deviations from goal (p-value = 0.13).

Table 5. Cluster membership by attributed mode. Number and percent per cluster

	Overall	No Stated Deviations from Goal: Cluster 1	No Stated Deviations from Goal: Cluster 2	No Stated Deviations from Goal: Cluster 3	Deviations from Goal: Cluster 1	Deviations from Goal: Cluster 2	Deviations from Goal: Cluster 3
Scrambled	1 (3%)	1 (20%)	0	0	0	0	0
Opportunistic	16 (46%)	3 (40%)	1 (33%)	9 (75%)	3 (60%)	0	0
Tactical	11 (31%)	1 (20%)	1 (33%)	2 (17%)	2 (40%)	3 (60%)	2 (40%)
Strategic	7 (20%)	0	1 (33%)	1 (8%)	0	2 (40%)	3 (60%)
Number of Encounters	35	5	3	12	5	5	5

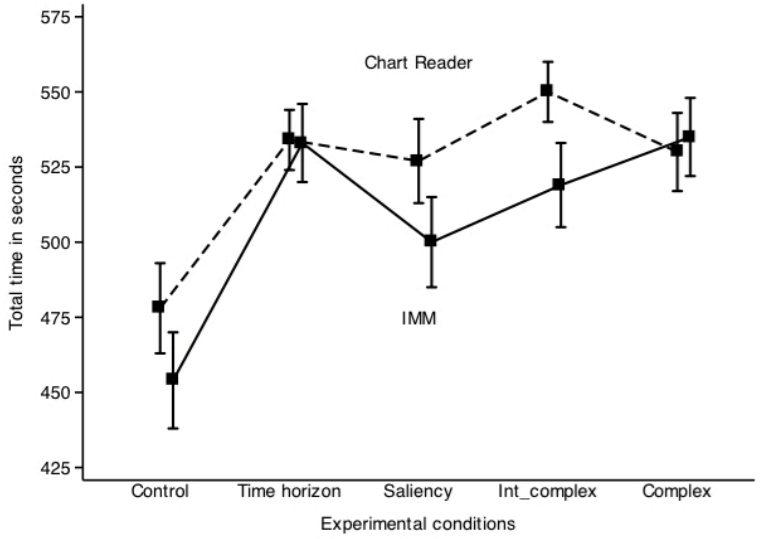
The cluster classifications were not associated with other measured variables. A Kruskal-Wallis non-parametric tests was used to consider differences in years since graduation, use of protocols, site, provider type, pressure, and motivation. Goal complexity, the main patient characteristic measured, was not related to the clusters either (all p-values > 0.1).

The specified hypotheses were tested but results were not statistically significant.

Aim 2

Principal Findings. The time, in seconds, to complete each session was measured and compared for IMM and Chart Reader across various experimental conditions. The control vignettes required approximately one minute less time to complete than the others. The differences in time required between IMM and Chart Reader were not consistent across vignettes but where large differences existed, the time required using IMM was less than Chart Reader (CR). (Figure 5)

Figure 5. Profile plot of means and plus/minus one standard error for time to completion (seconds) by application and experimental conditions



The time spent was modeled using a mixed effects linear regression. The time variable was continuous and not too seriously non-normal (the residual analyses indicated the model fit well). The patient ID was included as a random term in the model to account for this nested effect. The predictors were the application (IMM / CR) and the five experimental conditions. Covariates included the order in which the provider completed the patient simulations, the provider's number of years in primary practice, and whether the provider has used a CPRS. In selecting the final form of the model, interactions between the application a provider used and the experimental conditions, the order in which patients were seen, and the provider's years in practice were considered. None of the interaction terms were significant. There were statistically significant differences in time spent between IMM and Chart Reader as well as between each experimental condition compared to the control. (Table 6) The difference between IMM and

Chart Reader was not significantly different among experimental conditions (as indicated by the lack of significance in interaction terms). None of the covariates had a significant effect on time spent.

Table 6. Results of linear regression model of time spent.

	Estimated Coefficient	Standard Error	*Test Statistic (z)*	p value	95% Confidence Interval
IMM/CR	-17.98	8.79	-2.05	0.041	-35.2, -0.7
Time horizon	70.86	15.77	4.49	< 0.001	39.9, 101.8
Saliency	48.68	15.77	3.09	0.002	17.8, 79.6
Interruption complex	68.72	15.81	4.35	< 0.001	37.7, 99.7
Complex	67.83	15.84	4.28	< 0.001	36.8, 98.9
Patient order	1.70	1.54	1.11	0.267	-1.3, 4.7
Years practicing	-0.29	0.57	-0.51	0.610	-1.4, 0.8
Used CPRS	0.60	9.01	0.07	0.947	-17.1, 18.3
Constant	465.13	17.06	27.27	< 0.001	431.7, 498.6

The process of extracting concepts pertinent to health care delivery from the A&P text written by study participants is continuing. These concepts include the control and status of the patient's relevant problems, planned use of medication and non-medication interventions, and planned monitoring (e.g. lab tests) and follow up encounters.

Three physicians reviewed the patient cases and agreed on appropriate management options. With their input, a reference standard A&P was developed for each case and has been used to build algorithms that will drive the analysis of concepts extracted from each A&P text. A score of assessment accuracy and plan appropriateness will be calculated for each A&P written by each study participant.

Conclusions

In Aim 1, the translation of COCOM is promising for targeting characteristics that predict higher levels of performance on tasks related to chronic disease management. The phenomenological characteristics may be specifically targeted and maximized in design of information systems that produce higher quality of care at lower cognitive load.

In Aim 2, despite their unfamiliarity with the integrated display of multiple relationships, providers were faster using the novel GUI.

Discussion

In Aim 1, there was a moderately successful translation of COCOM to the practice of medicine. The lack of strong correlations among variables in the measurement model was surprising. It was assumed that for any given encounter, the values of most variables would track together. However, upon further reflection, COCOM is a phenomenological model. It does not predict mechanisms of behavior only that certain behaviors will result in a more orderly conduct of business, which should result in better outcomes.

Despite the phenomenological nature of COCOM, most raters agreed about the overall mode of control. This agreement suggested that there were patterns of behavior in which some variables tracked each other. In cluster analysis, patterns of control were found in which variables generally increased. As expected, these patterns were clearer in cases where there were deviations from control.

Cluster analysis also highlighted a theoretical problem with the action selection variable. This variable was prominent in all three clusters and generally spoiled the visual progression from low-to-high levels of variables. Upon closer inspection, action selection is about the intensity of intervention and relates more the patient's condition than the provider's reasoning. The data will be reanalyzed without this variable and findings will be reported in scholarly journals.

Aim 2 was an unexpected success for the new visualization of the medical record. With only a few minutes of instruction, providers were significantly faster using the completely unfamiliar GUI. The largest improvement in time was in the case of interruptions in considering complex patients. This is consistent with expectations, as the GUI was designed to help with complex sense making and to be robust to interruptions, as relationships are explicit in the presentation and don't need to be recreated in the mind of the provider.

Analysis is ongoing to answer the question whether providers create more accurate assessments and more appropriate plans of care.

Significance

The Integrated Medication Manager addresses three policy imperatives. First, it provides for medication reconciliation that exceeds the standards of Joint Commission rules.[17] Beyond just reconciling list of medications, IMM naturally enforces a workflow in which medications may be reconciled to conditions and goals. Second, it meets Joint Commission's standard that all medications have a documented indication.[18] Third, the Integrated Medication Manager supports AMA and CMS documentation requirements regarding problem assessments[19]: it depicts a directional change in status.

An EHR GUI, such as IMM, based on the theories of COCOM to help improve medication management will increase accurate and appropriate patient care by decreasing medical errors, cost, and missed opportunities for health care coordination. This system will also improve (i.e. decrease) the time and energy providers spend searching for pertinent information necessary for health care plans all of which will ultimately improve patients' health and well-being.

The investigators and co-investigators practice within the VA Health Care System and are integral in the creation of the next VA EHR. These positions and roles can ensure that the findings of this study are integrated into the next generation EHR in the VA and potentially outside as well.

Implications

All types of prescribing providers, pharmacists, and nurses will be affected as well as over 5 million VA patients. However, the relevance of this project extends beyond the VA and the specific clinical topic of hypertension. The focus of this grant is on the effects of integrating conditions, therapies, and goals—not on condition-specific decision support. If we can identify behaviors that predict better decision making and can design software to facilitate those

behaviors at a lower cognitive load, we can both speed the design of effective software and use behaviors as surrogate measures of design effectiveness. These findings present an important opportunity to advance the science of clinical medical informatics and will be used as a basis for development of iEHR.

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List of Publications and Products

Dr. Nebeker is the VHA lead for the Presentation Layer for the DoD-VA Integrated Electronic Health Record (iEHR). His team will use the translated COCOM framework to guide the acquisition, design, and evaluation of GUIs for iEHR. The mocked up system has broad clinical support in VA and DoD and will form the basis for production of a new paradigm for EHRs to be developed for the iEHR.

We have given numerous poster and oral presentations at AHRQ and VA HSR&D scientific meetings.

Appendixes

Appendix 1: Post Observation Interview Questions

Table A1. Post observation interview questions

Question
For the purposes of the transcript, can you tell me this patient's active problems and current medications? Feel free to refer to your notes.
Now we will talk about the patient's problems. We will first talk about hypertension (*if no HTN, the most important problem*). If we have enough time, we will review a 2nd problem.
Could you please summarize how you are managing this problem for this patient?
Can you elaborate on the different factors, steps, or components you have to consider when thinking about managing this problem? I am looking for information such as social and administrative issues, pros and cons of a particular intervention, and when you consider assigning tasks to other people to help manage the problem.
For this problem, what would you say you are trying to achieve, what are your goals?
Can you elaborate on the goals for achieving clinical outcomes?
How do the goals for this problem interact with the patient's other medical problems?
Are you achieving your goals and how did you decide that?
What is the metric or indicator you track for this patient? For example, diastolic versus systolic, home versus clinic, nurses measurements versus your own, etc.
If you have other goals related to hypertension management, what do you explicitly track to evaluate those goals?
An example of an explicit metric for hypertension is office measurement of systolic blood pressure. Is there any way you explicitly measure progress to know whether you have achieved your clinical goals for this problem? What is the metric or indicator you track?
So let's say you have feedback on (this metric) _____ and the other metrics you may have mentioned. What are the values (upper and lower limits) that would indicate you are not achieving your goals for this patient's problem? This may not be so-called "normal limits."
You have talked about the information needed for follow up. Now talk about the plan for obtaining and evaluating this information. Please provide explanations for your choices.
If you made changes in the treatment plan today for this problem, please briefly summarize again those changes and explain why you made them? If there were no changes, why not?
Based on your understanding of this patient's problem, what do you expect to happen with each of your goals (*restate if necessary*) and within what time frame?
Some people use nationally accepted protocols, some people use their own based on their clinical expertise and understanding of the literature, and some don't use a protocol. Do you have a standard protocol for this problem? Briefly, what is it?
If you used a protocol, how well does the protocol you used apply to this patient's problem? (9-point scales; 1= not well to 9 = very well)
Did you deviate from the protocol? If so, why?
Considering your expertise with this problem, how would you rate your degree of comfort in handling this problem for this patient? (9-point scale; 1 = extremely uncomfortable to 0 = extremely comfortable)
How much do you <u>not</u> want to deal with this problem? (9-point scale; 1 = excited to deal with it to 9 = really don't want to deal with it)
Did you have any problems with the information being inadequate or unreliable? What were they?
How did you deal with uncertainty caused by inadequate or unreliable information when making your treatment plan?
How busy are you feeling right now?
How much mental and perceptual activity was required (e.g., thinking, deciding, calculating, remembering, looking, searching, etc.) during the visit? (9-point scale; 1 = low to 9 = high)
How much time pressure did you feel due to the rate or pace at which the tasks or task elements occurred? Was the pace slow and leisurely or rapid and frantic? (9-point scale; 1 = low to 9 = high)

Table A1. Post observation interview questions (continued)

Question
Would the patient say that you are his/her primary physician?
How familiar are you with *all aspects of this patient, including their medical, personal & social* situation? (9-point scale; 1 = not at all to 9 = very)
What year did you get your clinical degree?
How many patients have you seen or do you expect to see this morning/afternoon?

Appendix 2. Coding Constructs on Disease Specific Construct Coding Sheets

Table A2. Coding constructs on disease specific construct coding sheets

Category	Type	Coding
Evaluation of Outcome	1. History	No status mentioned
		Status addressed but no data points given
		1 data point
		2 data points
		3+ data points
		Data prior to last visit was considered
	2. Uncertainty	No uncertainty
		Inferred: yes uncertainty
		Stated: yes uncertainty
		Explanation of uncertainty
	3. Explicitness of deviations	No deviation or not mentioned
		Yes deviation: inferred
		Yes deviation: stated
		No deviation or not mentioned
	4. Model	Model/cause not articulated
		Model/cause articulated and certain
		Model/cause articulated but uncertain
		Plan to address model uncertainty
	5. Expectations	No expectations
		Stated expectations
Action selection (decision making) & goal complexity	6. Action	No decisions made/not addressed
		Monitoring and feedback
		Continue plan (no change in plan, no consult/procedure)
		Treatment/change in plan
		Consultant/procedure
	7. Goal Complexity	No explicit target value stated
		Explicit target value stated
		Stated: quantifications of completing risk and benefits
	8. Goal customization	Customized to patient disease
		Customized to patient preferences
	9. Outcome expectations	Expectations of control given plan
		Interactions with goals of other conditions: positive
		Interactions with goals of other conditions: negative
	10. Addressing Uncertainty	Uncertainty present: not addressed
		Uncertainty present: inferred that it was addressed
		Uncertainty present: stated that is was addressed
	11. Plan Specifications	Timing
		Mention of patient responsibility
		Mention of health provider responsibility
		Anticipates potential barriers to care
		Contingencies

Appendix 3: Integrated Medication Manager EHR

Figure A1. Integrated Medication Manager EHR