Grant Final Report

Grant ID: R18HS017190

Ambulatory Care Compact to Organize Risk and Decision-making (ACCORD)

Inclusive Project Dates: 09/01/07 – 08/31/11

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Abstract

Purpose: This project's objectives were to design, implement, and evaluate a comprehensive, practical, and innovative model of care delivery that incorporates shared decision-making. Ambulatory Care Compact to Organize Risk and Decision-making (ACCORD) allows patients to collaborate with clinicians to establish, monitor, and track clinical care plans to reduce the risk of lack of followup.

Scope: The project team developed ACCORD to help providers and patients manage followup of plans determined at primary care visits. The team selected the following domains to support with ACCORD: preventive health screenings, abnormal findings followup, and medication monitoring.

Methods: Two series of patient-provider focus groups were conducted as part of the iterative design effort. Implementation of the ACCORD systems included: definition of ACCORD temporal concepts; determination of representative use cases and business rules; definition of the ACCORD template and population of the ACCORD template library; development of the ACCORD authoring tool and definition of authoring guidelines; implementation of the ACCORD event detection engine and scheduler; and integration with provider and patient systems. A randomized controlled trial to evaluate the ACCORD system in the largest primary care practice at Massachusetts General Hospital will be performed imminently.

Results: The preliminary results from the focus groups showed the need for a model that would support a high variability in patient-provider collaborative decision-making styles, rather than imposing an ideal concept of shared decision-making. A comprehensive software system for authoring, proposing, and accepting ACCORDs was implemented based on a usability and model evaluation.

Key Words: shared decisionmaking; health care informatics

Final Report

Purpose

In this Final Report, we share the design, implementation, and lessons learned in the development of an innovative model of care delivery that enables patients and primary care providers (PCPs) to agree upon shared care plans that incorporate patient and provider preferences: Ambulatory Care Compact to Organize Risk and Decision-making (ACCORD). This "compact" between a patient and his or her own PCP is supported by an information architecture and software designed to facilitate the creation, initiation, and longitudinal tracking of these preferred care plans.

The project activities were organized into three steps. Step one was to design a model for patient-centered primary care that facilitates patient-clinician partnerships that results in documented followup care plans that can be tracked reliably to reduce the risk of care plans being lost to followup. Step two was to develop a clinical informatics architecture and software (i.e., ACCORD) within an established practice-based research network (PBRN) to create and track these clinical compacts and to make visible any deviations from them. Step three remains ahead and is to conduct a randomized controlled trial (RCT) within the Massachusetts General Primary Care Practice-Based Research Network (MGPC-PBRN) to examine system adoption and differences in outcomes such as preventive screening test completion, and patient satisfaction and engagement.

Scope

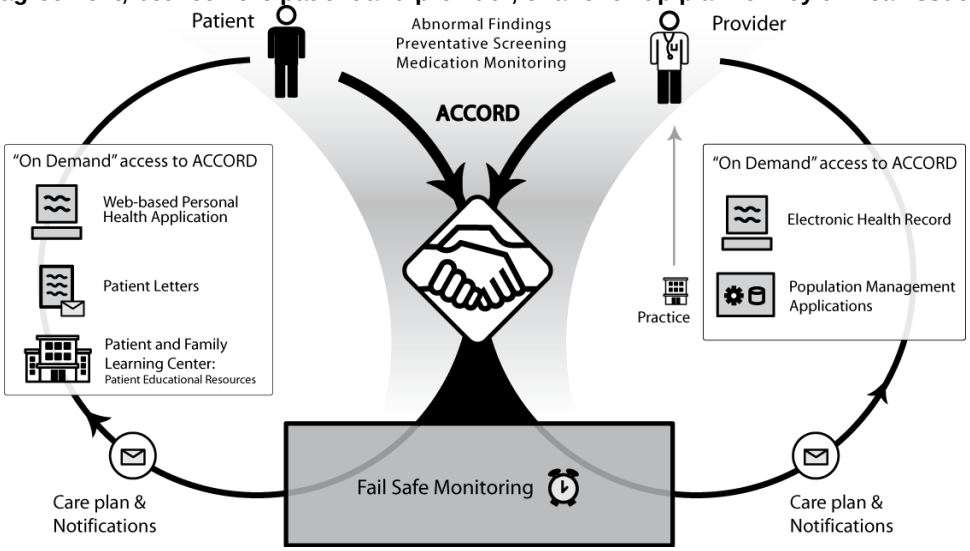
In 2006, the American College of Physicians warned that, "primary care, the backbone of the nation's health care system, is at grave risk of collapse."[1] Nearly half of PCPs report not having adequate time to spend with their patients,[2] resulting in patient dissatisfaction[3] and job frustration among PCPs.[4] Studies reveal low rates of appropriate preventive screening and marked shortcomings in the management of such chronic diseases as hypertension and diabetes.[5] Barriers to effective care have been attributed to lack of continuity in care, financial barriers, poor patient-physician communication, and "clinical inertia" – the empiric observation that indicated management changes are frequently not made during clinic visits.[6] Pressure to maintain high productivity also directly interferes with the core relationship established over time between patients and providers.

Failure to followup abnormal tests and failure of care providers to adhere to recommended guidelines are common quality concerns in primary care. Failure to followup on the increasing number and variety of diagnostic testing options is one of the fastest growing areas of malpractice litigation in outpatient medicine,[7-9] with 27% of all diagnostic-related claims related to systems errors such as poor tracking of diagnostic tests, inadequate patients monitoring, and failure of patient notification.[10] Up to one-third of physicians report no reliable method to ensure

that tests are completed and results adequately tracked,[11] and less than one-third are satisfied with their current system of abnormal test result management.[12]

Prior research supports the importance of patient-clinician collaboration in agreeing about treatment goals to manage chronic health problems,[13, 14] to communicate about the provision of preventive services[15] and to promote medication adherence.[16] Current systems lack comprehensive, practical approaches to translating a model of collaborative, patient-centered care that engages patients, clinicians and practices together in the *explicit* creation and execution of shared clinical care plans. In response, we proposed to design a primary care delivery system (ACCORD) to transform care within the MGPC-PBRN by involving patients and families in the design of tools to foster shared decisionmaking, to invigorate patient-clinician partnerships, and to share care plans visibly (Figure 1).

Figure 1. A schematic of the overall ACCORD model. An ACCORD is a clinical compact, or an explicit shared agreement, between the patient and provider, of a followup plan for key clinical issues.



The ACCORD model embraces the notion of "*jidoka"*, a concept described in the Toyota Production System, and a Japanese word that denotes rapid and visible detection of deviations so that corrective actions can be taken quickly and lessons learned to avoid future deviations. ACCORD helps to bring *jidoka* to care processes so that patient-clinician awareness, communication, action, and understanding can be enhanced.

The ACCORD approach:

- Allows providers and patients to easily and explicitly identify one of several alternative data- and/or evidence-based followup plans according to specific clinical and personal circumstances

- Allows practices to initiate followup plans on a population basis on behalf of clinicians (e.g., for screening)

- Supports the distribution of relevant web-based and non-web-based materials available to aid in informed decisionmaking by the patient,

- Creates an artifact (i.e. documentation) of the shared agreement, and

- Provides a tracking system that makes visible any deviations from the plan to all parties including the patient as well as their providers, so they can initiate corrective action.

ACCORDs are relevant anywhere a well-defined future care plan can be identified as part of a clinical management decision, including priority areas for improvement in health care quality identified by the Institute of Medicine[17] of evidence-based cancer screening, medication management, self-management of chronic health conditions and tobacco-dependence treatment in adults. Within the context of this proposal, we are targeting ACCORDs for situations where significant risk emerges in the ambulatory domain even *after* care decisions may have been made, because of the lack of explicit, monitored followup plans: 1) medication management such as new drug therapy starts where followup to monitor for adverse reactions (including laboratory test monitoring), effectiveness, and compliance are critical, 2) screening, where lack of adherence may lead to adverse outcomes, 3) abnormal tests followup where interval time may be variable and difficult to track properly, and 4) chronic disease management where regular testing and/or followup must occur to avoid poor outcomes.

The Massachusetts General Primary Care practice-based research network consists of a collection of primary care practices anchored at a major urban academic medical center. The study is conducted at the largest practice that resides at MGH's main campus. At this practice, providers use the Oncall electronic health record system (EHR), an EHR that was developed internally at MGH. The patient population is a diverse mix of Medicare/Medicaid, commercially insured, and free care patients.

Methods

Specific Aim 1

To design a model for patient-centered primary care that facilitates patient-clinician partnerships that results in documented followup care plans that can be tracked reliably to reduce the risk of care plans being lost to followup in busy primary care networks.

Our design approach included two focus group series to gather functional requirements and community feedback from across the practice-based research network. Patient candidates were stratified by race/ethnicity to ensure representation from minority groups as described below. Low-fidelity and fully functional ACCORD prototypes were produced for the first and second series of patient-provider focus groups, respectively.

Focus Group Series 1. Patient and physician participants were drawn from 13 out of 15 member-practices of the MGPC-PRBN. All primary care physicians (PCPs) were eligible to participate in the focus groups. Eligible patients included those linked to a specific PCP who

were between 40-75 years of age, were English speaking, had a visit with their provider within the past year, and lived within 15 miles of Massachusetts General Hospital (to keep travel to and from the focus groups reasonably under one hour each way – previous experience has shown us that patients will not travel more than an hour for these types of activities). In addition to being asked to participate in focus groups, network PCPs were emailed a list of 10 of their patients selected via a random sample stratified by race/ethnicity and were asked to exclude any patients who they felt it would not be appropriate to invite to a focus group for any reason. All patients who were not explicitly excluded by their physician were invited. Those who reported that they *both* frequently used email (for work or to stay in touch with friends and family) *and* frequently searched for information on the Internet were classified as high Internet users. Patients who reported they did not frequently use both email and search were classified as low Internet users.

We conducted seven 90-minute focus groups including two with physicians only; three with patients only (one low Internet use, one high Internet use, and one mixed group); and two groups that each involved physicians and patients from their own practices. The patient focus groups explored how patients currently work with their physicians to make decisions, how they seek out information, their interest in using a system like ACCORD, what features they would want the system to have, and how they would want to learn about and use it. The physician focus groups explored views about shared decision-making, including which clinical areas are most appropriate for shared decision-making and how the system would fit into their current workflow. The combined focus groups were conducted to help uncover themes that might otherwise remain hidden in conversations among participants with similar experiences. Transcripts of the focus groups were analyzed using an inductive approach based on grounded theory to best describe the themes discussed by the focus group participants.[18] This work was done by five members of the study team working independently in two groups, with all discrepancies resolved via consultation between the senior study team members in each group.

Focus Group Series 2. Six volunteer primary care provider-patient pairs used a live version of the ACCORD system in hypothetical and real scenarios suggested by their own experiences and issues. Two sessions were run, each two and one half hours long on site at the MGH Laboratory of Computer Science. Three of the pairs participated in each of these sessions.

At each session, the teams were given an initial orientation to the system and the purpose of the sessions. Each participant was handed a sheet with a selection of 3 or 4 scenarios to choose from, based on their own interests. These selections were chosen from a library of scenarios:

- a new echocardiogram result that revealed moderate aortic stenosis
- a chest x-ray that showed a possible lung nodule
- a history of persistent microscopic hematuria and urinalysis results showing blood
- new subacute abdominal pain
- advanced care planning
- options to address erectile dysfunction
- evaluation and management of persistent low back pain

- starting a new medication for elevated cholesterol results
- deciding on preventive colon cancer screening

Each was also given a personal schedule for rotating through different rooms (which represented either patient homes or provider offices). Each participant had an opportunity to consider use of ACCORD in the pre-visit, visit, or post-visit contexts. The user sessions were recorded using ScreenFlow® software that user audio and video are coordinated with mouse movements. A facilitator observed all sessions. After three rotations, the three teams were brought together to discuss the experience in a facilitated focus group that was audio recorded. Questions regarding how readily people can learn the ACCORD model, how well ACCORD can be incorporated into clinical work flow, and general usability were addressed.

Specific Aim 2

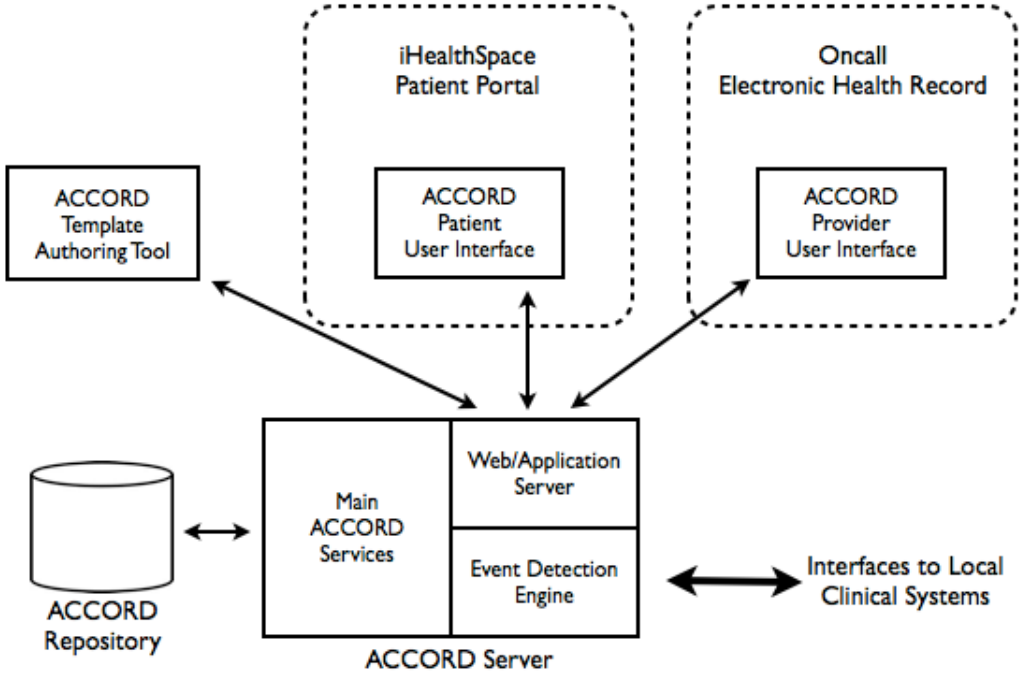
To develop a health information technology architecture and software (ACCORD) to support the patient-centered care delivery model designed in Specific Aim 1.

The goal of this aim was to develop the information technology that can facilitate provider-patient decision-making and the establishment of explicit, shared care plans that can be monitored over time for deviations from plan. This involved the creation of four major software components: a provider user interface to allow physicians to propose ACCORDs customized for patients, a patient user interface to allow patients to accept them based on their own preferences, an authoring tool to create ACCORD templates, and an ACCORD server to construct interactive Web pages that manage and present all the data associated with the first three components, as well as to operate as the engine to activate and monitor ACCORDs over time. Additionally, the design of the provider and patient user interfaces had to allow them to be embedded into existing clinical systems being used; namely, the electronic health record (EHR) and the patient portal. The overall architecture of the ACCORD system is shown in Figure 2 below.

Software Development Technologies. All ACCORD software was developed using Java, Open Source Java-based frameworks, HTML5 and Javascript. Portions of the Web browser-based software for the authoring tool, provider interface, and patient interface were developed in Adobe's Flash/Flex technology.

ACCORD Provider User Interface. The method used to design and develop the provider user interface was a combination of iterative prototyping of navigable screen designs based on a combination of our fundamental ACCORD concept, focus group feedback, and the evolution of the ACCORD data model driven primarily from template authoring (described below). As a Web-based client user interface, this application is generated by the ACCORD Server and in presented as Web pages in a standard Web browser. The user interface was optimized for rapid workflow. Screens were designed to allow a provider to quickly find an ACCORD by clinical topic, select the patient-appropriate options to recommend from a simple visual interface, and review and propose the ACCORD.

Figure 2. A diagram of the overall architecture of ACCORD with its major software components and their relationship to clinical systems at MGH.



Physician feedback consistently emphasized that this module needed to be integrated smoothly with clinician workflow. The primary method used to achieve this was to construct the provider user interface so it could be embedded directly within the practice's EHR. Other methods to enhance integration included: 1) generating clinical documentation with a coded problem and problem-linked comment for the structured problem list; 2) integrating ACCORD event notification with the clinician's results management module in the EHR; 3) implementing notifications regarding overdue actions so they occur in systems that providers and patients are already using (messaging module in EHR, email); and 4) use of a mechanism to offer ACCORDs in "batches" to a set of patients who meet a set of predefined criteria: any system that can identify a particular subset patients can launch ACCORD with the patient list, allowing a clinician to propose an ACCORD to all of the patients in the list in a single step. In this scenario a provider proposes the same ACCORD with the same possible options to a group of patients, but because of ACCORD's bilateral design, each patient still has the ability to accept or decline the ACCORD with their individual preferences intact.

ACCORD Patient User Interface. Similar to the provider user interface, the patient user interface was also designed as a Web-based application. The method used to design and develop this component mimicked the provider user interface, not only in technical methods, but also more literally in sharing the actual visual layout and screens with the final review step in the provider interface. This was done intentionally to align as closely as possible what the provider sees when proposing an ACCORD with what the patient sees when accepting one. The practice's patient portal, iHealthSpace, is the integrated delivery platform for the ACCORD patient module. iHealthSpace also offers patients secure messaging with e-mail notification, prescription renewal capabilities, laboratory and diagnostic results viewing, and access to view and request

appointments. This component was designed to make itself available through the portal only to patients of primary care physicians randomized to the intervention arm the study.

ACCORD Authoring Tool. An interactive authoring tool was designed and developed to support online authoring of ACCORD templates. An ACCORD template provides a structured representation of the plan of care to be jointly considered by the physician and patient seeking to form an ACCORD. Every available ACCORD is first defined as a template. An ACCORD template is used to drive the ACCORD server to produce the provider and patient user interfaces with which providers and patients can interact when proposing and accepting ACCORDs. Initially, investigators from the research team authored a number of templates manually. These were analyzed to determine the data elements that an ACCORD template must have to satisfy the characteristics described above. From this, a data model for the template was constructed that also accounted for the temporal aspect of ACCORDs. A functional prototype of the ACCORD template authoring tool was developed and provided to three internists who are also medical informatics faculty at the MGH Laboratory of Computer Science. They were given an introduction to the tool, and given the task of developing one template each using the tool. The three subjects then met with two members of the research team to discuss their experiences. As the project developed, the ACCORD template database evolved into a repository for all ACCORD metadata, kept as a SQL Server database. For example, each template is typically associated with one or more diagnoses that are coded with the SNOMED terminology. This allows clinical documentation about an ACCORD to be linked to an EHR problem list that also uses a SNOMED coded vocabulary. Lessons learned from the focus groups and research team testing were then used to establish a set of authoring guidelines.

ACCORD Server. The ACCORD Server was created as a collection of key modules. Web application server technologies (Apache, JBOSS) were used to support the delivery of the Web browser-based provider and patient user interfaces. The ACCORD repository was designed as a relational database schema and implemented using Microsoft SQL Server. The core ACCORD services and the event detection engine (detailed separately below) were developed as Java services.

The fundamental business rules that govern the lifecycle for the ACCORD system were developed early in the project by performing use case modeling of the workflow of clinical providers through several key scenarios including but not limited to: 1) a clinical condition that required followup care on a regular basis, 2) a new clinical condition discovered through a diagnostic result and needing a followup care plan, and 3) the case of missed followup care and the resulting process (or lack thereof) to manage this oversight. Through iterative discussion among the research team, informal interviews with colleagues, and feedback from the focus group series completed as part of Specific Aim 1, these rules were refined over time and expressed within the ACCORD Server software.

ACCORD event detection and scheduling engine. A core concept of ACCORD from inception has been the notification of both patients and clinicians when scheduled actions in the agreed upon plan of care become overdue. The underlying machinery that makes it possible to track whether or not the plan laid out in an ACCORD is being followed, and mobilize attention when an ACCORD is not on track, has three elements:

Data Services. A significant part of the work involved ensuring that the "clinical observations" specified by ACCORD template authors could be mapped to the local coding schemes and data retrieval services of the study sites' clinical systems that contain instances of real-world observations. This was critical so that the sites' system could detect reliably clinical events that impact the progression of an ACCORD. For laboratory results and medication lists, distinct terminologies allowed straightforward mapping between ACCORD observations and data elements specified in the sites' clinical systems such as laboratory reporting or order entry. On the other hand, diagnostic and other clinical reports (e.g., a colonoscopy report) in the sites' clinical systems are not coded with a terminology. Instead we established a library of regular expressions that could match text patterns from the narrative text of these clinical reports to identify them. In some cases, refinement and reformulation of the observations themselves were needed. For example, authors created a "referral visit" observation that did not distinguish between the presence of a referral and the actual confirmation of the visit. From an ACCORD standpoint, detecting the referral was of little value — whether the recommended visit actually occurred was the critical observation.

Event Detection. The *ACCORD event detection engine* is the component that monitors all active ACCORDs and checks on the status of all the expected clinical events associated with ACCORDs. Expected clinical events are those events (e.g., colonoscopy completed) that must occur to prevent an ACCORD from alerting as deviating from its intended course. This was implemented using an open source business rules engine (DROOLS). Each of the rules use the metadata acquired above to search for the specific types of events defined in the chosen care plan option in the ACCORD.

Scheduling and Notification. The *ACCORD scheduler* is the software component that monitors the timing of events associated with the chosen plan of care and triggers notifications if the event is not detected by the expected due date. The potential schedules for specific events are defined within each ACCORD template. A rule-based framework is used to determine the unique and discrete path a message can take through the system.

Specific Aim 3

> To implement and evaluate ACCORD in a randomized controlled study within the Massachusetts General Primary Care Practice-Based Research Network (MGPC-PBRN).

Providers from the largest practice within the Massachusetts General Primary Care Practice-Based Research Network MGPC-PBRN will be randomized to 1 of 2 arms: Arm 1: implementation of the ACCORD system, or Arm 2: usual care. Outcomes will be measured at the patient level, and analyzed as described below in Outcomes and Analysis. Primary outcomes of our study will include population-level measures of the patients' experience of care (CAHPS® survey), patient-level measures of shared decisionmaking skills and activation stage, and quality of care (e.g., colon cancer or breast cancer screening rates). We do not intend to submit the CAHPS® survey data to the CAHPS Database (formerly known as the NCBD). The limitation of the ACCORD study population to patient portal users will make benchmark comparisons involving this population problematic to interpret. The EHR will be the data source to assess

whether patients are receiving the appropriate care for prevention, treatment, and management of the IOM's priority areas. Within the context of this work, patients are not able to access reports of ambulatory care quality and safety for their providers, so we will not be reporting these data. Similarly, this project is not in a low-resourced rural and urban safety net setting where health IT diffusion low. The percent of eligible patients within the study practice who have access to their personal health information, including medication therapy, and/or customized decision support will be derived from MGH's iHealthSpace patient portal. Finally, the percent of ambulatory clinicians within the practice who routinely use measurement tools to evaluate their patient's experience will come from pre-existing hospital CAHPS reporting processes.

Randomization. Staff physicians at Internal Medicine Associates (IMA), one of the practices in the MGPC-PBRN, will be approached and asked to participate in this study. Information about the study, its goals and objectives, will be explained in detail. Physicians consenting to participate will be randomized to intervention and control groups in a one to one manner. Patients of these physicians as detailed in the next section will participate. Patients in the intervention group will not be consented for use of the ACCORD system since it will be the standard of care for these patients' physicians and all use of the ACCORD system will be under the direction of their personal physician. Patient consent will only focus on patient surveys in intervention and control groups.

Eligibility. Providers: All staff physicians at the IMA are eligible.
Patients: English-speaking patients with any ambulatory contact in the Internal Medical Associates (IMA) primary care practice and who are cared for by a participating physician (both intervention and control PCPs) will be eligible. Specifically, we will identify eligible patients in two phases. In phase 1, IMA staff will enroll as many patients as possible to sign up for iHealthSpace, the practice's patient-facing Web portal. This patient population will be analyzed for patient-centered outcome measures involving patient experience of care and measures of decisionmaking and activation, comparing those who have used ACCORD to those who have not.

Phase 1 eligibility criteria. Inclusion criteria: Adult patients 18 years or older seen in the IMA in the past three years that are 1) linked to a specific IMA PCP, and 2) signed up for the practice's patient portal, iHealthSpace.

Exclusion criteria: Patients who 1) subsequently die during the course of the study intervention, 2) the registration system lists the patient as having a PCP who is not in the IMA.

For enrolled patients in Phase 1, we will identify through the EHR those events that would trigger one of the ACCORDs that we are analyzing for impact on specific quality of care measures. These ACCORDs include 1) colorectal cancer screening and surveillance, 2) abnormal radiology result or incidental finding, and 3) new medication start that requires a followup laboratory test. All patients of intervention PCPs will be able to use the ACCORD system, but only patients identified in Phase 2 will be used in formal analyses.

Phase 2 eligibility criteria. All patients of intervention PCPs will be able to use the ACCORD system, but only patients identified in Phase 2 will be used in formal analyses.

Inclusion criteria: Enrolled patients in Phase 1, and identified as meeting criteria for at least one of the three ACCORDs used for formal analyses:

1. Colorectal cancer screening: Patients that are 50 to 69 years of age with no documented colonoscopy in the past 10 years; or documented sigmoidoscopy, barium enema, or computed tomography (CT) colonography in the past 5 years.

2. Abnormal radiology result: Patients 18 years old or older with an abnormal radiology result (including plain x-ray, CT, magnetic resonance imaging, ultrasound) that requires additional followup imaging.

3. New medication start: Patients 18 years old or older who start new medications for hypertension or hyperlipidemia that require a followup laboratory test.

Exclusion criteria: Patients who 1) subsequently died during the course of the study intervention, 2) do not read or write English, or 3) meet exclusion criteria for ACCORDs listed below:

a. Colorectal cancer screening: Patients with a history of prior total colectomy.

b. Abnormal radiology result: Patient requiring biopsy or consultation for abnormal imaging finding or patient in whom recommended followup imaging is one year or more.

c. New medication start: Patient previously treated with same medicine or class of medicines within the prior 6 months and having had appropriate laboratory monitoring.

Expected Enrollment. Patients of participating physicians who are enrolled in iHealthSpace, the practice's Web-based patient portal, are eligible to participate in ACCORD and will be included in patient survey response analyses. The number of eligible patients is estimated to be 2,000 to 5,000. While the ACCORD model has been designed and developed to apply to shared, monitored care planning of many conditions, only the three selected ACCORDs (detailed in *Eligibility Criteria*) will be analyzed in detail. These domains were selected because lack of followup in the ambulatory setting in these cases is common, and can confer significant risk to patients. The number of eligible patients in each of the selected ACCORD domains is estimated to be between 100 to 200 patients, for a total of 300 to 600 eligible patients.

Outcomes and Analysis. The change in all primary outcome measures (described in detail below) performed at baseline and followup will be calculated for intervention and control groups. We will test the interaction between group and time and account for potential 'cluster effects' (correlations among patients within the same provider) using a mixed effects model where each cluster is treated as a random effect. We will examine the potential effects of differing patient (e.g., age, gender, race and insurance status) and provider characteristics (e.g., gender, years since graduation, full-time/part-time). These factors will be included in the multiple regression models if they are considered as potential predictors or effect modifiers of outcomes. All statistical analysis will be performed using SAS statistical software. Statistical significance will be defined as a two-tailed p-value <0.05.

Time to event analyses will include: 1) time to preventive test completion in intervention and control patients, and 2) time from test ordering to recognition of abnormal test result with action taken. Survival analysis techniques will be used to study the time between an abnormal or missing result and the subsequent followup action. Kaplan-Meier curves will be used to estimate

the time-to followup for each study group and the log-rank test will be used to compare the distribution. Cox-proportional hazard models or other parametric models (if proved more adequate) will be used to study the group difference controlling for other effect modifiers

Outcome: Technical Quality of Care Assessment. Technical quality of care is currently measured as part of routine quality assessment activities in MGPC-PBRN practices. We will formally assess quality measures for the three specified ACCORDs:

- For colorectal cancer screening: Compare time-to-event screening rates among eligible patients overdue at baseline in intervention and control patients.

- For abnormal radiology results: Compare (1) the proportion of abnormal radiology results with completed followup imaging within the recommended interval and (2) time-to-followup test in intervention and control patients.

- For new medication starts: Compare the proportion of required followup laboratory tests following new medication starts in intervention and control patients.

Outcome: Patient Experience of Care Assessment at Baseline and 1 Year Followup. Similarly, all patients who sign up for iHealthSpace will be asked to complete the CAHPS® survey as part of routine care. For patients of participating physicians in intervention and control groups, a followup CAHPS® survey will be requested after 1-year. Informed consent will be obtained from the patient at the time of survey completion in iHealthSpace. Patients of PCPs randomized to the intervention will also be asked to complete a patient satisfaction survey regarding their use of ACCORD system tools after 1-year of followup. Informed consent will be obtained from the patient at the time of survey completion in iHealthSpace.

Outcome: Physician Satisfaction at Baseline and 1 Year Followup. All study physicians will complete a baseline survey regarding their satisfaction with shared decisionmaking after signing an informed consent to be a participating PCP in the study. All PCPs will repeat this survey after 1-year of followup and intervention PCPs will complete additional questions regarding their satisfaction with the use of ACCORD system tools.

Results

Specific Aim 1

To design a model for patient-centered primary care that facilitates patient-clinician partnerships that results in documented followup care plans that can be tracked reliably to reduce the risk of care plans being lost to followup in busy primary care networks.

Focus Group Series 1. Twelve PCPs participated in one of the seven focus groups, 4 in each physician-only group and 2 in each combined group. Overall, physicians were mostly male

(58.3%), had a mean age of 54.1 years, graduated from medical school an average of 27.1 years ago, and have been employed at MGPC an average of 21.1 years. Thirty-nine PCPs responded to the initial emailed patient list and indicated 85 patients who should not be contacted for study inclusion. Of the remaining 1,457 patients, 41 participated in one of the seven focus groups. All demographic data were collected from patient registration as no personal health information was collected at the focus groups. Patients were mostly female (68.3%) and white (87.8%), had a mean age of 57.7 years, had their last clinic visit 6.4 months ago on average, and are not likely to be seen in a community health center (14.6%). Focus group composition is summarized in Tables 1 and 2 below.

Table 1. Focus group type and participants.

Group	Type	Number of physicians	Number of patients
1	Physicians only	4	n/a
2	Physicians only	4	n/a
3	Patients only, low internet use	n/a	7
4	Patients only, mixed internet use	n/a	10
5	Patients only, high internet use	n/a	10
6	Physicians and patients	2	8
7	Physicians and patients	2	6
	Total number of participants	*12*	*41*

Table 2. Focus group characteristics.

Characteristic	Physicians (n=12)	Patients (n=41)
All participants		
Mean age	54.1	57.7
Percent male	58.3	31.7
Physicians		
Mean years since medical school graduation	27.1	n/a
Mean years working at this hospital	21.1	n/a
Patients		
Percent white race	n/a	87.8
Mean number of months since last clinic visit	n/a	6.4

Focus group discussion centered on: patient and provider perception of decisionmaking, strategies patients and providers use to improve shared decisionmaking, desired characteristics of the ACCORD system from the patient and provider perspectives, and perceived benefits and concerns of the ACCORD system. Desired characteristics reported included: integration with specialists (patients), integrations with clinical information systems and workflow (providers), enabling topic-specific communication (patients), opportunity to prepare topics before upcoming visits (providers and patients) and for post-visit review (providers), access to vetted information authored within and outside of the MGH (patients), automated detection of events suitable for ACCORD (e.g., detect that a chest xray report contains mention of a "solitary pulmonary nodule"). Patients variably reported that reminders would be useful; many already use a variety of personal systems. Providers cited “always on” reminders to patients and adjustable reminders to providers as a desired characteristic of the ACCORD system. Patients believed that ACCORD had the potential to provide more direct access to the information patients need, reduce barriers to communicating with their physician, and clarify care plans. Providers felt that a mechanism to

expose patients to appropriate topics and educational materials prior to a visit would be useful, allowing the patient to participate more effectively in decisionmaking. Chronic disease management, preventive health care, medication management, and followup of non-urgent but potentially concerning findings were all areas reported as amenable to shared decisionmaking. Participants noted concerns with regards to the security of health information accessible via the Internet, the difficulty of locating relevant and up-to-date consumer health information, the potential limited utility of the system for patients with low Internet or computer literacy, and the need for integration of ACCORDs with care plans created by patients with other care providers not participating in ACCORD. Both providers and patients expressed concerns regarding the time it would take for providers and patients to use the ACCORD system during visits. They thought that any reduction of the time available for human interaction during office visits would create barriers to use during those visits.

Focus Group Series 2. The second set of focus groups were conducted after system development and involved use of a working prototype ACCORD system in simulated clinical scenarios, followed by group discussion. Key findings included:

- All patients and physicians understood the purpose of ACCORDs quickly, though some physicians and patients were not certain there was enough value to definitely use it.
- Physicians were able to propose, and patients were able to accept, ACCORDs with little training or explanation.
- Patients were more likely than physicians to see value in allocating time to use the system.
- Even physicians that were able to make full use of the system during the focus group sessions believed it must be fully integrated within their EHR workflow.
- A key challenge is getting providers to grasp how ACCORD can complement or replace many, though perhaps not all, of their existing ad hoc reminder systems.
- ACCORD appears to be most suitable for use by both physicians and patients either before or after a visit, while they voiced skepticism about taking up precious face-to-face time at visits for any new activities, including the use of ACCORD.
- Physicians and patients had divergent views of how restrictive they found the ACCORD system to be. Physicians perceived ACCORD option menus as restrictive, but did not offer any suggestions for alternative approaches. Patients did not share these concerns.

Specific Aim 2

> To develop a health information technology architecture and software (ACCORD) to support the patient-centered care delivery model designed in Specific Aim 1.

The four major components of ACCORD were designed and developed to support the ability of a provider to propose an ACCORD for a patient from their EHR (Figure 3), for the patient to

review and accept the ACCORD through their patient portal (Figures 4 and 5), and for the ACCORD system to then monitor the active ACCORD. Over the lifecycle of an ACCORD, the system can identify the clinical events that confirm the care plan as well as detect the missing events that indicate a deviation from the plan, and send out alerts to patients and providers to correct those deviations.

ACCORD Templates and Authoring Tool. A major part of making the ACCORD system work is the creation of suitable ACCORD templates from which providers and patients can select. The ACCORD authoring tool was developed as a comprehensive way to create and maintain ACCORD templates:

- An ACCORD *template* allows an author to structure information about a clinical issue (e.g., colon cancer screening) so that it can be presented to providers and patients simply and effectively for decisionmaking during the formation of an ACCORD (Figures 6,7).

- Template *options* represent the mutually exclusive choices (e.g., routine screening by colonoscopy) available to the patient and provider for addressing the clinical issue. Options comprise one or more *actions* (Figure 8).

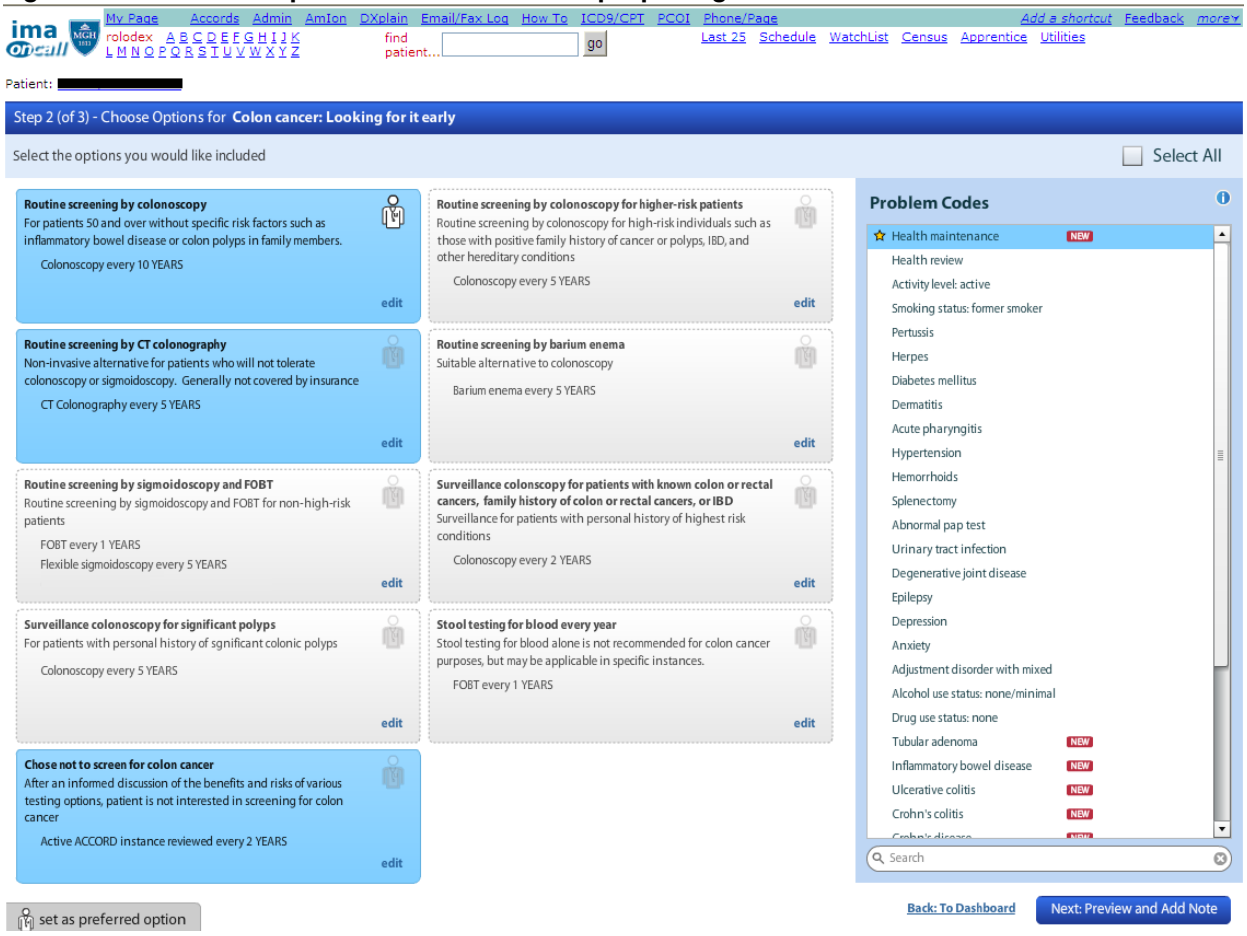
- *Actions* are scheduled observations. The criteria for fulfilling ACCORD options are expressed in terms of actions; e.g., colonoscopy every 10 years (Figure 9).

- *Observations* are the representations within ACCORD of clinical events and data that are stored in clinical systems. Authors can create new observations to use within a template, but to make the template operational within a given practice environment, the observation must be connected to an automated method to actually retrieve the data from clinical systems. This is done within the ACCORD event detection engine. This allows the knowledge within ACCORD templates to be created independently from the capabilities of specific clinical systems, but also to be connected to those systems later for operations.

- *Indications* are the criteria defining the patients to whom an ACCORD template might be relevant (e.g., age greater than 50 years).

- *Key terms* are the controlled vocabulary terms used in finding data related to an ACCORD template. They might be linked at the template, option, or observation level.

Figure 3. A view of the provider interface when proposing an ACCORD to screen for colon cancer.



- *Linked problem codes*. Local configuration with problem codes to guide linkage with clinical documentation into the appropriate sections of the locally available EHR and support problem threading. Each template is associated with a list of possible clinical problems; a "preferred" problem is indicated. This information will be combined with the existing patient problem list from the primary care clinic's EHR system to provide an ordered list of default selections from which the clinician may choose one. *Linked knowledge codes and indications*. Addition of local metadata to link to the relevant, locally available knowledge resources. Annotation with indications will support keyword searches for templates that will use the same terms used in clinical queries that find appropriate patient candidates for those ACCORDs.

- *Linked test or procedure codes.* Local configuration that associates observations with specific data services and the appropriate parameters (usually codes) for those data services.

Figure 4. A list of pending and active ACCORDs that the patient can see from their patient portal. Selecting the "Colon cancer: Looking for it early" ACCORD allows the patient to review the ACCORD for acceptance (Fig. 5).

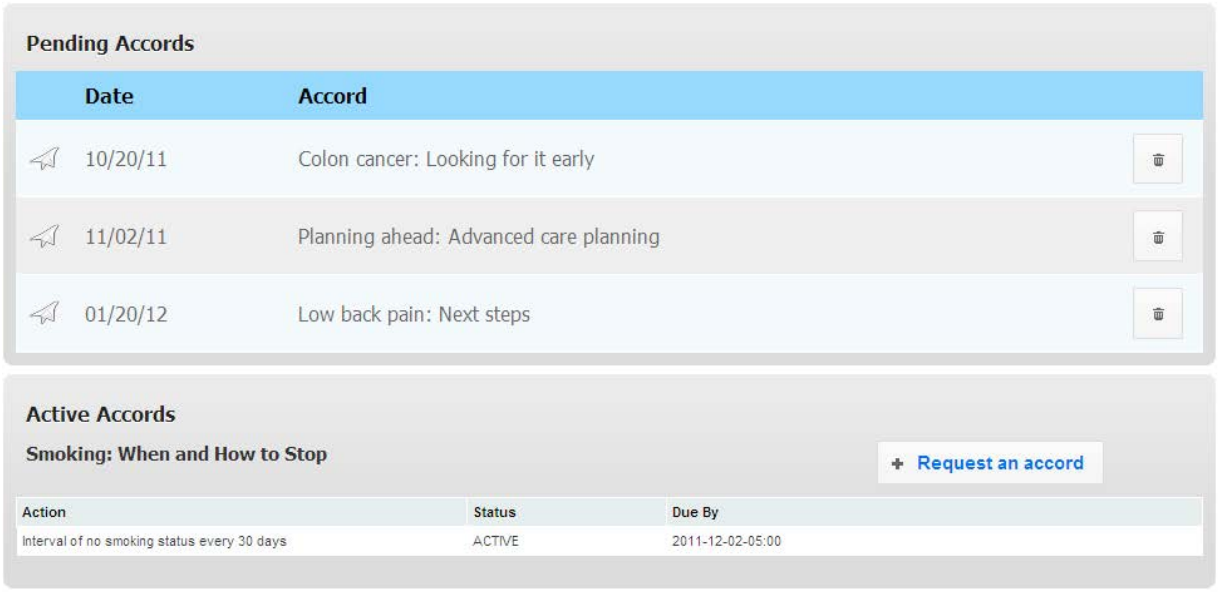


Figure 5. A view of the patient interface to review and accept (or decline) an ACCORD to screen for colon cancer.

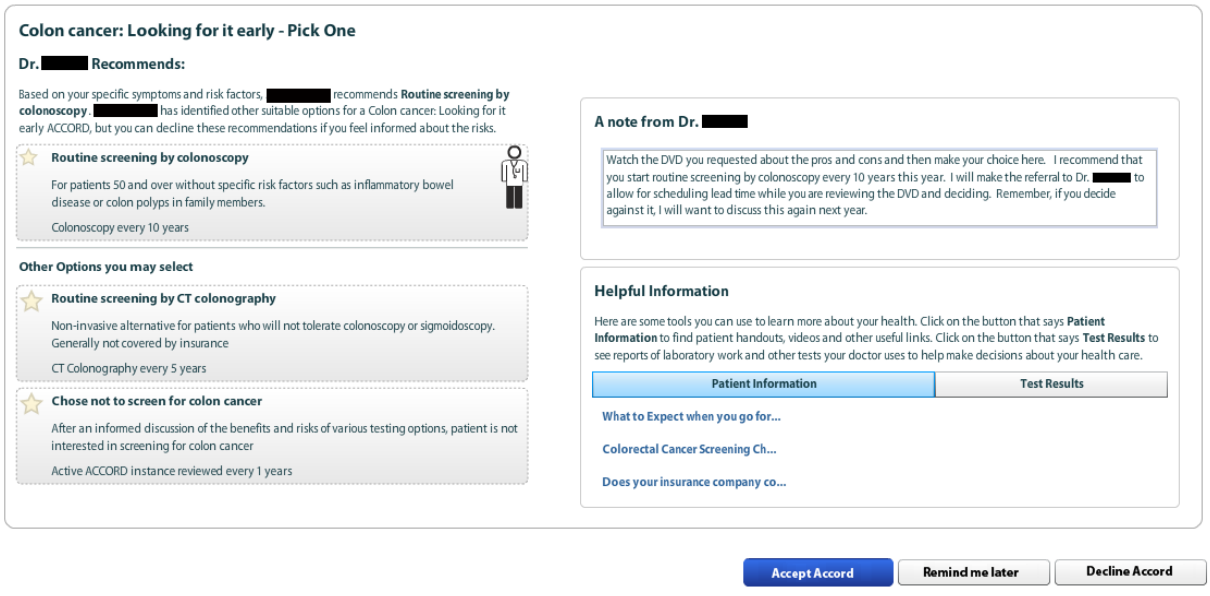


Figure 6. Selecting an ACCORD by topic in ACCORD template authoring tool

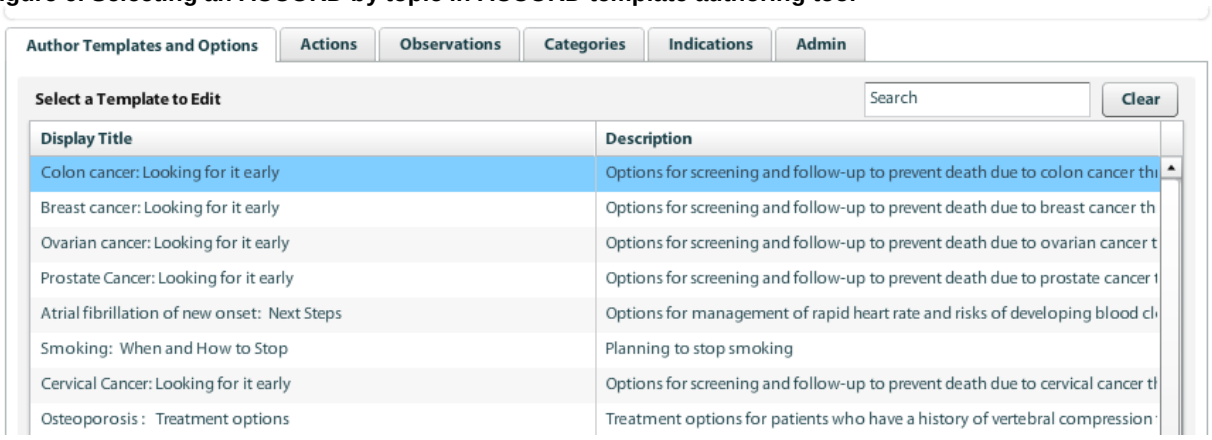
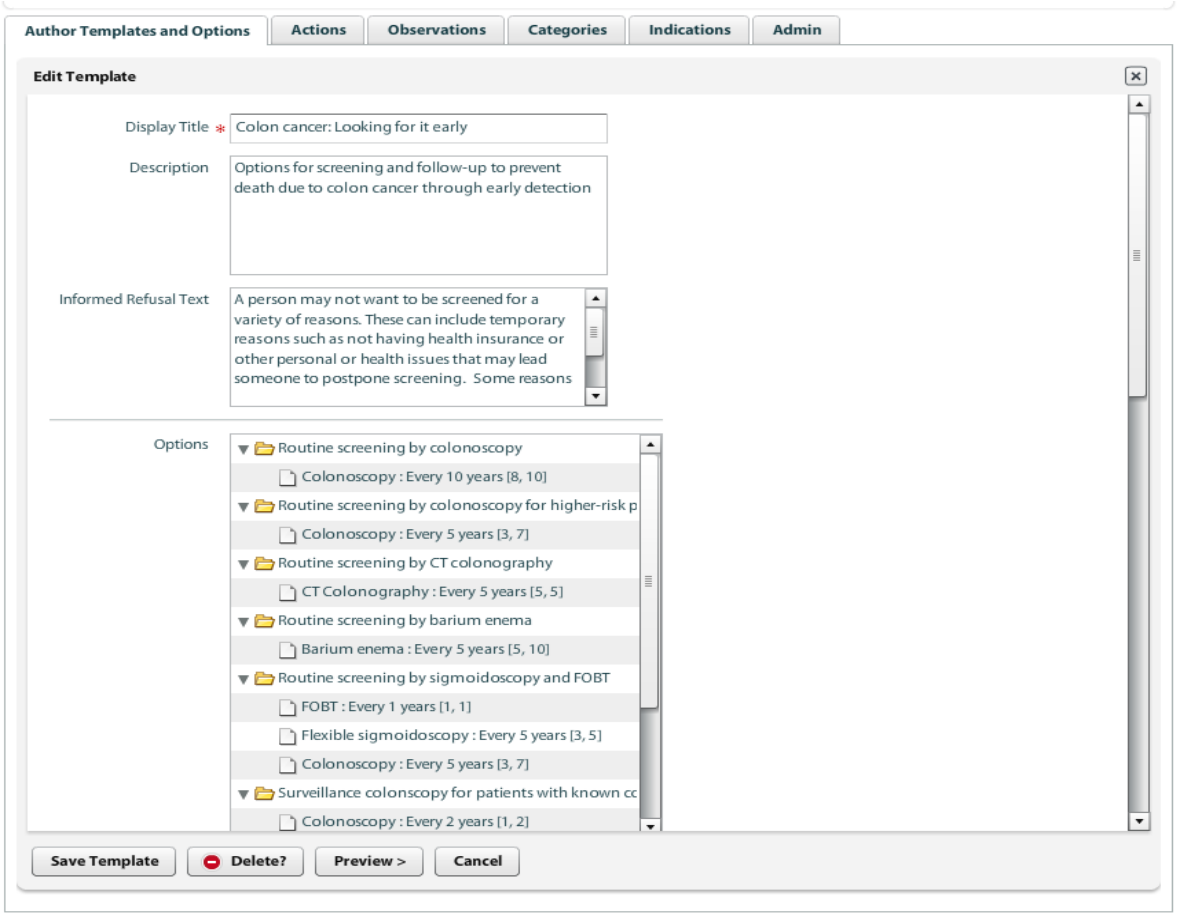


Figure 7. Option structure in authoring tool for template *Colon cancer: Looking for it early*



ACCORD Business Rules and Representative Use Cases

- *Provider proposal*. Typically a provider will "propose" an ACCORD with recommended options for the care plan pre-selected. The provider may indicate that a particular option is "preferred".

- *Patient request*. A patient may "request" that a provider propose an ACCORD on specific clinical issues. This request is selected from a simple list of available ACCORD titles with accompanying descriptions, and without access to detailed options.

- *Acceptance and Review*. An ACCORD is created after the provider proposes and the patient accepts an ACCORD by selecting the care plan option preferred. ACCORDs can be proposed and reviewed by the provider through the EHR used at the practice, and requested and reviewed for acceptance by the patient through a patient portal.

- *Instant-ACCORD.* A provider may propose an ACCORD while simultaneously accepting an option on behalf of the patient (still respecting the patient's choice). This is intended for use during patient visits when provider and patient agree on a care plan face-to-face.

- *Notification*. Both patients and providers are notified when scheduled actions in the agreed upon plan of care become overdue. Providers may also elect to be notified if the patient does not review a proposed ACCORD within a specified time period.

- *Option customization*. A provider may customize the schedule for selected care options within allowable limits, but may not remove or add specific actions within an option.

- *Decline vs. Ignore*. Patient requests or provider proposals may be explicitly declined if either party does not wish to create an ACCORD for a specific issue. ACCORDs may also be ignored (see *Notification* above). ACCORDs may be unilaterally closed by the provider in cases where patients do not respond to reminders and alerts.

Figure 8. Internal structure of an ACCORD option *Routine screening by colonoscopy*

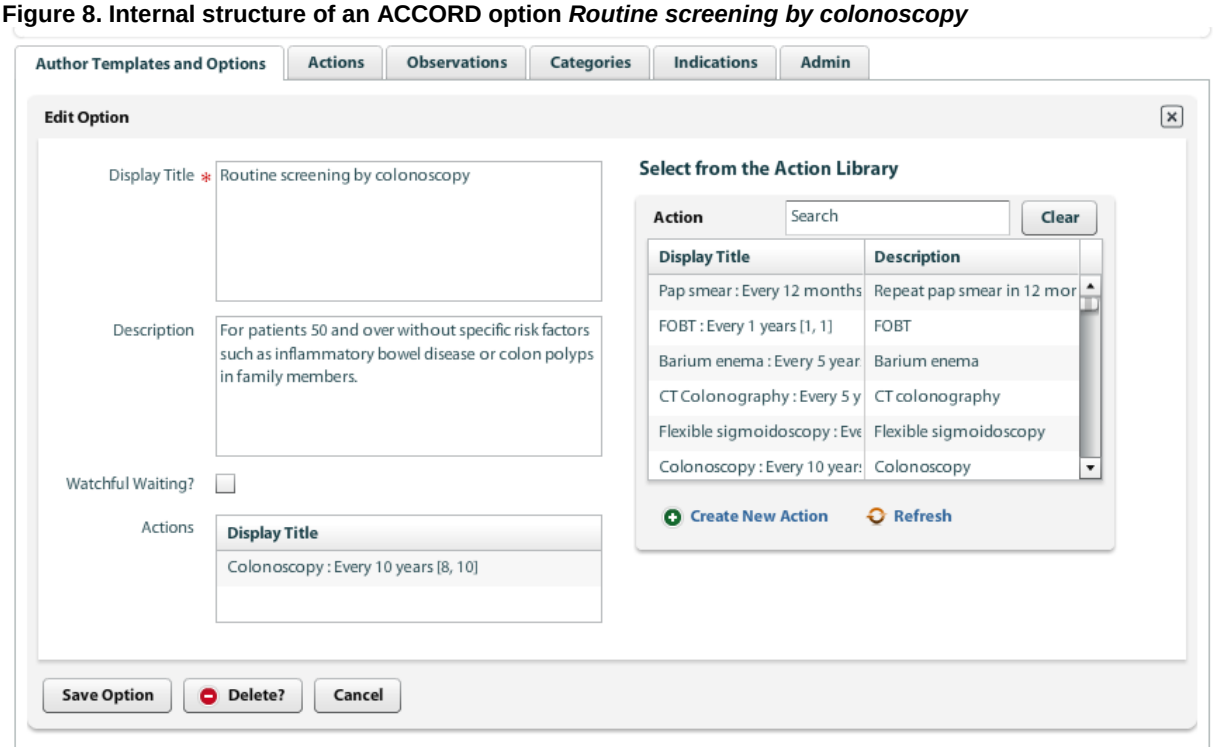
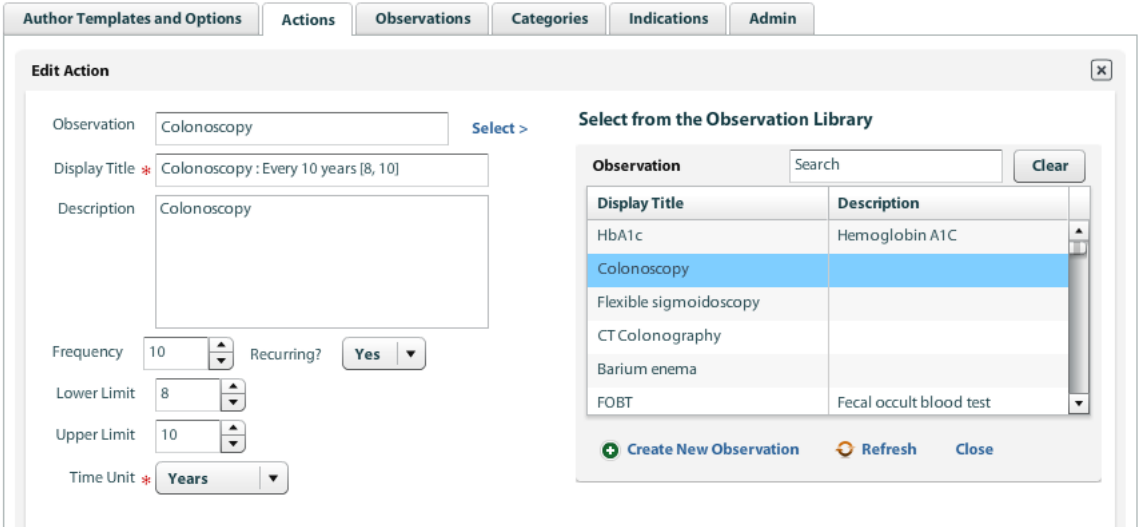


Figure 9. Internal structure of an action: have a colonoscopy every 10 years



- *External events*. When a patient enters data indicating that an ACCORD has been satisfied outside the MGH or Partners HealthCare system, the provider for the ACCORD will be notified by email.

- *Reset*. When all pending clinical events for an ACCORD have occurred such that the care plan is satisfied, the ACCORD is automatically reset to monitor for the next cycle (e.g., colonoscopy completed, ACCORD reset to monitor for another colonoscopy within

10 years from the date of last completion. Because this implies that the care plan is proceeding as planned, no alerts are generated.

- *Renegotiate*. An ACCORD's origin date is reset when the ACCORD is renegotiated and confirmed.

Watchful waiting vs. informed refusal. One particularly challenging definitional issue was to differentiate between an explicit option for "watchful waiting" that can be recommended by the physician, from the several ways that a patient can fail to respond to a proposed plan of care. By default, all ACCORDs allow a patient to choose an option to "do nothing". We clarified operationally the difference between author-specified options for "watchful waiting" (e.g., due to patient age or comorbidities) that require physician and patient agreement and the option where the patient declines the physician recommended options and elects to "do nothing" — also known as an "informed refusal". We also include in this latter category cases in which the proposed ACCORD is "neglected"; i.e., the patient neither accepts nor declines the proposed ACCORD.

Guidelines for Template Authors. Over the course of the project, two different approaches to authoring an ACCORD template emerged. An initial approach attempts to formulate the options in terms of the actual tests or procedures that need to be performed. An alternative approach attempts to formulate the clinical care options in terms of the patient's clinical situation. For example, in the ACCORD for colon cancer screening, the first approach might describe an option as "Colonoscopy every 5 years", while the second approach might describe the option as "Routine screening by colonoscopy for higher risk patients". We found that physicians naturally formulate clinical care options in terms of the actions they must take (the first approach) because they are intrinsically aware of *why*. This can make it difficult for them to frame clinical options in language that has real meaning to patients. However, based on the focus groups and team testing in patient roles, we found that the second, more patient-centric approach promotes a more consistent shared meaning between the provider and the patient. Physician knowledge of the relevant diagnostics and/or treatments can actually impede their ability to describe care plan choices in a way that matches patients' understanding and health knowledge.

The need to develop ACCORD templates that were truly suitable for both patients and providers led us to articulate some specific authoring guidelines:

1. *Select topics appropriate for use in the ACCORD system*. Issues that have evidence-based guidelines are best, and referencing the guidelines is useful. Topics for which ACCORDs may be unsuitable include those where:

    - Patients cannot be grouped into a modest number of treatment or risk classes (less than 8 to 10, because larger sets cannot be reviewed onscreen easily by users) because too many individual patient attributes need to be considered (e.g., metabolic syndrome)

    - Topics which are symptom-based where there exists a large number of combinations from enumerating all logically possible combinations of actions (e.g., abdominal pain)

2. *Lump, then split*. Authors need to select the granularity of the ACCORD (e.g., a single diabetes management ACCORD vs. individual ACCORDs for managing various aspects of diabetes such as hyperglycemia management, cholesterol management, and eye care management)

    - First try "lumping", which entails combining all aspects of managing a clinical condition or issue comprehensively into options within a single ACCORD. This approach appears to naturally fit physicians' mental model.

    - Split the ACCORD if a "lumped" approach leads to use of more than 6 to 8 options. One common possibility is to split "new onset" of a condition into a separate ACCORD (e.g., new onset diabetes vs. diabetes).

3. *Topic language*. To make templates easier to find in a list, template titles should begin with the template's clinical focus (e.g., "Cervical Cancer Prevention: Screening Options for Low Risk Patients", rather than "Screening Options for Patients at Low Risk for Cervical Cancer")

4. *Label options using language that has meaning to patients.* Options should use language that patients not only understand, but that also supports patients' mental models regarding their health situation. For example, occult hematuria may be caused by bladder cancer. Additional context such as patient occupation or behaviors (e.g., smoking) may indicate that a particular patient is at higher risk for bladder cancer. Including this information in ACCORD language may help the patient understand why a care plan that includes additional diagnostic testing is important. "Bladder imaging for patients at high risk for cancer" is an example of such an option. Many guidelines are flowchart-based and temporal, tailored toward helping the provider narrow options and identify "what to do next" at the expense of "why are we doing what to do next". This can widen the gap of shared meaning between the patient and the provider, and the ramifications of this go well beyond ACCORD. From a cost-effectiveness point of view, jumping to actions prior to a meaning-based partnership with patients and their preferences may accelerate health care costs. The ACCORD model of explicitly describing the shared options in a care plan as meaningful to both patients and providers has become a focus of our current work. "Get a stress test within 2 weeks" is not a valid option based in patient meaning, it's an action. "Exercise testing to rule out the risk of future heart attack" would be preferred language for this option.

5. *Classify options based on classes of patients.* Patients may grouped by:

    - Risk — even if the immediate courses of actions appear to be the same. Risk connects to the often-unstated rationale for actions that helps patients to understand.

    - Presumed etiology – similar causes often lead to similar care plan options.

    - Timing — different patient states may be grouped if at a particular point in time they are managed similarly with common care plan options.

6. *Consider Actions, then Options*. Authors may not be aware that ACCORD actions correspond to the tasks physicians typically think of when formulating care plans (e.g., procedures or tests), but actions must be grouped under options in an ACCORD template. When authoring a new ACCORD template with options, physician authors will often misidentify lower-level actions as top-level options. Authors may want to write out all relevant actions first before trying to formulate options that include subsets of those actions.

Specific Aim 3

To implement and evaluate ACCORD in a randomized controlled study within the Massachusetts General Primary Care Practice-Based Research Network (MGPC-PBRN).

While the study design has been established and logistics for conducting the study at the largest MGPC-PBRN practice, the Internal Medicine Associates, the actual study has been delayed due to a dependency on the practice's adoption of iHealthSpace, a locally developed Web-based patient portal. This patient portal is the host for the ACCORD module that patients will use, and is therefore a prerequisite for the study. Factors independent of this project were responsible for the delay of iHealthSpace; namely, the demand for a broad array of portal features (unrelated to ACCORD) prior to rollout, resulted in unanticipated delays in its implementation and adoption.

iHealthSpace was released fully at the study site in March 2011 and patient enrollment is currently ongoing. The practice expects broad use of the patient portal. In addition, adoption is planned at a second primary care practice, and plans are in place to enroll patients from five total practices (2 specialty and 3 primary care) by the end of the year. To date, iHealthSpace has a total enrollment of 9,805 patient users. In particular, in the study site approximately 25% of patients have enrolled and used it, accounting for 8,658 patient users. We expect well over 10,000 patient users in the study practice by the end of March 2012. Of the current users, 4,550 (53%) are women, 187 (3%) are caregivers, and 4,147 (48%) are older than 60 years of age. Consequently we are confident that the ACCORD study period can begin in 2012 and conclude by December 2012. Results will be analyzed and published following study completion, and attributed to this grant.

Discussion

The ACCORD model has the following characteristics:

- **Choice**: Providers and patients can choose from alternative evidence- and expert-based followup care plans according to clinical and personal circumstances to establish an explicit shared care compact (ACCORD).

- **Individual or population-based workflow**: Clinicians can initiate ACCORDs individually or on a population basis (e.g., for screening); patients provide informed acceptance or refusal individually.

- **Self-documenting**: Care plan options selected by the patient or clinician are also associated with customized documentation that is entered into the EHR; i.e., language to document automatically a patient's acceptance or informed refusal of a recommended care plan.

- **High visibility:** Patients can review and update their ACCORDs at any time.

- ***"Jidoka"*:** ACCORDs are monitored continuously for deviations from care plans and make deviations immediately visible to all parties.

- **Perpetual:** ACCORDs can cycle continuously without need for any action, providing fail-safe monitoring when appropriately followed.

From the earliest stages of design throughout development, we observed that providers were concerned about workload and flexibility, with usable solutions requiring a high degree of integration with existing systems and workflow. At the same time, making systems as generalizable and reusable as possible is a desirable goal of designing new health information technology. Achieving both characteristics challenged us to address a number of specific integration issues:

- connectivity between ACCORD and local health IT systems to ensure secure patient and provider messaging (i.e. not email, except for notification of new message);

- institution-specific controlled vocabularies for medications, clinical problems, coded physical exam findings such as "foot exam" , vital signs, and laboratory results;

- institution- and system-specific pattern matching algorithms for identifying a clinical event whose evidence is described only by uncoded narrative clinical reports;

- institution- and system-specific methods of physician and patient identifier schemes;

- Integrated user interface and single sign-on to ACCORD for patients who sign into the patient portal, and providers who sign into the EHR, despite the fact that the ACCORD server is a system independent from both the patient portal and the EHR;

- integration issues related to workflow determined by the design of the local system, that is certain ACCORD functionality requires that the EHR at the study site includes other applications (e.g., results management application, functionality that enables generating patient lists, or with population management tools).

As a consequence of these issues the actual ACCORD implementation has had to address technical (and non-technical) dependencies on local clinical data repositories, patient and provider messaging solutions, and institution-specific application programming interfaces (APIs), services and coding schemes. These integration steps were possible because our research team had access to production systems, including the local EHR and its associated patient portal. Making ACCORD tools broadly available would require a significant investment in additional data mapping and configuration tools. This issue is not unique to ACCORD, as almost any

clinical systems innovation that has a significant impact on clinical workflow will require points of integration. The original vision for ACCORD was a portable system that could be used loosely coupled to clinical systems. The current system is a comprehensive software package that requires significant configuration and integration with local institutional systems to be of practical use. Major advances in open systems, common nomenclatures, and interoperability will be needed to disseminate systems such as ACCORD. Policies at the national level to promote such systems characteristics are therefore critical.

References

1. The impending collapse of primary care medicine and its implications for the state of the nation's health care. American College of Physicians, January 30, 2006. http://www.acponline.org/advocacy/events/state_of_healthcare/statehc06_1.pdf Accessed November 14, 2011.

2. Center for Studying Health System Change. Physician Survey. http://CTSonline.s-3.com/psurvey.asp. Accessed November 14, 2011

3. Safran DG. Defining the future of primary care: what can we learn from patients? *Ann Intern Med.* 2003;138:248-55

4. Ostbye T, Yarnall KS, Krause KM, Pollak KI, Gradison M, Michener JL. Is there time for management of patients with chronic diseases in primary care? *Ann Fam Med.* 2005;3:209-14.

5. Schuster MA, McGlynn EA, Brook RH. How good is the quality of health care in the United States? *Milbank Q.* 1998;76:517-63, 09.

6. Chassin MR, Galvin RW. The urgent need to improve health care quality. Institute of Medicine National Roundtable on Health Care Quality. *Jama.* 1998;280:1000-5

7. Harris G, Bartlett EE, Rehmar M, et al. Early diagnosis of breast changes. Risk management and quality of care approach. *J Fla Med Assoc.* 1996;83:466-9.

8. Kravitz RL, Rolph JE, Petersen L. Omission-related malpractice claims and the limits of defensive medicine. *Med Care Res Rev.* 1997;54:456-71

9. Osuch JR, Bonham VL, Morris LL. Primary care guide to managing a breast mass: a legal perspective on risk management. *Medscape Womens Health.* 1998;3:3

10. Shaefer MA. CRICO Office-based malpractice cases: 1989-1998. Risk Management Foundation Forum, 2000. http://www.rmf.harvard.edu/files/documents/Forum_V20N2.pdf. Accessed November 14, 2011.

11. Boohaker EA, Ward RE, Uman JE, McCarthy BD. Patient notification and followup of abnormal test results. A physician survey. *Arch Intern Med.* 1996;156:327-31.

12. Murff HJ, Gandhi TK, Karson AK, et al. Primary care physician attitudes concerning followup of abnormal test results and ambulatory decision support systems. *Int J Med Inform.* 2003;71:137-49.

13. Fletcher B, Berra K, Ades P, et al. Managing abnormal blood lipids: a collaborative approach. *Circulation.* 2005;112:3184-209

14. Heisler M, Vijan S, Anderson RM, Ubel PA, Bernstein SJ, Hofer TP. When do patients and their physicians agree on diabetes treatment goals and strategies, and what difference does it make? *J Gen Intern Med.* 2003;18:893-902.

15. Flach SD, McCoy KD, Vaughn TE, Ward MM, Bootsmiller BJ, Doebbeling BN. Does patient-centered care improve provision of preventive services? *J Gen Intern Med.* 2004;19:1019-26.

16. Haynes RB, McDonald HP, Garg AX. Helping patients follow prescribed treatment: clinical applications. *Jama.* 2002;288:2880-3.

17. *Priority Areas for National Action: Transforming Health Care Quality.* Summary of Institute of Medicine report. January 2003. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/qual/iompriorities.htm

18. Barney G. Glaser and Anselm L. Strauss. 1967. *The Discovery of Grounded Theory: Strategies for Qualitative Research*. New York: Aldine de Gruyter.

List of Publications and Products

Chung J, Berkowicz DA, Ho B, Jernigan M, Chueh HC. Creating a place for caregivers in personal health: the iHealthSpace copilot program and diabetes care. J Diabetes Sci Technol. 2011 Jan 1;5(1):39-46

Chung J, Weinick R, Berkowicz DA, Ashburner J, Chueh HC. The Design of a Shared Decision-Making Tool. (in progress)

Chueh HC, Estey G, Jernigan M, Chung, J, Berkowicz DA. The ACCORD Model: An Information Architecture for Choice-based, Reliable Care Planning. (in progress)

http://project-redcap.org. REDCap Shared Library. Search for “CAHPS”. REDCap implementation of CAHPS Clinician and Group Survey Adult Primary Care 1.0 4 point scale and 6 point scale questionnaires, with and without supplemental questions. Implemented and made available for download in collaboration with the REDCap consortium.

http://project-redcap.org. REDCap Shared Library. Search for “Self-efficacy”. REDCap implementation of the Decision Self-Efficacy Scale. Implemented and made available for download in collaboration with the REDCap consortium.